Effective 2024-01-03 thru 2024-05-01

ARVIS® Shoulder Surgical Navigation System Instructions for Use

Model: ARV-01

⚠WARNING: This document should always be used in conjunction with the ARVIS® Shoulder Surgical Technique Guide P/N 22000 which contains additional product instructions. Access the Surgical Technique Guide at www.insightmedsys.com/resources with password “ARVIS”.

Insight Medical Systems, Inc.
www.insightmedsys.com

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System Information

Precaution

Federal (USA) law restricts this device to sale by or on the order of a physician.

General Warnings

- Read all instructions prior to use.
- Do not operate the system without proper training. It is the surgeon's responsibility to be familiar with this technique prior to surgery.
- Navigation output does not supersede the surgeon's clinical judgment.
- Use only accessories provided with the system. Do not substitute cables or any other components. Do not connect any accessories not provided by the manufacturer to the device's USB connectors, including the headlight output connector. Do not attempt to use a computing device other than the computer module provided with the system.
- Prior to use, check the instruments for wear or damage. Replace damaged or worn instruments before use.
- Prior to use, the coracoid process should be evaluated for suitability of mount fixation utilizing pins.
- The eyepiece includes a headlight, infrared emitter, and Class I laser. The surfaces near the headlight, as well as other surfaces, may become hot during use. Touch only parts of the eyepiece intended for adjustment.
- To avoid potential interference with pacemakers, do not place any system component near the patient's or user's chest. There is a potential for electromagnetic interference. If the device interferes with other equipment, reposition or discontinue use of the device. If the device receives harmful interference affecting its function, discontinue use.
- Do not modify or service any system component.
- The **ARVIS** system includes the eyepiece, belt pack, battery, chargers, and instrument set. Instruments are provided NON-STERILE and must be cleaned and sterilized prior to each use. Electrical components are NON-STERILE and must not be sterilized.
- To avoid the risk or electric shock, this equipment must only be connected to a supply mains with protective earth.
- To maintain cybersecurity and correct operation, do not change settings on the provided computer module except as directed by Insight Medical Systems.
  - Do not enable Wi-Fi or cellular communication except as directed by Insight Medical Systems.
  - Do not install or remove applications or store non-Insight data.
  - Insight recommends installing a password to restrict access to the computer module.
  - Insight recommends trusted users remember to control any removable drives used to transport encrypted plan files to the system and not use drives for any purposes other than storing and transferring plan data files.
  - Confirm password and/or plan import in advance of patient being anesthetized
  - Review and confirm patient and plan details before plan selection

System Description

ARVIS Shoulder is a computer-controlled surgical navigation system for shoulder arthroplasty. It combines software, electronic hardware and surgical instruments to intraoperatively track tools and locate anatomical structures and display feedback to the user. The system aids the surgeon in executing an approved preoperative plan. For information on preoperative planning, please refer to the planning software Instructions for Use and User Manual.

The **ARVIS** Eyepiece contains stereo IR tracking cameras, a color camera, stereo display, IR illumination, and IR laser illuminator. A visible headlight is mounted to the eyepiece and connected via a micro-USB cable. The eyepiece communicates with the Belt Pack via a USB-C cable. All system instructions, prompts, alerts, and outputs are displayed to the surgeon on the eyepiece display.

The Belt Pack includes the computer module, battery, and power management board. The Belt Pack supplies power to the eyepiece and runs the **ARVIS** Shoulder Application Software.

The **ARVIS** electronics are worn on the surgeon's body during surgery. There is no interface to external equipment except for the **ARVIS** Battery Charger, which recharges the battery when not in use.

ARVIS uses the tracking cameras to measure the positions of trackers on the patient or instruments. **ARVIS** displays measurements as described in Performance Claims. Measurements are not displayed when a required tracker is not detected and in

range of the tracking cameras. Valid camera operating range extends at least from 40cm to 70cm from the eyepiece, but **ARVIS** may be able to provide accurate measurements at shorter or longer ranges.

Performance Claims

ARVIS Shoulder measures the following parameters with the stated accuracy in simulated use on benchtop fixtures.

- Drill inclination and version with an average absolute error of ≤ 1.5 °
- Superior/Inferior and Anterior/Posterior location of drill entry point with an average absolute error of ≤ 1.5mm on each axis
- Glenoid implant inclination and version with an average absolute error of ≤ 1.5 °

- Rotation of the glenoid implant about its central axis with an average absolute error of ≤ 1.5 °
- Length range of a virtual screw (up to 50mm) extending from a theoretical glenoid baseplate with an average absolute error of ≤ 0.5mm

Clinical accuracy depends on accurate registration and inputs to the **ARVIS** Shoulder Application Software. The system has been validated in simulated clinical use (cadaver) to achieve the following accuracy:

- Superior/Inferior and Anterior/Posterior location of glenoid implant with an average absolute error of ≤ 1.5mm on each axis
- Glenoid implant inclination and version with an average absolute error of ≤ 3.0 °
- Rotation of the glenoid implant about its central axis with an average absolute error of ≤ 3.0 °
- Length range of a virtual screw (up to 50mm) extending from a theoretical glenoid baseplate with an average absolute error of ≤ 2.0mm

Principle of Operation

ARVIS Shoulder is an image-based surgical navigation system. A patient's preoperative CT scan of the shoulder joint is required to create a preoperative surgical plan that includes a landmarked digital bone model which is matched to intraoperative landmarks registered by the surgeon.

ARVIS uses cameras in the eyepiece to measure locations and angles between trackers mounted on the patient and trackers mounted on instruments. By prompting the user through a procedure-specific workflow to register the reference tracker to anatomic landmarks, the **ARVIS** Shoulder Application Software running on the belt pack calculates and displays positions of the instruments relative to the patient's anatomy.

Intended Use

The **ARVIS** system is a computer-controlled navigation system intended to provide intra-operative measurements to the surgeon to aid in selection and positioning of orthopedic implant components.

Indications For Use

ARVIS ® Shoulder is indicated for assisting the surgeon in the positioning and alignment of implants relative to reference alignment axes and landmarks in stereotactic orthopedic surgery.

The system aids the surgeon in making intraoperative measurements and locating anatomical structures of the shoulder joint based on the patient's preoperative imaging.

ARVIS® Shoulder is indicated for total shoulder arthroplasty using the Enovis AltiVate implant system.

Contraindications

- Significant loss of bone affecting identification of the required landmarks
- Excessive soft tissue interference affecting identification of the required landmarks
- Severe osteoporosis at fixation site(s), including but not limited to weakness of the coracoid process which could lead to adverse effects
- The presence of infection
- Any contraindication associated with shoulder arthroplasty surgery

Adverse Effects

Possible adverse effects include premature implant failure, dislocation or instability, decreased range of motion, infection, tissue injury, nerve injury and weakness, fracture, foreign body reaction, increased anesthesia time, heart attack, vascular injury, neck injury, burns, electrical shock, and cardiovascular injury.

Compatibility

- **ARVIS** Shoulder is indicated for use with the Enovis AltiVate® implant system.
- Steinmann Pins (x2), 2.5mm x 100mm, are required for the Mechanical Mount.
- Precision AI Surgical Planning Software must be used for preoperative planning before navigation.
- Stryker® Flyte®or T7® helmet together with provided compatible adaptors can be used to wear the **ARVIS** Eyepiece.

User Profile

The **ARVIS** system is to be used by orthopedic surgeons and operating room staff who perform shoulder arthroplasty. Users should reference the ARVIS® Shoulder Surgical Technique Guide P/N 22000 for step-by-step product instructions. Training on product usage is available, and strongly recommended.

To arrange training, contact Insight Medical Systems, Inc.

Usage Environment

The **ARVIS** system is designed for use within hospital operating room environments. Infrared Radiation (IR) sources, including operating room lights and windows, may interfere with the cameras that are part of the **ARVIS** system. Avoid environments with excessive IR sources.

The **ARVIS** system is designed for use in a hospital operating room within the following conditions:

- Temperature (15 to 25°C)
- Humidity (20-80% non-condensing)
- Pressure (70-106 kPa)

The **ARVIS** Eyepiece is worn on the surgeon's head. The **ARVIS** Belt Pack is worn on the surgeon's belt or waistband. No electronic hardware is applied to the patient. The surgeon stands adjacent to the patient to operate.

The **ARVIS** Battery Charger is intended to be used outside the operating room.

Definition of Symbols

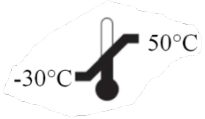
The following symbols are used in the **ARVIS** system labeling:

Follow Instructions for use

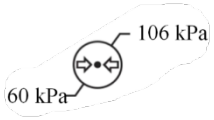
Do not dispose in trash

Non-Sterile

Humidity



Storage Temperature



Pressure

Manufacturer

Serial Number

Catalog Number

Hardware Information

ARVIS Shoulder Instrument Set Components (P/N 21300)

Catalog Number	Description
21100	Instrument Tray Base, Shoulder
11000	Instrument Tray Lid
25000	Stylus Drill Guide
23000	Mechanical Mount
24000	Tracker A, Mechanical
26000	Cobb Elevator, 1 in
10800	3.5mm Hex Driver
18300	Glenoid Drill Guide
18400	Reverse Baseplate Registration Tool
18500	Reference Pin Guide

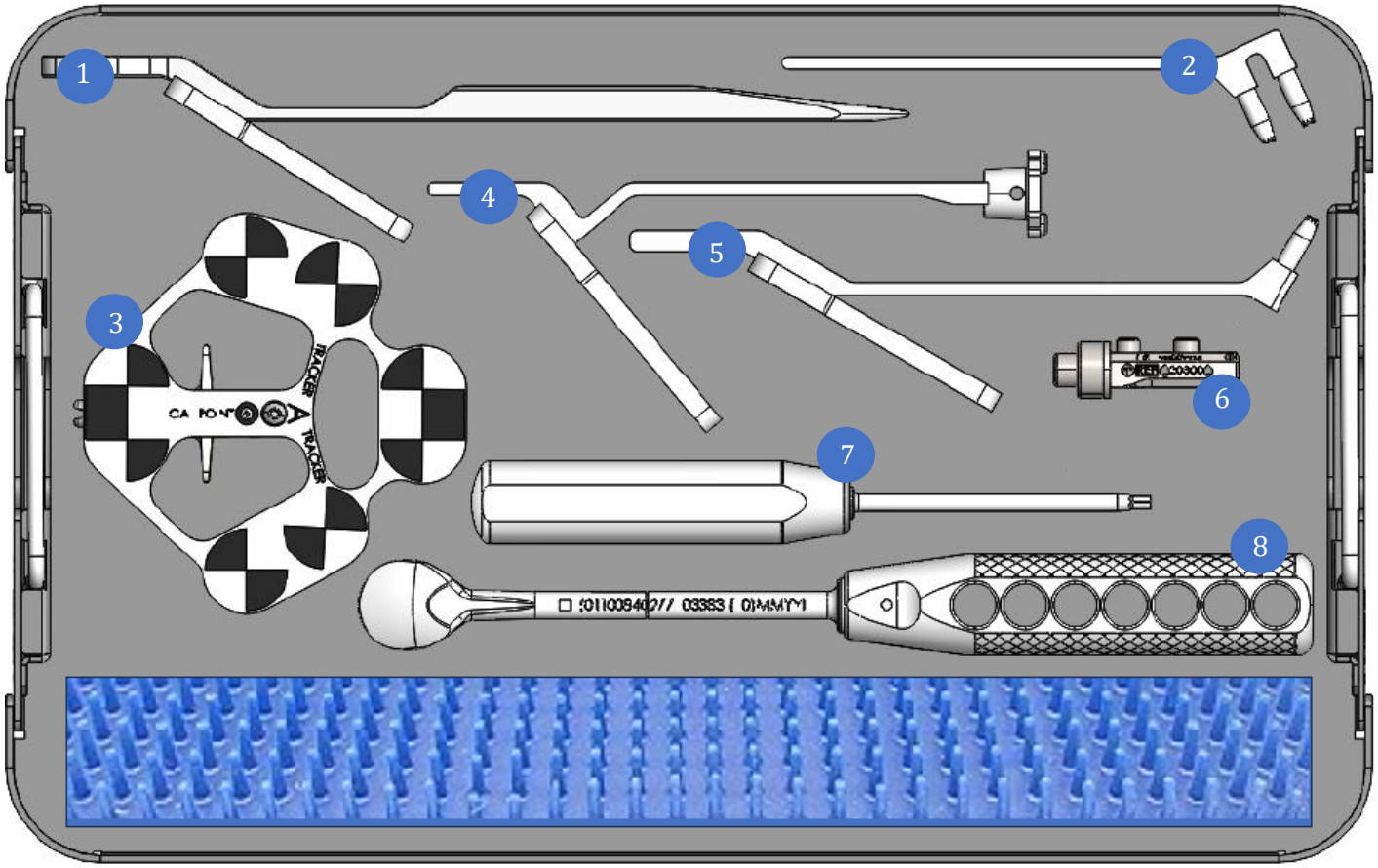
ARVIS Electronic Hardware Components and Accessories (P/N 14100)

Catalog Number	Description
12400	ARVIS Eyepiece Assembly
12500	ARVIS Belt Pack
12700	ARVIS Computer Module
12800	ARVIS Battery
13200	ARVIS Eyepiece Cable
13000	ARVIS Battery Charger
13800	ARVIS Charger Power Supply
13900	ARVIS Charger Cord, USA
15200	Charger, 25W USB-C, USA
14103	Cable Hook
17700	ARVIS Installation Kit

Use only accessories supplied by the manufacturer.

Optional Additional ARVIS Accessories

Catalog Number	Description
17100	ARVIS Headband
17500	FLYTE Mounting Kit
21700	T7 Adapter Kit



1. Stylus Drill Guide
2. Reference Pin Guide
3. Tracker A, Mechanical
4. Reverse Baseplate Registration Tool
5. Glenoid Drill Guide
6. Mechanical Mount
7. 3.5mm Hex Driver
8. Cobb Elevator, 1 in

Electronics Cleaning Instructions

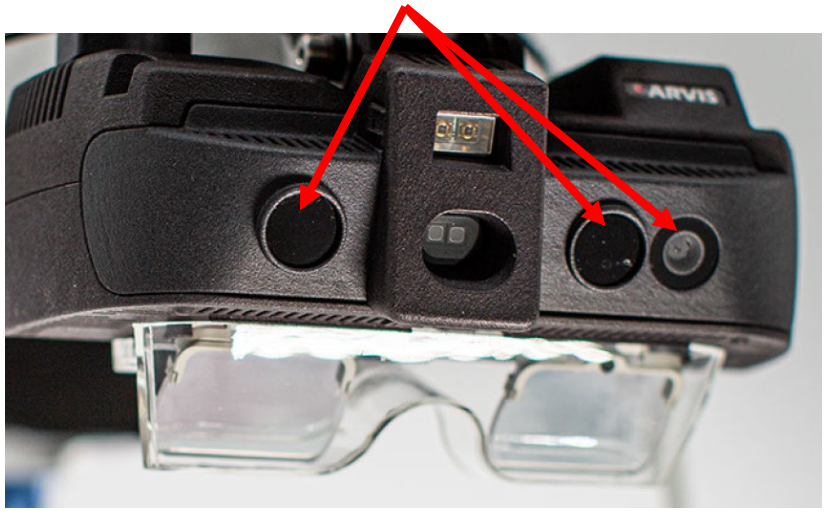
The electronic hardware components comprising the **ARVIS** system are the Eyepiece, Belt Pack, Battery, and Chargers. The electronic hardware components are re-usable.

- The Chargers are not intended for use in the operating room.
- The Eyepiece does not provide eye protection. If there is a likelihood of airborne blood or other soil, the user is advised to wear a legally marketed face shield for protection. The user is further advised to wear a legally marketed surgical gown or toga when a likelihood of soiling exists.

With appropriate attire, the electronic components of the **ARVIS** system should not need frequent cleaning, but they may be cleaned as described below as needed.

- Remove the **ARVIS** Battery and shut down the **ARVIS** Computer Module.
- Wipe with isopropyl alcohol solution (70-99%) using a lint-free cloth for one minute. Follow all label instructions for isopropyl alcohol.
- Do not use abrasive brushes or cloths.
- Take care not to scratch the camera covers. Visually inspect each camera cover after cleaning to verify that there are no scratches or residue.
- Take care not to introduce excess liquids into the Eyepiece via the cooling vents.
- Do not immerse. Do not sterilize. Allow to dry fully prior to use.
- Do not use phenolic disinfectants, as they may damage the Eyepiece or Belt Pack enclosures.

Camera Covers



Instrument Cleaning Instructions

The ARVIS Instruments are re-usable. Clean and Sterilize all instruments prior to first use and after every use.

1. Clean the instruments as soon as possible after use and avoid allowing soiled instruments to dry. Immerse, or use moist towels or sponges soaked with distilled or de-ionized water to keep moist prior to cleaning.
2. Disassemble instruments into the component parts listed in the "**ARVIS** Instrument Set Components" table.
    a. Separate tracker from mount.
    b. Loosen both clamping screws in Mechanical Mount 23000.
3. Rinse instruments under running cold utility (tap) water to remove gross soil.
    a. While rinsing, actuate all moving parts of the instruments and use a soft bristled brush to aid in removal of gross soil.
4. Flush utility (tap) water through lumens and other hard to reach areas of instruments.
5. An ultrasonic cleaner may be optionally used.
6. Load the instruments into automated parts washer for processing.
7. Run the automated washer with the following parameters:
    a. Pre-wash for 2 minutes with cold tap water.
    b. Enzyme wash for 2 minutes with hot tap water and enzymatic detergent prepared per the manufacturer's directions for use.
    c. Rinse for 5 minutes with 43°C (nominal) de-ionized or reverse-osmosis water.
    d. Dry for 7 minutes at 90°C (nominal).

Note: Use of water-soluble lubricants is recommended for instruments with moving parts or those intended to be assembled intraoperatively to another instrument.

Autoclave Sterilization of Re-Usable Instruments

- Wrapped pre-vacuum, 4 minutes at 270°F (132°C). Dry time is 75 minutes*. Use an FDA-cleared wrap or sterile barrier. (Validation is based on use of Halyard Health H400.)
- Unwrapped pre-vacuum ("Flash"), 4 minutes at 270°F (132°C).
  *In addition to the prescribed dry time, an additional 30 minute cool down after removal from the sterilization chamber is recommended to ensure the devices are free from condensation and other moisture.

The recommended sterilization process has been validated to produce a sterility assurance level of (10^{-6}) when parts have been cleaned to the instructions above. Other steam cycles and cleaning procedures have not been evaluated and must be qualified by the user.

Effective sterilization is predicated on thorough cleaning and drying processes. Failure to do so will compromise the sterilization process and render the processed instrument unsuitable for clinical use.

Disposal

Do not throw any part of this system in the trash. Dispose of components in accordance with local regulations.

Storage and Transportation

Temperature: -30 to 50 °C; Humidity: 10 to 90% RH; (non-condensing); Pressure: 60 kPa to 106 kPa.

Handle with care.

Maintenance

Prior to each use, check the instruments for wear or damage. Note especially the condition of tracker markings and fit of interfaces between trackers and tracker mounts. Although the system's instruments do not have a usage limit and are expected to last for extended use, damaged or worn instruments should be replaced. Use of damaged instruments may lead to errors in navigation.

Follow instructions for the proper inspection, cleaning, and sterilization (as applicable) of system components. No further maintenance is required. Do not service or modify any system component.

Any part failing to perform as intended should be reported to the manufacturer for resolution.

Warranty

The product is warranted to be free from defects in material and workmanship.

Electrical Safety

This equipment has been tested and found to comply with EMC limits per IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interface with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Consult Insight Medical Systems or authorized representative for help.

FCC ID: SH6MDBT42Q This device compiles with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

Operating Conditions: Temperature: 15-25 °C; Humidity: 20-80% (RH) non-condensing; Pressure: 70-106kPa.

Warning: This device is designed for very specific tasks. Use in an environment containing EM disturbances outside the capability of this device may compromise the surgical outcome.

Warning: This device is not designed for use next to or stacked with other equipment. Use next to or stacked with other equipment should be avoided due to improper operation.

Warning: Use of batteries, computing modules or cables other than those provided by Insight Medical Systems could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ARVIS® system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Note: This device has been tested for electromagnetic immunity and shown to maintain essential performance (tracking error ≤5mm) when exposed to expected levels of electromagnetic disturbances (further defined in the subsequent tables). The system has internal software quality controls, which stop progression through the workflow. If a user repeatedly fails to progress beyond a step in the workflow, the user should first ensure they are properly following the surgical technique and that there are no obstructions blocking the eyepiece. If still unable to proceed, the user should discontinue use of the device.

The ARVIS system is battery powered, which modifies the applicable EMC immunity tests. Shown here are the emissions and immunity tests applicable to the ARVIS system comprised of the eyepiece, belt pack, battery and USB cable assembly that is worn by the user during surgery.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.		
EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
RF Emissions CISPR 11	Group 1	The ARVIS product uses RF energy only for internal function (except for intentional communication). RF emissions are very low and not likely to cause interference with nearby electronic equipment.
RF Emissions CISPR 11	Class A	The ARVIS product is suitable for use in all non-domestic establishments.
RF emissions IEC 61000-3-2	N/A	
RF emissions IEC 61000-3-3	N/A	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/-15 kV air	+/- 8 kV contact +/-15 kV air	Normal ESD preventions should be taken, including use in the absence of floors covered with synthetic material. Relative humidity should be at least 20%.
Electrical fast transient / burst IEC 61000-4-4	Not Applicable to Battery Powered ARVIS		
Surge IEC 61000-4-5	Not Applicable to Battery Powered ARVIS		
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable to Battery Powered ARVIS		
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4.8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
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IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Conducted RF IEC 61000-4-6	Not Applicable to Battery Powered ARVIS		
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ARVIS product (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 2.3*(P)^{1/2}$ $d = 2.3*(P)^{1/2}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

RECOMMENDED SEPARATION DISTANCES TO NEARBY TRANSMITTERS	
The ARVIS system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ARVIS system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ARVIS system as recommended below, according to the maximum output power of the communications equipment.	
Nearby Transmitter's EIRP (W)	**Minimum Separation Distance (m)**
10	1.33
1	0.42
0.1	0.13
0.01	0.04

In addition to the battery powered ARVIS system, support equipment is provided to charge the ARVIS battery as needed. This support equipment is not part of the operating environment and is not required during surgery. The support equipment has been tested to the standards shown in this table.

Safety & EMC	**In combination with included external AC/DC power supply**	
Regulatory Approvals	Europe	CE
	International	CB
Electromagnetic Emissions	Europe	EN55011, EN55032, level B
	USA	FCC15 class B
Electromagnetic Immunity	ESD Immunity	EN/IEC61000-4-2
	Electromagnetic field immunity	EN/IEC61000-4-3
	EFT / Burt	EN/IEC61000-4-4
	Surge	EN/IEC61000-4-5
	Conducted Immunity	EN/IEC61000-4-6
	Magnetic Fields	EN/IEC61000-4-8
	Voltage dips, short instrumentations & voltage variations	EN/IEC61000-4-11
	Immunity characteristics	EN55024

Further Information

If further information on this product is needed or you wish to obtain a return product authorization, please contact Insight Medical Systems Customer Service at 512-832-9500 (Central Time 8:00 AM - 5:00 PM) in the USA.

Insight Medical Systems, Inc.
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Suite 200
Austin, TX 78758-5415
USA

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ARVIS uses the tracking cameras to measure the positions of trackers on the patient or instruments. **ARVIS** displays measurements as described in Performance Claims. Measurements are not displayed when a required tracker is not detected and in

range of the tracking cameras. Valid camera operating range extends at least from 40cm to 70cm from the eyepiece, but **ARVIS** may be able to provide accurate measurements at shorter or longer ranges.

Performance Claims

ARVIS Shoulder measures the following parameters with the stated accuracy in simulated use on benchtop fixtures.

- Drill inclination and version with an average absolute error of ≤ 1.5 °
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Clinical accuracy depends on accurate registration and inputs to the **ARVIS** Shoulder Application Software. The system has been validated in simulated clinical use (cadaver) to achieve the following accuracy:

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Principle of Operation

ARVIS Shoulder is an image-based surgical navigation system. A patient's preoperative CT scan of the shoulder joint is required to create a preoperative surgical plan that includes a landmarked digital bone model which is matched to intraoperative landmarks registered by the surgeon.

ARVIS uses cameras in the eyepiece to measure locations and angles between trackers mounted on the patient and trackers mounted on instruments. By prompting the user through a procedure-specific workflow to register the reference tracker to anatomic landmarks, the **ARVIS** Shoulder Application Software running on the belt pack calculates and displays positions of the instruments relative to the patient's anatomy.

Intended Use

The **ARVIS** system is a computer-controlled navigation system intended to provide intra-operative measurements to the surgeon to aid in selection and positioning of orthopedic implant components.

Indications For Use

ARVIS ® Shoulder is indicated for assisting the surgeon in the positioning and alignment of implants relative to reference alignment axes and landmarks in stereotactic orthopedic surgery.

The system aids the surgeon in making intraoperative measurements and locating anatomical structures of the shoulder joint based on the patient's preoperative imaging.

ARVIS® Shoulder is indicated for total shoulder arthroplasty using the Enovis AltiVate implant system.

Contraindications

- Significant loss of bone affecting identification of the required landmarks
- Excessive soft tissue interference affecting identification of the required landmarks
- Severe osteoporosis at fixation site(s), including but not limited to weakness of the coracoid process which could lead to adverse effects
- The presence of infection
- Any contraindication associated with shoulder arthroplasty surgery

Adverse Effects

Possible adverse effects include premature implant failure, dislocation or instability, decreased range of motion, infection, tissue injury, nerve injury and weakness, fracture, foreign body reaction, increased anesthesia time, heart attack, vascular injury, neck injury, burns, electrical shock, and cardiovascular injury.

Compatibility

- **ARVIS** Shoulder is indicated for use with the Enovis AltiVate® implant system.
- Steinmann Pins (x2), 2.5mm x 100mm, are required for the Mechanical Mount.
- Precision AI Surgical Planning Software must be used for preoperative planning before navigation.
- Stryker® Flyte®or T7® helmet together with provided compatible adaptors can be used to wear the **ARVIS** Eyepiece.

User Profile

The **ARVIS** system is to be used by orthopedic surgeons and operating room staff who perform shoulder arthroplasty. Users should reference the ARVIS® Shoulder Surgical Technique Guide P/N 22000 for step-by-step product instructions. Training on product usage is available, and strongly recommended.

To arrange training, contact Insight Medical Systems, Inc.

Usage Environment

The **ARVIS** system is designed for use within hospital operating room environments. Infrared Radiation (IR) sources, including operating room lights and windows, may interfere with the cameras that are part of the **ARVIS** system. Avoid environments with excessive IR sources.

The **ARVIS** system is designed for use in a hospital operating room within the following conditions:

- Temperature (15 to 25°C)
- Humidity (20-80% non-condensing)
- Pressure (70-106 kPa)

The **ARVIS** Eyepiece is worn on the surgeon's head. The **ARVIS** Belt Pack is worn on the surgeon's belt or waistband. No electronic hardware is applied to the patient. The surgeon stands adjacent to the patient to operate.

The **ARVIS** Battery Charger is intended to be used outside the operating room.

Definition of Symbols

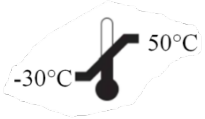
The following symbols are used in the **ARVIS** system labeling:

Follow Instructions for use

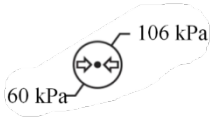
Do not dispose in trash

Non-Sterile

Humidity



Storage Temperature



Pressure

Manufacturer

Serial Number

Catalog Number

Hardware Information

ARVIS Shoulder Instrument Set Components (P/N 21300)

Catalog Number	Description
21100	Instrument Tray Base, Shoulder
11000	Instrument Tray Lid
25000	Stylus Drill Guide
23000	Mechanical Mount
24000	Tracker A, Mechanical
26000	Cobb Elevator, 1 in
10800	3.5mm Hex Driver
18300	Glenoid Drill Guide
18400	Reverse Baseplate Registration Tool
18500	Reference Pin Guide

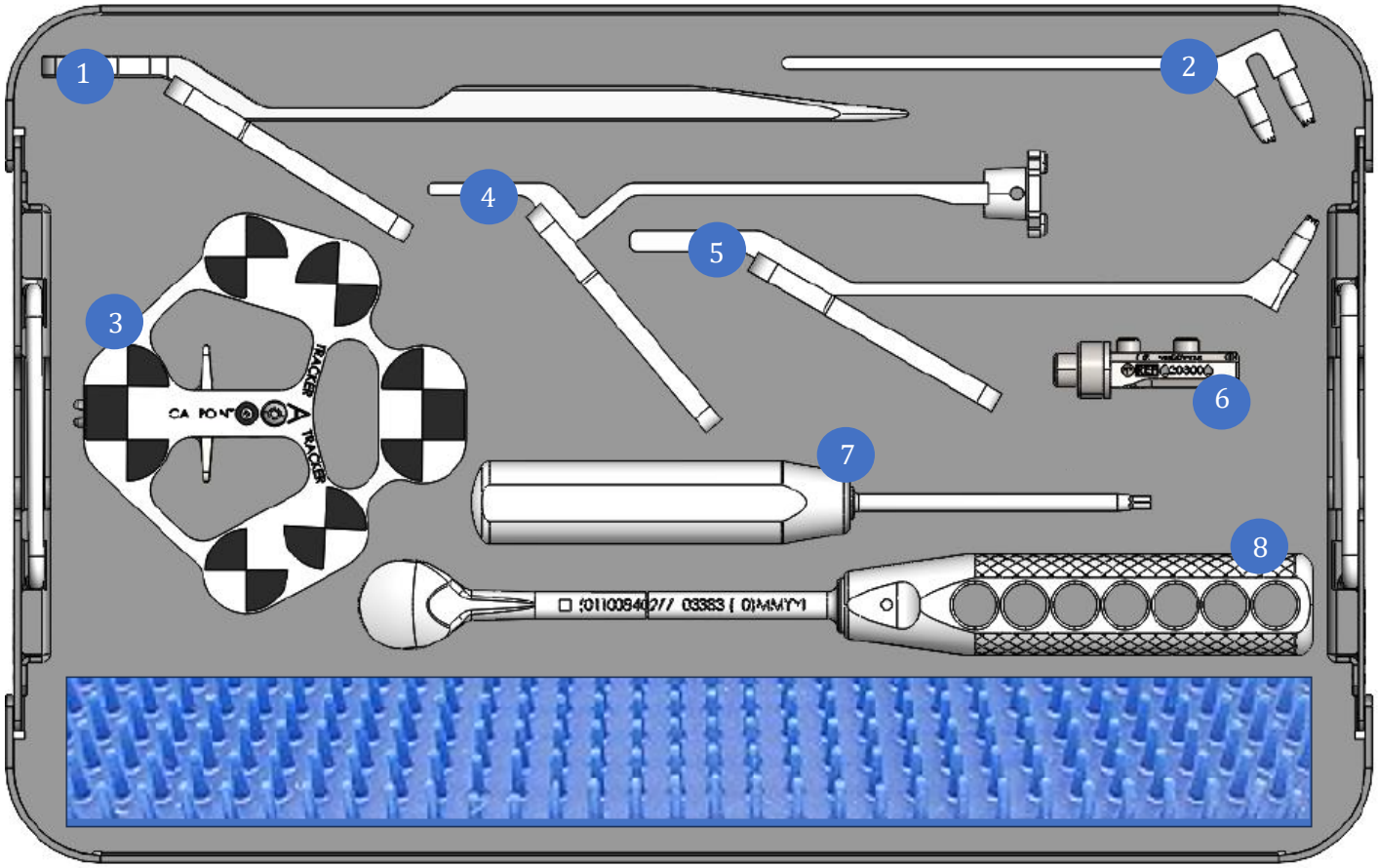
ARVIS Electronic Hardware Components and Accessories (P/N 14100)

Catalog Number	Description
12400	ARVIS Eyepiece Assembly
12500	ARVIS Belt Pack
12700	ARVIS Computer Module
12800	ARVIS Battery
13200	ARVIS Eyepiece Cable
13000	ARVIS Battery Charger
13800	ARVIS Charger Power Supply
13900	ARVIS Charger Cord, USA
15200	Charger, 25W USB-C, USA
14103	Cable Hook
17700	ARVIS Installation Kit

Use only accessories supplied by the manufacturer.

Optional Additional ARVIS Accessories

Catalog Number	Description
17100	ARVIS Headband
17500	FLYTE Mounting Kit
21700	T7 Adapter Kit



1. Stylus Drill Guide
2. Reference Pin Guide
3. Tracker A, Mechanical
4. Reverse Baseplate Registration Tool
5. Glenoid Drill Guide
6. Mechanical Mount
7. 3.5mm Hex Driver
8. Cobb Elevator, 1 in

Electronics Cleaning Instructions

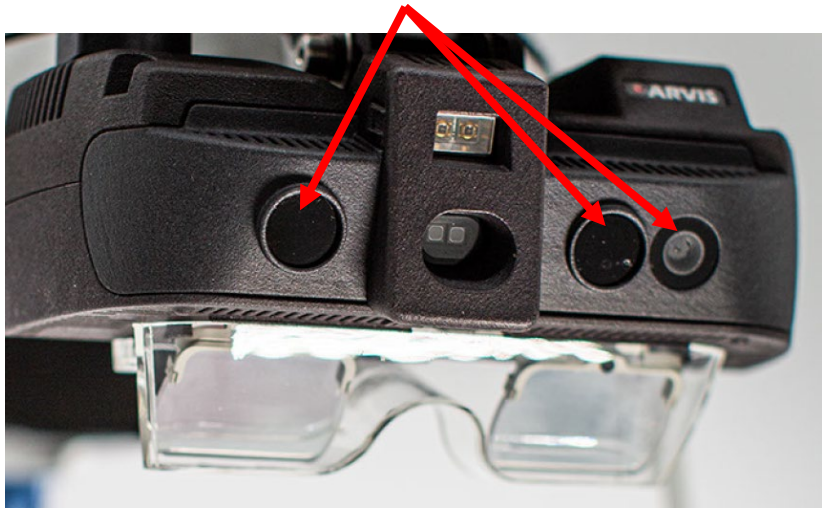
The electronic hardware components comprising the **ARVIS** system are the Eyepiece, Belt Pack, Battery, and Chargers. The electronic hardware components are re-usable.

- The Chargers are not intended for use in the operating room.
- The Eyepiece does not provide eye protection. If there is a likelihood of airborne blood or other soil, the user is advised to wear a legally marketed face shield for protection. The user is further advised to wear a legally marketed surgical gown or toga when a likelihood of soiling exists.

With appropriate attire, the electronic components of the **ARVIS** system should not need frequent cleaning, but they may be cleaned as described below as needed.

- Remove the **ARVIS** Battery and shut down the **ARVIS** Computer Module.
- Wipe with isopropyl alcohol solution (70-99%) using a lint-free cloth for one minute. Follow all label instructions for isopropyl alcohol.
- Do not use abrasive brushes or cloths.
- Take care not to scratch the camera covers. Visually inspect each camera cover after cleaning to verify that there are no scratches or residue.
- Take care not to introduce excess liquids into the Eyepiece via the cooling vents.
- Do not immerse. Do not sterilize. Allow to dry fully prior to use.
- Do not use phenolic disinfectants, as they may damage the Eyepiece or Belt Pack enclosures.

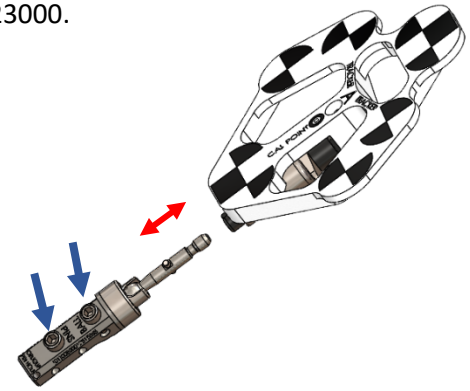
Camera Covers



Instrument Cleaning Instructions

The ARVIS Instruments are re-usable. Clean and Sterilize all instruments prior to first use and after every use.

1. Clean the instruments as soon as possible after use and avoid allowing soiled instruments to dry. Immerse, or use moist towels or sponges soaked with distilled or de-ionized water to keep moist prior to cleaning.
2. Disassemble instruments into the component parts listed in the "**ARVIS** Instrument Set Components" table.
    a. Separate tracker from mount.
    b. Loosen both clamping screws in Mechanical Mount 23000.



3. Rinse instruments under running cold utility (tap) water to remove gross soil.
    a. While rinsing, actuate all moving parts of the instruments and use a soft bristled brush to aid in removal of gross soil.
4. Flush utility (tap) water through lumens and other hard to reach areas of instruments.
5. An ultrasonic cleaner may be optionally used.
6. Load the instruments into automated parts washer for processing.
7. Run the automated washer with the following parameters:
    a. Pre-wash for 2 minutes with cold tap water.
    b. Enzyme wash for 2 minutes with hot tap water and enzymatic detergent prepared per the manufacturer's directions for use.
    c. Rinse for 5 minutes with 43°C (nominal) de-ionized or reverse-osmosis water.
    d. Dry for 7 minutes at 90°C (nominal).
8. After cleaning, instruments (disassembled, if applicable) should be visually inspected. All steps of the cleaning process should be repeated for incompletely cleaned instruments.

Note: Use of water-soluble lubricants is recommended for instruments with moving parts or those intended to be assembled intraoperatively to another instrument.

Autoclave Sterilization of Re-Usable Instruments

- Wrapped pre-vacuum, 4 minutes at 270°F (132°C). Dry time is 75 minutes*. Use an FDA-cleared wrap or sterile barrier. (Validation is based on use of Halyard Health H400.)
- Unwrapped pre-vacuum ("Flash"), 4 minutes at 270°F (132°C).
  *In addition to the prescribed dry time, an additional 30 minute cool down after removal from the sterilization chamber is recommended to ensure the devices are free from condensation and other moisture.

The recommended sterilization process has been validated to produce a sterility assurance level of (10^{-6}) when parts have been cleaned to the instructions above. Other steam cycles and cleaning procedures have not been evaluated and must be qualified by the user.

Effective sterilization is predicated on thorough cleaning and drying processes. Failure to do so will compromise the sterilization process and render the processed instrument unsuitable for clinical use.

Disposal

Do not throw any part of this system in the trash. Dispose of components in accordance with local regulations.

Storage and Transportation

Temperature: -30 to 50 °C; Humidity: 10 to 90% RH; (non-condensing); Pressure: 60 kPa to 106 kPa.

Handle with care.

Maintenance

Prior to each use, check the instruments for wear or damage. Note especially the condition of tracker markings and fit of interfaces between trackers and tracker mounts. Although the system's instruments do not have a usage limit and are expected to last for extended use, damaged or worn instruments should be replaced. Use of damaged instruments may lead to errors in navigation.

Follow instructions for the proper inspection, cleaning, and sterilization (as applicable) of system components. No further maintenance is required. Do not service or modify any system component.

Any part failing to perform as intended should be reported to the manufacturer for resolution.

Warranty

The product is warranted to be free from defects in material and workmanship.

Electrical Safety

This equipment has been tested and found to comply with EMC limits per IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interface with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Consult Insight Medical Systems or authorized representative for help.

FCC ID: SH6MDBT42Q This device compiles with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

Operating Conditions: Temperature: 15-25 °C; Humidity: 20-80% (RH) non-condensing; Pressure: 70-106kPa.

Warning: This device is designed for very specific tasks. Use in an environment containing EM disturbances outside the capability of this device may compromise the surgical outcome.

Warning: This device is not designed for use next to or stacked with other equipment. Use next to or stacked with other equipment should be avoided due to improper operation.

Warning: Use of batteries, computing modules or cables other than those provided by Insight Medical Systems could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ARVIS® system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Note: This device has been tested for electromagnetic immunity and shown to maintain essential performance (tracking error ≤5mm) when exposed to expected levels of electromagnetic disturbances (further defined in the subsequent tables). The system has internal software quality controls, which stop progression through the workflow. If a user repeatedly fails to progress beyond a step in the workflow, the user should first ensure they are properly following the surgical technique and that there are no obstructions blocking the eyepiece. If still unable to proceed, the user should discontinue use of the device.

The ARVIS system is battery powered, which modifies the applicable EMC immunity tests. Shown here are the emissions and immunity tests applicable to the ARVIS system comprised of the eyepiece, belt pack, battery and USB cable assembly that is worn by the user during surgery.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.		
EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
RF Emissions CISPR 11	Group 1	The ARVIS product uses RF energy only for internal function (except for intentional communication). RF emissions are very low and not likely to cause interference with nearby electronic equipment.
RF Emissions CISPR 11	Class A	The ARVIS product is suitable for use in all non-domestic establishments.
RF emissions IEC 61000-3-2	N/A	
RF emissions IEC 61000-3-3	N/A	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/-15 kV air	+/- 8 kV contact +/-15 kV air	Normal ESD preventions should be taken, including use in the absence of floors covered with synthetic material. Relative humidity should be at least 20%.
Electrical fast transient / burst IEC 61000-4-4	Not Applicable to Battery Powered ARVIS		
Surge IEC 61000-4-5	Not Applicable to Battery Powered ARVIS		
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable to Battery Powered ARVIS		
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4.8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Conducted RF IEC 61000-4-6	Not Applicable to Battery Powered ARVIS		
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ARVIS product (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 2.3*(P)^{1/2}$ $d = 2.3*(P)^{1/2}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

RECOMMENDED SEPARATION DISTANCES TO NEARBY TRANSMITTERS	
The ARVIS system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ARVIS system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ARVIS system as recommended below, according to the maximum output power of the communications equipment.	
Nearby Transmitter's EIRP (W)	**Minimum Separation Distance (m)**
10	1.33
1	0.42
0.1	0.13
0.01	0.04

In addition to the battery powered ARVIS system, support equipment is provided to charge the ARVIS battery as needed. This support equipment is not part of the operating environment and is not required during surgery. The support equipment has been tested to the standards shown in this table.

Safety & EMC	**In combination with included external AC/DC power supply**	
Regulatory Approvals	Europe	CE
	International	CB
Electromagnetic Emissions	Europe	EN55011, EN55032, level B
	USA	FCC15 class B
Electromagnetic Immunity	ESD Immunity	EN/IEC61000-4-2
	Electromagnetic field immunity	EN/IEC61000-4-3
	EFT / Burt	EN/IEC61000-4-4
	Surge	EN/IEC61000-4-5
	Conducted Immunity	EN/IEC61000-4-6
	Magnetic Fields	EN/IEC61000-4-8
	Voltage dips, short instrumentations & voltage variations	EN/IEC61000-4-11
	Immunity characteristics	EN55024

Further Information

If further information on this product is needed or you wish to obtain a return product authorization, please contact Insight Medical Systems Customer Service at 512-832-9500 (Central Time 8:00 AM - 5:00 PM) in the USA.

Insight Medical Systems, Inc.
9801 Metric Blvd
Suite 200
Austin, TX 78758-5415
USA

Effective 2024-06-18 thru 2024-06-24

ARVIS® Shoulder Surgical Navigation System Instructions for Use

Model: ARV-01

⚠WARNING: This document should always be used in conjunction with the ARVIS® Shoulder Surgical Technique Guide P/N 22000 which contains additional product instructions. Access the Surgical Technique Guide at www.insightmedsys.com/resources with password “ARVIS”.

Insight Medical Systems, Inc.
www.insightmedsys.com

Table of Contents

System Information

Precaution

Federal (USA) law restricts this device to sale by or on the order of a physician.

General Warnings

- Read all instructions prior to use.
- Do not operate the system without proper training. It is the surgeon's responsibility to be familiar with this technique prior to surgery.
- Navigation output does not supersede the surgeon's clinical judgment.
- Use only accessories provided with the system. Do not substitute cables or any other components. Do not connect any accessories not provided by the manufacturer to the device's USB connectors, including the headlight output connector. Do not attempt to use a computing device other than the computer module provided with the system.
- Prior to use, check the instruments for wear or damage. Replace damaged or worn instruments before use.
- Prior to use, the coracoid process should be evaluated for suitability of mount fixation utilizing pins.
- The eyepiece includes a headlight, infrared emitter, and Class I laser. The surfaces near the headlight, as well as other surfaces, may become hot during use. Touch only parts of the eyepiece intended for adjustment.
- To avoid potential interference with pacemakers, do not place any system component near the patient's or user's chest. There is a potential for electromagnetic interference. If the device interferes with other equipment, reposition or discontinue use of the device. If the device receives harmful interference affecting its function, discontinue use.
- Do not modify or service any system component.
- The **ARVIS** system includes the eyepiece, belt pack, battery, chargers, and instrument set. Instruments are provided NON-STERILE and must be cleaned and sterilized prior to each use. Electrical components are NON-STERILE and must not be sterilized.
- To avoid the risk or electric shock, this equipment must only be connected to a supply mains with protective earth.
- To maintain cybersecurity and correct operation, do not change settings on the provided computer module except as directed by Insight Medical Systems.
  - Do not enable Wi-Fi or cellular communication except as directed by Insight Medical Systems.
  - Do not install or remove applications or store non-Insight data.
  - Insight recommends installing a password to restrict access to the computer module.
  - Insight recommends trusted users remember to control any removable drives used to transport encrypted plan files to the system and not use drives for any purposes other than storing and transferring plan data files.
  - Confirm password and/or plan import in advance of patient being anesthetized
  - Review and confirm patient and plan details before plan selection

System Description

ARVIS Shoulder is a computer-controlled surgical navigation system for shoulder arthroplasty. It combines software, electronic hardware and surgical instruments to intraoperatively track tools and locate anatomical structures and display feedback to the user. The system aids the surgeon in executing an approved preoperative plan. For information on preoperative planning, please refer to the planning software Instructions for Use and User Manual.

The **ARVIS** Eyepiece contains stereo IR tracking cameras, a color camera, stereo display, IR illumination, and IR laser illuminator. A visible headlight is mounted to the eyepiece and connected via a micro-USB cable. The eyepiece communicates with the Belt Pack via a USB-C cable. All system instructions, prompts, alerts, and outputs are displayed to the surgeon on the eyepiece display.

The Belt Pack includes the computer module, battery, and power management board. The Belt Pack supplies power to the eyepiece and runs the **ARVIS** Shoulder Application Software.

The **ARVIS** electronics are worn on the surgeon's body during surgery. There is no interface to external equipment except for the **ARVIS** Battery Charger, which recharges the battery when not in use.

ARVIS uses the tracking cameras to measure the positions of trackers on the patient or instruments. **ARVIS** displays measurements as described in Performance Claims. Measurements are not displayed when a required tracker is not detected and in

range of the tracking cameras. Valid camera operating range extends at least from 40cm to 70cm from the eyepiece, but **ARVIS** may be able to provide accurate measurements at shorter or longer ranges.

Performance Claims

ARVIS Shoulder measures the following parameters with the stated accuracy in simulated use on benchtop fixtures.

- Drill inclination and version with an average absolute error of ≤ 1.5 °
- Superior/Inferior and Anterior/Posterior location of drill entry point with an average absolute error of ≤ 1.5mm on each axis
- Glenoid implant inclination and version with an average absolute error of ≤ 1.5 °

- Rotation of the glenoid implant about its central axis with an average absolute error of ≤ 1.5 °
- Length range of a virtual screw (up to 50mm) extending from a theoretical glenoid baseplate with an average absolute error of ≤ 0.5mm

Clinical accuracy depends on accurate registration and inputs to the **ARVIS** Shoulder Application Software. The system has been validated in simulated clinical use (cadaver) to achieve the following accuracy:

- Superior/Inferior and Anterior/Posterior location of glenoid implant with an average absolute error of ≤ 1.5mm on each axis
- Glenoid implant inclination and version with an average absolute error of ≤ 3.0 °
- Rotation of the glenoid implant about its central axis with an average absolute error of ≤ 3.0 °
- Length range of a virtual screw (up to 50mm) extending from a theoretical glenoid baseplate with an average absolute error of ≤ 2.0mm

Principle of Operation

ARVIS Shoulder is an image-based surgical navigation system. A patient's preoperative CT scan of the shoulder joint is required to create a preoperative surgical plan that includes a landmarked digital bone model which is matched to intraoperative landmarks registered by the surgeon.

ARVIS uses cameras in the eyepiece to measure locations and angles between trackers mounted on the patient and trackers mounted on instruments. By prompting the user through a procedure-specific workflow to register the reference tracker to anatomic landmarks, the **ARVIS** Shoulder Application Software running on the belt pack calculates and displays positions of the instruments relative to the patient's anatomy.

Intended Use

The **ARVIS** system is a computer-controlled navigation system intended to provide intra-operative measurements to the surgeon to aid in selection and positioning of orthopedic implant components.

Indications For Use

ARVIS ® Shoulder is indicated for assisting the surgeon in the positioning and alignment of implants relative to reference alignment axes and landmarks in stereotactic orthopedic surgery.

The system aids the surgeon in making intraoperative measurements and locating anatomical structures of the shoulder joint based on the patient's preoperative imaging.

ARVIS® Shoulder is indicated for total shoulder arthroplasty using the Enovis AltiVate implant system.

Contraindications

- Significant loss of bone affecting identification of the required landmarks
- Excessive soft tissue interference affecting identification of the required landmarks
- Severe osteoporosis at fixation site(s), including but not limited to weakness of the coracoid process which could lead to adverse effects
- The presence of infection
- Any contraindication associated with shoulder arthroplasty surgery

Adverse Effects

Possible adverse effects include premature implant failure, dislocation or instability, decreased range of motion, infection, tissue injury, nerve injury and weakness, fracture, foreign body reaction, increased anesthesia time, heart attack, vascular injury, neck injury, burns, electrical shock, and cardiovascular injury.

Compatibility

- **ARVIS** Shoulder is indicated for use with the Enovis AltiVate® implant system.
- Steinmann Pins (x2), 2.5mm x 100mm, are required for the Mechanical Mount. The system was validated using 170-00-002 Tech Shoulder Pack.
- Precision AI Surgical Planning Software must be used for preoperative planning before navigation.
- Stryker® Flyte®or T7® helmet together with provided compatible adaptors can be used to wear the **ARVIS** Eyepiece.

User Profile

The **ARVIS** system is to be used by orthopedic surgeons and operating room staff who perform shoulder arthroplasty. Users should reference the ARVIS® Shoulder Surgical Technique Guide P/N 22000 for step-by-step product instructions. Training on product usage is available, and strongly recommended.

To arrange training, contact Insight Medical Systems, Inc.

Usage Environment

The **ARVIS** system is designed for use within hospital operating room environments. Infrared Radiation (IR) sources, including operating room lights and windows, may interfere with the cameras that are part of the **ARVIS** system. Avoid environments with excessive IR sources.

The **ARVIS** system is designed for use in a hospital operating room within the following conditions:

- Temperature (15 to 25°C)
- Humidity (20-80% non-condensing)
- Pressure (70-106 kPa)

The **ARVIS** Eyepiece is worn on the surgeon's head. The **ARVIS** Belt Pack is worn on the surgeon's belt or waistband. No electronic hardware is applied to the patient. The surgeon stands adjacent to the patient to operate.

The **ARVIS** Battery Charger is intended to be used outside the operating room.

Definition of Symbols

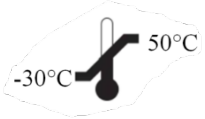
The following symbols are used in the **ARVIS** system labeling:

Follow Instructions for use

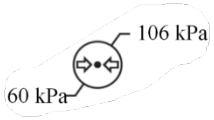
Do not dispose in trash

Non-Sterile

Humidity



Storage Temperature



Pressure

Manufacturer

Serial Number

Catalog Number

Hardware Information

ARVIS Shoulder Instrument Set Components (P/N 21300)

Catalog Number	Description
21100	Instrument Tray Base, Shoulder
11000	Instrument Tray Lid
22100	In-Line Trigger Stylus
23000	Mechanical Mount
24000	Tracker A, Mechanical
26000	Cobb Elevator, 1 in
10800	3.5mm Hex Driver
18300	Glenoid Drill Guide
22200	Reverse Registration Tool
18500	Reference Pin Guide

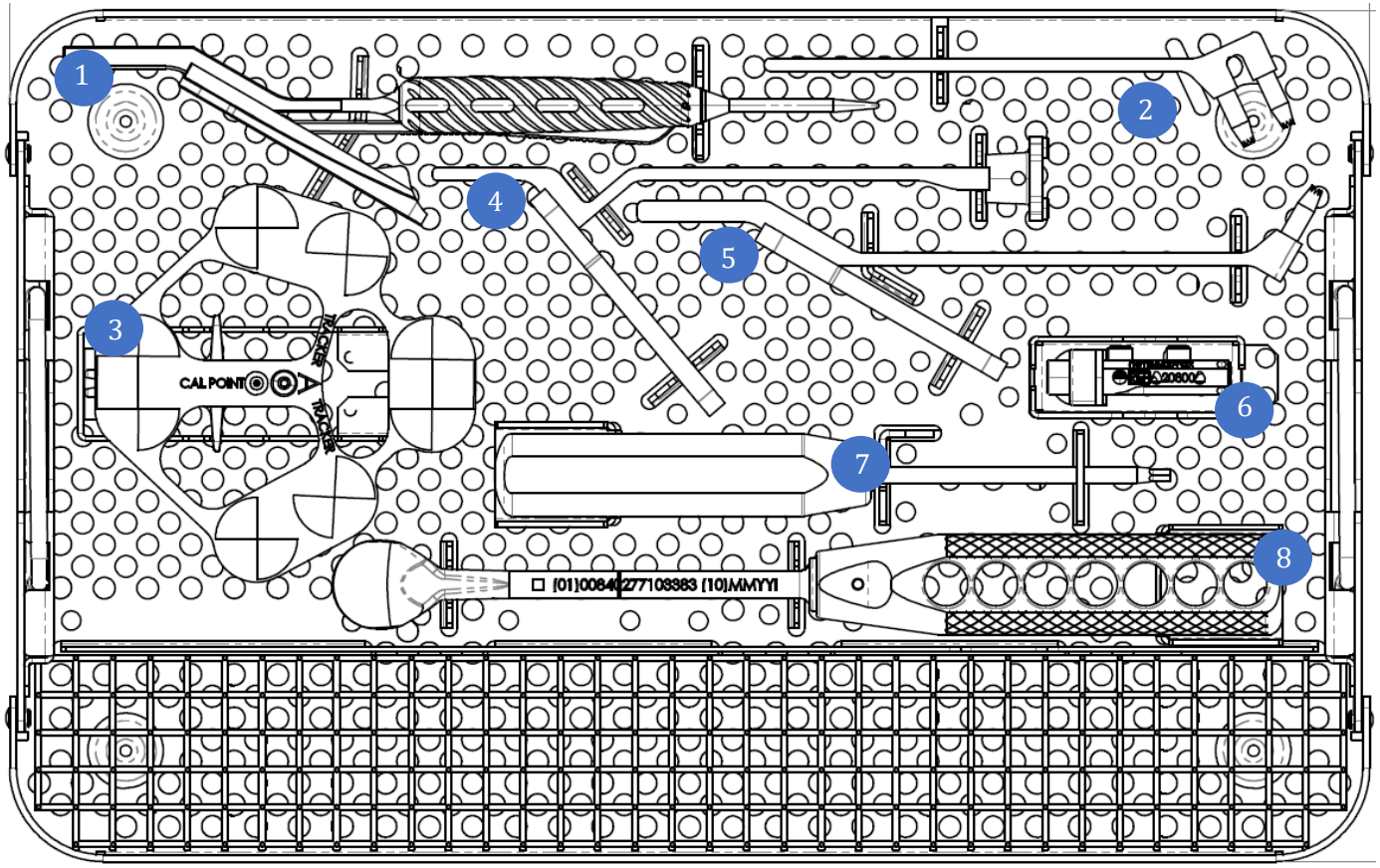
ARVIS Electronic Hardware Components and Accessories (P/N 22300)

Catalog Number	Description
12400	ARVIS Eyepiece Assembly
12500	ARVIS Belt Pack
12700	ARVIS Computer Module
12800	ARVIS Battery
13200	ARVIS Eyepiece Cable
13000	ARVIS Battery Charger
13800	ARVIS Charger Power Supply
13900	ARVIS Charger Cord, USA
15200	Charger, 25W USB-C, USA
17700	ARVIS Installation Kit

Use only accessories supplied by the manufacturer.

Surgeon/Case-Specific ARVIS Accessories

Catalog Number	Description
17100	ARVIS Headband
17500	FLYTE Mounting Kit
21700	T7 Adapter Kit
170-00-002	Tech Shoulder Pack



1. In-Line Trigger Stylus
2. Reference Pin Guide
3. Tracker A, Mechanical
4. Reverse Registration Tool
5. Glenoid Drill Guide
6. Mechanical Mount
7. 3.5mm Hex Driver
8. Cobb Elevator, 1 in

Electronics Cleaning Instructions

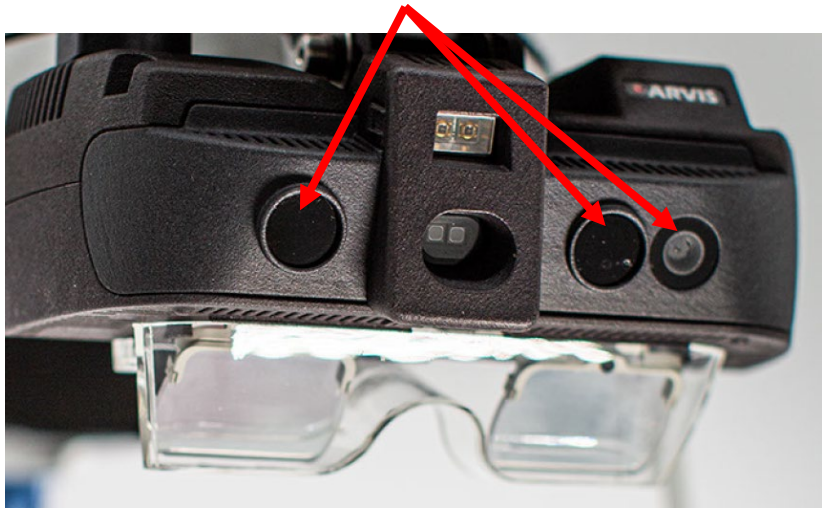
The electronic hardware components comprising the **ARVIS** system are the Eyepiece, Belt Pack, Battery, and Chargers. The electronic hardware components are re-usable.

- The Chargers are not intended for use in the operating room.
- The Eyepiece does not provide eye protection. If there is a likelihood of airborne blood or other soil, the user is advised to wear a legally marketed face shield for protection. The user is further advised to wear a legally marketed surgical gown or toga when a likelihood of soiling exists.

With appropriate attire, the electronic components of the **ARVIS** system should not need frequent cleaning, but they may be cleaned as described below as needed.

- Remove the **ARVIS** Battery and shut down the **ARVIS** Computer Module.
- Wipe with isopropyl alcohol solution (70-99%) using a lint-free cloth for one minute. Follow all label instructions for isopropyl alcohol.
- Do not use abrasive brushes or cloths.
- Take care not to scratch the camera covers. Visually inspect each camera cover after cleaning to verify that there are no scratches or residue.
- Take care not to introduce excess liquids into the Eyepiece via the cooling vents.
- Do not immerse. Do not sterilize. Allow to dry fully prior to use.
- Do not use phenolic disinfectants, as they may damage the Eyepiece or Belt Pack enclosures.

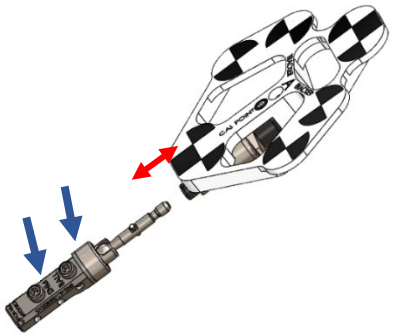
Camera Covers



Instrument Cleaning Instructions

The ARVIS Instruments are re-usable. Clean and Sterilize all instruments prior to first use and after every use.

1. Clean the instruments as soon as possible after use and avoid allowing soiled instruments to dry. Immerse, or use moist towels or sponges soaked with distilled or de-ionized water to keep moist prior to cleaning.
2. Disassemble instruments into the component parts listed in the "**ARVIS** Instrument Set Components" table.
    a. Separate tracker from mount.
    b. Loosen both clamping screws in Mechanical Mount 23000.



3. Rinse instruments under running cold utility (tap) water to remove gross soil.
    a. While rinsing, actuate all moving parts of the instruments and use a soft bristled brush to aid in removal of gross soil.
4. Flush utility (tap) water through lumens and other hard to reach areas of instruments.
5. An ultrasonic cleaner may be optionally used.
6. Load the instruments into automated parts washer for processing.
7. Run the automated washer with the following parameters:
    a. Pre-wash for 2 minutes with cold tap water.
    b. Enzyme wash for 2 minutes with hot tap water and enzymatic detergent prepared per the manufacturer's directions for use.
    c. Rinse for 5 minutes with 43°C (nominal) de-ionized or reverse-osmosis water.
    d. Dry for 7 minutes at 90°C (nominal).
8. After cleaning, instruments (disassembled, if applicable) should be visually inspected. All steps of the cleaning process should be repeated for incompletely cleaned instruments.

Note: Use of water-soluble lubricants is recommended for instruments with moving parts or those intended to be assembled intraoperatively to another instrument.

Autoclave Sterilization of Re-Usable Instruments

- Wrapped pre-vacuum, 4 minutes at 270°F (132°C). Dry time is 75 minutes*. Use an FDA-cleared wrap or sterile barrier. (Validation is based on use of Halyard Health H400.)
- Unwrapped pre-vacuum ("Flash"), 4 minutes at 270°F (132°C).
  *In addition to the prescribed dry time, an additional 30 minute cool down after removal from the sterilization chamber is recommended to ensure the devices are free from condensation and other moisture.

The recommended sterilization process has been validated to produce a sterility assurance level of (10^{-6}) when parts have been cleaned to the instructions above. Other steam cycles and cleaning procedures have not been evaluated and must be qualified by the user.

Effective sterilization is predicated on thorough cleaning and drying processes. Failure to do so will compromise the sterilization process and render the processed instrument unsuitable for clinical use.

Disposal

Do not throw any part of this system in the trash. Dispose of components in accordance with local regulations.

Storage and Transportation

Temperature: -30 to 50 °C; Humidity: 10 to 90% RH; (non-condensing); Pressure: 60 kPa to 106 kPa.

Handle with care.

Maintenance

Prior to each use, check the instruments for wear or damage. Note especially the condition of tracker markings and fit of interfaces between trackers and tracker mounts. Although the system's instruments do not have a usage limit and are expected to last for extended use, damaged or worn instruments should be replaced. Use of damaged instruments may lead to errors in navigation.

Follow instructions for the proper inspection, cleaning, and sterilization (as applicable) of system components. No further maintenance is required. Do not service or modify any system component.

Any part failing to perform as intended should be reported to the manufacturer for resolution.

Warranty

The product is warranted to be free from defects in material and workmanship.

Electrical Safety

This equipment has been tested and found to comply with EMC limits per IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interface with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Consult Insight Medical Systems or authorized representative for help.

FCC ID: SH6MDBT42Q This device compiles with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

Operating Conditions: Temperature: 15-25 °C; Humidity: 20-80% (RH) non-condensing; Pressure: 70-106kPa.

Warning: This device is designed for very specific tasks. Use in an environment containing EM disturbances outside the capability of this device may compromise the surgical outcome.

Warning: This device is not designed for use next to or stacked with other equipment. Use next to or stacked with other equipment should be avoided due to improper operation.

Warning: Use of batteries, computing modules or cables other than those provided by Insight Medical Systems could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ARVIS® system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Note: This device has been tested for electromagnetic immunity and shown to maintain essential performance (tracking error ≤5mm) when exposed to expected levels of electromagnetic disturbances (further defined in the subsequent tables). The system has internal software quality controls, which stop progression through the workflow. If a user repeatedly fails to progress beyond a step in the workflow, the user should first ensure they are properly following the surgical technique and that there are no obstructions blocking the eyepiece. If still unable to proceed, the user should discontinue use of the device.

The ARVIS system is battery powered, which modifies the applicable EMC immunity tests. Shown here are the emissions and immunity tests applicable to the ARVIS system comprised of the eyepiece, belt pack, battery and USB cable assembly that is worn by the user during surgery.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.		
EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
RF Emissions CISPR 11	Group 1	The ARVIS product uses RF energy only for internal function (except for intentional communication). RF emissions are very low and not likely to cause interference with nearby electronic equipment.
RF Emissions CISPR 11	Class A	The ARVIS product is suitable for use in all non-domestic establishments.
RF emissions IEC 61000-3-2	N/A	
RF emissions IEC 61000-3-3	N/A	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/-15 kV air	+/- 8 kV contact +/-15 kV air	Normal ESD preventions should be taken, including use in the absence of floors covered with synthetic material. Relative humidity should be at least 20%.
Electrical fast transient / burst IEC 61000-4-4	Not Applicable to Battery Powered ARVIS		
Surge IEC 61000-4-5	Not Applicable to Battery Powered ARVIS		
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable to Battery Powered ARVIS		
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4.8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Conducted RF IEC 61000-4-6	Not Applicable to Battery Powered ARVIS		
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ARVIS product (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 2.3*(P)^{1/2}$ $d = 2.3*(P)^{1/2}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

RECOMMENDED SEPARATION DISTANCES TO NEARBY TRANSMITTERS	
The ARVIS system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ARVIS system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ARVIS system as recommended below, according to the maximum output power of the communications equipment.	
Nearby Transmitter's EIRP (W)	**Minimum Separation Distance (m)**
10	1.33
1	0.42
0.1	0.13
0.01	0.04

In addition to the battery powered ARVIS system, support equipment is provided to charge the ARVIS battery as needed. This support equipment is not part of the operating environment and is not required during surgery. The support equipment has been tested to the standards shown in this table.

Safety & EMC	**In combination with included external AC/DC power supply**	
Regulatory Approvals	Europe	CE
	International	CB
Electromagnetic Emissions	Europe	EN55011, EN55032, level B
	USA	FCC15 class B
Electromagnetic Immunity	ESD Immunity	EN/IEC61000-4-2
	Electromagnetic field immunity	EN/IEC61000-4-3
	EFT / Burt	EN/IEC61000-4-4
	Surge	EN/IEC61000-4-5
	Conducted Immunity	EN/IEC61000-4-6
	Magnetic Fields	EN/IEC61000-4-8
	Voltage dips, short instrumentations & voltage variations	EN/IEC61000-4-11
	Immunity characteristics	EN55024

Further Information

If further information on this product is needed or you wish to obtain a return product authorization, please contact Insight Medical Systems Customer Service at 1-800-456-8696 (Central Time 8:00 AM - 5:00 PM) in the USA.

Insight Medical Systems, Inc.
9801 Metric Blvd
Suite 200
Austin, TX 78758-5415
USA

Effective 2024-06-24 thru 2025-03-12

ARVIS® Shoulder Surgical Navigation System Instructions for Use

Model: ARV-01

⚠WARNING: This document should always be used in conjunction with the ARVIS® Shoulder Surgical Technique Guide P/N 22000 which contains additional product instructions. Access the Surgical Technique Guide at www.insightmedsys.com/resources with password “ARVIS”.

Insight Medical Systems, Inc.
www.insightmedsys.com

Table of Contents

System Information

Precaution

Federal (USA) law restricts this device to sale by or on the order of a physician.

General Warnings

- Read all instructions prior to use.
- Do not operate the system without proper training. It is the surgeon's responsibility to be familiar with this technique prior to surgery.
- Navigation output does not supersede the surgeon's clinical judgment.
- Use only accessories provided with the system. Do not substitute cables or any other components. Do not connect any accessories not provided by the manufacturer to the device's USB connectors, including the headlight output connector. Do not attempt to use a computing device other than the computer module provided with the system.
- Prior to use, check the instruments for wear or damage. Replace damaged or worn instruments before use.
- Prior to use, the coracoid process should be evaluated for suitability of mount fixation utilizing pins.
- The eyepiece includes a headlight, infrared emitter, and Class I laser. The surfaces near the headlight, as well as other surfaces, may become hot during use. Touch only parts of the eyepiece intended for adjustment.
- To avoid potential interference with pacemakers, do not place any system component near the patient's or user's chest. There is a potential for electromagnetic interference. If the device interferes with other equipment, reposition or discontinue use of the device. If the device receives harmful interference affecting its function, discontinue use.
- Do not modify or service any system component.
- The **ARVIS** system includes the eyepiece, belt pack, battery, chargers, and instrument set. Instruments are provided NON-STERILE and must be cleaned and sterilized prior to each use. Electrical components are NON-STERILE and must not be sterilized.
- To avoid the risk or electric shock, this equipment must only be connected to a supply mains with protective earth.
- To maintain cybersecurity and correct operation, do not change settings on the provided computer module except as directed by Insight Medical Systems.
    - Do not enable Wi-Fi or cellular communication except as directed by Insight Medical Systems.
    - Do not install or remove applications or store non-Insight data.
    - Insight recommends installing a password to restrict access to the computer module.
    - Insight recommends trusted users remember to control any removable drives used to transport encrypted plan files to the system and not use drives for any purposes other than storing and transferring plan data files.
    - Confirm password and/or plan import in advance of patient being anesthetized
    - Review and confirm patient and plan details before plan selection

System Description

ARVIS Shoulder is a computer-controlled surgical navigation system for shoulder arthroplasty. It combines software, electronic hardware and surgical instruments to intraoperatively track tools and locate anatomical structures and display feedback to the user. The system aids the surgeon in executing an approved preoperative plan. For information on preoperative planning, please refer to the planning software Instructions for Use and User Manual.

The **ARVIS** Eyepiece contains stereo IR tracking cameras, a color camera, stereo display, IR illumination, and IR laser illuminator. A visible headlight is mounted to the eyepiece and connected via a micro-USB cable. The eyepiece communicates with the Belt Pack via a USB-C cable. All system instructions, prompts, alerts, and outputs are displayed to the surgeon on the eyepiece display.

The Belt Pack includes the computer module, battery, and power management board. The Belt Pack supplies power to the eyepiece and runs the **ARVIS** Shoulder Application Software.

The **ARVIS** electronics are worn on the surgeon's body during surgery. There is no interface to external equipment except for the **ARVIS** Battery Charger, which recharges the battery when not in use.

ARVIS uses the tracking cameras to measure the positions of trackers on the patient or instruments. **ARVIS** displays measurements as described in Performance Claims. Measurements are not displayed when a required tracker is not detected and in

range of the tracking cameras. Valid camera operating range extends at least from 40cm to 70cm from the eyepiece, but **ARVIS** may be able to provide accurate measurements at shorter or longer ranges.

Performance Claims

ARVIS Shoulder measures the following parameters with the stated accuracy in simulated use on benchtop fixtures.

- Drill inclination and version with an average absolute error of ≤ 1.5 °
- Superior/Inferior and Anterior/Posterior location of drill entry point with an average absolute error of ≤ 1.5mm on each axis
- Glenoid implant inclination and version with an average absolute error of ≤ 1.5 °

- Rotation of the glenoid implant about its central axis with an average absolute error of ≤ 1.5 °
- Length range of a virtual screw (up to 50mm) extending from a theoretical glenoid baseplate with an average absolute error of ≤ 0.5mm

Clinical accuracy depends on accurate registration and inputs to the **ARVIS** Shoulder Application Software. The system has been validated in simulated clinical use (cadaver) to achieve the following accuracy:

- Superior/Inferior and Anterior/Posterior location of glenoid implant with an average absolute error of ≤ 1.5mm on each axis
- Glenoid implant inclination and version with an average absolute error of ≤ 3.0 °
- Rotation of the glenoid implant about its central axis with an average absolute error of ≤ 3.0 °
- Length range of a virtual screw (up to 50mm) extending from a theoretical glenoid baseplate with an average absolute error of ≤ 2.0mm

Principle of Operation

ARVIS Shoulder is an image-based surgical navigation system. A patient's preoperative CT scan of the shoulder joint is required to create a preoperative surgical plan that includes a landmarked digital bone model which is matched to intraoperative landmarks registered by the surgeon.

ARVIS uses cameras in the eyepiece to measure locations and angles between trackers mounted on the patient and trackers mounted on instruments. By prompting the user through a procedure-specific workflow to register the reference tracker to anatomic landmarks, the **ARVIS** Shoulder Application Software running on the belt pack calculates and displays positions of the instruments relative to the patient's anatomy.

Intended Use

The **ARVIS** system is a computer-controlled navigation system intended to provide intra-operative measurements to the surgeon to aid in selection and positioning of orthopedic implant components.

Indications For Use

ARVIS ® Shoulder is indicated for assisting the surgeon in the positioning and alignment of implants relative to reference alignment axes and landmarks in stereotactic orthopedic surgery.

The system aids the surgeon in making intraoperative measurements and locating anatomical structures of the shoulder joint based on the patient's preoperative imaging.

ARVIS® Shoulder is indicated for total shoulder arthroplasty using the Enovis AltiVate implant system.

Contraindications

- Significant loss of bone affecting identification of the required landmarks
- Excessive soft tissue interference affecting identification of the required landmarks
- Severe osteoporosis at fixation site(s), including but not limited to weakness of the coracoid process which could lead to adverse effects
- The presence of infection
- Any contraindication associated with shoulder arthroplasty surgery

Adverse Effects

Possible adverse effects include premature implant failure, dislocation or instability, decreased range of motion, infection, tissue injury, nerve injury and weakness, fracture, foreign body reaction, increased anesthesia time, heart attack, vascular injury, neck injury, burns, electrical shock, and cardiovascular injury.

Compatibility

- **ARVIS** Shoulder is indicated for use with the Enovis AltiVate® implant system.
- Steinmann Pins (x2), 2.5mm x 100mm, are required for the Mechanical Mount. The system was validated using 170-00-002 Tech Shoulder Pack.
- Precision AI Surgical Planning Software must be used for preoperative planning before navigation.
- Stryker® Flyte®or T7® helmet together with provided compatible adaptors can be used to wear the **ARVIS** Eyepiece.

User Profile

The **ARVIS** system is to be used by orthopedic surgeons and operating room staff who perform shoulder arthroplasty. Users should reference the ARVIS® Shoulder Surgical Technique Guide P/N 22000 for step-by-step product instructions. Training on product usage is available, and strongly recommended.

To arrange training, contact Insight Medical Systems, Inc.

Usage Environment

The **ARVIS** system is designed for use within hospital operating room environments. Infrared Radiation (IR) sources, including operating room lights and windows, may interfere with the cameras that are part of the **ARVIS** system. Avoid environments with excessive IR sources.

The **ARVIS** system is designed for use in a hospital operating room within the following conditions:

- Temperature (15 to 25°C)
- Humidity (20-80% non-condensing)
- Pressure (70-106 kPa)

The **ARVIS** Eyepiece is worn on the surgeon's head. The **ARVIS** Belt Pack is worn on the surgeon's belt or waistband. No electronic hardware is applied to the patient. The surgeon stands adjacent to the patient to operate.

The **ARVIS** Battery Charger is intended to be used outside the operating room.

Definition of Symbols

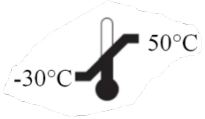
The following symbols are used in the **ARVIS** system labeling:

Follow Instructions for use

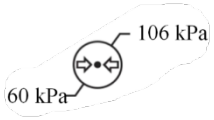
Do not dispose in trash

Non-Sterile

Humidity



Storage Temperature



Pressure

Manufacturer

Serial Number

Catalog Number

Hardware Information

ARVIS Shoulder Instrument Set Components (P/N 21300)

Catalog Number	Description
21100	Instrument Tray Base, Shoulder
11000	Instrument Tray Lid
22100	In-Line Trigger Stylus
23000	Mechanical Mount
24000	Tracker A, Mechanical
26000	Cobb Elevator, 1 in
10800	3.5mm Hex Driver
18300	Glenoid Drill Guide
22200	Reverse Registration Tool
18500	Reference Pin Guide

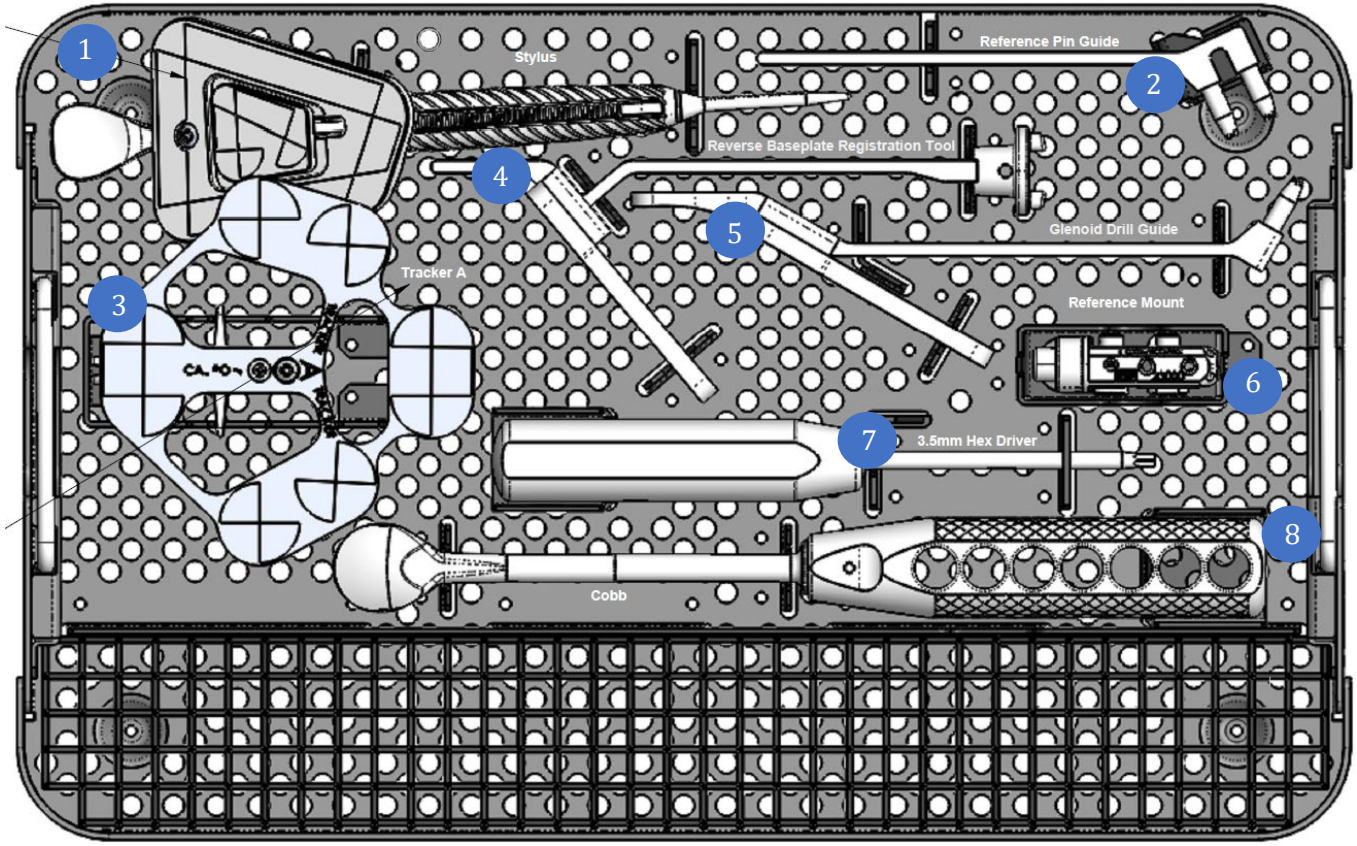
ARVIS Electronic Hardware Components and Accessories (P/N 22300)

Catalog Number	Description
12400	ARVIS Eyepiece Assembly
12500	ARVIS Belt Pack
12700	ARVIS Computer Module
12800	ARVIS Battery
13200	ARVIS Eyepiece Cable
13000	ARVIS Battery Charger
13800	ARVIS Charger Power Supply
13900	ARVIS Charger Cord, USA
15200	Charger, 25W USB-C, USA
17700	ARVIS Installation Kit

Use only accessories supplied by the manufacturer.

Surgeon/Case-Specific ARVIS Accessories

Catalog Number	Description
17100	ARVIS Headband
17500	FLYTE Mounting Kit
21700	T7 Adapter Kit
170-00-002	Tech Shoulder Pack



1. In-Line Trigger Stylus
2. Reference Pin Guide
3. Tracker A, Mechanical
4. Reverse Registration Tool
5. Glenoid Drill Guide
6. Mechanical Mount
7. 3.5mm Hex Driver
8. Cobb Elevator, 1 in

Electronics Cleaning Instructions

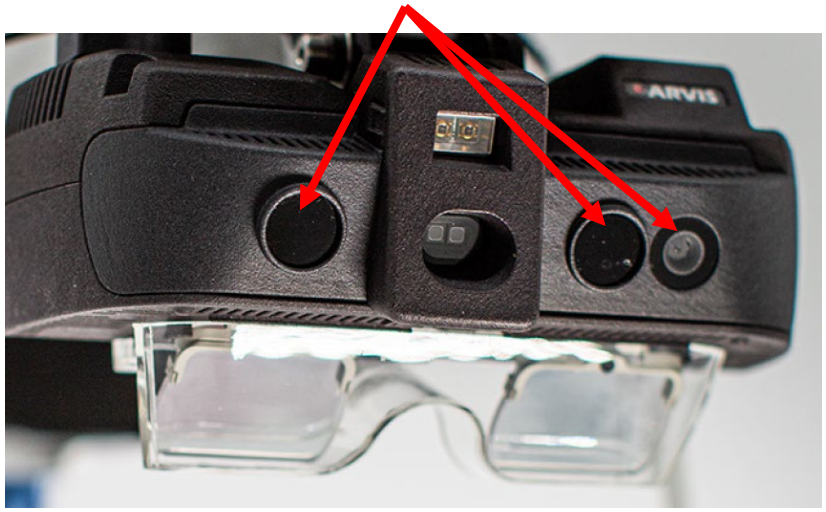
The electronic hardware components comprising the **ARVIS** system are the Eyepiece, Belt Pack, Battery, and Chargers. The electronic hardware components are re-usable.

- The Chargers are not intended for use in the operating room.
- The Eyepiece does not provide eye protection. If there is a likelihood of airborne blood or other soil, the user is advised to wear a legally marketed face shield for protection. The user is further advised to wear a legally marketed surgical gown or toga when a likelihood of soiling exists.

With appropriate attire, the electronic components of the **ARVIS** system should not need frequent cleaning, but they may be cleaned as described below as needed.

- Remove the **ARVIS** Battery and shut down the **ARVIS** Computer Module.
- Wipe with isopropyl alcohol solution (70-99%) using a lint-free cloth for one minute. Follow all label instructions for isopropyl alcohol.
- Do not use abrasive brushes or cloths.
- Take care not to scratch the camera covers. Visually inspect each camera cover after cleaning to verify that there are no scratches or residue.
- Take care not to introduce excess liquids into the Eyepiece via the cooling vents.
- Do not immerse. Do not sterilize. Allow to dry fully prior to use.
- Do not use phenolic disinfectants, as they may damage the Eyepiece or Belt Pack enclosures.

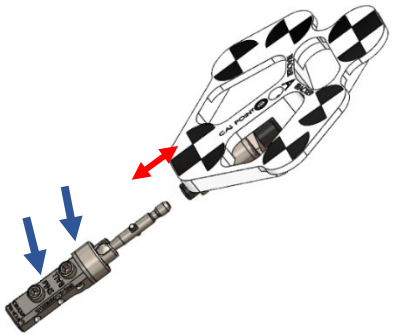
Camera Covers



Instrument Cleaning Instructions

The ARVIS Instruments are re-usable. Clean and Sterilize all instruments prior to first use and after every use.

1. Clean the instruments as soon as possible after use and avoid allowing soiled instruments to dry. Immerse, or use moist towels or sponges soaked with distilled or de-ionized water to keep moist prior to cleaning.
2. Disassemble instruments into the component parts listed in the "**ARVIS** Instrument Set Components" table.
    a. Separate tracker from mount.
    b. Loosen both clamping screws in Mechanical Mount 23000.



3. Rinse instruments under running cold utility (tap) water to remove gross soil.
    a. While rinsing, actuate all moving parts of the instruments and use a soft bristled brush to aid in removal of gross soil.
4. Flush utility (tap) water through lumens and other hard to reach areas of instruments.
5. An ultrasonic cleaner may be optionally used.
6. Load the instruments into automated parts washer for processing.
7. Run the automated washer with the following parameters:
    a. Pre-wash for 2 minutes with cold tap water.
    b. Enzyme wash for 2 minutes with hot tap water and enzymatic detergent prepared per the manufacturer's directions for use.
    c. Rinse for 5 minutes with 43°C (nominal) de-ionized or reverse-osmosis water.
    d. Dry for 7 minutes at 90°C (nominal).
8. After cleaning, instruments (disassembled, if applicable) should be visually inspected. All steps of the cleaning process should be repeated for incompletely cleaned instruments.

Note: Use of water-soluble lubricants is recommended for instruments with moving parts or those intended to be assembled intraoperatively to another instrument.

Autoclave Sterilization of Re-Usable Instruments

- Wrapped pre-vacuum, 4 minutes at 270°F (132°C). Dry time is 75 minutes*. Use an FDA-cleared wrap or sterile barrier. (Validation is based on use of Halyard Health H400.)
- Unwrapped pre-vacuum ("Flash"), 4 minutes at 270°F (132°C).
  *In addition to the prescribed dry time, an additional 30 minute cool down after removal from the sterilization chamber is recommended to ensure the devices are free from condensation and other moisture.

The recommended sterilization process has been validated to produce a sterility assurance level of (10^{-6}) when parts have been cleaned to the instructions above. Other steam cycles and cleaning procedures have not been evaluated and must be qualified by the user.

Effective sterilization is predicated on thorough cleaning and drying processes. Failure to do so will compromise the sterilization process and render the processed instrument unsuitable for clinical use.

Disposal

Do not throw any part of this system in the trash. Dispose of components in accordance with local regulations.

Storage and Transportation

Temperature: -30 to 50 °C; Humidity: 10 to 90% RH; (non-condensing); Pressure: 60 kPa to 106 kPa.

Handle with care.

Maintenance

Prior to each use, check the instruments for wear or damage. Note especially the condition of tracker markings and fit of interfaces between trackers and tracker mounts. Although the system's instruments do not have a usage limit and are expected to last for extended use, damaged or worn instruments should be replaced. Use of damaged instruments may lead to errors in navigation.

Follow instructions for the proper inspection, cleaning, and sterilization (as applicable) of system components. No further maintenance is required. Do not service or modify any system component.

Any part failing to perform as intended should be reported to the manufacturer for resolution.

Warranty

The product is warranted to be free from defects in material and workmanship.

Electrical Safety

This equipment has been tested and found to comply with EMC limits per IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interface with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Consult Insight Medical Systems or authorized representative for help.

FCC ID: SH6MDBT42Q This device compiles with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

Operating Conditions: Temperature: 15-25 °C; Humidity: 20-80% (RH) non-condensing; Pressure: 70-106kPa.

Warning: This device is designed for very specific tasks. Use in an environment containing EM disturbances outside the capability of this device may compromise the surgical outcome.

Warning: This device is not designed for use next to or stacked with other equipment. Use next to or stacked with other equipment should be avoided due to improper operation.

Warning: Use of batteries, computing modules or cables other than those provided by Insight Medical Systems could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ARVIS® system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Note: This device has been tested for electromagnetic immunity and shown to maintain essential performance (tracking error ≤5mm) when exposed to expected levels of electromagnetic disturbances (further defined in the subsequent tables). The system has internal software quality controls, which stop progression through the workflow. If a user repeatedly fails to progress beyond a step in the workflow, the user should first ensure they are properly following the surgical technique and that there are no obstructions blocking the eyepiece. If still unable to proceed, the user should discontinue use of the device.

The ARVIS system is battery powered, which modifies the applicable EMC immunity tests. Shown here are the emissions and immunity tests applicable to the ARVIS system comprised of the eyepiece, belt pack, battery and USB cable assembly that is worn by the user during surgery.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.		
EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
RF Emissions CISPR 11	Group 1	The ARVIS product uses RF energy only for internal function (except for intentional communication). RF emissions are very low and not likely to cause interference with nearby electronic equipment.
RF Emissions CISPR 11	Class A	The ARVIS product is suitable for use in all non-domestic establishments.
RF emissions IEC 61000-3-2	N/A	
RF emissions IEC 61000-3-3	N/A	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/-15 kV air	+/- 8 kV contact +/-15 kV air	Normal ESD preventions should be taken, including use in the absence of floors covered with synthetic material. Relative humidity should be at least 20%.
Electrical fast transient / burst IEC 61000-4-4	Not Applicable to Battery Powered ARVIS		
Surge IEC 61000-4-5	Not Applicable to Battery Powered ARVIS		
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable to Battery Powered ARVIS		
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4.8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Conducted RF IEC 61000-4-6	Not Applicable to Battery Powered ARVIS		
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ARVIS product (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 2.3*(P)^{1/2}$ $d = 2.3*(P)^{1/2}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

RECOMMENDED SEPARATION DISTANCES TO NEARBY TRANSMITTERS	
The ARVIS system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ARVIS system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ARVIS system as recommended below, according to the maximum output power of the communications equipment.	
Nearby Transmitter's EIRP (W)	**Minimum Separation Distance (m)**
10	1.33
1	0.42
0.1	0.13
0.01	0.04

In addition to the battery powered ARVIS system, support equipment is provided to charge the ARVIS battery as needed. This support equipment is not part of the operating environment and is not required during surgery. The support equipment has been tested to the standards shown in this table.

Safety & EMC	**In combination with included external AC/DC power supply**	
Regulatory Approvals	Europe	CE
	International	CB
Electromagnetic Emissions	Europe	EN55011, EN55032, level B
	USA	FCC15 class B
Electromagnetic Immunity	ESD Immunity	EN/IEC61000-4-2
	Electromagnetic field immunity	EN/IEC61000-4-3
	EFT / Burt	EN/IEC61000-4-4
	Surge	EN/IEC61000-4-5
	Conducted Immunity	EN/IEC61000-4-6
	Magnetic Fields	EN/IEC61000-4-8
	Voltage dips, short instrumentations & voltage variations	EN/IEC61000-4-11
	Immunity characteristics	EN55024

Further Information

If further information on this product is needed or you wish to obtain a return product authorization, please contact Insight Medical Systems Customer Service at 1-800-456-8696 (Central Time 8:00 AM - 5:00 PM) in the USA.

Insight Medical Systems, Inc.
9801 Metric Blvd
Suite 200
Austin, TX 78758-5415
USA

Effective 2025-03-12 thru 2025-05-22

ARVIS® Shoulder Surgical Navigation System Instructions for Use

Model: ARV-01

⚠WARNING: This document should always be used in conjunction with the ARVIS® Shoulder Surgical Technique Guide P/N IN-22000 which contains additional product instructions. Access the Surgical Technique Guide at www.insightmedsys.com/resources with password "ARVIS".

Insight Medical Systems, Inc.
www.insightmedsys.com

Table of Contents

System Information

Precaution

Federal (USA) law restricts this device to sale by or on the order of a physician.

General Warnings

- Read all instructions prior to use.
- Do not operate the system without proper training. The surgeon must be familiar with the ARVIS Shoulder Navigation system and the respective compatible implant system's Instructions for Use (IFU) and surgical technique guidelines before proceeding with surgery.
- Navigation output does not supersede the surgeon's clinical judgment.
- Use only accessories provided with the system. Do not substitute cables or any other components. Do not connect any accessories not provided by the manufacturer to the device's USB connectors, including the headlight output connector. Do not attempt to use a computing device other than the computer module provided with the system.
- Prior to use, check the instruments for wear or damage. Replace damaged or worn instruments before use.
- Prior to use, the coracoid process should be evaluated for suitability of mount fixation utilizing pins.
- The eyepiece includes a headlight, infrared emitter, and Class I laser. The surfaces near the headlight, as well as other surfaces, may become hot during use. Touch only parts of the eyepiece intended for adjustment.
- To avoid potential interference with pacemakers, do not place any system component near the patient's or user's chest. There is a potential for electromagnetic interference. If the device interferes with other equipment, reposition or discontinue use of the device. If the device receives harmful interference affecting its function, discontinue use.
- Do not modify or service any system component.
- The **ARVIS** system includes the eyepiece, belt pack, battery, chargers, and instrument set. Instruments are provided NON-STERILE and must be cleaned and sterilized prior to each use. Electrical components are NON-STERILE and must not be sterilized.
- To avoid the risk or electric shock, this equipment must only be connected to a supply mains with protective earth.
- To maintain cybersecurity and correct operation, do not change settings on the provided computer module except as directed by Insight Medical Systems.
    - Do not enable Wi-Fi or cellular communication except as directed by Insight Medical Systems.
    - Do not install or remove applications or store non-Insight data.
    - Insight recommends installing a password to restrict access to the computer module.
    - Insight recommends trusted users remember to control any removable drives used to transport encrypted plan files to the system and not use drives for any purposes other than storing and transferring plan data files.
    - Confirm password and/or plan import in advance of patient being anesthetized

- Review and confirm patient and plan details before plan selection

System Description

ARVIS Shoulder is a computer-controlled surgical navigation system for shoulder arthroplasty. It combines software, electronic hardware and surgical instruments to intraoperatively track tools and locate anatomical structures and display feedback to the user. The system aids the surgeon in executing an approved preoperative plan.

The **ARVIS** Eyepiece contains stereo IR tracking cameras, a color camera, stereo display, IR illumination, and IR laser illuminator. A visible headlight is mounted to the eyepiece and connected via a micro-USB cable. The eyepiece communicates with the Belt Pack via a USB-C cable. All system instructions, prompts, alerts, and outputs are displayed to the surgeon on the eyepiece display.

The Belt Pack includes the computer module, battery, and power management board. The Belt Pack supplies power to the eyepiece and runs the **ARVIS** Shoulder Application Software.

The **ARVIS** electronics are worn on the surgeon's body during surgery. There is no interface to external equipment except for the **ARVIS** Battery Charger, which recharges the battery when not in use.

ARVIS uses the tracking cameras to measure the positions of trackers on the patient or instruments. **ARVIS** displays measurements as described in Performance Claims. Measurements are not displayed when a required tracker is not detected and in

range of the tracking cameras. Valid camera operating range extends at least from 40cm to 70cm from the eyepiece, but **ARVIS** may be able to provide accurate measurements at shorter or longer ranges.

Performance Claims

ARVIS Shoulder measures the following parameters with the stated accuracy in simulated use on benchtop fixtures.

- Drill inclination and version with an average absolute error of ≤ 1.5 °
- Superior/Inferior and Anterior/Posterior location of drill entry point with an average absolute error of ≤ 1.5mm on each axis
- Glenoid implant inclination and version with an average absolute error of ≤ 1.5 °
- Rotation of the glenoid implant about its central axis with an average absolute error of ≤ 1.5 °

- Length range of a virtual screw (up to 50mm) extending from a theoretical glenoid baseplate with an average absolute error of ≤ 0.5mm

Clinical accuracy depends on accurate registration and inputs to the **ARVIS** Shoulder Application Software. The system has been validated in simulated clinical use (cadaver) to achieve the following accuracy:

- Superior/Inferior and Anterior/Posterior location of glenoid implant with an average absolute error of ≤ 1.5mm on each axis
- Glenoid implant inclination and version with an average absolute error of ≤ 3.0 °
- Rotation of the glenoid implant about its central axis with an average absolute error of ≤ 3.0 °
- Length range of a virtual screw (up to 50mm) extending from a theoretical glenoid baseplate with an average absolute error of ≤ 2.0mm

Principle of Operation

ARVIS Shoulder is an image-based surgical navigation system. A patient's preoperative CT scan of the shoulder joint is required to create a preoperative surgical plan that includes a landmarked digital bone model which is matched to intraoperative landmarks registered by the surgeon.

ARVIS uses cameras in the eyepiece to measure locations and angles between trackers mounted on the patient and trackers mounted on instruments. By prompting the user through a procedure-specific workflow to register the reference tracker to anatomic landmarks, the **ARVIS** Shoulder Application Software running on the belt pack calculates and displays positions of the instruments relative to the patient's anatomy.

Intended Use

The **ARVIS** system is a computer-controlled navigation system intended to provide intra-operative measurements to the surgeon to aid in selection and positioning of orthopedic implant components.

Indications For Use

ARVIS ® Shoulder is indicated for assisting the surgeon in the positioning and alignment of implants relative to reference alignment axes and landmarks in stereotactic orthopedic surgery.

The system aids the surgeon in making intraoperative measurements and locating anatomical structures of the shoulder joint based on the patient's preoperative imaging.

The system is intended to be used with the head mounted ARVIS® Eyepiece display for augmented reality visualization and information, such as visualization of the preoperative plan and display of instrument and implant alignment information. The augmented/ virtual displayed information should not be relied upon solely for absolute positional/alignment information and should always be used in conjunction with the displayed stereotaxic information.

ARVIS® Shoulder is indicated for total shoulder arthroplasty using the Enovis AltiVate, LimaCorporate PRIMA, and LimaCorporate SMR implant systems.

Contraindications

- Significant loss of bone affecting identification of the required landmarks
- Excessive soft tissue interference affecting identification of the required landmarks

- Severe osteoporosis at fixation site(s), including but not limited to weakness of the coracoid process which could lead to adverse effects
- The presence of infection
- Any contraindication associated with shoulder arthroplasty surgery

Adverse Effects

Possible adverse effects include premature implant failure, dislocation or instability, decreased range of motion, infection, tissue injury, nerve injury and weakness, fracture, foreign body reaction, increased anesthesia time, heart attack, vascular injury, neck injury, burns, electrical shock, and cardiovascular injury.

Please inform the manufacturer and the national authority if you believe a product-related incident has occurred while using this device

Compatibility

- **ARVIS** Shoulder is indicated for use with the Enovis AltiVate®, LimaCorporate PRIMA, and LimaCorporate SMR implant systems.
- Steinmann Pins (x2), 2.5mm x 100mm, are required for the Mechanical Mount. The system was validated using 170-00-002 Tech Shoulder Pack.
- Precision AI Surgical Planning Software must be used for preoperative planning before navigation.
- Stryker® Flyte®or T7® helmet together with provided compatible adaptors can be used to wear the **ARVIS** Eyepiece.

User Profile

The **ARVIS** system is to be used by orthopedic surgeons and operating room staff who perform shoulder arthroplasty. Users should reference the ARVIS® Shoulder Surgical Technique Guide P/N IN-22000 for step-by-step product instructions. Training on product usage is available, and strongly recommended.

To arrange training, contact Insight Medical Systems, Inc.

Usage Environment

The **ARVIS** system is designed for use within hospital operating room environments. Infrared Radiation (IR) sources, including operating room lights and windows, may interfere with the cameras that are part of the **ARVIS** system. Avoid environments with excessive IR sources.

The **ARVIS** system is designed for use in a hospital operating room within the following conditions:

- Temperature (15 to 25°C)
- Humidity (20-80% non-condensing)
- Pressure (70-106 kPa)

The **ARVIS** Eyepiece is worn on the surgeon's head. The **ARVIS** Belt Pack is worn on the surgeon's belt or waistband. No electronic hardware is applied to the patient. The surgeon stands adjacent to the patient to operate.

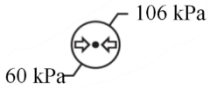
The **ARVIS** Battery Charger is intended to be used outside the operating room.

Patient Population

ARVIS is intended for patients undergoing orthopaedic surgery where rigid anatomic structures, such as the pelvis, femur, or tibia; can be identified and referenced.

Definition of Symbols

The following symbols are used in the **ARVIS** system labeling:

	Follow Instructions for use
	Do not dispose in trash
	Non-Sterile
	Humidity
	Storage Temperature
	Pressure
	Manufacturer
	Serial Number
	Catalog Number
	Caution

Hardware Information

ARVIS Shoulder Instrument Set Components (P/N IN-21300)

Catalog Number	Description
IN-21100	Instrument Tray Base, Shoulder
IN-11000	Instrument Tray Lid
IN-22100	In-Line Trigger Stylus
IN-23000	Mechanical Mount
IN-24000	Tracker A, Mechanical
IN-26000	Cobb Elevator, 1 in
IN-10800	3.5mm Hex Driver
IN-18300	Glenoid Drill Guide
IN-22200	Reverse Registration Tool
IN-18500	Reference Pin Guide

ARVIS Electronic Hardware Components and Accessories (P/N IN-50010[1])

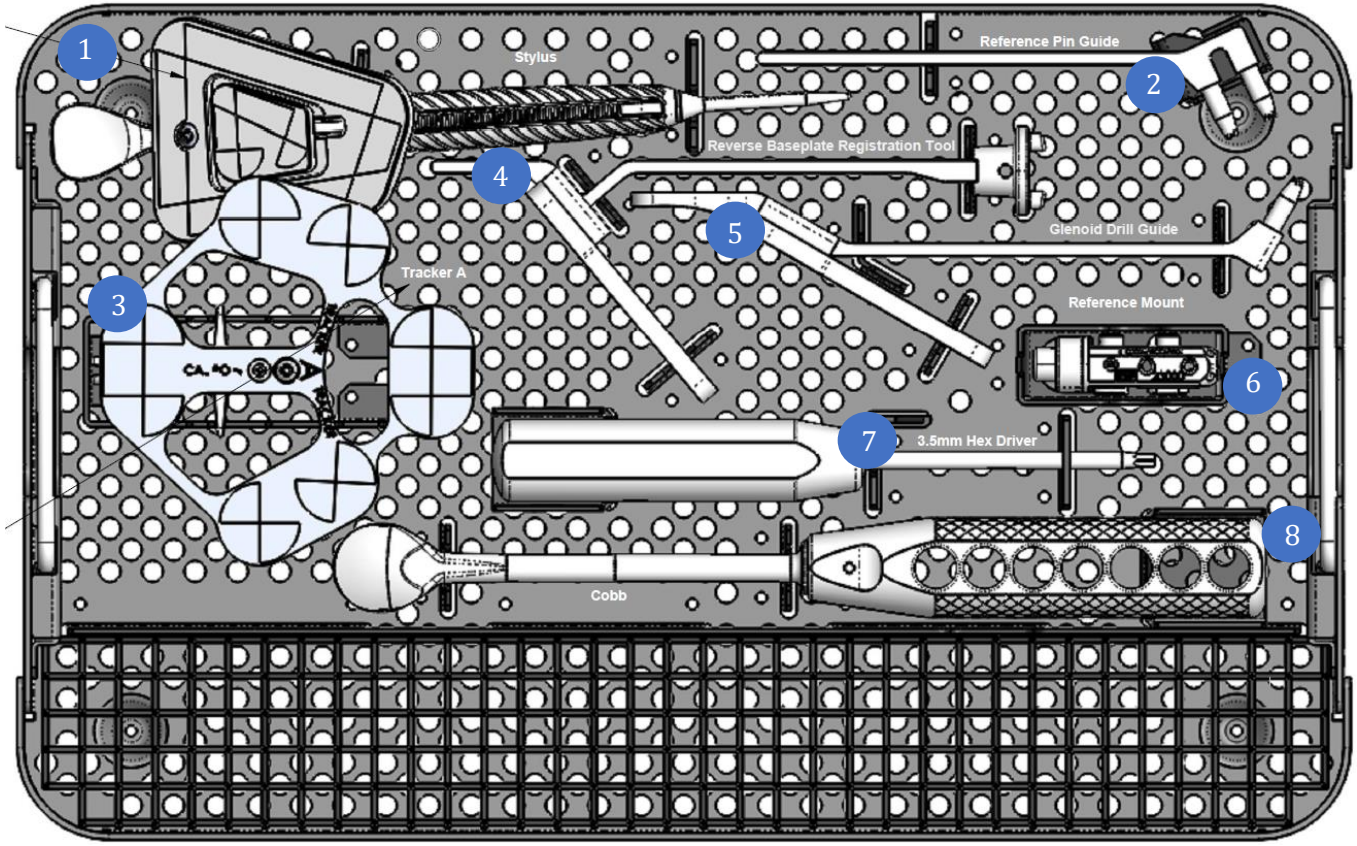
Catalog Number	Description
IN-12400	ARVIS Eyepiece Assembly
IN-12500	ARVIS Belt Pack
IN-12700	ARVIS Computer Module
IN-12800	ARVIS Battery
IN-13200	ARVIS Eyepiece Cable
IN-13000	ARVIS Battery Charger
IN-13800	ARVIS Charger Power Supply
IN-15202	Cable, USB-C, 1m
IN-17700	ARVIS Installation Kit

Use only accessories supplied by the manufacturer.

Surgeon/Case-Specific ARVIS Accessories

Catalog Number	Description
IN-17100	ARVIS Headband
IN-17500	FLYTE Mounting Kit
IN-21700	T7 Adapter Kit
170-00-002	Tech Shoulder Pack
IN-13900	ARVIS Charger Cord, USA
IN-13910	ARVIS Charger Cord, AU
IN-15201	Wall Adapter, 25W, USA
IN-15221	ARVIS Wall Adapter, AU

1. Alternative versions of Electronic Hardware are available with ARVIS accessories included, including but not limited to IN-22300



1. In-Line Trigger Stylus
2. Reference Pin Guide
3. Tracker A, Mechanical
4. Reverse Registration Tool
5. Glenoid Drill Guide
6. Mechanical Mount
7. 3.5mm Hex Driver
8. Cobb Elevator, 1 in

Electronics Cleaning Instructions

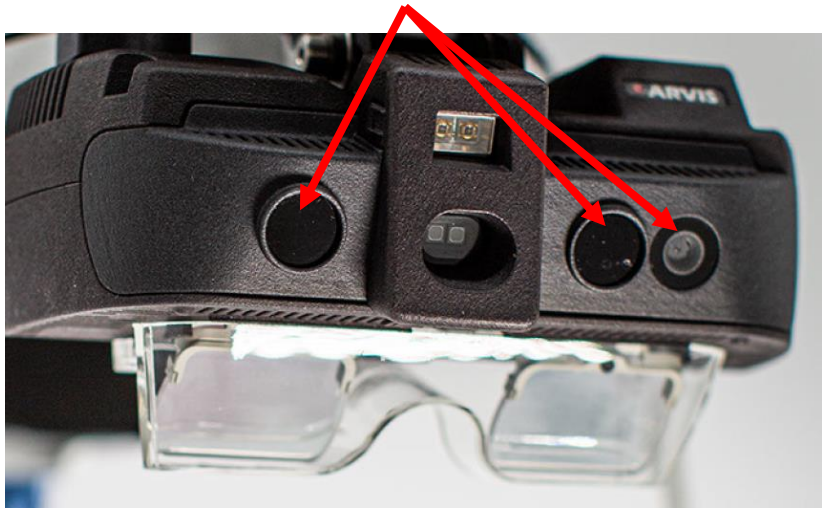
The electronic hardware components comprising the **ARVIS** system are the Eyepiece, Belt Pack, Battery, and Chargers. The electronic hardware components are re-usable.

- The Chargers are not intended for use in the operating room.
- The Eyepiece does not provide eye protection. If there is a likelihood of airborne blood or other soil, the user is advised to wear a legally marketed face shield for protection. The user is further advised to wear a legally marketed surgical gown or toga when a likelihood of soiling exists.

With appropriate attire, the electronic components of the **ARVIS** system should not need frequent cleaning, but they may be cleaned as described below as needed.

- Remove the **ARVIS** Battery and shut down the **ARVIS** Computer Module.
- Wipe with isopropyl alcohol solution (70-99%) using a lint-free cloth for one minute. Follow all label instructions for isopropyl alcohol.
- Do not use abrasive brushes or cloths.
- Take care not to scratch the camera covers. Visually inspect each camera cover after cleaning to verify that there are no scratches or residue.
- Take care not to introduce excess liquids into the Eyepiece via the cooling vents.
- Do not immerse. Do not sterilize. Allow to dry fully prior to use.
- Do not use phenolic disinfectants, as they may damage the Eyepiece or Belt Pack enclosures.

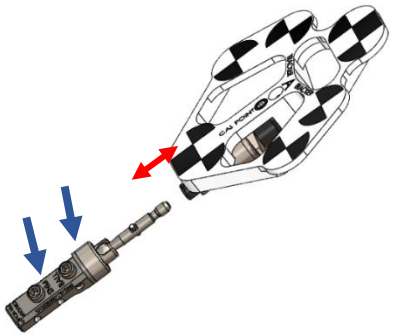
Camera Covers



Instrument Cleaning Instructions

The ARVIS Instruments are re-usable. Clean and Sterilize all instruments prior to first use and after every use.

1. Clean the instruments as soon as possible after use and avoid allowing soiled instruments to dry. Immerse, or use moist towels or sponges soaked with distilled or de-ionized water to keep moist prior to cleaning.
2. Disassemble instruments into the component parts listed in the "**ARVIS** Instrument Set Components" table.
    a. Separate tracker from mount.
    b. Loosen both clamping screws in Mechanical Mount IN-23000.



3. Rinse instruments under running cold utility (tap) water to remove gross soil.
    a. While rinsing, actuate all moving parts of the instruments and use a soft bristled brush to aid in removal of gross soil.
4. Flush utility (tap) water through lumens and other hard to reach areas of instruments.
5. An ultrasonic cleaner may be optionally used.
6. Load the instruments into automated parts washer for processing.
7. Run the automated washer with the following parameters:
    a. Pre-wash for 2 minutes with cold tap water.
    b. Enzyme wash for 2 minutes with hot tap water and enzymatic detergent prepared per the manufacturer's directions for use.
    c. Rinse for 5 minutes with 43°C (nominal) de-ionized or reverse-osmosis water.
    d. Dry for 7 minutes at 90°C (nominal).
8. After cleaning, instruments (disassembled, if applicable) should be visually inspected. All steps of the cleaning process should be repeated for incompletely cleaned instruments.

Note: Use of water-soluble lubricants is recommended for instruments with moving parts or those intended to be assembled intraoperatively to another instrument.

Autoclave Sterilization of Re-Usable Instruments

- Wrapped pre-vacuum, 4 minutes at 270°F (132°C). Dry time is 75 minutes*. Use an FDA-cleared wrap or sterile barrier. (Validation is based on use of Halyard Health H400.)
- Unwrapped pre-vacuum ("Flash"), 4 minutes at 270°F (132°C).
  *In addition to the prescribed dry time, an additional 30 minute cool down after removal from the sterilization chamber is recommended to ensure the devices are free from condensation and other moisture.

The recommended sterilization process has been validated to produce a sterility assurance level of (10^{-6}) when parts have been cleaned to the instructions above. Other steam cycles and cleaning procedures have not been evaluated and must be qualified by the user.

Effective sterilization is predicated on thorough cleaning and drying processes. Failure to do so will compromise the sterilization process and render the processed instrument unsuitable for clinical use.

Disposal

Do not throw any part of this system in the trash. Dispose of components in accordance with local regulations.

Storage and Transportation

Temperature: -30 to 50 °C; Humidity: 10 to 90% RH; (non-condensing); Pressure: 60 kPa to 106 kPa.

Handle with care.

Maintenance

Prior to each use, check the instruments for wear or damage. Note especially the condition of tracker markings and fit of interfaces between trackers and tracker mounts. Although the system's instruments do not have a usage limit and are expected to last for extended use, damaged or worn instruments should be replaced. Use of damaged instruments may lead to errors in navigation.

Follow instructions for the proper inspection, cleaning, and sterilization (as applicable) of system components. No further maintenance is required. Do not service or modify any system component.

Any part failing to perform as intended should be reported to the manufacturer for resolution.

Warranty

The product is warranted to be free from defects in material and workmanship.

Electrical Safety

This equipment has been tested and found to comply with EMC limits per IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interface with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Consult Insight Medical Systems or authorized representative for help.

FCC ID: SH6MDBT42Q This device compiles with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

Operating Conditions: Temperature: 15-25 °C; Humidity: 20-80% (RH) non-condensing; Pressure: 70-106kPa.

Warning: This device is designed for very specific tasks. Use in an environment containing EM disturbances outside the capability of this device may compromise the surgical outcome.

Warning: This device is not designed for use next to or stacked with other equipment. Use next to or stacked with other equipment should be avoided due to improper operation.

Warning: Use of batteries, computing modules or cables other than those provided by Insight Medical Systems could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ARVIS® system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Note: This device has been tested for electromagnetic immunity and shown to maintain essential performance (tracking error ≤5mm) when exposed to expected levels of electromagnetic disturbances (further defined in the subsequent tables). The system has internal software quality controls, which stop progression through the workflow. If a user repeatedly fails to progress beyond a step in the workflow, the user should first ensure they are properly following the surgical technique and that there are no obstructions blocking the eyepiece. If still unable to proceed, the user should discontinue use of the device.

Disturbances to the ARVIS System when in use may result in:

- Loss of Tracker visibility
- Loss of ARVIs Eyepiece functionality
- Unexpected shut down of the system

The ARVIS system is battery powered, which modifies the applicable EMC immunity tests. Shown here are the emissions and immunity tests applicable to the ARVIS system comprised of the eyepiece, belt pack, battery and USB cable assembly that is worn by the user during surgery.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
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EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
RF Emissions CISPR 11	Group 1	The ARVIS product uses RF energy only for internal function (except for intentional communication). RF emissions are very low and not likely to cause interference with nearby electronic equipment.
RF Emissions CISPR 11	Class A	The ARVIS product is suitable for use in all non-domestic establishments.
RF emissions IEC 61000-3-2	N/A	
RF emissions IEC 61000-3-3	N/A	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/-15 kV air	+/- 8 kV contact +/-15 kV air	Normal ESD preventions should be taken, including use in the absence of floors covered with synthetic material. Relative humidity should be at least 20%.
Electrical fast transient / burst IEC 61000-4-4	Not Applicable to Battery Powered ARVIS		
Surge IEC 61000-4-5	Not Applicable to Battery Powered ARVIS		
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable to Battery Powered ARVIS		
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4.8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
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IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Conducted RF IEC 61000-4-6	Not Applicable to Battery Powered ARVIS		
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ARVIS product (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 2.3*(P)^{1/2}$ $d = 2.3*(P)^{1/2}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

RECOMMENDED SEPARATION DISTANCES TO NEARBY TRANSMITTERS	
The ARVIS system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ARVIS system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ARVIS system as recommended below, according to the maximum output power of the communications equipment.	
Nearby Transmitter's EIRP (W)	**Minimum Separation Distance (m)**
10	1.33
1	0.42
0.1	0.13
0.01	0.04

In addition to the battery powered ARVIS system, support equipment is provided to charge the ARVIS battery as needed. This support equipment is not part of the operating environment and is not required during surgery. The support equipment has been tested to the standards shown in this table.

Safety & EMC	**In combination with included external AC/DC power supply**	
Regulatory Approvals	Europe	CE
	International	CB
Electromagnetic Emissions	Europe	EN55011, EN55032, level B
	USA	FCC15 class B
Electromagnetic Immunity	ESD Immunity	EN/IEC61000-4-2
	Electromagnetic field immunity	EN/IEC61000-4-3
	EFT / Burt	EN/IEC61000-4-4
	Surge	EN/IEC61000-4-5
	Conducted Immunity	EN/IEC61000-4-6
	Magnetic Fields	EN/IEC61000-4-8
	Voltage dips, short instrumentations & voltage variations	EN/IEC61000-4-11
	Immunity characteristics	EN55024

Preoperative Planning

The goal of preoperative planning for ARVIS® Shoulder is to define CT-based anatomical models and references, and desired implant positions for use during stereotactic surgery to assist the surgeon in the positioning of orthopedic implants.

Operating Instruction

The planning software is web based and does not require installation.
To log into the platform the user first needs to enter their username and password. To obtain access to the website, please contact https://www.precisionai.com.au/contact/.
The planning software consists of several pages for various stages of the surgical planning process.
The surgeries overview page provides an overview of all the surgical cases that are available for that account.
To commence planning and for more detailed instructions, please refer to the ARVIS® Shoulder Surgical Technique Guide P/N IN-22000.

Privacy Statement

All personal patient information stored within the software will be deidentified before being stored. No personal patient information will be shared with third parties. All information sent to third parties will be deidentified before sending.

Warnings and Precautions

- This software must only be used by trained, qualified persons, aware of the directions for use.
- Ensure that the minimum system requirements are used as outlined in this document.

Packaging and Labelling

The software is web-based, therefore, there is no packaging requirement applicable for this software. However, a copy of these Instructions for Use will be made available to each user prior to use of the software.

Cybersecurity

The software operates within a secure operating platform which includes systems to monitor and identify vulnerabilities and reduce any risks of cyber-attacks.

System Requirements

Minimum and recommended system requirements for using the planning software are as follows:

Minimum system requirements

Web browser:
Google Chrome (v.107 or later)
Mozilla Firefox (v.109.0 or later)
Apple Safari (v.16 or later)

Operating system:
Microsoft Windows 8 or newer
MacOS 10.x or newer

Screen resolution:
1280 x 800

Internet:
Internet connection required.
Internet connection 10Mbps or higher

Recommended system requirements

Web browser:

Google Chrome (v.107 or later)

Operating system:
Microsoft Windows 10 or 11
MacOS 12.x

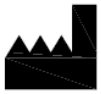
Screen resolution:
1920 x 1080

Symbol Legend (Planning software)

	Software version number
	Software release date

Further Information

If further information on this product is needed or you wish to obtain a return product authorization, please contact Customer Service at 1-800-456-8696 (Central Time 8:00 AM - 5:00 PM) in the USA.



Kico Knee Innovation Company Pty Limited
Unit 1, 25 Frenchs Forest Rd E,
Frenchs Forest, NSW 2086
AUSTRALIA
Email: compliance@360med.care

Effective 2025-05-22 thru 2025-07-29

ARVIS® Shoulder Surgical Navigation System Instructions for Use

Model: ARV-01

CE 2797

⚠ WARNING: This document should always be used in conjunction with the ARVIS® Shoulder Surgical Technique Guide P/N IN-22000 which contains additional product instructions. Access the Surgical Technique Guide at www.insightmedsys.com/resources with password "ARVIS".

Insight Medical Systems, Inc.
www.insightmedsys.com

Table of Contents

System Information

Precaution

Federal (USA) law restricts this device to sale by or on the order of a physician.

General Warnings

- Read all instructions prior to use.
- Do not operate the system without proper training. The surgeon must be familiar with the ARVIS Shoulder Navigation system and the respective compatible implant system's Instructions for Use (IFU) and surgical technique guidelines before proceeding with surgery.
- Navigation output does not supersede the surgeon's clinical judgment.
- Use only accessories provided with the system. Do not substitute cables or any other components. Do not connect any accessories not provided by the manufacturer to the device's USB connectors, including the headlight output connector. Do not attempt to use a computing device other than the computer module provided with the system.
- Prior to use, check the instruments for wear or damage. Replace damaged or worn instruments before use.
- Prior to use, the coracoid process should be evaluated for suitability of mount fixation utilizing pins.
- The eyepiece includes a headlight, infrared emitter, and Class I laser. The surfaces near the headlight, as well as other surfaces, may become hot during use. Touch only parts of the eyepiece intended for adjustment.
- To avoid potential interference with pacemakers, do not place any system component near the patient's or user's chest. There is a potential for electromagnetic interference. If the device interferes with other equipment, reposition or discontinue use of the device. If the device receives harmful interference affecting its function, discontinue use.
- Do not modify or service any system component.
- The **ARVIS** system includes the eyepiece, belt pack, battery, chargers, and instrument set. Instruments are provided NON-STERILE and must be cleaned and sterilized prior to each use. Electrical components are NON-STERILE and must not be sterilized.
- To avoid the risk or electric shock, this equipment must only be connected to a supply mains with protective earth.
- To maintain cybersecurity and correct operation, do not change settings on the provided computer module except as directed by Insight Medical Systems.
  - Do not enable Wi-Fi or cellular communication except as directed by Insight Medical Systems.
  - Do not install or remove applications or store non-Insight data.
  - Insight recommends installing a password to restrict access to the computer module.
  - Insight recommends trusted users remember to control any removable drives used to transport encrypted plan files to the system and not use drives for any purposes other than storing and transferring plan data files.

- Confirm password and/or plan import in advance of patient being anesthetized
- Review and confirm patient and plan details before plan selection

- Stainless steel surgical instrumentation may contain nickel which is a known sensitizer. Sound medical judgement should be used if nickel sensitivity or allergy is suspected.

System Description

ARVIS Shoulder is a computer-controlled surgical navigation system for shoulder arthroplasty. It combines software, electronic hardware and surgical instruments to intraoperatively track tools and locate anatomical structures and display feedback to the user. The system aids the surgeon in executing an approved preoperative plan.

The **ARVIS** Eyepiece contains stereo IR tracking cameras, a color camera, stereo display, IR illumination, and IR laser illuminator. A visible headlight is mounted to the eyepiece and connected via a micro-USB cable. The eyepiece communicates with the Belt Pack via a USB-C cable. All system instructions, prompts, alerts, and outputs are displayed to the surgeon on the eyepiece display.

The Belt Pack includes the computer module, battery, and power management board. The Belt Pack supplies power to the eyepiece and runs the **ARVIS** Shoulder Application Software.

The **ARVIS** electronics are worn on the surgeon's body during surgery. There is no interface to external equipment except for the **ARVIS** Battery Charger, which recharges the battery when not in use.

ARVIS uses the tracking cameras to measure the positions of trackers on the patient or instruments. **ARVIS** displays measurements as described in Performance Claims. Measurements are not displayed when a required tracker is not detected and in

range of the tracking cameras. Valid camera operating range extends at least from 40cm to 70cm from the eyepiece, but **ARVIS** may be able to provide accurate measurements at shorter or longer ranges.

Performance Claims

ARVIS Shoulder measures the following parameters with the stated accuracy in simulated use on benchtop fixtures.

- Drill inclination and version with an average absolute error of ≤ 1.5 °
- Superior/Inferior and Anterior/Posterior location of drill entry point with an average absolute error of ≤ 1.5mm on each axis

- Glenoid implant inclination and version with an average absolute error of ≤ 1.5 °
- Rotation of the glenoid implant about its central axis with an average absolute error of ≤ 1.5 °
- Length range of a virtual screw (up to 50mm) extending from a theoretical glenoid baseplate with an average absolute error of ≤ 0.5mm

Clinical accuracy depends on accurate registration and inputs to the **ARVIS** Shoulder Application Software. The system has been validated in simulated clinical use (cadaver) to achieve the following accuracy:

- Superior/Inferior and Anterior/Posterior location of glenoid implant with an average absolute error of ≤ 1.5mm on each axis
- Glenoid implant inclination and version with an average absolute error of ≤ 3.0 °
- Rotation of the glenoid implant about its central axis with an average absolute error of ≤ 3.0 °
- Length range of a virtual screw (up to 50mm) extending from a theoretical glenoid baseplate with an average absolute error of ≤ 2.0mm

Principle of Operation

ARVIS Shoulder is an image-based surgical navigation system. A patient's preoperative CT scan of the shoulder joint is required to create a preoperative surgical plan that includes a landmarked digital bone model which is matched to intraoperative landmarks registered by the surgeon.

ARVIS uses cameras in the eyepiece to measure locations and angles between trackers mounted on the patient and trackers mounted on instruments. By prompting the user through a procedure-specific workflow to register the reference tracker to anatomic landmarks, the **ARVIS** Shoulder Application Software running on the belt pack calculates and displays positions of the instruments relative to the patient's anatomy.

Intended Use

The **ARVIS** system is a computer-controlled navigation system intended to provide intra-operative measurements to the surgeon to aid in selection and positioning of orthopedic implant components.

Indications For Use

ARVIS ® Shoulder is indicated for assisting the surgeon in the positioning and alignment of implants relative to reference alignment axes and landmarks in stereotactic orthopedic surgery.

The system aids the surgeon in making intraoperative measurements and locating anatomical structures of the shoulder joint based on the patient's preoperative imaging.

The system is intended to be used with the head mounted ARVIS® Eyepiece display for augmented reality visualization and information, such as visualization of the preoperative plan and display of instrument and implant alignment information. The augmented/ virtual displayed information should not be relied upon solely for absolute positional/alignment information and should always be used in conjunction with the displayed stereotaxic information.

ARVIS® Shoulder is indicated for total shoulder arthroplasty using the Enovis AltiVate, LimaCorporate PRIMA, and LimaCorporate SMR implant systems.

Contraindications

- Significant loss of bone affecting identification of the required landmarks
- Excessive soft tissue interference affecting identification of the required landmarks
- Severe osteoporosis at fixation site(s), including but not limited to weakness of the coracoid process which could lead to adverse effects
- The presence of infection
- Any contraindication associated with shoulder arthroplasty surgery

Adverse Effects

Possible adverse effects include premature implant failure, dislocation or instability, decreased range of motion, infection, tissue injury, nerve injury and weakness, fracture, foreign body reaction, increased anesthesia time, heart attack, vascular injury, neck injury, burns, electrical shock, and cardiovascular injury.

Please inform the manufacturer and the national authority if you believe a product-related incident has occurred while using this device

Compatibility

- ***ARVIS*** Shoulder is indicated for use with the Enovis AltiVate®, LimaCorporate PRIMA, and LimaCorporate SMR implant systems.
- Steinmann Pins (x2), 2.5mm x 100mm, are required for the Mechanical Mount. The system was validated using 170-00-002 Tech Shoulder Pack.
- Precision AI Surgical Planning Software must be used for preoperative planning before navigation.
- Stryker® Flyte®or T7® helmet together with provided compatible adaptors can be used to wear the ***ARVIS*** Eyepiece.

User Profile

The ***ARVIS*** system is to be used by orthopedic surgeons and operating room staff who perform shoulder arthroplasty. Users should reference the ARVIS® Shoulder Surgical Technique Guide P/N 22000 for step-by-step product instructions. Training on product usage is available, and strongly recommended.

To arrange training, contact Insight Medical Systems, Inc.

Usage Environment

The ***ARVIS*** system is designed for use within hospital operating room environments. Infrared Radiation (IR) sources, including operating room lights and windows, may interfere with the cameras that are part of the ***ARVIS*** system. Avoid environments with excessive IR sources.

The ***ARVIS*** system is designed for use in a hospital operating room within the following conditions:

- Temperature (15 to 25°C)
- Humidity (20-80% non-condensing)
- Pressure (70-106 kPa)

The ***ARVIS*** Eyepiece is worn on the surgeon's head. The ***ARVIS*** Belt Pack is worn on the surgeon's belt or waistband. No electronic

hardware is applied to the patient. The surgeon stands adjacent to the patient to operate.

The **ARVIS** Battery Charger is intended to be used outside the operating room.

Patient Population

ARVIS is intended for patients undergoing orthopaedic surgery where rigid anatomic structures, such as the pelvis, femur, or tibia; can be identified and referenced.

Clinical Benefit

Surgical and navigation instruments assist in the implantation of prostheses and do not have a direct therapeutic or diagnostic function.

Definition of Symbols

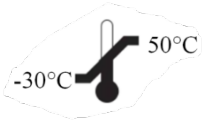
The following symbols are used in the **ARVIS** system labeling:

Follow Instructions for use

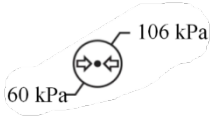
Do not dispose in trash

Non-Sterile

Humidity



Storage Temperature



Pressure

Manufacturer

Serial Number

Catalog Number

Caution

Authorized Representative in the EU

Importer

Hardware Information

ARVIS Shoulder Instrument Set Components (P/N IN-21300)

Catalog Number	Description
IN-21100	Instrument Tray Base, Shoulder
IN-11000	Instrument Tray Lid
IN-22100	In-Line Trigger Stylus
IN-23000	Mechanical Mount
IN-24000	Tracker A, Mechanical
IN-26000	Cobb Elevator, 1 in
IN-10800	3.5mm Hex Driver
IN-18300	Glenoid Drill Guide
IN-22200	Reverse Registration Tool
IN-18500	Reference Pin Guide

ARVIS Electronic Hardware Components and Accessories (P/N IN-50010[1])

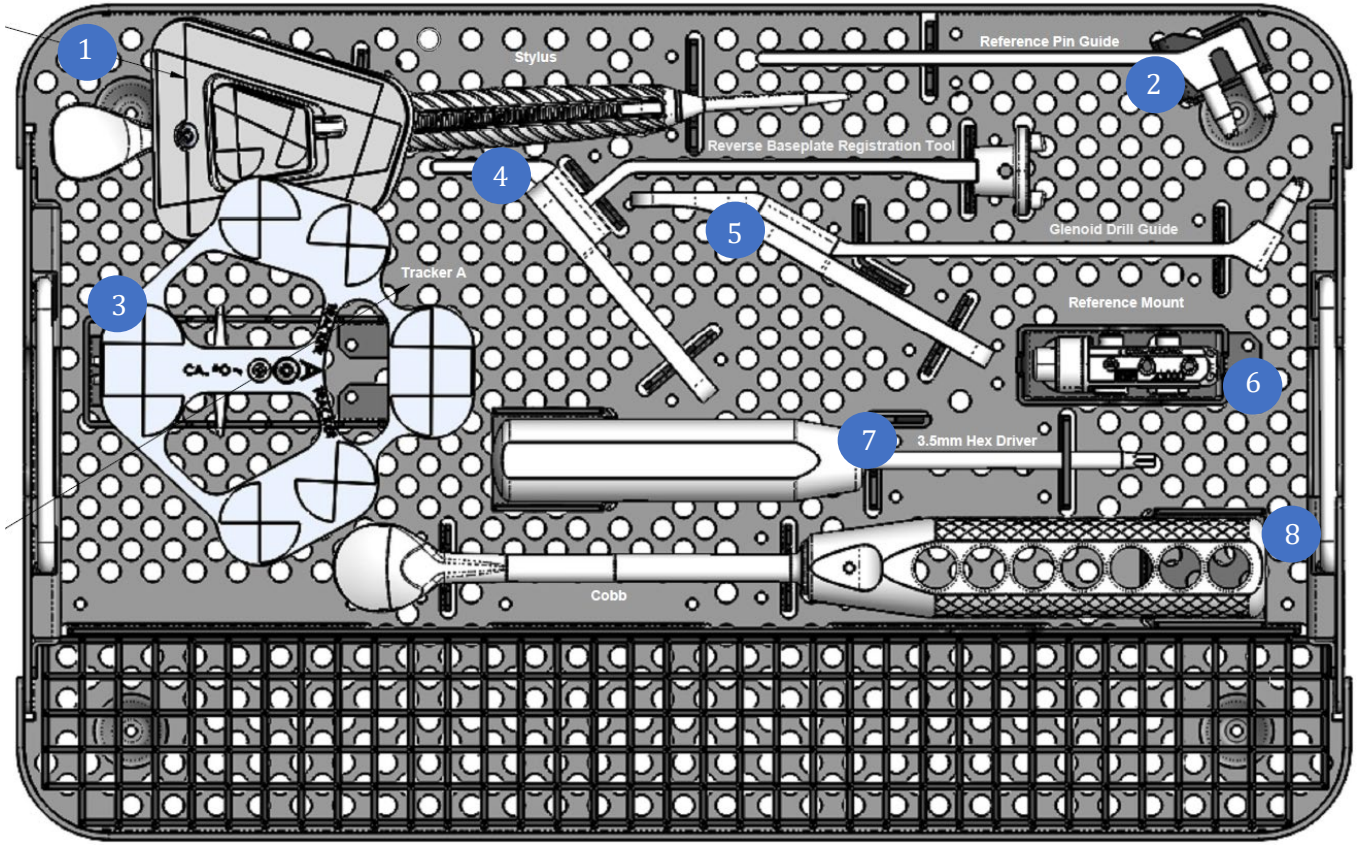
Catalog Number	Description
IN-12400	ARVIS Eyepiece Assembly
IN-12500	ARVIS Belt Pack
IN-12700	ARVIS Computer Module
IN-12800	ARVIS Battery
IN-13200	ARVIS Eyepiece Cable
IN-13000	ARVIS Battery Charger
IN-13800	ARVIS Charger Power Supply
IN-15202	Cable, USB-C, 1m
IN-17700	ARVIS Installation Kit

Use only accessories supplied by the manufacturer.

Surgeon/Case-Specific ARVIS Accessories

Catalog Number	Description
17100	ARVIS Headband[2]
17500	FLYTE Mounting Kit[2]
21700	T7 Adapter Kit[2]
170-00-002	Tech Shoulder Pack
IN-13900	ARVIS Charger Cord, USA
IN-13910	ARVIS Charger Cord, AU
IN-13920	ARVIS Charger Cord, EU
IN-15201	Wall Adapter, 25W, USA
IN-15221	ARVIS Wall Adapter, AU
IN-15211	ARVIS Wall Adapter, EU

1. Alternative versions of Electronic Hardware are available with ARVIS accessories included, including but not limited to IN-22300
2. See IN-14001 for mounting instructions.



1. In-Line Trigger Stylus
2. Reference Pin Guide
3. Tracker A, Mechanical
4. Reverse Registration Tool
5. Glenoid Drill Guide
6. Mechanical Mount
7. 3.5mm Hex Driver
8. Cobb Elevator, 1 in

Electronics Cleaning Instructions

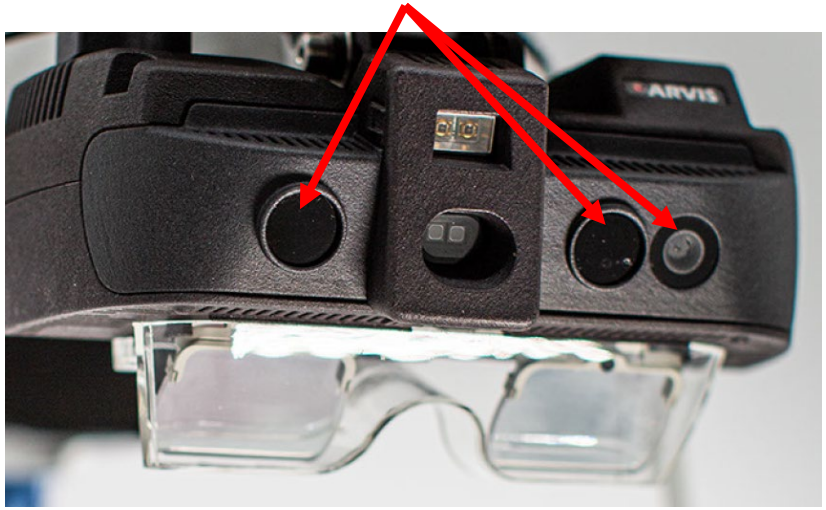
The electronic hardware components comprising the **ARVIS** system are the Eyepiece, Belt Pack, Battery, and Chargers. The electronic hardware components are re-usable.

- The Chargers are not intended for use in the operating room.
- The Eyepiece does not provide eye protection. If there is a likelihood of airborne blood or other soil, the user is advised to wear a legally marketed face shield for protection. The user is further advised to wear a legally marketed surgical gown or toga when a likelihood of soiling exists.

With appropriate attire, the electronic components of the **ARVIS** system should not need frequent cleaning, but they may be cleaned as described below as needed.

- Remove the **ARVIS** Battery and shut down the **ARVIS** Computer Module.
- Wipe with isopropyl alcohol solution (70-99%) using a lint-free cloth for one minute. Follow all label instructions for isopropyl alcohol.
- Do not use abrasive brushes or cloths.
- Take care not to scratch the camera covers. Visually inspect each camera cover after cleaning to verify that there are no scratches or residue.
- Take care not to introduce excess liquids into the Eyepiece via the cooling vents.
- Do not immerse. Do not sterilize. Allow to dry fully prior to use.
- Do not use phenolic disinfectants, as they may damage the Eyepiece or Belt Pack enclosures.

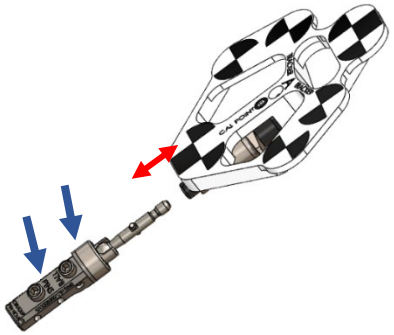
Camera Covers



Instrument Cleaning Instructions

The ARVIS Instruments are re-usable. Clean and Sterilize all instruments prior to first use and after every use.

1. Clean the instruments as soon as possible after use and avoid allowing soiled instruments to dry. Immerse, or use moist towels or sponges soaked with distilled or de-ionized water to keep moist prior to cleaning.
2. Disassemble instruments into the component parts listed in the "**ARVIS** Instrument Set Components" table.
    a. Separate tracker from mount.
    b. Loosen both clamping screws in Mechanical Mount 23000.



3. Rinse instruments under running cold utility (tap) water to remove gross soil.
    a. While rinsing, actuate all moving parts of the instruments and use a soft bristled brush to aid in removal of gross soil.
4. Flush utility (tap) water through lumens and other hard to reach areas of instruments.
5. An ultrasonic cleaner may be optionally used.
6. Load the instruments into automated parts washer for processing.
7. Run the automated washer with the following parameters:
    a. Pre-wash for 2 minutes with cold tap water.
    b. Enzyme wash for 2 minutes with hot tap water and enzymatic detergent prepared per the manufacturer's directions for use.
    c. Rinse for 5 minutes with 43°C (nominal) de-ionized or reverse-osmosis water.
    d. Dry for 7 minutes at 90°C (nominal).
8. After cleaning, instruments (disassembled, if applicable) should be visually inspected. All steps of the cleaning process should be repeated for incompletely cleaned instruments.

Note: Use of water-soluble lubricants is recommended for instruments with moving parts or those intended to be assembled intraoperatively to another instrument.

Autoclave Sterilization of Re-Usable Instruments

- Wrapped pre-vacuum, 4 minutes at 270°F (132°C). Dry time is 75 minutes*. Use an FDA-cleared wrap or sterile barrier. (Validation is based on use of Halyard Health H400.)
- Unwrapped pre-vacuum ("Flash"), 4 minutes at 270°F (132°C).
  *In addition to the prescribed dry time, an additional 30 minute cool down after removal from the sterilization chamber is recommended to ensure the devices are free from condensation and other moisture.

The recommended sterilization process has been validated to produce a sterility assurance level of (10^{-6}) when parts have been cleaned to the instructions above. Other steam cycles and cleaning procedures have not been evaluated and must be qualified by the user.

Effective sterilization is predicated on thorough cleaning and drying processes. Failure to do so will compromise the sterilization process and render the processed instrument unsuitable for clinical use.

Disposal

Do not throw any part of this system in the trash. Dispose of components in accordance with local regulations and the standard waste procedures of the healthcare institution.

Storage and Transportation

Temperature: -30 to 50 °C; Humidity: 10 to 90% RH; (non-condensing); Pressure: 60 kPa to 106 kPa.

Handle with care.

Maintenance

Prior to each use, check the instruments for wear or damage. Note especially the condition of tracker markings and fit of interfaces between trackers and tracker mounts. Although the system's instruments do not have a usage limit and are expected to last for extended use, damaged or worn instruments should be replaced. Use of damaged instruments may lead to errors in navigation.

Follow instructions for the proper inspection, cleaning, and sterilization (as applicable) of system components. No further maintenance is required. Do not service or modify any system component.

Any part failing to perform as intended should be reported to the manufacturer for resolution.

Warranty

The product is warranted to be free from defects in material and workmanship.

Electrical Safety

This equipment has been tested and found to comply with EMC limits per IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interface with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Consult Insight Medical Systems or authorized representative for help.

FCC ID: SH6MDBT42Q This device compiles with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

Operating Conditions: Temperature: 15-25 °C; Humidity: 20-80% (RH) non-condensing; Pressure: 70-106kPa.

Warning: This device is designed for very specific tasks. Use in an environment containing EM disturbances outside the capability of this device may compromise the surgical outcome.

Warning: This device is not designed for use next to or stacked with other equipment. Use next to or stacked with other equipment should be avoided due to improper operation.

Warning: Use of batteries, computing modules or cables other than those provided by Insight Medical Systems could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ARVIS® system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Note: This device has been tested for electromagnetic immunity and shown to maintain essential performance (tracking error ≤5mm) when exposed to expected levels of electromagnetic disturbances (further defined in the subsequent tables). The system has internal software quality controls, which stop progression through the workflow. If a user repeatedly fails to progress beyond a step in the workflow, the user should first ensure they are

properly following the surgical technique and that there are no obstructions blocking the eyepiece. If still unable to proceed, the user should discontinue use of the device.

Disturbances to the ARVIS System when in use may result in:

- Loss of Tracker visibility
- Loss of ARVIs Eyepiece functionality
- Unexpected shut down of the system

The ARVIS system is battery powered, which modifies the applicable EMC immunity tests. Shown here are the emissions and immunity tests applicable to the ARVIS system comprised of the eyepiece, belt pack, battery and USB cable assembly that is worn by the user during surgery.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.		
EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
RF Emissions CISPR 11	Group 1	The ARVIS product uses RF energy only for internal function (except for intentional communication). RF emissions are very low and not likely to cause interference with nearby electronic equipment.
RF Emissions CISPR 11	Class A	The ARVIS product is suitable for use in all non-domestic establishments.
RF emissions IEC 61000-3-2	N/A	
RF emissions IEC 61000-3-3	N/A	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The ARVIS system is intended for use in the electromagnetic environment specified below. The customer or the user of the ARVIS system should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/-15 kV air	+/- 8 kV contact +/-15 kV air	Normal ESD preventions should be taken, including use in the absence of floors covered with synthetic material. Relative humidity should be at least 20%.
Electrical fast transient / burst IEC 61000-4-4	Not Applicable to Battery Powered ARVIS		
Surge IEC 61000-4-5	Not Applicable to Battery Powered ARVIS		
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable to Battery Powered ARVIS		
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4.8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
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IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Conducted RF IEC 61000-4-6	Not Applicable to Battery Powered ARVIS		
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ARVIS product (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 2.3*(P)^{1/2}$ $d = 2.3*(P)^{1/2}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

RECOMMENDED SEPARATION DISTANCES TO NEARBY TRANSMITTERS	
The ARVIS system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ARVIS system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ARVIS system as recommended below, according to the maximum output power of the communications equipment.	
Nearby Transmitter's EIRP (W)	**Minimum Separation Distance (m)**
10	1.33
1	0.42
0.1	0.13
0.01	0.04

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The planning software consists of several pages for various stages of the surgical planning process.
The surgeries overview page provides an overview of all the surgical cases that are available for that account.
To commence planning and for more detailed instructions, please refer to the ARVIS® Shoulder Surgical Technique Guide P/N 22000.

Privacy Statement

All personal patient information stored within the software will be deidentified before being stored. No personal patient information will be shared with third parties. All information sent to third parties will be deidentified before sending.

Warnings and Precautions

- This software must only be used by trained, qualified persons, aware of the directions for use.
- Ensure that the minimum system requirements are used as outlined in this document.

Packaging and Labelling

The software is web-based, therefore, there is no packaging requirement applicable for this software. However, a copy of these Instructions for Use will be made available to each user prior to use of the software.

Cybersecurity

The software operates within a secure operating platform which includes systems to monitor and identify vulnerabilities and reduce any risks of cyber-attacks.

System Requirements

Minimum and recommended system requirements for using the planning software are as follows:

Minimum system requirements

Web browser:
Google Chrome (v.107 or later)
Mozilla Firefox (v.109.0 or later)
Apple Safari (v.16 or later)

Operating system:
Microsoft Windows 8 or newer
MacOS 10.x or newer

Screen resolution:
1280 x 800

Internet:
Internet connection required.
Internet connection 10Mbps or higher
Recommended system requirements

Web browser:
Google Chrome (v.107 or later)

Operating system:
Microsoft Windows 10 or 11
MacOS 12.x

Screen resolution:
1920 x 1080

Symbol Legend (Planning software)

LOT	Software version number
	Software release date

EC REP MedEnvoy Global B.V.
Prinses Margrietplantsoen 33 - Suite 123
2595 AM The Hague
THE NETHERLANDS

Further Information

If further information on this product is needed or you wish to obtain a return product authorization, please contact Customer Service at 1-800-456-8696 (Central Time 8:00 AM - 5:00 PM) in the USA.

Kico Knee Innovation Company Pty Limited
Unit 1, 25 Frenchs Forest Rd E,
Frenchs Forest, NSW 2086
AUSTRALIA
Email: compliance@360med.care

Gültig vom 22.05.2025 bis zum 29.07.2025

Betriebsanleitung für das chirurgische ARVIS® - Navigationssystem für die Schulter

CE
2797

Modell: ARV-01

⚠ WARNUNG: Dieses Dokument sollte immer in Verbindung mit dem ARVIS®-Operationstechnik-Leitfaden für die Schulter, P/N IN-22000, verwendet werden, der zusätzliche Produktanweisungen enthält. Greifen Sie auf den Operationstechnik-Leitfaden zu unter www.insightmedsys.com/resources mit dem Passwort „ARVIS“.

Insight Medical Systems, Inc. www.insightmedsys.com

Inhaltsverzeichnis

Systeminformationen

Vorsichtsmaßnahme

Nach dem Bundesrecht der USA darf diese Vorrichtung nur durch einen Arzt oder auf Anweisung eines Arztes verkauft werden.

Allgemeine Warnhinweise

- Lesen Sie alle Anweisungen vor der Verwendung.
- Bedienen Sie das System nicht ohne ordnungsgemäße Schulung. Der Chirurg muss mit dem ARVIS-Navigationssystem für die Schulter und den jeweiligen kompatiblen Implantatsystemen sowie deren Betriebsanleitung (IFU) und Operationstechnik-Richtlinien vertraut sein, bevor er mit der Operation fortfährt.
- Die Navigationsergebnisse ersetzen nicht die klinische Beurteilung durch den Chirurgen.
- Verwenden Sie nur das Zubehör, das mit dem System geliefert wird. Kabel oder andere Komponenten dürfen nicht ersetzt werden. Schließen Sie kein Zubehör, das nicht vom Hersteller bereitgestellt wurde, an die USB-Anschlüsse des Geräts an, einschließlich des Ausgangsanschlusses für einen Scheinwerfer. Versuchen Sie nicht, ein anderes Rechengerät als das mit dem System bereitgestellte Computermodul zu verwenden.
- Überprüfen Sie die Instrumente vor der Verwendung auf Abnutzung oder Beschädigung. Ersetzen Sie beschädigte oder abgenutzte Instrumente vor der Verwendung.
- Vor der Verwendung sollte der Processus coracoideus auf seine Eignung für die Fixierung mittels Pins überprüft werden.
- Das Okular umfasst einen Scheinwerfer, einen Infrarotsender und einen Laser der Klasse I. Die Oberflächen in der Nähe des Scheinwerfers sowie andere Oberflächen können während der Verwendung heiß werden. Berühren Sie nur die Teile des Okulars, die zur Einstellung vorgesehen sind.

Um mögliche Interferenzen mit Herzschrittmachern zu vermeiden, platzieren Sie keine Systemkomponenten in der Nähe des Brustbereichs des Patienten oder Benutzers. Es besteht die Möglichkeit für elektromagnetische Interferenzen. Wenn das Gerät andere Geräte stört, positionieren Sie es neu oder stellen Sie die Nutzung des Geräts ein. Wenn das Gerät schädliche Interferenzen empfängt, die seine Funktion beeinträchtigen, stellen Sie den Betrieb ein.

- Modifizieren oder warten Sie keine Systemkomponente.
- Das **ARVIS** -System umfasst das Okular, das Gürtelpack, den Akku, die Ladegeräte und das Instrumentenset. Die Instrumente werden NICHT-STERIL geliefert und müssen vor jedem Gebrauch gereinigt und sterilisiert werden. Elektrische Komponenten sind NICHT-STERIL und dürfen nicht sterilisiert werden.
- Um das Risiko eines Stromschlags zu vermeiden, darf dieses Gerät nur an eine Netzstromversorgung mit Schutzerdung angeschlossen werden.
- Um die Cybersicherheit und den ordnungsgemäßen Betrieb zu gewährleisten, ändern Sie die Einstellungen des mitgelieferten Computermoduls nur nach Anweisung von Insight Medical Systems.
    - Aktivieren Sie weder W-LAN noch die Mobilfunkkommunikation, es sei denn, Insight Medical Systems weist Sie dazu an.
    - Installieren oder entfernen Sie keine Anwendungen oder speichern Sie keine anderen Insight-Daten.
    - Insight empfiehlt, ein Passwort einzurichten, um den Zugriff auf das Computermodul einzuschränken.
    - Insight empfiehlt vertrauenswürdigen Benutzern, sich daran zu erinnern, alle Wechsellaufwerke, die zum Transport verschlüsselter Plandatendateien zum System verwendet werden, zu kontrollieren und die Laufwerke nicht für andere Zwecke als die Speicherung und Übertragung von Plandatendateien zu verwenden.
    - Bestätigen Sie das Passwort und/oder den Import des Plans, bevor der Patient anästhesiert wird.

- Überprüfen und bestätigen Sie die Angaben zum Patienten und zum Plan, bevor Sie einen Plan auswählen.

- Chirurgische Instrumente aus Edelstahl können Nickel enthalten, das als bekannter Sensibilisator gilt. Bei Verdacht auf eine Nickelüberempfindlichkeit oder -allergie sollte ein fundiertes medizinisches Urteil gefällt werden.

Systembeschreibung

ARVIS Shoulder ist ein computergesteuertes-chirurgisches Navigationssystem für Schulterarthroplastik. Es vereint Software, elektronische Hardware und chirurgische Instrumente, um intraoperativ Werkzeuge zu verfolgen, anatomische Strukturen zu lokalisieren und dem Benutzer Rückmeldungen anzuzeigen. Das System unterstützt den Chirurgen bei der Durchführung eines genehmigten präoperativen Plans.

Das **ARVIS**-Okular enthält IR-Nachverfolgungskameras, eine Farbkamera, ein Stereodisplay, eine IR-Beleuchtung und einen IR-Laserstrahler. Ein sichtbarer Scheinwerfer ist am Okular angebracht und über ein Mikro-USB-Kabel angeschlossen. Das Okular kommuniziert mit dem Gürtelpack über ein USB-C-Kabel. Alle Systemanweisungen, Eingabeaufforderungen, Warnmeldungen und Ausgaben werden dem Chirurgen auf dem Okulardisplay angezeigt.

Das Belt Pack umfasst das Computermodul, den Akku und die Stromverwaltungsplatine. Das Gürterlpack liefert Strom zum Okular und führt die **ARVIS**-Anwendungssoftware für die Schulter.

Die elektronischen **ARVIS**-Geräte werden während der Operation am Körper des Chirurgen getragen. Es gibt keine Schnittstelle zu externen Geräten, außer dem **ARVIS**-Akkuladegerät, das den Akku auflädt, wenn er nicht in Gebrauch ist.

ARVIS verwendet die Verfolgungskameras, um die Positionen der Tracker am Patienten oder an den Instrumenten zu erfassen. **ARVIS** zeigt Messungen an, wie sie in den Leistungsmermalen beschrieben sind. Die Messungen werden nicht angezeigt, wenn ein erforderlicher Tracker nicht erkannt wird und nicht in Reichweite der Nachverfolgungskameras ist. Der gültige Arbeitsbereich der Kamera reicht mindestens von 40 cm bis 70 cm vom Okular entfernt, aber **ARVIS** kann möglicherweise auch bei kürzeren oder längeren Entfernungen genaue Messungen liefern.

Leistungsmerkmale

ARVIS Shoulder misst die folgenden Parameter mit der angegebenen Genauigkeit im simulierten Einsatz auf Tischbefestigungen.

- Die Inklination und Ausführung des Bohrers mit einem durchschnittlich absoluten Fehler von ≤ 1,5°
- Die Lage des Eintrittspunkts des Bohrers (superior/inferior und anterior/posterior) mit einem durchschnittlichen absoluten Fehler von ≤ 1,5 mm auf jeder Achse
- Inklination und Ausführung des glenoiden Implantats mit einem durchschnittlichen absoluten Fehler von ≤ 1,5°
- Rotation des glenoiden Implantats um seine zentrale Achse mit einem durchschnittlichen absoluten Fehler von ≤ 1,5°

- Längenbereich einer virtuellen Schraube (bis zu 50 mm), die von einer theoretischen Glenoid Baseplate ausgeht, mit einem durchschnittlichen absoluten Fehler von ≤ 0,5 mm

Die klinische Genauigkeit hängt von der präzisen Registrierung und den Eingaben in die **ARVIS**-Anwendungssoftware für die Schulter ab. Das System wurde im simulierten klinischen Einsatz (Kadaver) validiert, um die folgende Genauigkeit zu erreichen:

- Die Lage des glenoiden Implantats (superior/inferior und anterior/posterior) mit einem durchschnittlichen absoluten Fehler von ≤ 1,5 mm auf jeder Achse
- Inklination und Ausrichtung des glenoiden Implantats mit einem durchschnittlichen absoluten Fehler von ≤ 3,0°
- Rotation des glenoiden Implantats um seine zentrale Achse mit einem durchschnittlichen absoluten Fehler von ≤ 3,0°
- Längenbereich einer virtuellen Schraube (bis zu 50 mm), die von einer theoretischen Glenoid Baseplate ausgeht, mit einem durchschnittlichen absoluten Fehler von ≤ 2,0 mm

Funktionsweise

ARVIS Shoulder ist ein auf Bildern basierendes - chirurgisches Navigationssystem. Die präoperative CT-Aufnahme des Schultergelenks eines Patienten ist erforderlich, um einen präoperativen Operationsplan zu erstellen, der ein digitales Knochenmodell mit Orientierungspunkten enthält, das mit den vom Chirurgen registrierten intraoperativen Markierungen abgeglichen wird.

ARVIS verwendet Kameras im Okular, um Positionen und Winkel zwischen Trackern zu messen, die am Patienten und an Instrumenten befestigt sind. Durch das Führen des Benutzers durch einen- spezifischen Arbeitsablauf zur Registrierung des Referenztrackers an anatomischen Orientierungspunktenberechnet und zeigt die auf dem Gürtelpack laufende **ARVIS**-Anwendungssoftware für die Schulter die Positionen der Instrumente im Verhältnis zur Anatomie des Patienten an.

Vorgesehener Zweck

Das **ARVIS** System ist ein computergesteuertes-Navigationssystem, das dem Chirurgen intra-operative Messungen zur Verfügung stellt, um ihn bei der Auswahl und Positionierung von orthopädischen Implantatkomponenten zu unterstützen.

Indikationen zur Verwendung

ARVIS® Shoulder ist für die Unterstützung des Chirurgen bei der Positionierung und Ausrichtung von Implantaten relativ zu Referenzachsen und Orientierungspunkten in der stereotaktischen orthopädischen Chirurgie vorgesehen.

Das System unterstützt den Chirurgen bei der Durchführung intraoperativer Messungen und der Lokalisierung von anatomischen Strukturen des Schultergelenks des Patienten auf Basis der präoperativen Bildgebung.

Das System ist für die Verwendung mit dem kopfmontierten ARVIS®-Okular-Display zur Visualisierung der und Information zur erweiterten Realität vorgesehen, wie z. B. zur Visualisierung des präoperativen Plans und zur Anzeige von Informationen zur Ausrichtung von Instrumenten und Implantaten. Die erweiterten/virtuellen dargestellten Informationen sollten nicht allein für absolute Positions-/Ausrichtungsinformationen herangezogen werden, sondern immer in Verbindung mit den angezeigten stereotaktischen Informationen verwendet werden.

ARVIS® Shoulder ist für die Totalendoprosthetik der Schulter bei Verwendung der Implantatsysteme Enovis AltiVate, LimaCorporate PRIMA und LimaCorporate SMR vorgesehen.

Kontraindikationen

- Erheblicher Knochenverlust, der die Identifizierung der erforderlichen Orientierungspunkte beeinträchtigt
- Beeinträchtigung durch überschüssiges Weichteilgewebe, die die Identifizierung der erforderlichen Orientierungspunkte beeinträchtigt
- Schwere Osteoporose an der/den Fixationsstelle(n), einschließlich, aber nicht beschränkt auf eine Schwäche des Processus coracoideus, die zu nachteiligen Auswirkungen führen könnte.
- Vorliegen einer Infektion
- Jede Kontraindikation im Zusammenhang mit einer Schulterprothesenoperation

Nebenwirkungen

Mögliche unerwünschte Wirkungen umfassen vorzeitiges Implantatversagen, Luxation oder Instabilität, eingeschränkten Bewegungsumfang, Infektion, Gewebeschädigung, Nervenverletzungen und -schwäche, Fraktur, Fremdkörperreaktion, verlängerte Anästhesiezeit, Herzinfarkt, Gefäßverletzung, Halsverletzungen, Verbrennungen, Stromschlag und kardiovaskuläre Verletzungen.

Bitte informieren Sie den Hersteller und die nationale Behörde, wenn Sie glauben, dass es bei der Verwendung dieses Geräts zu einem produktbezogenen Zwischenfall- gekommen ist.

Kompatibilität

- **ARVIS** Shoulder ist für den Einsatz mit den Enovis AltiVate®, LimaCorporate PRIMA und LimaCorporate SMR Implantatsystemen vorgesehen.
- Für die mechanische Befestigung werden zwei Steinmann-Nägel (x2), 2,5 mm x 100 mm, benötigt. Das System wurde mit 170-00-002 Tech Shoulder Pack validiert.
- Die Precision AI-Planungssoftware für Operationen muss für die präoperative Planung vor der Navigation genutzt werden.
- Der Stryker® Flyte®- oder T7®-Helm kann zusammen mit den bereitgestellten kompatiblen Adaptern zum Tragen des **ARVIS**-Okulars verwendet werden.

Benutzerprofil

Das **ARVIS**-System soll von orthopädischen Chirurgen und OP-Personal verwendet werden, die eine Schulterendoprosthetik durchführen. Benutzer sollten den Operationstechnik-Leitfaden für ARVIS® Shoulder, P/N IN-22000, für Schritt-für-Schritt Produktanweisungen zu Rate ziehen. Eine Schulung zur Verwendung des Produkts ist verfügbar und wird dringend empfohlen.

Um eine Schulung zu vereinbaren, kontaktieren Sie Insight Medical Systems, Inc.

Nutzungsumgebung

Das **ARVIS**-System ist für den Einsatz im Operationssaal eines Krankenhauses konzipiert. Infrarotstrahlungsquellen (IR), einschließlich Operationssaallichter und -fenster, können die Kameras des **ARVIS**-Systems stören. Meiden Sie Umgebungen mit übermäßigen IR-Quellen.

Das **ARVIS**-System ist für den Einsatz im Operationssaal eines Krankenhauses unter den folgenden Bedingungen vorgesehen:

- Temperatur (15 bis 25 °C)
- Luftfeuchtigkeit (20-80% nicht-kondensierend)
- Druck (70-106 kPa)

Das **ARVIS**-Okular wird am Kopf des Chirurgen getragen. Das **ARVIS**-Gürtelpack wird am Gürtel oder am Hosenbund des Chirurgen getragen. Es wird keine elektronische Hardware am Patienten angewendet. Der Chirurg steht neben dem Patienten, um die Operation durchzuführen.

Das **ARVIS**-Akkuladegerät ist für die Verwendung außerhalb des Operationssaals vorgesehen.

Patientenpopulation

ARVIS ist für Patienten vorgesehen, die sich einer orthopädischen Operation unterziehen, bei der starre anatomische Strukturen, wie Becken, Oberschenkelknochen oder Schienbein, identifiziert und referenziert werden können.

Klinischer Nutzen

Chirurgische Navigationsinstrumente unterstützen bei der Implantation von Prothesen und haben keine direkte therapeutische oder diagnostische Funktion.

Definition von Symbolen

Die folgenden Symbole werden im ARVIS-System zur Kennzeichnung verwendet:

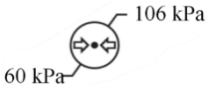
Befolgen Sie die Anweisungen zur Verwendung

Nicht im Abfall entsorgen

Nicht-steril

Luftfeuchtigkeit

Lagertemperatur



Druck

Hersteller

Bestellnummer

EU-Bevollmächtigter

Importeur

Hardware-Informationen

Instrumentensatz-Komponenten für ARVIS Shoulder (P/N IN-21300)

Bestellnummer	Beschreibung
IN-21100	Instrumententräger Basis, Schulter
IN-11000	Instrumententräger Deckel
IN-22100	In-Line-Trigger-Stift
IN-23000	Mechanische Halterung
IN-24000	Tracker A, Mechanisch
IN-26000	Cobb-Elevatorium, 1 Zoll
IN-10800	Sechskantdreher, 3,5mm
IN-18300	Glenoid-Bohrführung
IN-22200	Tool zur Rückwärtsregistrierung
IN-18500	Referenz-Pin-Leitfaden

Elektronische ARVIS-Hardwarekomponenten und -Zubehör (P/N IN-50010[1])

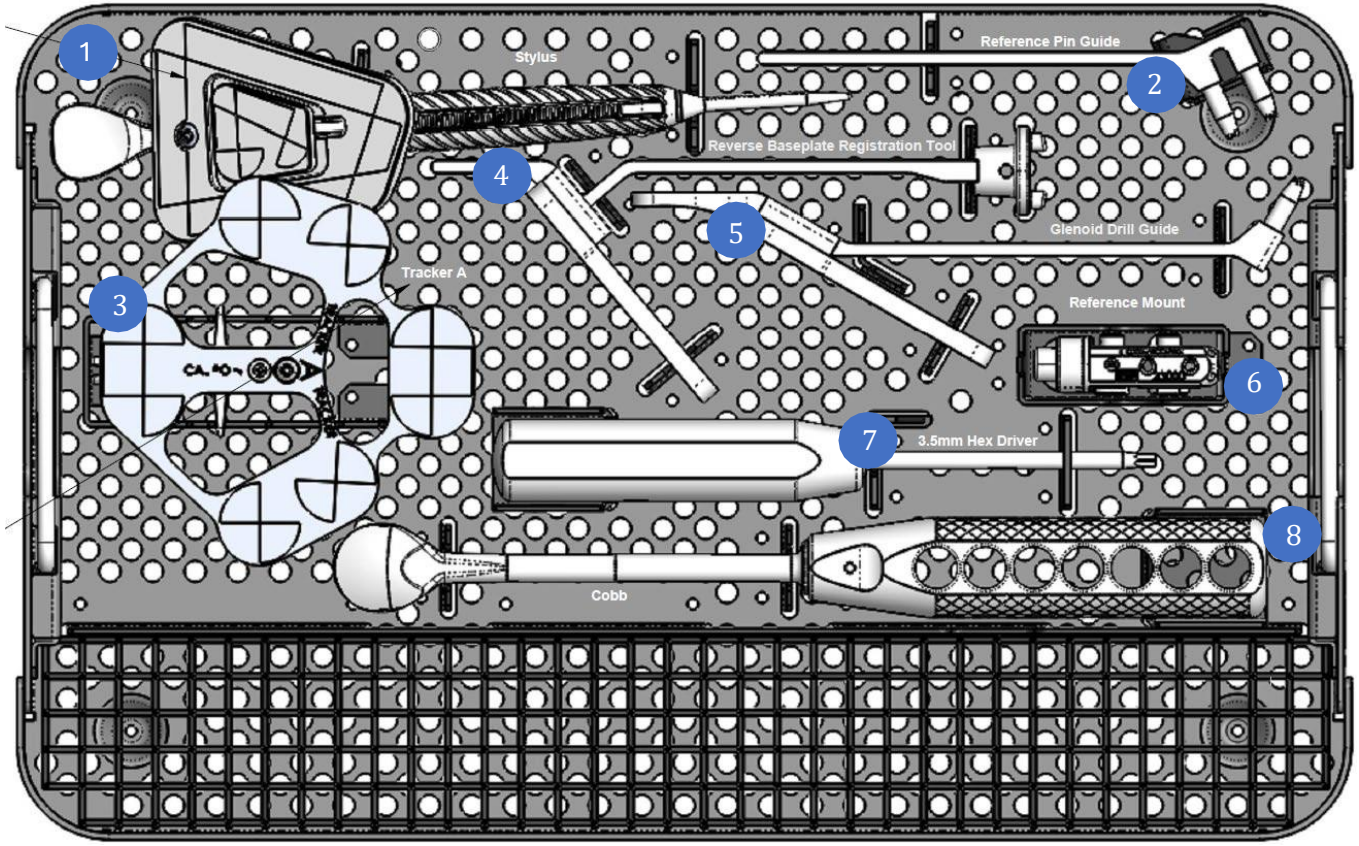
Bestellnummer	Beschreibung
IN-12400	ARVIS-Okular-Baugruppe
IN-12500	ARVIS-Gurtpaket
IN-12700	ARVIS-Computermodul
IN-12800	ARVIS-Akku
IN-13200	ARVIS-Okularkabel
IN-13000	ARVIS-Akkuladegerät
IN-13800	Netzteil für ARVIS-Ladegerät
IN-15202	Kabel, USB-C, 1m
IN-17700	ARVIS-Installationskit

Verwenden Sie nur Zubehör, das vom Hersteller mitgeliefert wurde.

Chirurg/Fall-spezifisches ARVIS -Zubehör

Bestellnummer	Beschreibung
IN-17100	ARVIS-Kopfband [2]
IN-17500	FLYTE-Montagekit [2]
IN-21700	T7-Adapter-Kit [2]
170-00-002	Tech Shoulder Pack
IN-13900	ARVIS-Ladekabel, USA
IN-13910	ARVIS-Ladekabel, AU
IN-13920	ARVIS-Ladekabel, EU
IN-15201	Netzteiladapter, 25 W, USA
IN-15221	ARVIS-Netzteiladapter, AU
IN-15211	ARVIS-Netzteiladapter, EU

1. Alternative Versionen der Elektronik-Hardware sind mit ARVIS-Zubehör erhältlich, einschließlich, aber nicht beschränkt auf IN-22300
2. Siehe IN-14001 für Montageanleitungen.



1. In-Line-Trigger-Stift
2. Referenz-Pin-Leitfaden
3. Tracker A, Mechanisch
4. Tool zur Rückwärtsregistrierung
5. Glenoid-Bohrführung
6. Mechanische Halterung
7. Sechskantdreher, 3,5mm
8. Cobb-Elevatorium, 1 Zoll

Reinigungsanweisungen für elektronische Geräte

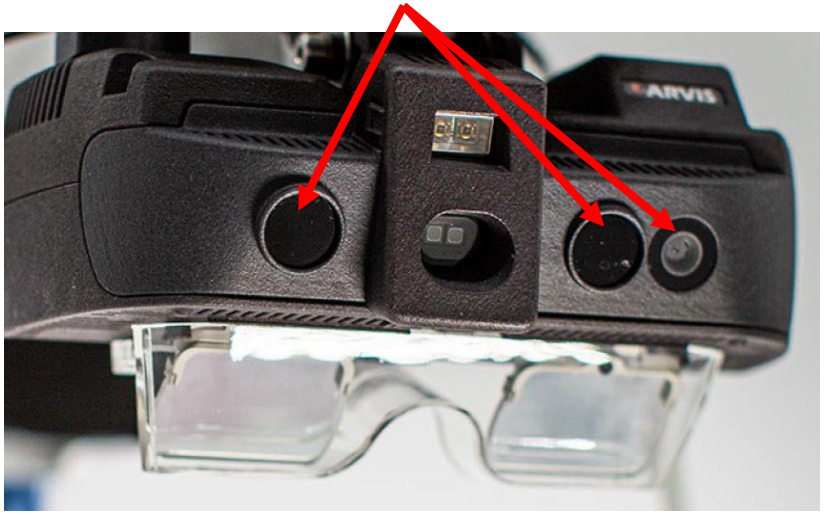
Die Elektronik-Hardwarekomponenten des **ARVIS** -Systems sind das Okular, das Gürtelpack, der Akku, und die Ladegeräte. Die Elektronik-Hardwarekomponenten-sind wiederverwendbar.

- Die Ladegeräte sind nicht für den Einsatz im Operationssaal vorgesehen.
- Das Okular bietet keinen Augenschutz. Wenn die Wahrscheinlichkeit besteht, dass Blut oder andere Verunreinigungen in die Luft gelangen, wird dem Benutzer empfohlen, einen gesetzlich zugelassenen Gesichtsschutz zum Schutz zu tragen. Dem Benutzer wird außerdem empfohlen, eine gesetzlich zugelassene chirurgische Kleidung oder Toga zu tragen, wenn eine Wahrscheinlichkeit der Verschmutzung besteht.

Mit geeigneter Bekleidung müssen die elektronischen Komponenten des **ARVIS**-Systems nicht häufig gereinigt werden, sie können jedoch bei Bedarf wie unten beschrieben gereinigt werden.

- Entfernen Sie den **ARVIS**-Akku und fahren Sie das **ARVIS**-Computermodul herunter.
- Mit einer Isopropylalkohollösung (70-99%) und einem fusselfreien-Tuch eine Minute lang abwischen. Befolgen Sie alle Anweisungen auf dem Etikett für Isopropylalkohol.
- Verwenden Sie keine scheuernden Bürsten oder Tücher.
- Achten Sie darauf, die Abdeckungen der Kamera nicht zu zerkratzen. Überprüfen Sie jede Kameraabdeckung nach der Reinigung visuell, um sicherzustellen, dass keine Kratzer oder Rückstände vorhanden sind.
- Achten Sie darauf, keine überschüssigen Flüssigkeiten über die Kühlöffnungen in das Okular einzubringen.
- Nicht eintauchen. Nicht sterilisieren. Vor der Verwendung vollständig trocknen lassen.
- Verwenden Sie keine phenolischen Desinfektionsmittel, da diese das Okular- oder Gürtelpackgehäuse beschädigen können.

Abdeckungen für Kameras

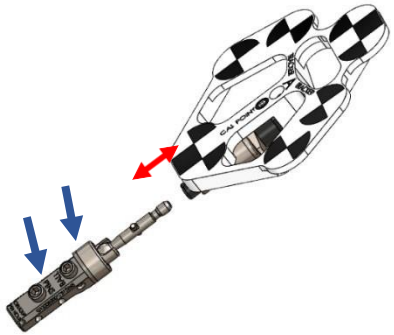


Anweisungen zur Instrumentenreinigung

Die ARVIS-Instrumente sind -wiederverwendbar. Reinigen und sterilisieren Sie alle Instrumente vor der ersten Verwendung und nach jeder Verwendung.

1. Reinigen Sie die Instrumente so schnell wie möglich nach Gebrauch und lassen Sie verschmutzte Instrumente nicht trocknen. Tauchen Sie ein oder verwenden Sie feuchte Handtücher oder Schwämme, die mit destilliertem oder de-ionisiertem Wasser getränkt sind, um sie vor der Reinigung feucht zu halten.

2. Zerlegen Sie die Instrumente in die Einzelteile, die in der Tabelle „**ARVIS**-Instrumentensatz-Komponenten“ aufgelistet sind.
    a. Trennen Sie den Tracker von der Halterung.
    b. Lösen Sie beide Klemmschrauben an der mechanischen Halterung IN-23000.



3. Spülen Sie die Instrumente unter fließendem kaltem Leitungswasser ab, um groben Schmutz zu entfernen.
    a. Während des Spülens betätigen Sie alle beweglichen Teile der Instrumente und verwenden Sie eine Bürste mit weichen Borsten, um groben Schmutz zu entfernen.
4. Spülen Sie Leitungswasser durch die Lumen und andere schwer zugängliche Bereiche der Instrumente.
5. Ein Ultraschallreinigungsgerät kann optional verwendet werden.
6. Laden Sie die Instrumente zur Verarbeitung in das automatische Teilewaschgerät.
7. Lassen Sie die automatische Waschmaschine mit den folgenden Parametern laufen:
    a. Vor-dem Waschen 2 Minuten lang mit kaltem Leitungswasser spülen.
    b. 2 Minuten lang mit heißem Leitungswasser und enzymatischem Reinigungsmittel gemäß den Anweisungen des Herstellers waschen.
    c. Spülen Sie 5 Minuten lang mit 43 °C (nominal) de-ionisiertem oder Umkehr-Osmosewasser.
    d. 7 Minuten lang bei 90 °C (nominal) trocknen.
8. Nach der Reinigung sollten die Instrumente (zerlegt, wenn zutreffend) visuell inspiziert werden. Bei unvollständig gereinigten Instrumenten sollten alle Schritte des Reinigungsprozesses wiederholt werden.

    Hinweis: Für Instrumente mit beweglichen Teilen oder solche, die intraoperativ mit einem anderen Instrument verbunden werden sollen, wird die Verwendung von wasserlöslichen-Schmiermitteln empfohlen.

Autoklaven-Sterilisation von wiederverwendbaren -Instrumenten

- Eingewickelt prä-Vakuum, 4 Minuten bei 270 °F (132 °C). Die Trockenzeit beträgt 75 Minuten*. Verwenden Sie einen von der FDA- zugelassenen Wickel oder eine sterile Barriere. (Die Validierung basiert auf der Verwendung von Halyard Health H400.)
- Unverpacktes prä-Vakuum („Flash“), 4 Minuten bei 270°F (132°C).

*Zusätzlich zur vorgeschriebenen Trockenzeit wird eine weitere 30-minütige Abkühlzeit nach der Entnahme aus der Sterilisationskammer empfohlen, um sicherzustellen, dass die Geräte frei von Kondensation und anderer Feuchtigkeit sind.

Das empfohlene Sterilisationsverfahren wurde validiert, um ein Sterilitätssicherungsniveau von (10^{-6}) zu erreichen, wenn die Teile gemäß den obigen Anweisungen gereinigt wurden. Andere Dampfzyklen und Reinigungsverfahren wurden nicht bewertet und müssen vom Benutzer qualifiziert werden.

Eine effektive Sterilisation setzt gründliche Reinigungs- und Trocknungsprozesse voraus. Andernfalls wird der Sterilisationsprozess beeinträchtigt, was das aufbereitete Instrument für den klinischen Gebrauch ungeeignet macht.

Entsorgung

Werfen Sie keine Teile dieses Systems in den Müll. Entsorgen Sie die Bauteile gemäß den lokalen Vorschriften und den standardmäßigen Abfallverfahren der Gesundheitseinrichtung.

Lagerung und Transport

Temperatur: -30 bis 50 °C; Luftfeuchtigkeit: 10 bis 90 % rF; (nicht-kondensierend); Druck: 60 kPa bis 106 kPa.

Mit Vorsicht zu handhaben.

Wartung

Überprüfen Sie die Instrumente vor jeder Verwendung auf Abnutzung oder Beschädigungen. Achten Sie besonders auf den Zustand der Markierungen der Tracker und auf die Passform der Schnittstellen zwischen Trackern und Trackerhalterungen. Obwohl die Instrumente des Systems keine Begrenzung der Nutzungsdauer haben und für eine lange Nutzung ausgelegt sind, sollten beschädigte oder abgenutzte Instrumente ersetzt werden. Die Verwendung beschädigter Instrumente kann zu Fehlern bei der Navigation führen.

Befolgen Sie die Anweisungen zur ordnungsgemäßen Inspektion, Reinigung und Sterilisation (falls zutreffend) der Systemkomponenten. Keine weitere Wartung erforderlich. Warten oder modifizieren Sie keine Systemkomponente.

Alle Teile, die nicht wie vorgesehen funktionieren, sollten dem Hersteller zur Behebung gemeldet werden.

Garantie

Das Produkt ist garantiert frei von Material- und Verarbeitungsfehlern.

Elektrische Sicherheit

Dieses Gerät wurde getestet und erfüllt die EMV-Grenzwerte gemäß IEC 60601-1-2. Diese Grenzwerte wurden so ausgelegt, dass ein angemessener Schutz gegen funktechnische Störungen in einer typischen medizinischen Umgebung geboten ist. Das Gerät erzeugt, verwendet und kann Hochfrequenzenergie abstrahlen. Wenn es nicht gemäß diesen Anweisungen installiert und verwendet wird, kann es andere Geräte in der Nähe durch schädliche Interferenzen beeinträchtigen. Bei bestimmten Installationen können Interferenzen jedoch nicht ausgeschlossen werden. Falls dieses Gerät schädliche Interferenzen mit anderen Geräten verursacht, was durch Aus- und Einschalten des Geräts festgestellt werden kann, wird dem Benutzer empfohlen, die Interferenzen durch eine oder mehrere der folgenden Maßnahmen zu beheben:

- Das Empfangsgerät neu ausrichten oder an einen anderen Ort verlegen.
- Den Abstand zwischen den Geräten vergrößern.
- Wenden Sie sich an Insight Medical Systems oder einen autorisierten Vertreter, um Hilfe zu erhalten.

FCC-ID: SH6MDBT42Q Dieses Gerät entspricht Teil 15 der FCC-Vorschriften. Es darf nur betrieben werden, wenn die folgenden beiden Bedingungen erfüllt sind: (1) Dieses Gerät darf keine schädlichen Interferenzen verursachen und (2) es muss alle empfangenen Interferenzen akzeptieren, einschließlich Interferenzen, die einen unerwünschten Betrieb verursachen können.

Betriebsbedingungen: Temperatur: 15-25°C; Luftfeuchtigkeit: 20-80 % (rF) nicht kondensierend; Druck: 70-106 kPa.

Warnung: Dieses Gerät ist für sehr spezifische Aufgaben konzipiert. Die Verwendung in einer Umgebung mit EM-Störungen, die außerhalb der Leistungsfähigkeit dieses Geräts liegen, könnte das Operationsergebnis beeinträchtigen.

Warnung: Dieses Gerät ist nicht für die Verwendung neben oder im Stapel mit anderen Geräten vorgesehen. Die Verwendung neben oder im Stapel mit anderen Geräten sollte wegen unsachgemäßen Betriebs vermieden werden.

Warnung: Die Verwendung von Akkus, Rechenmodulen oder Kabeln, die nicht von Insight Medical Systems bereitgestellt werden, könnte zu erhöhten elektromagnetischen Emissionen oder einer verringerten elektromagnetischen Störfestigkeit dieses Geräts führen und zu einer fehlerhaften Funktion führen.

Warnung: Tragbare HF-Kommunikationsgeräte (einschließlich Peripheriegeräte wie Antennenkabel und externe Antennen) sollten in einem Abstand von mindestens 30 cm (12 Zoll) zu jedem Teil des ARVIS®-Systems verwendet werden, einschließlich der vom Hersteller spezifizierten Kabel. Andernfalls kann es zu einer Beeinträchtigung der Leistung der betreffenden Geräte kommen.

Hinweis: Aufgrund seiner EMISSIONS-Eigenschaften ist dieses Gerät für den Einsatz in Industriegebieten und Krankenhäusern geeignet (CISPR 11 Klasse A). Wenn es in einer Wohnumgebung verwendet wird (für die normalerweise CISPR 11 Klasse B erforderlich ist), bietet dieses Gerät möglicherweise keinen ausreichenden Schutz für Funkfrequenz-Kommunikationsdienste. Der Benutzer muss möglicherweise Schutzmaßnahmen ergreifen-wie z. B. die Geräte an einem anderen Ort aufzustellen oder neu auszurichten.

Hinweis: Dieses Gerät wurde auf elektromagnetische Störfestigkeit getestet und es wurde nachgewiesen, dass es die wesentliche Leistung aufrechterhält (Verfolgungsfehler ≤ 5mm), wenn sie den erwarteten elektromagnetischen Störungen ausgesetzt sind (näher definiert in den nachfolgenden Tabellen). Das System verfügt über interne Software-Qualitätskontrollen, die den Fortschritt im Arbeitsablauf stoppen. Wenn ein Benutzer wiederholt nicht über einen Schritt im Arbeitsablauf hinauskommt, sollte er sich zunächst vergewissern, dass er die chirurgische Technik ordnungsgemäß anwendet und dass keine Hindernisse das Okular blockieren. Sollte es weiterhin nicht möglich sein, voranzukommen, sollte der Benutzer die Verwendung des Geräts einstellen.

Störungen des ARVIS-Systems während des Betriebs können zu Folgendem führen:

- Verlust der Sichtbarkeit des Trackers
- Verlust der Funktion des ARVI-Okulars
- Unerwartetes Herunterfahren des Systems

Das ARVIS-System wird mit Akkus betrieben, was die anwendbaren EMV-Störfestigkeitsprüfungen verändert. Hier werden die Emissions- und Störfestigkeitsprüfungen des ARVIS-Systems angezeigt, bestehend aus Okular, Gürtelpack, Akkus und USB-Kabelbaugruppe, die vom Benutzer während der Operation getragen wird.

RICHTLINIEN UND HERSTELLERERKLÄRUNG – ELEKTROMAGNETISCHE EMISSIONEN		
Das ARVIS-System ist für den Einsatz in der nachfolgend spezifizierten elektromagnetischen Umgebung vorgesehen. Der Kunde oder der Benutzer des ARVIS-Systems sollte sicherstellen, dass es in einer solchen Umgebung verwendet wird.		
EMISSIONSTEST	**ÜBEREINSTIMMUNG**	**ELEKTROMAGNETISCHE UMGEBUNG-LEITFADEN**
HF-Emissionen CISPR 11	Gruppe 1	Das ARVIS-Produkt nutzt HF-Energie ausschließlich für interne Funktionen (außer für die beabsichtigte Kommunikation). Die HF-Emissionen sind sehr gering und es ist unwahrscheinlich, dass sie Interferenzen bei in der Nähe befindlichen elektronischen Geräten verursachen.
HF-Emissionen CISPR 11	Klasse A	Das ARVIS-Produkt eignet sich für den Einsatz in allen nicht-domestischen Einrichtungen.
HF-Emissionen IEC 61000-3-2	KEINE	
HF-Emissionen IEC 61000-3-3	KEINE	

LEITFADEN UND HERSTELLERERKLÄRUNG – ELEKTROMAGNETISCHE IMMUNITÄT			
Das ARVIS-System ist für den Einsatz in der nachfolgend spezifizierten elektromagnetischen Umgebung vorgesehen. Der Kunde oder der Benutzer des ARVIS-Systems sollte sicherstellen, dass es in einer solchen Umgebung verwendet wird.			
STÖRFESTIGKEITSPRÜFUNG	**IEC 60601 PRÜFPEGEL**	**ÜBEREINSTIMMUNG-SPEGEL**	**ELEKTROMAGNETISCHE UMGEBUNG - LEITLINIE**
Elektrostatische Entladung (ESD) IEC 61000-4-2	+/- 8 kV Kontakt +/- 15 kV Luft	+/- 8 kV Kontakt +/- 15 kV Luft	Normale ESD-Vorkehrungen sollten getroffen werden, einschließlich der Verwendung an Orten ohne Böden, die mit synthetischem Material bedeckt sind. Die relative Luftfeuchtigkeit sollte mindestens 20 % betragen.
Schnelle transiente elektrische Störgröße/Bursts IEC 61000-4-4	Nicht zutreffend für akkubetriebene ARVIS		

LEITFADEN UND HERSTELLERERKLÄRUNG – ELEKTROMAGNETISCHE IMMUNITÄT			
Das ARVIS-System ist für den Einsatz in der nachfolgend spezifizierten elektromagnetischen Umgebung vorgesehen. Der Kunde oder der Benutzer des ARVIS-Systems sollte sicherstellen, dass es in einer solchen Umgebung verwendet wird.			
STÖRFESTIGKEITSPRÜFUNG	**IEC 60601 PRÜFPEGEL**	**ÜBEREINSTIMMUNG-SPEGEL**	**ELEKTROMAGNETISCHE UMGEBUNG - LEITLINIE**
Stoßspannungen IEC 61000-4-5	Nicht zutreffend für akkubetriebene ARVIS		
Spannungseinbrüche, kurze Unterbrechungen und Spannungsschwankungen an den Stromeingangsleitungen IEC 61000-4-11	Nicht zutreffend für akkubetriebene ARVIS		
Netzfrequenz (50/60 Hz) Magnetfeld IEC 61000-4.8	30 A/m	30 A/m	Magnetfelder mit Netzfrequenz sollten den typischen Werten einer kommerziellen oder Krankenhausumgebung entsprechen.
Geleitete HF IEC 61000-4-6	Nicht zutreffend für akkubetriebene ARVIS		
Abgestrahlte HF IEC 61000- 4-3	3 V/m 80 MHz bis 2,7 GHz	3 V/m	Tragbare und mobile HF-Kommunikationsgeräte sollten nicht näher an einem beliebigen Teil des ARVIS-Produkts (einschließlich Kabeln) verwendet werden, als der empfohlene Trennungsabstand, der aus der für die Frequenz des Senders geltenden Gleichung berechnet wird. Empfohlener Trennungsabstand $d = 2,3*(P)^{1/2}$ $d = 2,3 * (P)^{1/2}$ 800 MHz bis 2,7 GHz wobei P die maximale Ausgangsnennleistung des Senders in Watt (W) und d den empfohlenen Mindestabstand in Metern (m) gemäß den Angaben des Senderherstellers darstellt. Die Feldstärken stationärer HF-Sender, wie durch eine elektromagnetische Vor-Ort-Überprüfung bestimmt, sollten in jedem Frequenzbereich geringer sein als das Übereinstimmungsniveau.

EMPFOHLENE ABSTÄNDE ZU NAHEGELEGENEN SENDERN	
Das ARVIS-System ist für den Einsatz in einer elektromagnetischen Umgebung bestimmt, in der die abgestrahlten HF-Störungen kontrolliert werden. Der Kunde oder der Benutzer des ARVIS-Systems kann zur Vermeidung elektromagnetischer Störungen beitragen, indem er einen Mindestabstand zwischen tragbaren und mobilen HF-Kommunikationsgeräten (Sendern) und dem ARVIS-System entsprechend den unten empfohlenen Abständen gemäß der maximalen Ausgangsleistung des Kommunikationsgeräts einhält.	
EIRP des nahegelegenen Senders (W)	**Minimaler Trennungsabstand (m)**
10	1.33
1	0.42
0.1	0.13
0.01	0.04

Zusätzlich zum akkubetriebenen ARVIS-System wird Unterstützungsequipment bereitgestellt, um den ARVIS-Akku bei Bedarf aufzuladen. Dieses Unterstützungsequipment ist nicht Teil der Betriebsumgebung und wird während der Operation nicht benötigt. Das Unterstützungsequipment wurde nach den in dieser Tabelle aufgeführten Standards getestet.

Sicherheit und EMV	**In Kombination mit dem mitgelieferten externen Wechsel-/Gleichstromnetzteil**	
Behördliche Zulassungen	Europe	CE
	International	CB
Elektromagnetische Emissionen	Europa	EN55011, EN55032, Klasse B
	USA	FCC15 Klasse B
Elektromagnetische Störfestigkeit	ESD-Störfestigkeit	DE/IEC61000-4-2
	Störfestigkeit des elektromagnetischen Felds	EN/IEC61000-4-3
	EFT/Burt	DE/IEC61000-4-4
	Stoßspannungen	DE/IEC61000-4-5
	Leitungsgebundene Störfestigkeit	DE/IEC61000-4-6
	Magnetfelder	EN/IEC61000-4-8
	Spannungseinbrüche, kurze Instrumentierungen und Spannungsschwankungen	EN/IEC61000-4-11
	Eigenschaften der Störfestigkeit	EN55024

Präoperative Planung

Das Ziel der präoperativen Planung für ARVIS® Shoulder ist es, CT-basierte anatomische Modelle und Referenzen sowie gewünschte Implantatpositionen für die stereotaktische Chirurgie festzulegen, um den Chirurgen bei der Positionierung von orthopädischen Implantaten zu unterstützen.

Bedienungsanweisungen

Die Planungssoftware ist webbasiert und erfordert keine Installation. Um sich auf der Plattform anzumelden, muss der Benutzer zunächst seinen Benutzernamen und sein Passwort eingeben. Um Zugang zur Website zu erhalten, wenden Sie sich bitte an https://www.precisionai.com.au/contact/.
Die Planungssoftware umfasst mehrere Seiten für die verschiedenen Phasen des chirurgischen Planungsprozesses.
Die Übersichtsseite für Operationen bietet einen Überblick über alle chirurgischen Fälle, die für dieses Konto verfügbar sind.
Um mit der Planung zu beginnen und weitere detaillierte Anweisungen zu erhalten, beachten Sie bitte den ARVIS®-Operationstechnik-Leitfaden für die Schulter, P/N 22000.

Datenschutzerklärung

Alle in der Software gespeicherten persönlichen Patientendaten werden vor der Speicherung anonymisiert. Es werden keine persönlichen Patientendaten an Dritte weitergegeben. Alle Informationen, die an Dritte gesendet werden, werden vor der Übermittlung anonymisiert.

Warnhinweise und Vorsichtsmaßnahmen

- Diese Software darf nur von geschulten, qualifizierten Personen verwendet werden, die mit der Gebrauchsanweisung vertraut sind.
- Stellen Sie sicher, dass die in diesem Dokument beschriebenen Mindestsystemanforderungen verwendet werden.

Verpackung und Etikettierung

Die Software ist webbasiert, daher gibt es keine Verpackungsanforderung für diese Software. Jedoch wird jedem Nutzer ein Exemplar dieser Betriebsanleitung vor der Verwendung der Software zur Verfügung gestellt.

Cybersicherheit

Die Software arbeitet innerhalb einer sicheren Betriebsplattform, die Systeme zur Überwachung und Erkennung von Schwachstellen umfasst und das Risiko von Cyberangriffen-verringert.

Systemvoraussetzungen

Die minimalen und empfohlenen Systemanforderungen für die Verwendung der Planungssoftware sind wie folgt:

Mindestsystemanforderungen Webbrowser:

Google Chrome (v.107 oder neuer) Mozilla Firefox (v.109.0 oder neuer) Apple Safari (v.16 oder neuer)

Betriebssystem:

Microsoft Windows 8 oder neuer, MacOS 10.x oder neuer

Bildschirmauflösung:

1280 x 800

Internet:

Internetverbindung erforderlich. Internetverbindung 10 Mbit/s oder höher

Empfohlene Systemanforderungen

Webbrowser:
Google Chrome (v.107 oder neuer)

Betriebssystem:
Microsoft Windows 10 oder 11 macOS 12.x

Bildschirmauflösung:
1920 x 1080

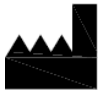
Symbol-Legende (Planungssoftware)

Software-Versionsnummer

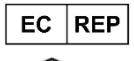
Veröffentlichungsdatum der Software

Weitere Informationen

Wenn Sie weitere Informationen zu diesem Produkt benötigen oder eine Rückgabegenehmigung beantragen möchten, wenden Sie sich bitte an den Kundendienst unter 1-800-456-8696 (Central Time 8:00-17:00 Uhr) in den USA.



Kico Knee Innovation Company Pty Limited Unit 1,
25 Frenchs Forest Rd E,
Frenchs Forest, NSW 2086 AUSTRALIEN
E-Mail: compliance@360med.care



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ARVIS® ist eine eingetragene Handelsmarke von Insight Medical Systems, Inc.

En vigueur du 22.05.2025 au 29.07.2025

wInstructions d'utilisation du système de navigation chirurgicale pour l'épaule ARVIS®

CE 2797

Modèle : ARV-01

⚠ AVERTISSEMENT : Ce document doit toujours être utilisé conjointement avec le Guide de technique chirurgicale de l'épaule ARVIS® P/N IN-22000, qui contient des instructions supplémentaires sur le produit. Accédez au Guide de Technique Chirurgicale à l'adresse www.insightmedsys.com/resources en saisissant le mot de passe « ARVIS ».

Table des matières

Informations système

Précautions

La législation fédérale américaine limite la vente de ce dispositif à la prescription médicale.

Avertissements généraux

- Lisez toutes les instructions avant utilisation.
- N'utilisez pas le système sans une formation appropriée. Le chirurgien doit être familiarisé avec le système de navigation ARVIS pour l'épaule et avec les instructions d'utilisation du système d'implant compatible respectif (ainsi qu'avec les lignes directrices concernant la technique chirurgicale) avant de procéder à l'opération.
- Les résultats de navigation ne remplacent pas le jugement clinique du chirurgien.
- Utilisez uniquement les accessoires fournis avec le système. Ne remplacez pas les câbles ou tout autre composant. Ne connectez aucun accessoire non fourni par le fabricant aux connecteurs USB de l'appareil, y compris le connecteur de sortie pour le phare. N'essayez pas d'utiliser un dispositif informatique autre que le module informatique fourni avec le système.
- Avant l'utilisation, vérifiez les instruments pour détecter toute usure ou tout dommage. Remplacez les instruments endommagés ou usés avant de les utiliser.
- Avant utilisation, le processus coracoïde doit être évalué pour déterminer s'il convient à la fixation du support à l'aide de broches.
- L'oculaire comprend un phare, un émetteur infrarouge et un laser de Classe I. Les surfaces proches du phare, ainsi que d'autres surfaces, peuvent devenir chaudes pendant l'utilisation. Ne touchez que les parties de l'oculaire prévues pour le réglage.

Pour éviter toute interférence potentielle avec les stimulateurs cardiaques, ne placez aucun composant du système près de la poitrine du patient ou de l'utilisateur. Il existe un potentiel d'interférence électromagnétique. Si l'appareil interfère avec d'autres équipements, repositionnez-le ou cessez de l'utiliser. Si l'appareil reçoit des interférences nuisibles affectant son fonctionnement, cessez de l'utiliser.

- Ne modifiez ni ne réparez aucun composant du système.
- Le système **ARVIS** comprend l'oculaire, le Belt pack, la batterie, les chargeurs et l'ensemble d'instruments. Les instruments sont fournis NON-STÉRILES et doivent être nettoyés et stérilisés avant chaque utilisation. Les composants électriques sont NON-STÉRILES et ne doivent pas être stérilisés.
- Pour éviter le risque de choc électrique, cet équipement doit uniquement être connecté à une alimentation principale avec mise à la terre protectrice.
- Pour garantir la cybersécurité et un fonctionnement correct, ne modifiez pas les paramètres du module informatique fourni, sauf indication contraire d'Insight Medical Systems.
    - N'activez pas la communication Wi-Fi ou cellulaire, sauf indication contraire d'Insight Medical Systems.
    - N'installez pas/ne supprimez pas d'applications ou ne stockez pas de données non-Insight.
    - Insight recommande d'installer un mot de passe pour restreindre l'accès au module informatique.
    - Insight recommande aux utilisateurs de confiance de se rappeler de contrôler les lecteurs amovibles utilisés pour transporter les fichiers de plan chiffrés vers le système et de ne pas utiliser les lecteurs à d'autres fins que le stockage et le transfert des fichiers de données de plan.
    - Confirmez le mot de passe et/ou l'importation du plan avant que le patient ne soit anesthésié.

- Vérifiez et confirmez les détails concernant le patient et le plan avant de choisir le plan.

- Les instruments chirurgicaux en acier inoxydable peuvent contenir du nickel, qui est un sensibilisateur connu. En cas de suspicion de sensibilité ou d'allergie au nickel, il convient d'exercer un jugement médical avisé.

Description du système

ARVIS Shoulder est un système de navigation chirurgicale contrôlé par ordinateur- utilisé pour l'arthroplastie de l'épaule. Il combine des logiciels, du matériel électronique et des instruments chirurgicaux permettant de suivre les outils et de localiser les structures anatomiques en peropératoire, et d'afficher des informations de retour à l'utilisateur. Le système aide le chirurgien à exécuter un plan préopératoire approuvé.

L'oculaire **ARVIS** comprend des caméras de suivi IR stéréo, une caméra couleur, un affichage stéréo, un éclairage IR et un illuminateur laser IR. Un phare visible est monté sur l'oculaire et connecté via un câble micro-USB. L'oculaire communique avec le Belt Pack via un câble USB-C. Toutes les instructions, invites, alertes et sorties du système sont affichées pour le chirurgien sur l'affichage de l'oculaire.

Le Belt Pack comprend le module informatique, la batterie et la carte de gestion de l'alimentation. Le Belt Pack fournit de l'énergie à l'oculaire et exécute le logiciel d'application pour l'épaule **ARVIS.**

Les appareils électroniques **ARVIS** sont portés sur le corps du chirurgien pendant l'opération. Il n'y a pas d'interface avec un équipement externe, à l'exception du chargeur de batterie **ARVIS**, qui recharge la batterie lorsqu'elle n'est pas utilisée.

ARVIS utilise les caméras de suivi pour mesurer les positions des trackers sur le patient ou sur les instruments. **ARVIS** affiche les mesures comme décrit dans les déclarations de performance. Les mesures ne sont pas affichées lorsqu'un tracker requis n'est pas détecté et est à portée des caméras de suivi. La plage de fonctionnement valide de la caméra s'étend au moins de 40 cm à 70 cm de l'oculaire, mais le système **ARVIS** peut être capable de fournir des mesures précises à des distances plus courtes ou plus longues.

Déclarations de performance

ARVIS Shoulder mesure les paramètres suivants avec l'exactitude indiquée dans une utilisation simulée sur des montages de banc.

- Inclinaison et orientation du foret avec une erreur absolue moyenne de ≤ 1,5°
- Localisation supérieure/inférieure et antérieure/postérieure du point d'entrée du foret avec une erreur absolue moyenne de ≤ 1,5 mm sur chaque axe
- Inclinaison et version de l'implant glénoïdien avec une erreur absolue moyenne de ≤ 1,5°
- Rotation de l'implant glénoïdien autour de son axe central avec une erreur absolue moyenne de ≤ 1,5°

- Plage de longueur d'une vis virtuelle (jusqu'à 50 mm) s'étendant à partir d'une plaque de base glénoïdienne théorique avec une erreur absolue moyenne de ≤ 0,5 mm

La précision clinique dépend de l'exactitude de l'enregistrement et des entrées dans le logiciel d'application **ARVIS** Shoulder. Le système a été validé dans le cadre d'une utilisation clinique simulée (cadavre) pour atteindre la précision suivante :

- emplacement supérieur/inférieur et antérieur/postérieur de l'implant glénoïdien avec une erreur absolue moyenne de ≤ 1,5 mm sur chaque axe
- Inclinaison et version de l'implant glénoïde avec une erreur absolue moyenne de ≤ 3,0°
- Rotation de l'implant glénoïde autour de son axe central avec une erreur absolue moyenne de ≤ 3,0°
- Plage de longueur d'une vis virtuelle (jusqu'à 50 mm) s'étendant à partir d'une plaque de base glénoïdienne théorique avec une erreur absolue moyenne ≤ 2,0 mm

Principe de fonctionnement

ARVIS Shoulder est un système de navigation chirurgicale basé sur l'image. Le scanner préopératoire de l'articulation de l'épaule du patient est nécessaire pour créer un plan chirurgical préopératoire qui comprend un modèle osseux numérique comportant des repères, lequel est aligné sur les repères peropératoires enregistrés par le chirurgien.

ARVIS utilise des caméras dans l'oculaire pour mesurer les emplacements et les angles entre les trackers montés sur le patient et ceux montés sur les instruments. En guidant l'utilisateur à travers un workflow-spécifique pour enregistrer le tracker de référence sur des repères anatomiques, le logiciel d'application **ARVIS** Shoulder fonctionnant sur le boîtier calcule et affiche les positions des instruments par rapport à l'anatomie du patient.

Utilisation prévue

Le système **ARVIS** est un système de navigation contrôlé par ordinateur -destiné à fournir des mesures intra-opératoires au chirurgien pour l'aider dans la sélection et le positionnement des composants de l'implant orthopédique.

Instructions d'utilisation

ARVIS® Shoulder a été conçu pour assister le chirurgien dans le positionnement et l'alignement des implants par rapport aux axes d'alignement de référence et aux repères en chirurgie orthopédique stéréotaxique.

Ce système aide le chirurgien à effectuer des mesures peropératoires et à localiser les structures anatomiques de l'articulation de l'épaule en se basant sur l'imagerie préopératoire du patient.

Il a été conçu pour être utilisé avec l'écran de visualisation en réalité augmentée ARVIS® Eyepiece monté sur la tête, permettant la visualisation du plan préopératoire et l'affichage des informations sur l'alignement des instruments et des implants. Les informations affichées en réalité augmentée/virtuelle ne doivent pas être utilisées uniquement pour obtenir des informations de positionnement/alignement absolues et doivent toujours être utilisées en conjonction avec les informations stéréotaxiques affichées.

ARVIS® Shoulder est indiqué pour l'arthroplastie totale de l'épaule en utilisant les systèmes d'implants Enovis AltiVate, LimaCorporate PRIMA et LimaCorporate SMR.

Contre-indications

- Perte osseuse significative affectant l'identification des repères requis
- Interférence excessive des tissus mous entravant l'identification des points de repère requis
- Ostéoporose sévère au(x) site(s) de fixation, y compris, mais non limitée à, la faiblesse du processus coracoïde qui pourrait entraîner des effets indésirables
- Présence d'une infection
- Toute contre-indication associée à la chirurgie d'arthroplastie de l'épaule

Effets indésirables

Les effets indésirables possibles incluent : défaillance prématurée de l'implant, luxation ou instabilité, diminution de l'amplitude des mouvements, infection, lésion des tissus, lésion nerveuse et faiblesse, fracture, réaction à un corps étranger, allongement de la durée de l'anesthésie, crise cardiaque, lésion vasculaire, lésion au cou, brûlures, choc électrique et lésion cardiovasculaire.

Veuillez informer le fabricant et l'autorité nationale si vous pensez qu'un incident lié au produit- est survenu lors de l'utilisation de cet appareil

Compatibilité

- **ARVIS** Shoulder est indiqué pour une utilisation avec les systèmes d'implants Enovis AltiVate®, LimaCorporate PRIMA et LimaCorporate SMR.
- Des broches de Steinmann (x2), 2,5 mm x 100 mm, sont nécessaires pour le montage mécanique. Le système a été validé en utilisant 170-00-002 Tech Shoulder Pack.
- Le logiciel de planification chirurgicale Precision AI doit être utilisé pour la planification préopératoire avant la navigation.
- Le casque Stryker® Flyte® ou T7®, ainsi que les adaptateurs compatibles fournis, peuvent être utilisés pour porter l'oculaire **ARVIS.**

Profil utilisateur

Le système **ARVIS** est destiné aux chirurgiens orthopédiques et au personnel des salles d'opération qui réalisent l'arthroplastie de l'épaule. Les utilisateurs doivent se référer au Guide de technique chirurgicale de l'épaule ARVIS® (P/N IN-22000) pour obtenir des instructions sur le produit étape-par-étape. Une formation sur l'utilisation du produit est disponible et fortement recommandée.

Pour organiser une formation, contactez Insight Medical Systems, Inc.

Environnement d'utilisation

Le système **ARVIS** a été conçu pour être utilisé dans les environnements de salles d'opération des hôpitaux. Les sources de rayonnement infrarouge (IR), y compris les lumières et les fenêtres des salles d'opération, peuvent interférer avec les caméras qui font partie du système **ARVIS.** Évitez les environnements avec des sources IR excessives.

Le système **ARVIS** a été conçu pour être utilisé dans une salle d'opération d'hôpital, dans les conditions suivantes :

- Température (15 à 25°C)
- Humidité (20-80 % non-condensée)
- Pression (70-106 kPa)

L'oculaire **ARVIS** est porté sur la tête du chirurgien. Le Belt Pack **ARVIS** est porté à la ceinture ou à la taille du chirurgien. Aucun composant électronique n'est appliqué sur le patient. Le chirurgien se tient à côté du patient pour opérer.

Le chargeur de batterie **ARVIS** est destiné à être utilisé en dehors de la salle d'opération.

Population de patients

ARVIS est destiné aux patients qui subissent une chirurgie orthopédique impliquant des structures anatomiques rigides (telles que le bassin, le fémur ou le tibia) qui peuvent être identifiées et référencées.

Bénéfice clinique

Les instruments chirurgicaux et de navigation facilitent l'implantation de prothèses et n'ont pas de fonction thérapeutique ou diagnostique directe.

Définition des symboles

Les symboles suivants sont utilisés dans le système de marquage ARVIS :

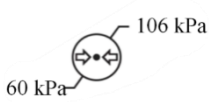
Suivez les instructions d'utilisation

Ne jetez pas à la poubelle

Non-stérile

Humidité

Température de stockage



Pression

Fabricant

Numéro de référence

Représentant autorisé dans l'Union Européenne

Importateur

Informations sur le matériel

Composants de l'instrumentation d'épaule ARVIS (P/N IN-21300)

Numéro de référence	Description
IN-21100	Base du plateau à instruments, épaule
IN-11000	Couvercle du plateau d'instruments
IN-22100	Stylet de déclenchement en ligne
IN-23000	Montage mécanique
IN-24000	Tracker A, mécanique
IN-26000	Ascenseur Cobb, 2,54 cm
IN-10800	Tournevis hexagonal de 3,5 mm
IN-18300	Guide de forage de la glène
IN-22200	Outil d'enregistrement inverse
IN-18500	Guide des broches de référence

Composants électroniques et accessoires matériels ARVIS (P/N IN-50010[1])

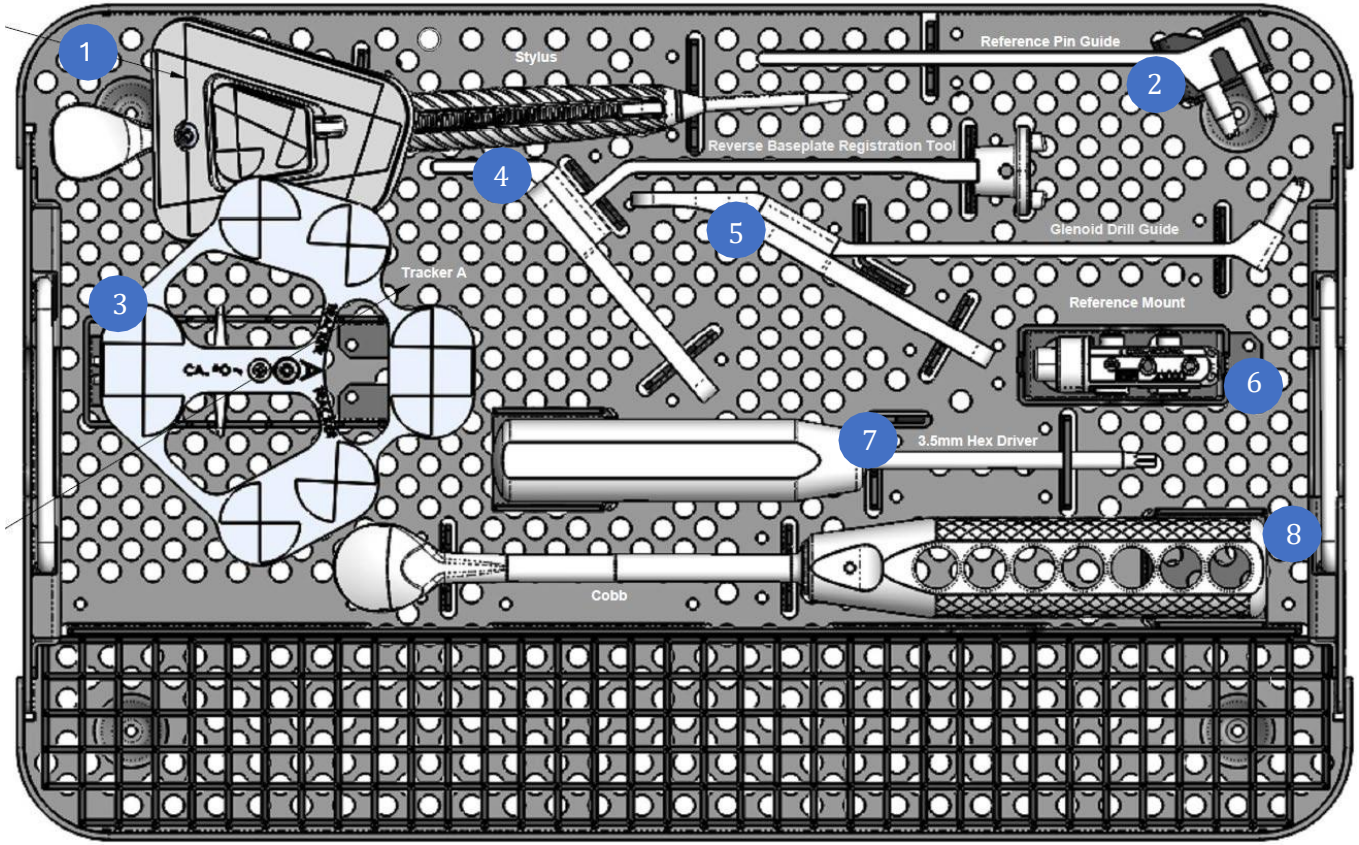
Numéro de référence	Description
IN-12400	Assemblage de l'oculaire ARVIS
IN-12500	Belt Pack ARVIS
IN-12700	Module informatique ARVIS
IN-12800	Batterie ARVIS
IN-13200	Câble de l'oculaire ARVIS
IN-13000	Chargeur de batterie ARVIS
IN-13800	Bloc d'alimentation du chargeur ARVIS
IN-15202	Câble, USB-C, 1 m
IN-17700	Kit d'installation ARVIS

N'utilisez que les accessoires fournis par le fabricant.

Accessoires - spécifiques pour chirurgien/cas - ARVIS

Numéro de référence	Description
IN-17100	Bandeau ARVIS[2]
IN-17500	Kit de montage FLYTE[2]
IN-21700	Kit d'adaptateur T7[2]
170-00-002	Tech Shoulder Pack
IN-13900	Cordon de charge ARVIS, États-Unis
IN-13910	Cordon de charge ARVIS, AU
IN-13920	Cordon de charge ARVIS, UE
IN-15201	Adaptateur mural, 25 W, États-Unis
IN-15221	Adaptateur mural ARVIS, AU
IN-15211	Adaptateur mural ARVIS, UE

1. D'autres versions du matériel électronique sont disponibles avec les accessoires ARVIS inclus, y compris, mais sans s'y limiter, -IN22300
2. Consultez IN-14001 pour les instructions de montage.



1. Stylet de déclenchement en ligne
2. Guide des broches de référence
3. Tracker A, mécanique
4. Outil d'enregistrement inverse
5. Guide de forage de la glène
6. Montage mécanique
7. Tournevis hexagonal de 3,5 mm
8. Ascenseur Cobb, 2,54 cm

Instructions de nettoyage des appareils électroniques

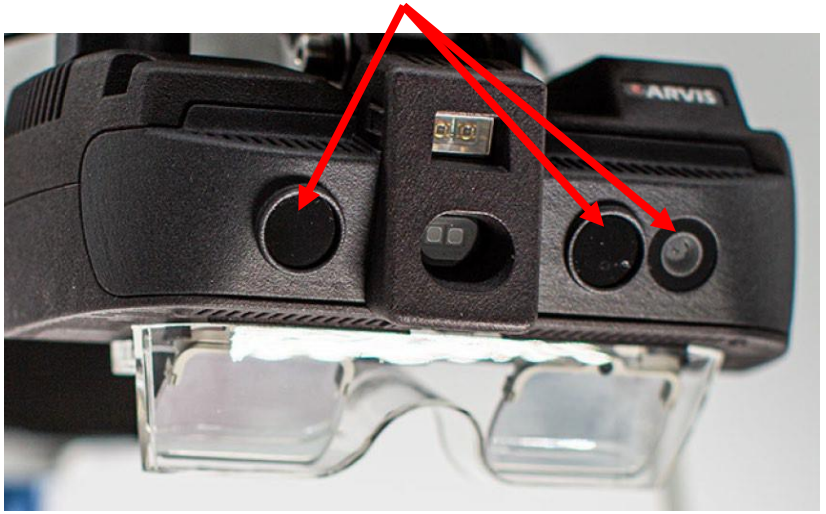
Les composants électroniques matériels du système **ARVIS** sont l'oculaire, le Belt pack, la batterie et les chargeurs. Les composants matériels électroniques sont réutilisables.

- Les chargeurs n'ont pas été conçus pour être utilisés en salle d'opération.
- L'oculaire ne fournit pas de protection pour les yeux. S'il y a une probabilité que du sang ou d'autres salissures soient en suspension dans l'air, il est conseillé à l'utilisateur de porter un écran facial homologué pour se protéger. Il est également recommandé à l'utilisateur de porter une blouse ou une toge chirurgicale légalement commercialisée lorsqu'il existe une probabilité de souillure.

Avec une tenue vestimentaire appropriée, les composants électroniques du système **ARVIS** ne devraient pas nécessiter de nettoyage fréquent, mais ils peuvent être nettoyés comme décrit ci-dessous si nécessaire.

- Retirez la batterie **ARVIS** et éteignez le module informatique **ARVIS**.
- Essuyez avec une solution d'alcool isopropylique (70-99 %) à l'aide d'un chiffon non-pelucheux pendant une minute. Suivez toutes les instructions figurant sur l'étiquette de l'alcool isopropylique.
- N'utilisez pas de brosses ou de chiffons abrasifs.
- Veillez à ne pas rayer les protections de la caméra. Inspectez visuellement chaque cache de caméra après le nettoyage pour vous assurer qu'il n'y a pas de rayures ni de résidus.
- Veillez à ne pas introduire de liquides en excès dans l'oculaire par les orifices de refroidissement.
- Ne pas immerger. Ne pas stériliser. Laissez sécher complètement avant utilisation.
- N'utilisez pas de désinfectants phénoliques, car ils peuvent endommager les boîtiers de l'oculaire ou le Belt pack.

Caches de caméra

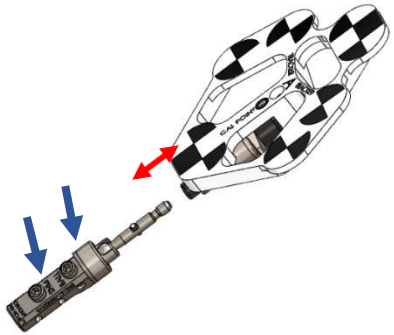


Instructions de nettoyage des instruments

Les instruments ARVIS sont ré-utilisables. Nettoyez et stérilisez tous les instruments avant la première utilisation et après chaque utilisation.

1. Nettoyez les instruments dès que possible après utilisation et évitez de laisser sécher les instruments souillés. Immergez, ou utilisez des serviettes humides ou des éponges imbibées d'eau distillée ou d'eau dé-ionisée pour maintenir l'humidité avant le nettoyage.

2. Démontez les instruments en les séparant selon les composants énumérés dans le tableau « Composants de l'ensemble d'instruments **ARVIS** ».
    a. Séparez le tracker de la monture.
    b. Desserrez les deux vis de serrage dans le montage mécanique IN-23000.



3. Rincez les instruments sous l'eau courante froide (robinet) pour éliminer les salissures grossières.
    a. Pendant le rinçage, faites tourner toutes les pièces mobiles des instruments et utilisez une brosse à poils doux pour faciliter l'élimination des salissures grossières.
4. Faites couler de l'eau du robinet à travers les lumières et autres zones difficiles d'accès des instruments.
5. Un nettoyeur ultrasonique peut également être utilisé.
6. Chargez les instruments dans le lave-pièces automatisé pour traitement.
7. Utilisez le lave-pièces automatique avec les paramètres suivants :
    a. Pré-lavez pendant 2 minutes à l'eau froide du robinet.
    b. Effectuez un lavage enzymatique pendant 2 minutes avec de l'eau chaude du robinet et un détergent enzymatique préparé selon les instructions du fabricant.
    c. Rincer pendant 5 minutes avec de l'eau déionisée ou de l'eau d'osmose inverse à 43°C (nominal).
    d. Séchez pendant 7 minutes à 90 °C (nominal).
8. Après le nettoyage, les instruments (démontés, le cas échéant) doivent être inspectés visuellement. Toutes les étapes du processus de nettoyage doivent être répétées pour les instruments qui ont été nettoyés de façon incomplète.

    Remarque : L'utilisation de lubrifiants solubles dans l'eau- est recommandée pour les instruments comportant des pièces mobiles ou destinés à être assemblés à un autre instrument au cours de l'intervention chirurgicale.

Stérilisation à l'autoclave des instruments réutilisables

- Pré-emballé sous vide, 4 minutes à 270°F (132°C). Le temps de séchage est de 75 minutes*. Utilisez une enveloppe autorisée par la FDA- ou une barrière stérile. (La validation est basée sur l'utilisation de Halyard Health H400.)
- Non pré-emballé sous vide (« Flash »), 4 minutes à 270 °F (132 °C).

    *En plus du temps de séchage prescrit, il est recommandé de laisser refroidir les dispositifs pendant 30 minutes supplémentaires après leur sortie de la chambre de stérilisation afin de s'assurer qu'ils sont exempts de condensation et d'autres formes d'humidité.

Le processus de stérilisation recommandé a été validé pour produire un niveau d'assurance de stérilité de (10^{-6}) lorsque les pièces ont été nettoyées selon les instructions ci-dessus. Les autres cycles de vapeur et procédures de nettoyage n'ont pas été évalués et doivent être qualifiés par l'utilisateur.

Une stérilisation efficace repose sur des processus de nettoyage et de séchage approfondis. Le non-respect de cette consigne compromettra le processus de stérilisation et rendra l'instrument traité impropre à une utilisation clinique.

Élimination

Ne jetez aucune partie de ce système à la poubelle. Jetez les composants conformément aux réglementations locales et aux procédures standard de gestion des déchets de l'établissement de soins de santé.

Stockage et transport

Température : -30 à 50°C ; Humidité : 10 à 90 % HR ;
(sans- condensation) ; Pression : 60 kPa à 106 kPa.

Manipuler avec précaution.

Maintenance

Avant chaque utilisation, vérifiez les instruments pour détecter toute usure ou tout dommage. Notez en particulier l'état des marquages des trackers et l'ajustement des interfaces entre les trackers et les montures de trackers. Bien que les instruments du système n'aient pas de limite d'utilisation et soient censés durer longtemps, les instruments endommagés ou usés doivent être remplacés. L'utilisation d'instruments endommagés peut provoquer des erreurs de navigation.

Respectez les instructions d'inspection, de nettoyage et de stérilisation (le cas échéant) des composants du système. Aucune maintenance supplémentaire n'est requise. Ne procédez à aucune maintenance ni modification d'un composant du système.

Toute pièce qui ne fonctionne pas comme prévu doit être signalée au fabricant pour qu'il puisse y remédier.

Garantie

Le produit est garanti sans défauts de matériaux et de fabrication.

Sécurité électrique

Cet équipement a été testé et jugé conforme aux limites CEM selon la norme CEI 60601-1-2. Ces limites ont été définies afin d'établir une protection raisonnable contre les perturbations dans une installation médicale type. Cet équipement génère, utilise et peut émettre de l'énergie radiofréquence et, s'il n'est pas installé et utilisé conformément à ces instructions, il peut causer des interférences nuisibles aux autres dispositifs à proximité. Il n'existe aucune garantie que de telles interférences ne se produiront pas dans une installation particulière. Si cet équipement cause des interférences nuisibles avec d'autres appareils, ce qui peut être déterminé en éteignant puis en rallumant l'équipement, l'utilisateur est encouragé à essayer de corriger ces interférences en appliquant une ou plusieurs des mesures suivantes :

- Réorienter ou déplacer l'appareil récepteur
- Augmenter la distance de séparation entre les équipements.
- Consultez Insight Medical Systems ou un représentant agréé pour obtenir de l'aide.

ID FCC : SH6MDBT42Q Cet appareil est conforme à la Partie 15 des règles de la FCC. Son utilisation est soumise aux deux conditions suivantes : (1) Cet appareil ne doit pas causer d'interférences nocives et (2) cet appareil doit accepter toute interférence reçue, y compris les interférences susceptibles de provoquer un fonctionnement indésirable.

Conditions de fonctionnement : Température : 15-25°C ; Humidité : 20-80% (RH) sans-condensation ; Pression : 70-106 kPa.

Avertissement : Ce dispositif a été conçu pour des tâches très spécifiques. L'utilisation dans un environnement contenant des perturbations électromagnétiques qui dépassent la capacité de cet appareil peut compromettre le résultat de l'intervention chirurgicale.

Avertissement : Cet appareil n'a pas été conçu pour être utilisé à côté d'autres équipements ou pour être empilé avec eux. L'utilisation à proximité ou empilée avec d'autres équipements doit être évitée en raison d'un fonctionnement incorrect.

Avertissement : L'utilisation de batteries, de modules informatiques ou de câbles autres que ceux fournis par Insight Medical Systems pourrait entraîner une augmentation des émissions électromagnétiques ou une diminution de l'immunité électromagnétique de cet équipement et un fonctionnement incorrect.

Avertissement : Les équipements de communication RF portables (y compris les périphériques tels que les câbles d'antenne et les antennes externes) ne doivent pas être utilisés à moins de 30 cm (12 pouces) de toute partie du système ARVIS®, y compris les câbles spécifiés par le fabricant. Sinon, il pourrait en résulter une dégradation des performances de cet équipement.

Remarque : les caractéristiques d'émission de cet équipement permettent de l'utiliser dans les zones industrielles et les hôpitaux (classe A de la norme CISPR 11). S'il est utilisé dans un environnement résidentiel (pour lequel la classe B de la norme CISPR 11 est normalement requise), cet équipement pourrait ne pas offrir une protection adéquate aux services de communication par radiofréquence. L'utilisateur pourrait avoir besoin de prendre des mesures d'atténuation, comme déplacer ou ré-orienter l'équipement.

Remarque : Cet appareil a été testé pour l'immunité électromagnétique et il a été démontré qu'il conservait les performances essentielles (erreur de suivi ≤ 5 mm) lorsqu'il est exposé aux niveaux attendus de perturbations électromagnétiques (définis plus en détail dans les tableaux suivants). Le système est doté de contrôles de qualité logiciels internes qui arrêtent la progression dans le flux de travail. Si un utilisateur ne parvient pas à franchir à plusieurs reprises une étape du flux de travail, il doit d'abord s'assurer qu'il suit correctement la technique chirurgicale et qu'aucun obstacle ne bloque l'oculaire. Si l'utilisateur n'y parvient toujours pas, il doit cesser d'utiliser le dispositif.

Les perturbations du système ARVIS lorsqu'il est en cours d'utilisation peuvent entraîner :

- Perte de visibilité du tracker
- Perte de fonctionnalité de l'oculaire ARVIS
- Arrêt inattendu du système

Le système ARVIS est alimenté par batterie, ce qui modifie les tests d'immunité CEM applicables. Les tests d'émission et d'immunité applicables au système ARVIS, composé de l'oculaire, du Belt pack, de la batterie et de l'ensemble de câbles USB portés par l'utilisateur pendant la chirurgie, sont illustrés ici.

INSTRUCTIONS ET DÉCLARATION DU FABRICANT - ÉMISSIONS ÉLECTROMAGNÉTIQUES		
Le système ARVIS a été conçu pour être utilisé dans l'environnement électromagnétique spécifié ci-dessous. Le client ou l'utilisateur du système ARVIS doit s'assurer qu'il est utilisé dans un tel environnement.		
TEST D'ÉMISSIONS	**CONFORMITÉ**	**ÉLECTROMAGNÉTIQUE ENVIRONNEMENT - CONSEILS**
Émissions RF - CISPR 11	Groupe 1	Le produit ARVIS utilise l'énergie RF uniquement pour ses fonctions internes (à l'exception des communications intentionnelles). Les émissions RF sont très faibles et ne devraient pas causer d'interférences avec les équipements électroniques à proximité.
Émissions RF - CISPR 11	Classe A	Ce produit ARVIS est adapté à une utilisation dans tous les établissements non domestiques.
Émissions RF CEI 61000-3-2	Sans objet	
Émissions RF CEI 61000-3-3	Sans objet	

CONSIGNES ET DÉCLARATION DU FABRICANT - IMMUNITÉ ÉLECTROMAGNÉTIQUE			
Le système ARVIS a été conçu pour être utilisé dans l'environnement électromagnétique spécifié ci-dessous. Le client ou l'utilisateur du système ARVIS doit s'assurer qu'il est utilisé dans un tel environnement.			
TEST D'IMMUNITÉ	**NIVEAU D'ESSAI CEI 60601**	**NIVEAU DE CONFORMITÉ**	**ENVIRONNEMENT ÉLECTROMAGNÉTIQUE - RECOMMANDATIONS**
Décharge électrostatique (ESD) CEI 61000-4-2	+/- 8 kV contact +/-15 kV dans l'air	+/- 8 kV contact +/-15 kV dans l'air	Les mesures normales de prévention des décharges électrostatiques doivent être prises, y compris l'utilisation en l'absence de sols recouverts de matériaux synthétiques. L'humidité relative doit être d'au moins 20 %.
Transitoires électriques rapides en salve CEI 61000-4-4	Non applicable aux systèmes ARVIS fonctionnant sur batterie		
Surtensions CEI 61000-4-5	Non applicable aux systèmes ARVIS fonctionnant sur batterie		

CONSIGNES ET DÉCLARATION DU FABRICANT - IMMUNITÉ ÉLECTROMAGNÉTIQUE			
Le système ARVIS a été conçu pour être utilisé dans l'environnement électromagnétique spécifié ci-dessous. Le client ou l'utilisateur du système ARVIS doit s'assurer qu'il est utilisé dans un tel environnement.			
TEST D'IMMUNITÉ	**NIVEAU D'ESSAI CEI 60601**	**NIVEAU DE CONFORMITÉ**	**ENVIRONNEMENT ÉLECTROMAGNÉTIQUE - RECOMMANDATIONS**
Creux de tension, interruptions brèves et variations de tension sur les lignes d'entrée d'alimentation électrique CEI 61000-4-11	Non applicable aux systèmes ARVIS fonctionnant sur batterie		
Fréquence électrique (50/60 Hz) Champ magnétique CEI 61000-4.8	30 A/m	30 A/m	Les champs magnétiques à la fréquence du réseau d'alimentation doivent correspondre à ceux d'un environnement commercial ou hospitalier typique.
Essais de CEM selon la norme CEI 61000-4-6	Non applicable aux systèmes ARVIS fonctionnant sur batterie		
Perturbations électromagnétiques transmises par rayonnement CEI 61000- 4-3	3 V/m 80 MHz à 2,7 GHz	3 V/m	Les équipements de communications RF portables et mobiles ne doivent pas être utilisés à moins d'une distance recommandée de toute partie du produit ARVIS (y compris les câbles), distance calculée à partir de l'équation applicable à la fréquence de l'émetteur. Distance de séparation recommandée $d = 2,3*(P)^{1/2}$ $d = 2,3*(P)^{1/2}$ de 800 MHz à 2,7 GHz où P est la puissance de sortie nominale maximale de l'émetteur exprimée en watts (W) selon la documentation du fabricant, et d est la distance de séparation recommandée exprimée en mètres (m). L'intensité des champs des émetteurs RF fixes, telle que déterminée par une étude de site électromagnétique, doit être inférieure au niveau de conformité dans chaque gamme de fréquences.

DISTANCES DE SÉPARATION RECOMMANDÉES PAR RAPPORT AUX ÉMETTEURS À PROXIMITÉ	
Le système ARVIS a été conçu pour être utilisé dans un environnement électromagnétique où les perturbations RF radiées sont contrôlées. Le client ou l'utilisateur du système ARVIS peut aider à prévenir les interférences électromagnétiques en maintenant une distance minimale entre les équipements de communications RF portables et mobiles (émetteurs) et le système ARVIS, comme recommandé ci-dessous, en fonction de la puissance de sortie maximale de l'équipement de communication.	
PIRE de l'émetteur voisin (W)	**Distance de séparation minimale (m)**
10	1,33
1	0,42
0,1	0,13
0,01	0,04

En plus du système ARVIS alimenté par batterie, un équipement de support est fourni pour recharger la batterie ARVIS si nécessaire. Cet équipement de soutien ne fait pas partie de l'environnement opératoire et n'est pas requis pendant l'opération. L'équipement de soutien a été testé selon les normes indiquées dans ce tableau.

Sécurité et CEM	**En combinaison avec l'alimentation externe CA/CC incluse**	
Approbations réglementaires	Europe	CE
	International	CB
Emissions électromagnétiques	Europe	EN55011, EN55032, niveau B
	États-Unis	FCC15 classe B
Immunité électromagnétique	Immunité ESD	EN/CEI 61000-4-2
	Immunité aux champs électromagnétiques	EN/CEI 61000-4-3
	EFT / Burt	EN/CEI 61000-4-4
	Surtensions	EN/CEI 61000-4-5
	Immunité conduite	EN/CEI 61000-4-6
	Champs magnétiques	EN/CEI 61000-4-8
	Creux de tension, instrumentations brèves & Variations de tension	FR/CEI 61000-4-11
	Caractéristiques de l'immunité	EN55024

Planification préopératoire

L'objectif de la planification préopératoire pour ARVIS® Shoulder est de définir des modèles anatomiques et des références basés sur la tomodensitométrie (CT)-, ainsi que les positions souhaitées pour les implants à utiliser pendant la chirurgie stéréotaxique, afin d'aider le chirurgien à positionner les implants orthopédiques.

Consignes d'utilisation

Le logiciel de planification est basé sur le web et ne nécessite pas d'installation.
Pour se connecter à la plateforme, l'utilisateur doit d'abord entrer son nom d'utilisateur et son mot de passe. Pour accéder au site web, veuillez contacter https://www.precisionai.com.au/contact/.
Le logiciel de planification consiste en plusieurs pages correspondant aux différentes étapes du processus de planification chirurgicale.
La page de présentation des opérations chirurgicales offre un aperçu de tous les cas chirurgicaux disponibles pour ce compte.
Pour commencer la planification et obtenir des instructions plus détaillées, veuillez vous référer au Guide de technique chirurgicale de l'épaule ARVIS® P/N 22000.

Déclaration de confidentialité

Toutes les informations personnelles des patients stockées dans le logiciel seront anonymisées avant d'être stockées. Aucune information personnelle des patients ne sera partagée avec des tiers. Toutes les informations envoyées à des tiers seront anonymisées avant d'être envoyées.

Mises en garde et précautions

- Ce logiciel doit être utilisé uniquement par des personnes formées et qualifiées, conscientes des instructions d'utilisation.
- Veillez à utiliser la configuration système minimale requise, comme indiqué dans ce document.

Emballage et étiquetage

Le logiciel est basé sur le web-, par conséquent, il n'y a pas d'exigence d'emballage applicable pour ce logiciel. Cependant, une copie de ces instructions d'utilisation sera mise à la disposition de chaque utilisateur avant l'utilisation du logiciel.

Cybersécurité

Le logiciel fonctionne sur une plateforme sécurisée qui comprend des systèmes de surveillance et d'identification des vulnérabilités et de réduction du risque de cyber-attaques.

Configuration requise

Les exigences minimales et recommandées du système pour utiliser le logiciel de planification sont les suivantes :

Configuration système minimale requise Navigateur Web :

Google Chrome (v.107 ou version ultérieure) Mozilla Firefox (v.109.0 ou version ultérieure) Apple Safari (v.16 ou version ultérieure)

Système d'exploitation :

Microsoft Windows 8 ou version ultérieure MacOS 10.x ou version ultérieure

Résolution de l'écran :

1280 × 800

Internet :

Connexion Internet requise. Connexion Internet de 10 Mbps ou plus

Configuration système recommandée

Navigateur web :
Google Chrome (v.107 ou version ultérieure)

Système d'exploitation :
Microsoft Windows 10 ou 11 MacOS 12.x

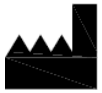
Résolution de l'écran :
1920 × 1080

Légende des symboles (logiciel de planification)

LOT	Numéro de version du logiciel
	Date de sortie du logiciel

Informations supplémentaires

Si vous avez besoin d'informations supplémentaires sur ce produit ou si vous souhaitez obtenir une autorisation de retour de produit, veuillez contacter le service clientèle au 1-800-456-8696 (heure centrale 8:00 AM - 5:00 PM) aux États-Unis.



Kico Knee Innovation Company Pty Limited Unit 1,
25 Frenchs Forest Rd E,
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Courriel : compliance@360med.care

EC REP

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PAYS-BAS

ARVIS® est une marque déposée d'Insight Medical Systems, Inc.

In vigore dal 22.05.2025 al 29.07.2025

ARVIS® Istruzioni per l'uso del sistema di navigazione chirurgica per la spalla

CE 2797

Modello: ARV-01

⚠ AVVERTENZA: questo documento deve essere sempre utilizzato insieme alla Guida alle tecniche chirurgiche della spalla ARVIS® cod. art. IN-22000, che contiene ulteriori istruzioni sul prodotto. Accedere alla Guida alle tecniche chirurgiche all'indirizzo www.insightmedsys.com/resources utilizzando la password "ARVIS".

Sommario

Informazioni sul sistema

Precauzioni

la legge federale degli Stati Uniti limita la vendita del presente dispositivo esclusivamente dietro prescrizione medica.

Avvertenze generali

- Leggere tutte le istruzioni prima dell'uso.
- Non utilizzare il sistema senza un'adeguata formazione. Prima di procedere con l'intervento, il chirurgo deve conoscere il sistema di navigazione chirurgica ARVIS Shoulder e le rispettive istruzioni per l'uso (IFU) del sistema di impianto compatibile e le linee guida sulle tecniche chirurgiche.
- I risultati della navigazione non sostituiscono il giudizio clinico del chirurgo.
- Utilizzare solo gli accessori forniti con il sistema. Non sostituire i cavi o altri componenti. Non collegare accessori non forniti dal produttore ai connettori USB del dispositivo, incluso il connettore di uscita per la lampada frontale. Non tentare di utilizzare dispositivi informatici diversi dal modulo del computer fornito con il sistema.
- Prima dell'uso, verificare che gli strumenti non siano usurati o danneggiati. Sostituire eventuali strumenti danneggiati o usurati prima dell'uso.
- Prima dell'uso, valutare il processo coracoideo per verificare l'idoneità del fissaggio tramite perni.
- L'oculare include una luce, un emettitore a infrarossi e un laser di Classe I. Le superfici vicino alla luce e le altre superfici, potrebbero riscaldarsi durante l'uso. Toccare solo le parti dell'oculare necessarie alla regolazione.

Per evitare potenziali interferenze con i pacemaker, non posizionare alcun componente del sistema vicino al torace del paziente o dell'utente. Esiste un potenziale rischio di interferenza elettromagnetica. Se il dispositivo interferisce con altre apparecchiature, riposizionare o interrompere l'uso del dispositivo. Se il dispositivo riceve interferenze dannose che compromettono il suo funzionamento, interromperne l'uso.

- Non modificare o riparare alcun componente del sistema.
- Il sistema **ARVIS** include l'oculare, il kit cintura, la batteria, i caricabatterie e il set di strumenti. Gli strumenti sono forniti NON-STERILI e devono essere puliti e sterilizzati prima di ogni utilizzo. I componenti elettrici sono NON-STERILI e non devono essere sterilizzati.
- Per evitare il rischio di scossa elettrica, questa apparecchiatura deve essere collegata esclusivamente a una rete di alimentazione con messa a terra protettiva.
- Per mantenere la sicurezza informatica e il corretto funzionamento, non modificare le impostazioni del modulo del computer fornito se non come indicato da Insight Medical Systems.
    - Non abilitare la comunicazione Wi-Fi o cellulare, se non come indicato da Insight Medical Systems.
    - Non installare o rimuovere applicazioni o memorizzare dati diversi da quelli di Insight.
    - Insight raccomanda di impostare una password per limitare l'accesso al modulo del computer.
    - Insight consiglia agli utenti fidati di ricordare di controllare qualsiasi unità rimovibile utilizzata per trasportare file di piani crittografati nel sistema e di non utilizzare le unità per scopi diversi dalla memorizzazione e dal trasferimento dei file di dati dei piani.
    - Confermare la password e/o l'importazione del piano prima che il paziente venga anestetizzato.

- Rivedere e confermare i dettagli del paziente e del piano prima della selezione del piano.

- Gli strumenti chirurgici in acciaio inossidabile possono contenere nichel, noto come sensibilizzante. Se si sospetta una sensibilità o un'allergia al nichel, è necessario consultare un medico esperto.

Descrizione del sistema

ARVIS Shoulder è un sistema di navigazione chirurgica controllato da computer per l'artroplastica della spalla. Combina software, hardware elettronico e strumenti chirurgici per tracciare gli strumenti in modo intraoperatorio, localizzare le strutture anatomiche e fornire un feedback all'utente. Il sistema supporta il chirurgo nell'esecuzione di un piano preoperatorio approvato.

L'oculare **ARVIS** contiene telecamere di tracciamento IR stereotassiche, una telecamera a colori, un display stereotassico, illuminazione IR e un illuminatore laser IR. Una lampada frontale visibile è montata sull'oculare e collegata tramite un cavo micro-USB. L'oculare comunica con il kit cintura tramite un cavo USB-C. Tutte le istruzioni, i messaggi, gli avvisi e i risultati del sistema vengono mostrati al chirurgo sul display dell'oculare.

Il kit cintura include il modulo computer, la batteria e la scheda di gestione dell'alimentazione. Il kit cintura alimenta l'oculare ed esegue il software applicativo **ARVIS** Shoulder.

L'elettronica **ARVIS** viene indossata sul corpo del chirurgo durante l'intervento chirurgico. Non esiste alcuna interfaccia con apparecchiature esterne, ad eccezione del caricabatterie **ARVIS**, che ricarica la batteria quando non è in uso.

ARVIS utilizza le telecamere di tracciamento per misurare le posizioni dei tracker sul paziente o sugli strumenti. **ARVIS** visualizza le misurazioni come descritto nelle dichiarazioni relative alle prestazioni. Quando un tracker richiesto non viene rilevato ed è nel raggio d'azione delle telecamere di tracciamento, le misurazioni non vengono visualizzate. La portata valida della telecamera si estende almeno da 40 cm a 70 cm dall'oculare, ma **ARVIS** può essere in grado di fornire misurazioni accurate a distanze sia inferiori che superiori.

Dichiarazioni relative alle prestazione

ARVIS Shoulder misura i seguenti parametri con la precisione dichiarata nell'uso simulato su attrezzature da banco.

- Inclinazione e versione del trapano con un errore assoluto medio ≤ 1,5°
- Posizionamento superiore/inferiore e anteriore/posteriore del punto di entrata del trapano con un errore assoluto medio ≤ 1,5 mm su ciascun asse
- Inclinazione e versione dell'impianto glenoideo con un errore assoluto medio ≤ 1,5°
- Rotazione dell'impianto glenoideo attorno al suo asse centrale con un errore assoluto medio ≤ 1,5°

- Intervallo di lunghezza di una vite virtuale (fino a 50 mm) che si estende da una placca basale glenoidea teorica con un errore assoluto medio ≤ 0,5 mm

L'accuratezza clinica dipende dall'accuratezza della registrazione e degli input al software applicativo **ARVIS** Shoulder. Il sistema è stato validato in un uso clinico simulato (cadaverico) per raggiungere la seguente accuratezza:

- Posizionamento superiore/inferiore e anteriore/posteriore dell'impianto glenoideo con un errore assoluto medio ≤ 1,5 mm su ciascun asse
- Inclinazione e versione dell'impianto glenoideo con un errore assoluto medio ≤ 3,0°
- Rotazione dell'impianto glenoideo attorno al suo asse centrale con un errore assoluto medio ≤ 3,0°
- Intervallo di lunghezza di una vite virtuale (fino a 50 mm) che si estende da una placca basale glenoidea teorica con un errore assoluto medio ≤ 2,0mm

Principio di funzionamento

ARVIS Shoulder è un sistema di navigazione chirurgica basato su immagini. La TAC preoperatoria dell'articolazione della spalla del paziente è necessaria per creare un piano chirurgico preoperatorio che include un modello osseo digitale con punti di riferimento, abbinato ai punti di riferimento intraoperatori registrati dal chirurgo.

L'oculare **ARVIS** integra delle telecamere che misurano le posizioni e gli angoli tra i tracker montati sul paziente e quelli montati sugli strumenti. Chiedendo all'utente di seguire un flusso di lavoro specifico per la procedura per registrare il tracker di riferimento sui punti di riferimento anatomici, il software applicativo **ARVIS** Shoulder, in esecuzione sul kit cintura, calcola e visualizza le posizioni degli strumenti rispetto all'anatomia del paziente.

Destinazione d'uso

Il sistema **ARVIS** è un sistema di navigazione controllato da computer progettato per fornire al chirurgo misurazioni intra-operatorie a supporto della selezione e del posizionamento dei componenti degli impianti ortopedici.

Indicazioni per l'uso

ARVIS® Shoulder è indicato per assistere il chirurgo nel posizionamento e nell'allineamento degli impianti rispetto agli assi di allineamento di riferimento e ai punti di riferimento nella chirurgia ortopedica stereotassica.

Il sistema aiuta il chirurgo a effettuare misurazioni intraoperatorie e a localizzare le strutture anatomiche dell'articolazione della spalla basandosi sulle immagini preoperatorie del paziente.

Il sistema è progettato per essere utilizzato con il display dell'oculare ARVIS® posizionato sulla testa dell'utente per la visualizzazione in realtà aumentata e per informazioni, come la visualizzazione del piano preoperatorio e l'allineamento degli strumenti e degli impianti. Le informazioni visualizzate aumentate/virtuali non devono essere considerate come unica fonte informativa per la posizione e l'allineamento assoluti e devono sempre essere usate insieme alle informazioni stereotassiche visualizzate.

ARVIS® Shoulder è indicato per l'artroplastica totale della spalla utilizzando i sistemi di impianti Enovis AltiVate, LimaCorporate PRIMA e LimaCorporate SMR.

Controindicazioni

- Perdita significativa di osso che compromette l'identificazione dei punti di riferimento richiesti
- Interferenza eccessiva dei tessuti molli che influisce sull'identificazione dei punti di riferimento richiesti
- Osteoporosi grave nel sito o nei siti di fissazione, inclusa ma non limitata alla debolezza del processo coracoideo, che potrebbe portare a effetti negativi
- Presenza di infezione
- Qualsiasi controindicazione associata alla chirurgia artroplastica della spalla

Effetti indesiderati

I possibili effetti indesiderati includono il danneggiamento prematuro dell'impianto, la dislocazione o l'instabilità, la riduzione della gamma di movimento, l'infezione, la lesione dei tessuti, la lesione e la debolezza dei nervi, la frattura, la reazione al corpo estraneo, l'aumento del tempo di anestesia, l'infarto, la lesione vascolare, la lesione al collo, le ustioni, lo shock elettrico e le lesioni cardiovascolari.

Informare il produttore e l'autorità nazionale se, durante l'utilizzo di questo dispositivo, si ritiene che si sia verificato un incidente legato al prodotto.

Compatibilità

- **ARVIS** Shoulder è indicato per l'uso con i sistemi di impianto Enovis AltiVate®, LimaCorporate PRIMA e LimaCorporate SMR.
- Per il supporto meccanico, è necessario utilizzare perni Steinmann (x2), 2,5 mm x 100 mm. Il sistema è stato convalidato utilizzando il Tech Shoulder Pack 170-00-002.
- Prima della navigazione è necessario utilizzare il software di pianificazione chirurgica Precision AI per la pianificazione preoperatoria.
- Per indossare l'oculare **ARVIS** è possibile utilizzare il casco Stryker® Flyte® o T7® insieme agli adattatori compatibili in dotazione.

Profilo utente

Il sistema **ARVIS** è destinato a essere utilizzato dai chirurghi ortopedici e dal personale di sala operatoria che eseguono l'artroplastica della spalla. Gli utenti devono fare riferimento alla Guida alla tecnica chirurgica della spalla ARVIS® cod. art. IN-22000 per le istruzioni sul prodotto passo-passo. La formazione sull'uso del prodotto è disponibile ed è fortemente consigliata.

Per organizzare un corso di formazione, contattare Insight Medical Systems, Inc.

Ambiente di utilizzo

Il sistema **ARVIS** è progettato per l'uso in sala operatoria ospedaliera. Le sorgenti di radiazioni infrarosse (IR), comprese le luci della sala operatoria e le finestre, possono interferire con le telecamere integrate nel sistema **ARVIS**. Evitare ambienti con fonti IR eccessive.

Il sistema **ARVIS** è progettato per l'uso in sala operatoria ospedaliera nelle seguenti condizioni:

- Temperatura (15-25 °C)
- Umidità (20-80% non-condensante)
- Pressione (70-106 kPa)

L'oculare **ARVIS** deve essere posizionato sulla testa del chirurgo. Il kit cintura **ARVIS** deve essere posizionato sulla cintura o alla vita del chirurgo. Al paziente non viene applicato alcun componente hardware elettronico. Il chirurgo sta vicino al paziente per operare.

Il caricabatterie **ARVIS** è progettato per essere utilizzato al di fuori della sala operatoria.

Popolazione di pazienti

Il sistema ARVIS è destinato a essere usato su pazienti sottoposti a interventi di chirurgia ortopedica in cui è possibile identificare e utilizzare come punti di riferimento strutture anatomiche rigide, come il bacino, il femore o la tibia.

Benefici clinici

Gli strumenti chirurgici e di navigazione supportano l'impianto di protesi e non hanno una funzione terapeutica o diagnostica diretta.

Definizione dei simboli

Nell'etichettatura del sistema ARVIS vengono utilizzati i seguenti simboli:

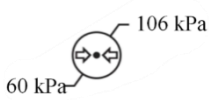
Seguire le istruzioni per l'uso

Non smaltire nei rifiuti indifferenziati

Non sterile

Umidità

Temperatura di conservazione



Pressione

Produttore

Numero di catalogo

Rappresentante autorizzato nell'UE

Importatore

Informazioni sull'hardware

Componenti del set di strumenti ARVIS Shoulder (cod. art. IN-21300)

Numero di catalogo	Descrizione
IN-21100	Base del vassoio strumenti, spalla
IN-11000	Coperchio del vassoio strumenti
IN-22100	Attivatore stilo in linea
IN-23000	Supporto meccanico
IN-24000	Tracker A, meccanico
IN-26000	Sollevatore Cobb Elevator, 1 pollice
IN-10800	Chiave esagonale da 3,5 mm
IN-18300	Guida per trapano glenoideo
IN-22200	Strumento di registrazione inversa
IN-18500	Guida ai perni di riferimento

Componenti hardware elettronici e accessori ARVIS (cod. art. IN-50010[1])

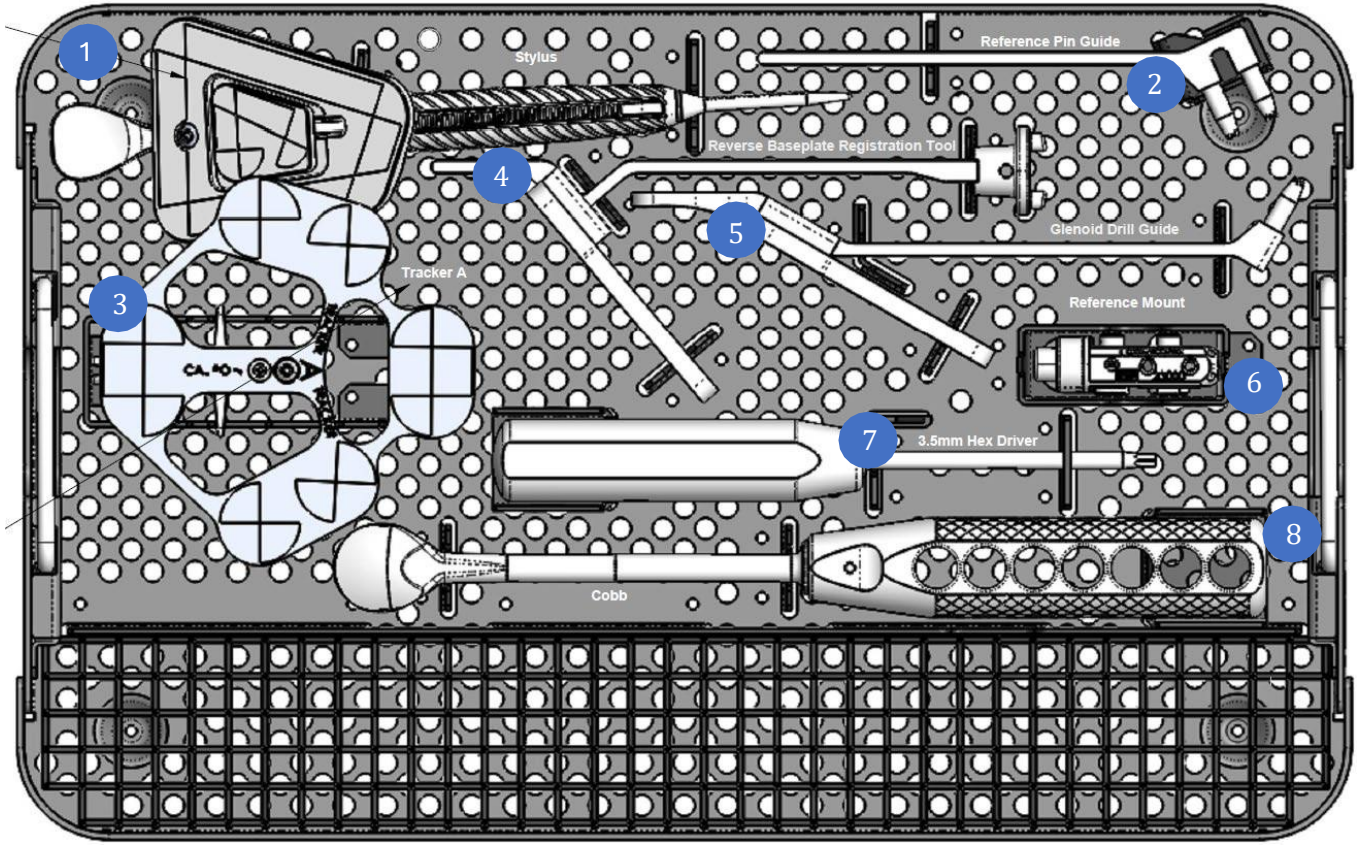
Numero di catalogo	Descrizione
IN-12400	Gruppo oculare ARVIS
IN-12500	Kit Cintura ARVIS
IN-12700	Modulo computer ARVIS
IN-12800	Batteria ARVIS
IN-13200	Cavo per oculare ARVIS
IN-13000	Caricabatterie ARVIS
IN-13800	Alimentatore del caricabatterie ARVIS
IN-15202	Cavo, USB-C, 1 m
IN-17700	Kit di installazione ARVIS

Utilizzare solo gli accessori forniti dal produttore.

Accessori ARVIS specifici per chirurgo o caso

Numero di catalogo	Descrizione
IN-17100	Fascia per la testa ARVIS[2]
IN-17500	Kit di montaggio FLYTE[2]
IN-21700	Kit adattatore T7[2]
170-00-002	Kit tecnico per spalla
IN-13900	Cavo del caricabatterie ARVIS, USA
IN-13910	Cavo del caricabatterie ARVIS, AU
IN-13920	Cavo del caricabatterie ARVIS, EU
IN-15201	Adattatore da parete, 25 W, USA
IN-15221	ARVIS Adattatore da parete, AU
IN-15211	ARVIS Adattatore da parete, EU

1. Sono disponibili versioni alternative dell'hardware elettronico con accessori ARVIS inclusi, tra cui, ad esempio, IN-22300
2. Per le istruzioni di montaggio, vedere IN-14001.



1. Attivatore stilo in linea
2. Guida ai perni di riferimento
3. Tracker A, meccanico
4. Strumento di registrazione inversa
5. Guida per trapano glenoideo
6. Supporto meccanico
7. Chiave esagonale da 3,5 mm
8. Sollevatore Cobb Elevator, 1 pollice

Istruzioni per la pulizia dei componenti elettronici

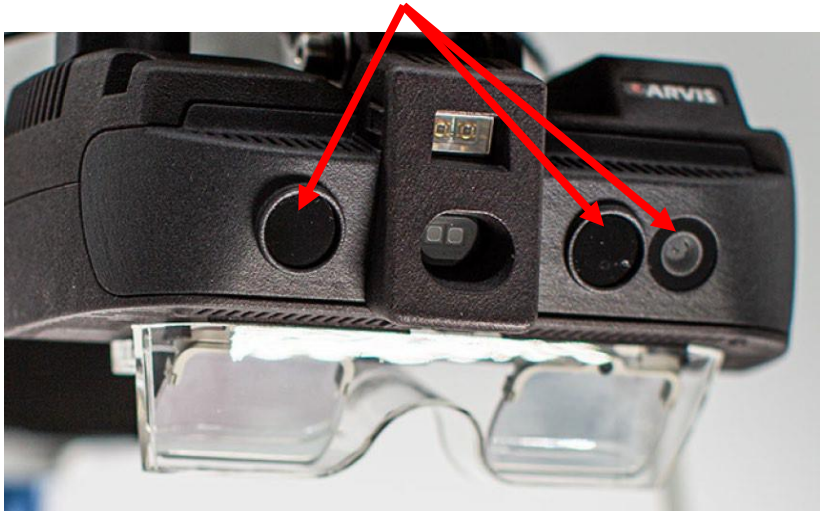
Le componenti hardware elettroniche che costituiscono il sistema **ARVIS** sono l'oculare, il kit cintura, la batteria e i caricatori. I componenti hardware elettronici sono riutilizzabili.

- I caricabatterie non sono destinati all'uso in sala operatoria.
- L'oculare non offre protezione per gli occhi. Se esiste la possibilità che sangue o altri contaminanti siano trasportati dall'aria, si consiglia all'utente di indossare uno schermo facciale legalmente approvato per la protezione. In caso di possibilità di contaminazione, si consiglia inoltre all'utente di indossare un camice chirurgico o altro indumento approvato.

Utilizzando indumenti adeguati, i componenti elettronici del sistema **ARVIS** non dovrebbero richiedere una pulizia frequente; tuttavia, se necessario, è possibile pulirli come descritto di seguito.

- Rimuovere la batteria **ARVIS** e spegnere il modulo computer **ARVIS**.
- Pulire per un minuto con una soluzione di alcol isopropilico (70-99%) utilizzando un panno privo di lanugine. Seguire tutte le istruzioni dell'etichetta relative all'alcool isopropilico.
- Non usare spazzole o tessuti abrasivi.
- Fare attenzione a non graffiare le coperture delle telecamere. Dopo la pulizia, ispezionare visivamente le coperture delle telecamere per verificare che presentino graffi o residui.
- Assicurarsi di non introdurre liquidi in eccesso nell'oculare attraverso le aperture di raffreddamento.
- Non immergere. Non sterilizzare. Lasciare asciugare completamente prima dell'uso.
- Non utilizzare disinfettanti fenolici, poiché potrebbero danneggiare le custodie dell'oculare o del kit cintura.

Coperture delle telecamere

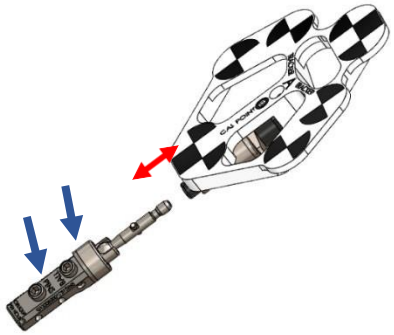


Istruzioni per la pulizia degli strumenti

Gli strumenti ARVIS sono riutilizzabili. Pulire e sterilizzare tutti gli strumenti prima del primo utilizzo e dopo ogni utilizzo.

1. Pulire gli strumenti il prima possibile dopo l'uso ed evitare che gli strumenti sporchi si asciughino. Prima della pulizia, immergere o utilizzare asciugamani umidi o spugne imbevute di acqua distillata o deionizzata per mantenere umido lo strumento.

2. Smontare gli strumenti fino a ottenere i componenti elencati nella tabella “Componenti del set di strumenti **ARVIS**”.
    a. Separare il tracker dal supporto di montaggio.
    b. Allentare le due viti di serraggio del supporto meccanico IN-23000.



3. Sciacquare gli strumenti con acqua corrente fredda (rubinetto) per rimuovere il grosso dello sporco.
    a. Durante il risciacquo, azionare tutte le parti mobili degli strumenti e usare una spazzola a setole morbide per facilitare la rimozione della gran parte dello sporco.
4. Far scorrere l’acqua del rubinetto attraverso i lumi e altre aree degli strumenti difficili da raggiungere.
5. Se si desidera, è possibile utilizzare un sistema di pulizia a ultrasuoni.
6. Per farlo, caricare gli strumenti in un sistema di pulizia automatizzato.
7. Effettuare il lavaggio automatico usando i seguenti parametri:
    a. Pre-lavaggio per 2 minuti con acqua di rubinetto fredda.
    b. Lavaggio con enzimi per 2 minuti con acqua calda di rubinetto e detergente enzimatico preparato secondo le indicazioni del produttore.
    c. Risciacquare per 5 minuti con acqua deionizzata o a osmosi inversa a 43 °C (nominale).
    d. Asciugare per 7 minuti a 90 °C (nominale).
8. Dopo la pulizia, gli strumenti (eventualmente smontati) devono essere ispezionati visivamente. Tutte le fasi del processo di pulizia devono essere ripetute per gli strumenti puliti in maniera incompleta.

    Nota: Per gli strumenti con parti mobili o quelli destinati ad essere assemblati intraoperatoriamente a un altro strumento, si consiglia l’uso di lubrificanti solubili in acqua.

Sterilizzazione in autoclave degli strumenti riutilizzabili

- Avvolto pre-vuoto, 4 minuti a 132 °C (270 °F). Il tempo di asciugatura è di 75 minuti*. Utilizzare un bendaggio autorizzato FDA oppure una barriera sterile. (La validazione si basa sull’uso di Halyard Health H400.)
- Non avvolto con pre-vuoto (“Flash”), 4 minuti a 132 °C (270 °F).

  *Oltre al tempo di asciugatura prescritto, si consiglia un ulteriore raffreddamento di 30 minuti dopo la rimozione dalla camera di sterilizzazione per garantire che i dispositivi siano privi di condensa e di altra umidità.

Il processo di sterilizzazione consigliato è stato convalidato per produrre un livello di garanzia di sterilità pari a (10^{-6}) quando i componenti sono stati puliti secondo le istruzioni sopra riportate. Altri cicli di vapore e procedure di pulizia non sono stati valutati e devono essere qualificati dall’utente.

Una sterilizzazione efficace si basa su processi di pulizia e asciugatura accurati. In caso contrario, il processo di sterilizzazione verrà compromesso e lo strumento trattato sarà inidoneo all’uso clinico.

Smaltimento

Non smaltire alcuna parte di questo sistema tra i rifiuti indifferenziati. Smaltire i componenti in conformità alle normative locali e le procedure standard sui rifiuti dell'istituto sanitario.

Conservazione e trasporto

Temperatura: -30-50°C; Umidità: 10-90% UR; (senza condensa); Pressione: da 60 kPa a 106 kPa.

Maneggiare con cura.

Manutenzione

Prima di ogni utilizzo, controllare che gli strumenti non siano usurati o danneggiati. Osservare con attenzione le condizioni dei contrassegni del tracker e l'adattamento delle interfacce tra i tracker e i supporti dei tracker. Sebbene gli strumenti del sistema non abbiano un limite d'uso e siano progettati per durare a lungo, gli strumenti danneggiati o usurati devono essere sostituiti. L'uso di strumenti danneggiati può portare a errori nella navigazione.

Seguire le istruzioni per la corretta ispezione, pulizia e sterilizzazione (se pertinente) dei componenti del sistema. Non è necessaria ulteriore manutenzione. Non effettuare manutenzione o modificare alcun componente del sistema.

Qualsiasi componente che non funziona come previsto dovrebbe essere segnalato al produttore per la risoluzione.

Garanzia

Il prodotto è garantito privo di difetti nei materiali e nella lavorazione.

Sicurezza elettrica

Questa apparecchiatura è stata collaudata ed è risultata conforme ai limiti EMC secondo la norma IEC 60601-1-2. Questi limiti sono stati concepiti per fornire una protezione ragionevole da interferenze dannose in un'installazione medica tipica. Questa apparecchiatura genera, utilizza e può irradiare energia a radiofrequenza; se non installata e utilizzata in conformità con le presenti istruzioni, potrebbe causare interferenze dannose ad altri dispositivi nelle vicinanze. Tuttavia, non vi è alcuna garanzia che non si verifichino interferenze in una particolare installazione. Qualora questo apparecchio causasse interferenze dannose con altri dispositivi, rilevabili accendendo e spegnendo l'apparecchio, si invita l'utente a cercare di correggerle adottando una o più delle seguenti misure:

- Riorientare o riposizionare il dispositivo ricevente.
- Aumentare la distanza di separazione tra le apparecchiature.
- Contattare Insight Medical Systems o un rappresentante autorizzato per ricevere assistenza.

FCC ID: SH6MDBT42Q Questo dispositivo è conforme alla Parte 15 delle norme FCC. Il funzionamento è soggetto alle due condizioni seguenti: (1) Questo dispositivo non può causare interferenze dannose e (2) deve accettare qualsiasi interferenza ricevuta, incluse quelle che potrebbero causare un funzionamento indesiderato.

Condizioni di funzionamento: Temperatura: 15-25 °C; Umidità: 20-80% (UR) senza condensa; Pressione: 70-106 kPa.

Avvertenza: questo dispositivo è stato progettato per attività molto specifiche. L'utilizzo in un ambiente con disturbi elettromagnetici al di fuori delle capacità di questo dispositivo può compromettere il risultato chirurgico.

Avvertenza: questo dispositivo non è progettato per essere utilizzato accanto o sovrapposto ad altre apparecchiature. L'uso accanto o sovrapposto ad altre apparecchiature deve essere evitato in quanto potrebbe causare un funzionamento improprio.

Avvertenza: l'uso di batterie, moduli di calcolo o cavi diversi da quelli forniti da Insight Medical Systems potrebbe causare un aumento delle emissioni elettromagnetiche o una riduzione dell'immunità elettromagnetica di questa apparecchiatura e causare un funzionamento improprio.

Avvertenza: le apparecchiature di comunicazione RF portatili (incluse le periferiche come i cavi dell'antenna e le antenne esterne) devono essere utilizzate a una distanza minima di 30 cm (12 pollici) da qualsiasi parte del sistema ARVIS®, compresi i cavi specificati dal produttore. In caso contrario, si rischia di compromettere le prestazioni di questa apparecchiatura.

Nota: le caratteristiche di EMISSIONE di questo apparecchio lo rendono idoneo all'uso in aree industriali e ospedaliere (CISPR 11 Classe A). Se utilizzato in un ambiente residenziale (per cui è normalmente richiesta la classe B della CISPR 11), questo apparecchio potrebbe non offrire un'adeguata protezione ai servizi di comunicazione a radiofrequenza. L'utente potrebbe dover adottare misure di mitigazione, come il riposizionamento o il riorientamento dell'apparecchiatura.

Nota: questo dispositivo è stato sottoposto a test per l'immunità elettromagnetica, che ne hanno dimostrato la capacità a mantenere le prestazioni essenziali (errore di tracciamento) ≤ 5 mm) quando è esposto ai livelli attesi di disturbi elettromagnetici (ulteriormente definiti nelle tabelle successive). Il sistema dispone di controlli interni di qualità del software, che bloccano l'avanzamento del flusso di lavoro. Se per più volte l'utente non riesce a completare una fase del flusso di lavoro, deve innanzitutto assicurarsi di seguire correttamente la tecnica chirurgica e verificare che non vi siano ostruzioni che bloccano l'oculare. Se non è ancora possibile procedere, l'utente deve interrompere l'uso del dispositivo.

Disturbi al sistema ARVIS durante l'uso possono causare:

- Perdita di visibilità del tracker
- Perdita della funzionalità dell'oculare ARVIS
- Arresto improvviso del sistema

Il sistema ARVIS è alimentato a batteria: questo modifica i test di immunità EMC pertinenti. Qui sono riportati i test di emissione e immunità applicabili al sistema ARVIS, composto dall'oculare, dal kit cintura, dalla batteria e dal gruppo del cavo USB che viene indossato dall'utente durante l'intervento chirurgico.

LINEE GUIDA E DICHIARAZIONE DEL PRODUTTORE – EMISSIONI ELETTROMAGNETICHE		
Il sistema ARVIS è destinato all'uso negli ambienti elettromagnetici specificati di seguito. Il cliente o l'utente del sistema ARVIS deve assicurarsi che venga utilizzato in tale ambiente.		
TEST EMISSIONI	**CONFORMITÀ**	**AMBIENTE ELETTROMAGNETICO AMBIENTE - LINEE GUIDA**
Emissioni RF CISPR 11	Gruppo 1	Il prodotto ARVIS utilizza l'energia RF solo per il funzionamento interno (ad eccezione della comunicazione intenzionale). Le emissioni RF sono molto basse ed è improbabile che causino interferenze con le apparecchiature elettroniche vicine.
Emissioni RF CISPR 11	Classe A	Il prodotto ARVIS è adatto all'uso in tutti gli ambienti non domestici.
Emissioni RF IEC 61000-3-2	N/D	
Emissioni RF IEC 61000-3-3	N/D	

LINEE GUIDA E DICHIARAZIONE DEL PRODUTTORE – IMMUNITÀ ELETTROMAGNETICA			
Il sistema ARVIS è destinato all'uso negli ambienti elettromagnetici specificati di seguito. Il cliente o l'utente del sistema ARVIS deve assicurarsi che venga utilizzato in tale ambiente.			
TEST DI IMMUNITÀ	**LIVELLO DI TEST IEC 60601**	**LIVELLO DI CONFORMITÀ**	**AMBIENTE ELETTROMAGNETICO - LINEE GUIDA**
Scarica elettrostatica (ESD) IEC 61000-4-2	+/-8 kV contatto +/-15 kV aria	+/-8 kV contatto +/-15 kV aria	È necessario adottare le normali misure di prevenzione delle scariche elettrostatiche, incluso l'uso in assenza di pavimenti rivestiti di materiale sintetico. L'umidità relativa dovrebbe essere almeno del 20%.
Transitori elettrici veloci/burst IEC 61000-4-4	Non applicabile ai sistemi ARVIS alimentati a batteria		
Sovratensione IEC 61000-4-5	Non applicabile ai sistemi ARVIS alimentati a batteria		

LINEE GUIDA E DICHIARAZIONE DEL PRODUTTORE – IMMUNITÀ ELETTROMAGNETICA			
Il sistema ARVIS è destinato all'uso negli ambienti elettromagnetici specificati di seguito. Il cliente o l'utente del sistema ARVIS deve assicurarsi che venga utilizzato in tale ambiente.			
TEST DI IMMUNITÀ	**LIVELLO DI TEST IEC 60601**	**LIVELLO DI CONFORMITÀ**	**AMBIENTE ELETTROMAGNETICO - LINEE GUIDA**
Cali di tensione, brevi interruzioni e variazioni di tensione sulle linee di ingresso dell'alimentazione IEC 61000-4-11	Non applicabile ai sistemi ARVIS alimentati a batteria		
Frequenza di alimentazione (50/60 Hz) Campo Magnetico IEC 61000-4.8	30 A/m	30 A/m	I campi magnetici a frequenza di rete dovrebbero attestarsi sui livelli tipici di un tipico luogo in un tipico ambiente commerciale o ospedaliero.
Radiofrequenze condotte IEC 61000-4-6	Non applicabile ai sistemi ARVIS alimentati a batteria		
Radiofrequenze irradiate IEC 61000- 4-3	3 V/m da 80 MHz a 2,7 GHz	3 V/m	Le apparecchiature portatili e mobili per comunicazioni a radiofrequenza dovrebbero essere utilizzate a una distanza non inferiore a quella di separazione consigliata da qualsiasi parte del prodotto ARVIS (compresi i cavi), calcolata dall'equazione applicabile alla frequenza del trasmettitore. Distanza di separazione consigliata $d = 2,3*(P)^{1/2}$ $d = 2,3*(P)^{1/2}$ 800 MHz a 2,7 GHz dove P corrisponde alla potenza nominale di uscita massima del trasmettitore espressa in watt (W) indicata dal produttore e d corrisponde alla distanza di separazione consigliata espressa in metri (m). Le intensità di campo dei trasmettitori RF fissi, determinate tramite un rilevamento elettromagnetico sul posto, devono essere inferiori al livello conforme in ciascun intervallo di frequenze.

DISTANZE DI SEPARAZIONE CONSIGLIATE PER I TRASMETTITORI VICINI	
Il sistema ARVIS è destinato all'uso in un ambiente elettromagnetico in cui i disturbi RF irradiati sono controllati. Il cliente o l'utente del sistema ARVIS può contribuire a evitare l'interferenza elettromagnetica mantenendo una distanza minima tra le apparecchiature di comunicazione RF portatili e mobili (trasmettitori) e il sistema ARVIS come raccomandato di seguito, in base alla massima potenza di uscita delle apparecchiature di comunicazione.	
EIRP del trasmettitore nelle vicinanze (W)	**Distanza minima di separazione (m)**
10	1,33
1	0,42
0,1	0,13
0,01	0,04

Oltre al sistema ARVIS alimentato a batteria, viene fornita l'attrezzatura di supporto per caricare la batteria ARVIS secondo necessità. Questa apparecchiatura di supporto non fa parte dell'ambiente operativo e non è necessaria durante l'intervento chirurgico. L'attrezzatura di supporto è stata testata secondo gli standard indicati in questa tabella.

Sicurezza e compatibilità EMC	**In combinazione con l'alimentatore esterno c.a./c.c. incluso**	
Approvazioni normative	Europa	CE
	Internazionale	CB
Emissioni elettromagnetiche	Europa	EN55011, EN55032, livello B
	USA	FCC15 classe B
Immunità elettromagnetica	Immunità ESD	EN/IEC61000-4-2
	Immunità ai campi elettromagnetici	EN/IEC61000-4-3
	EFT/Burt	EN/IEC61000-4-4
	Sovratensione	EN/IEC61000-4-5
	Immunità condotta	EN/IEC61000-4-6
	Campi magnetici	EN/IEC61000-4-8
	Cali di tensione, corto strumenti e variazioni di tensione	EN/IEC61000-4-11
	Caratteristiche dell'immunità	EN55024

Pianificazione preoperatoria

L'obiettivo della pianificazione preoperatoria per ARVIS® Shoulder è definire modelli anatomici e riferimenti basati sulla TC e le posizioni desiderate dell'impianto da utilizzare durante la chirurgia stereotassica per assistere il chirurgo nel posizionamento degli impianti ortopedici.

Istruzioni operative

Il software di pianificazione è basato su web e non richiede installazione. Per accedere alla piattaforma, l'utente deve prima inserire il proprio nome utente e la password. Per ottenere l'accesso al sito web, contattare https://www.precisionai.com.au/contact/.
Il software di pianificazione è composto da diverse pagine per le diverse fasi del processo di pianificazione chirurgica.
La pagina di panoramica degli interventi chirurgici fornisce una presentazione di tutti i casi chirurgici disponibili per quell'account.
Per avviare la pianificazione e per istruzioni più dettagliate, fare riferimento alla Guida alla tecnica chirurgica della spalla ARVIS® cod. art. 22000.

Informativa sulla privacy

Tutte le informazioni personali dei pazienti memorizzate nel software saranno anonimizzate prima di essere archiviate. Nessuna informazione personale del paziente verrà condivisa con terze parti. Tutte le informazioni inviate a terze parti saranno anonimizzate prima dell'invio.

Avvertenze e precauzioni

- Questo software deve essere utilizzato solo da persone addestrate e qualificate, che conoscano le istruzioni per l'uso.
- Assicurarsi che vengano utilizzati i requisiti minimi di sistema come indicato in questo documento.

Imballaggio ed etichettatura

Il software è basato sul web, pertanto non è richiesto alcun requisito di imballaggio per questo software. Tuttavia, una copia di queste Istruzioni per l'uso sarà messa a disposizione di ciascun utente prima dell'utilizzo del software.

Sicurezza informatica

Il software opera all'interno di una piattaforma operativa sicura che include sistemi per monitorare e identificare le vulnerabilità e ridurre i rischi di attacchi informatici.

Requisiti di sistema

I requisiti minimi e consigliati per l'utilizzo del software di pianificazione sono i seguenti:

Requisiti minimi di sistema Browser web:

Google Chrome (v.107 o versioni successive), Mozilla Firefox (v.109.0 o versioni successive), Apple Safari (v.16 o versioni successive)

Sistema operativo:

Microsoft Windows 8 o versioni successive MacOS 10.x o versioni successive

Risoluzione dello schermo:

1280 x 800

Internet:

È necessaria una connessione a Internet. Connessione Internet a 10 Mbps o superiore

Requisiti di sistema consigliati

Browser web:
Google Chrome (v.107 o successivo)

Sistema operativo:
Microsoft Windows 10 o 11 MacOS 12.x

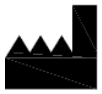
Risoluzione dello schermo:
1920 x 1080

Legenda dei simboli (software di pianificazione)

LOT	Numero di versione del software
	Data di rilascio del software

Ulteriori informazioni

Se sono necessarie ulteriori informazioni su questo prodotto o se si desidera ottenere un'autorizzazione al reso del prodotto, contattare il Servizio clienti al numero 1-800-456-8696 (8-17 CST) negli Stati Uniti.



Kico Knee Innovation Company Pty Limited Unit 1,
25 Frenchs Forest Rd E,
Frenchs Forest, NSW 2086 AUSTRALIA
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Paesi Bassi

Platné od 22.05.2025 do 29.07.2025

ARVIS® Návod na použitie chirurgického navigačného systému pre ramený kĺb

CE 2797

Model: ARV-01

⚠ VAROVANIE: Tento dokument musí vždy používať v spojení s príručkou chirurgickej techniky pre ramenný kĺb ARVIS® P/N IN-22000, ktorá obsahuje ďalšie pokyny k výrobku. Príručku chirurgickej techniky nájdete na adrese www.insightmedsys.com/resources po zadaní hesla „ARVIS“.

Obsah

Systémové informácie

Bezpečnostné opatrenie

Podľa federálnych zákonov (v USA) sa táto pomôcka smie predávať iba lekárom alebo na lekársky predpis.

Všeobecné varovania

- Pred použitím si prečítajte všetky pokyny.
- Systém neobsluhujte bez absolvovania náležitého školenia. Pred začatím operácie musí byť chirurg oboznámený s navigačným systémom ARVIS pre ramenný kĺb a návodom na použitie príslušného kompatibilného implantátového systému a s pokynmi pre techniku chirurgického zákroku.
- Výstup z navigácie nenahrádza klinický úsudok chirurga.
- Používajte iba príslušenstvo dodané so systémom. Nenahrádzajte káble ani žiadne iné komponenty. Ku konektorom USB zariadenia nepripájajte žiadne príslušenstvo, ktoré nedodáva výrobca, vrátane výstupného konektora svetlometov. Nepokúšajte sa používať iné počítačové zariadenie ako počítačový modul dodaný so systémom.
- Pred použitím skontrolujte, či nie sú opotrebované alebo poškodené nástroje. Poškodené alebo opotrebované nástroje pred použitím vymeňte.
- Pred použitím sa musí korakoidný výbežok vyhodnotiť z hľadiska vhodnosti upevnenia pomocou kolíkov.
- Okulár obsahuje svetlomet, infračervený žiarič a laser triedy I. Povrchy v blízkosti svetlometu, ako aj iné povrchy, sa môžu počas používania zahriať. Dotýkajte sa iba tých častí okulára, ktoré sú určené na nastavenie.

Aby sa zabránilo prípadnému rušeniu kardiostimulátorov, neumiestňujte žiadnu súčasť systému do blízkosti hrudníka pacienta alebo používateľa. Existuje možnosť elektromagnetického rušenia. Ak pomôcka ruší iné zariadenia, premiestnite ju alebo ju prestaňte používať. Ak pomôcka prijíma škodlivé rušenie, ktoré ovplyvňuje jej funkciu, prestaňte ju používať.

- Neupravujte ani nevykonávajte servis žiadného komponentu systému.
- Systém **ARVIS** obsahuje okulár, pásovú súpravu, batériu, nabíjačky a súpravu nástrojov. Nástroje sa dodávajú NESTERILNÉ a pred každým použitím sa musia vyčistiť a sterilizovať. Elektrické komponenty sú NESTERILNÉ a nesmú sa sterilizovať.
- Aby sa predišlo riziku zásahu elektrickým prúdom, toto zariadenie sa smie pripájať iba k sieti s ochranným uzemnením.
- V záujme zachovania kybernetickej bezpečnosti a správneho fungovania nemeňte nastavenia dodaného počítačového modulu, s výnimkou prípadov, keď tak priamo nariadi spoločnosť Insight Medical Systems.
    - Nepovoľujte sieť Wi-Fi ani mobilnú komunikáciu, s výnimkou prípadov, keď tak priamo nariadi spoločnosť Insight Medical Systems.
    - Neinštalujte ani neodstraňujte aplikácie ani neukladajte iné údaje, ako od spoločnosti Insight.
    - Spoločnosť Insight odporúča nastaviť heslo na obmedzenie prístupu k počítačovému modulu.
    - Spoločnosť Insight odporúča dôveryhodným používateľom, aby nezabudli kontrolovať všetky vymeniteľné disky používané na prenos zašifrovaných súborov plánu do systému a nepoužívali disky na iné účely ako na ukladanie a prenos súborov s údajmi plánu.
    - Pred anestéziou pacienta potvrďte heslo a/alebo import plánu.

- Pred výberom plánu skontrolujte a potvrďte údaje o pacientovi a pláne.

- Chirurgické nástroje z nehrdzavejúcej ocele môžu obsahovať nikel, ktorý je známy alergén. Pri podozrení na citlivosť na nikel alebo alergiu na nikel sa musí postupovať podľa zdravého lekárskeho úsudku.

Popis systému

ARVIS Shoulder je počítačom-riadený navigačný systém na artroplastiku ramena. Kombinuje softvér, elektronický hardvér a chirurgické nástroje na intraoperačné sledovanie nástrojov, lokalizáciu anatomických štruktúr a zobrazenie spätnej väzby používateľovi. Systém pomáha chirurgovi pri uskutočňovaní schváleného predoperačného plánu.

Okulár **ARVIS** obsahuje stereo IR sledovacie kamery, farebnú kameru, stereo displej, IR osvetlenie a IR laserový iluminátor. Na okulári je namontovaný viditeľný svetlomet, ktorý je pripojený pomocou kábla micro-USB. Okulár komunikuje s pásovou súpravou pomocou kábla USB-C. Všetky systémové pokyny, výzvy, upozornenia a výstupy sa zobrazujú chirurgovi na displeji okulára.

Pásová súprava obsahuje počítačový modul, batériu a riadiacu dosku napájania. Pásová súprava dodáva okuláru energiu a spúšťa aplikačný softvér **ARVIS** Shoulder.

Elektronika **ARVIS** sa počas operácie nosí na tele chirurga. Neexistuje žiadne rozhranie k externému zariadeniu okrem nabíjačky batérií **ARVIS**, ktorá dobíja batériu, keď sa nepoužíva.

Systém **ARVIS** používa sledovacie kamery na meranie polohy sledovacích zariadení na pacientovi alebo nástrojoch. Systém **ARVIS** zobrazuje merania podľa popisu v časti Nároky na výkon. Merania sa nezobrazujú, keď sa nezistí požadované sledovacie zariadenie a keď systém nie je v dosahu sledovacích kamier. Platný rozsah fungovania kamery siaha minimálne do vzdialenosti od 40 cm do 70 cm od okulára, ale systém **ARVIS** môže byť schopný poskytnúť presné merania aj v kratších alebo dlhších vzdialenostiach.

Nároky na výkon

ARVIS Shoulder meria nasledujúce parametre s uvedenou presnosťou pri simulovanom použití na stolových upevňovacích prípravkoch.

- Sklon vrtáka a verzia s priemernou absolútnou chybou ≤ 1,5°
- Vrchná/spodná a predná/zadná poloha miesta vstupu vrtáka s priemernou absolútnou chybou ≤ 1,5 mm na každej osi
- Sklon a verzia glenoidného implantátu s priemernou absolútnou chybou ≤ 1,5°
- Rotácia glenoidného implantátu okolo centrálnej osi s priemernou absolútnou chybou ≤ 1,5°
- Rozsah dĺžky virtuálnej skrutky (do 50 mm), ktorá vychádza z teoretickej základnej dosky glenoidu s priemernou absolútnou chybou ≤ 0,5 mm

Klinická presnosť závisí od presnej registrácie a vstupov do aplikačného softvéru **ARVIS** Shoulder. Systém bol overený pri simulovanom klinickom použití (kadáver), aby sa dosiahla nasledujúca presnosť:

- Horná/spodná a predná/zadná poloha glenoidného implantátu s priemernou absolútnou chybou ≤ 1,5 mm na každej osi
- Sklon a verzia glenoidného implantátu s priemernou absolútnou chybou ≤ 3,0°
- Rotácia glenoidného implantátu okolo jeho centrálnej osi s priemernou absolútnou chybou ≤ 3,0°
- Rozsah dĺžky virtuálnej skrutky (do 50 mm) vychádzajúcej z teoretickej základnej dosky glenoidu s priemernou absolútnou chybou ≤ 2,0 mm

Princíp fungovania

ARVIS Shoulder je chirurgický navigačný systém založený na obraze. Predoperačné CT vyšetrenie ramenného kĺbu pacienta je potrebné na vytvorenie predoperačného chirurgického plánu, ktorý obsahuje orientačný digitálny model kosti priradený k intraoperačným orientačným bodom registrovaným chirurgom.

Systém **ARVIS** používa kamery v okulári na meranie polôh a uhlov medzi sledovacími zariadeniami namontovanými na pacientovi a sledovacími zariadeniami namontovanými na nástrojoch. Softvér aplikácie **ARVIS** Shoulder, ktorý beží na pásovej súprave, vypočíta a zobrazí polohu nástrojov vzhľadom na anatómiu pacienta tým, že vyzve používateľa prostredníctvom špecifického pracovného postupu na registráciu referenčného sledovacieho zariadenia k anatomickým orientačným bodom.

Určené použitie

The **ARVIS** system is a computer-controlled navigation system intended to provide intra-operative measurements to the surgeon to aid in selection and positioning of orthopedic implant components.

Indikácie na použitie

ARVIS® Shoulder je určený na pomoc chirurgovi pri polohovaní a zarovnávaní implantátov vzhľadom na referenčné osi zarovnania a orientačné body v stereotaktickej ortopedickej chirurgii.

Systém pomáha chirurgovi pri vykonávaní intraoperačných meraní a lokalizácii anatomických štruktúr ramenného kĺbu na základe predoperačných snímok pacienta.

Systém je určený na použitie s náhlavnou súpravou ARVIS® Eyepiece na zobrazenie v rozšírenej realite a poskytovanie informácií, ako je vizualizácia predoperačného plánu a zobrazenie informácií o zarovnaní nástrojov a implantátov. Na rozšírené/virtuálne zobrazené informácie by sa nemalo spoliehať iba pre absolútne informácie o polohe/vyrovnaní a mali by sa vždy používať v spojení so zobrazenými stereotaxickými informáciami.

ARVIS® Shoulder je určený na totálnu artroplastiku ramena s použitím implantátových systémov Enovis AltiVate, LimaCorporate PRIMA a LimaCorporate SMR.

Kontraindikácie

- Výrazný úbytok kosti ovplyvňujúci identifikáciu požadovaných orientačných bodov
- Nadmerná interferencia mäkkých tkanív ovplyvňujúca identifikáciu potrebných orientačných bodov
- Závažná osteoporóza v mieste(-ach) fixácie, vrátane slabosti korakoidného výbežku, ktorá by mohla viesť k nežiaducim účinkom.
- Prítomnosť infekcie
- Akákoľvek kontraindikácia spojená s operáciou artroplastiky ramena

Nežiaduce účinky

Medzi možné nežiaduce účinky patrí predčasné zlyhanie implantátu, vykĺbenie alebo nestabilita, zníženie rozsahu pohybu, infekcia, poškodenie tkaniva, poranenie a slabosť nervov, zlomenina, reakcia na cudzie teleso, predĺženie času anestézie, srdcový infarkt, poranenie ciev, poranenie krku, popáleniny, elektrický šok a kardiovaskulárne poškodenie.

Ak sa domnievate, že pri používaní tejto pomôcky došlo k incidentu súvisiacemu s výrobkom, informujte o tom výrobcu a vnútroštátny orgán

Kompatibilita

- Systém **ARVIS** Shoulder je určený na použitie s implantátmi Enovis AltiVate®, LimaCorporate PRIMA a LimaCorporate SMR.
- Pre mechanickú montáž sú potrebné Steinmannove kolíky (x2), 2,5 mm x 100 mm. Systém bol overený pomocou technickej súpravy ramenného kĺbu 170-00-002.
- Softvér Precision AI Surgical Planning sa musí použiť na predoperačné plánovanie pred navigáciou.
- Prilbu Stryker® Flyte® alebo T7® spolu s dodanými kompatibilnými adaptérmi možno použiť na nosenie okulára **ARVIS**.

Profil používateľa

Systém **ARVIS** majú používať ortopedickí chirurgovia a personál na operačných sálach, ktorí vykonávajú artroplastiku ramena. Používatelia by si mali prečítať technickú príručku pre chirurgickú techniku ramena ARVIS® P/N IN-22000, v ktorej sú uvedené podrobné pokyny k produktu. Môžete sa zúčastniť školenia o používaní produktu, ktoré sa dôrazne odporúča.

Ak si chcete dohodnúť školenie, obráťte sa na spoločnosť Insight Medical Systems, Inc.

Prostredie používania

Systém **ARVIS** je určený na použitie na nemocničných operačných sálach. Zdroje infračerveného žiarenia (IR), vrátane svetiel na operačnej sále a okien, môžu rušiť kamery, ktoré sú súčasťou systému **ARVIS**. Vyhnite sa prostrediu s nadmerným množstvom zdrojov infračerveného žiarenia.

Systém **ARVIS** je navrhnutý na použitie na nemocničných operačných sálach za nasledujúcich podmienok:

- Teplota (15 až 25 °C)
- Vlhkosť (20 - 80 % nekondenzujúca)
- Tlak (70 - 106 kPa)

Okulár **ARVIS** sa nosí na hlave chirurga. Pásová súprava **ARVIS** sa nosí na opasku alebo páse chirurga. Pre pacienta sa nepoužíva žiadny elektronický hardvér. Počas operácie stojí chirurg v blízkosti pacienta.

Nabíjačka batérií **ARVIS** je určená na používanie mimo operačnej sály.

Populácia pacientov

Systém ARVIS je určený pre pacientov podstupujúcich ortopedickú operáciu, pri ktorej je možné identifikovať a používať ako referenciu pevné anatomické štruktúry, ako je panva, stehenná kosť alebo holenná kosť.

Klinický prínos

Chirurgické a navigačné nástroje pomáhajú pri implantácii protéz a nemajú priamu terapeutickú alebo diagnostickú funkciu.

Definícia symbolov

V označovaní systému ARVIS sa používajú nasledujúce symboly:

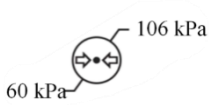
Postupujte podľa návodu na použitie

Nevyhadzujte do odpadu

Nesterilné

Vlhkosť

Teplota skladovania



Tlak

Výrobca

Katalógové číslo

Splnomocnený zástupca v EÚ

Dovozca

Informácie o hardvéri

Komponenty súpravy nástrojov pre ramenný kĺb ARVIS (P/N IN-21300)

Katalógové číslo	Popis
IN-21100	Podstavec na zásobník na nástroje, ramenný kĺb
IN-11000	Veko zásobníka na nástroje
IN-22100	In-Line spúšťací stylus
IN-23000	Mechanický držiak
IN-24000	Sledovacie zariadenie A, mechanické
IN-26000	Zdvíhacia pomôcka Cobb, 1 palec
IN-10800	3,5 mm šesťhranný skrutkovač
IN-18300	Vŕtací prípravok na glenoid
IN-22200	Nástroj na reverznú registráciu
IN-18500	Vodidlo referenčného kolíka

Elektronické hardvérové komponenty a príslušenstvo ARVIS (P/N IN-50010[1])

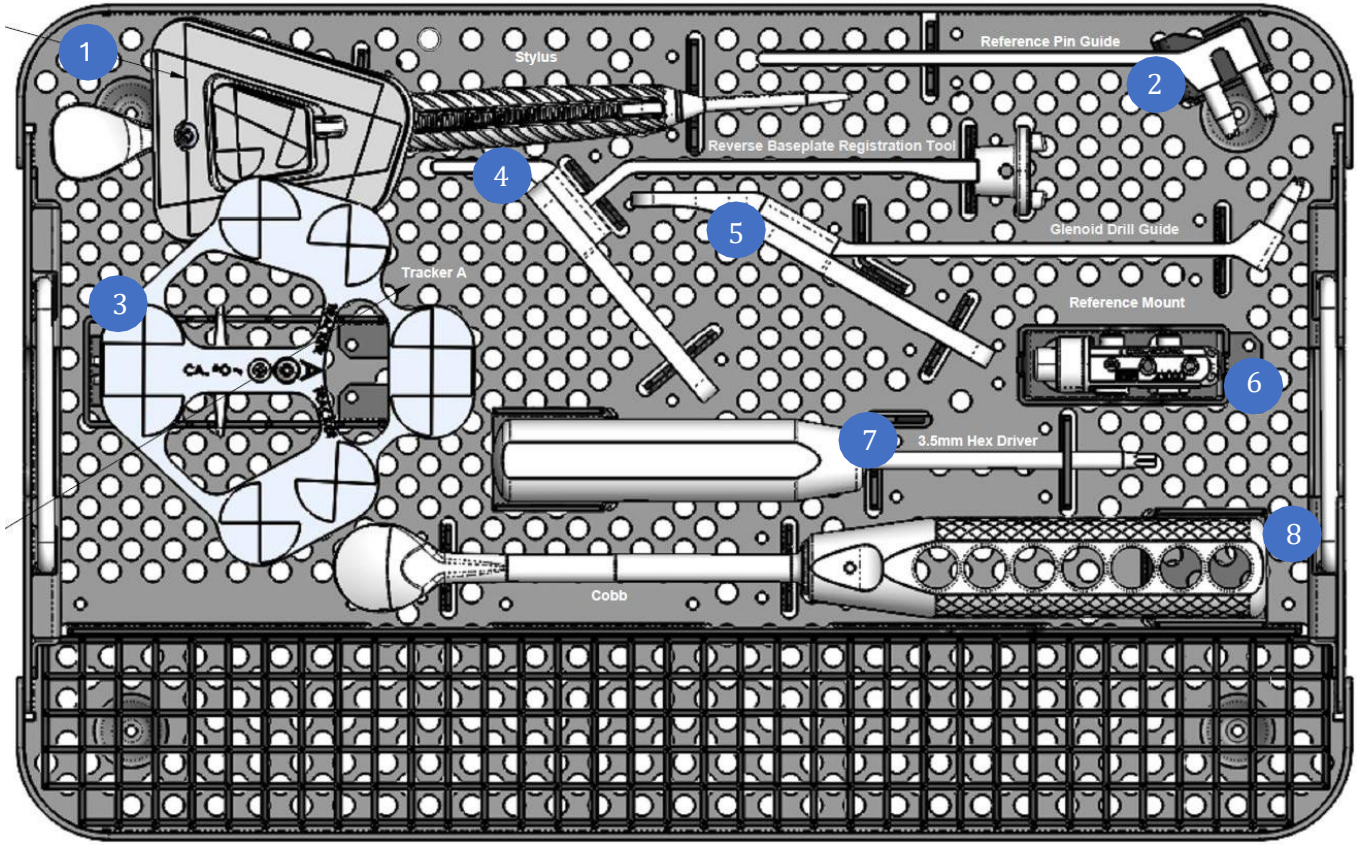
Katalógové číslo	Popis
IN-12400	Zostava okulára ARVIS
IN-12500	Pásová súprava ARVIS
IN-12700	Počítačový modul ARVIS
IN-12800	Batéria ARVIS
IN-13200	Kábel okulára ARVIS
IN-13000	Nabíjačka batérií ARVIS
IN-13800	Zdroj napájania nabíjačky ARVIS
IN-15202	Kábel, USB-C, 1 m
IN-17700	Inštalačná súprava ARVIS

Používajte iba príslušenstvo dodané výrobcom.

Príslušenstvo ARVIS špecifické pre chirurga/prípad

Katalógové číslo	Popis
IN-17100	Čelenka ARVIS[2]
IN-17500	Montážna súprava FLYTE[2]
IN-21700	Súprava adaptérov T7[2]
170-00-002	Technická súprava ramenného kĺbu
IN-13900	Nabíjací kábel ARVIS, USA
IN-13910	Nabíjací kábel ARVIS, AU
IN-13920	Nabíjací kábel ARVIS, EÚ
IN-15201	Sieťový adaptér, 25 W, USA
IN-15221	Nástenný adaptér ARVIS, AU
IN-15211	Nástenný adaptér ARVIS, EÚ

1. K dispozícii sú alternatívne verzie elektronického hardvéru s príslušenstvom ARVIS, okrem iného IN-22300
2. Pokyny na montáž nájdete v IN-14001.



1. In-Line spúšťací stylus
2. Vodidlo referenčného kolíka
3. Sledovacie zariadenie A, mechanické
4. Nástroj na reverznú registráciu
5. Vŕtací prípravok na glenoid
6. Mechanický držiak
7. 3,5 mm šesťhranný skrutkovač
8. Zdvíhacia pomôcka Cobb, 1 palec

Pokyny na čistenie elektroniky

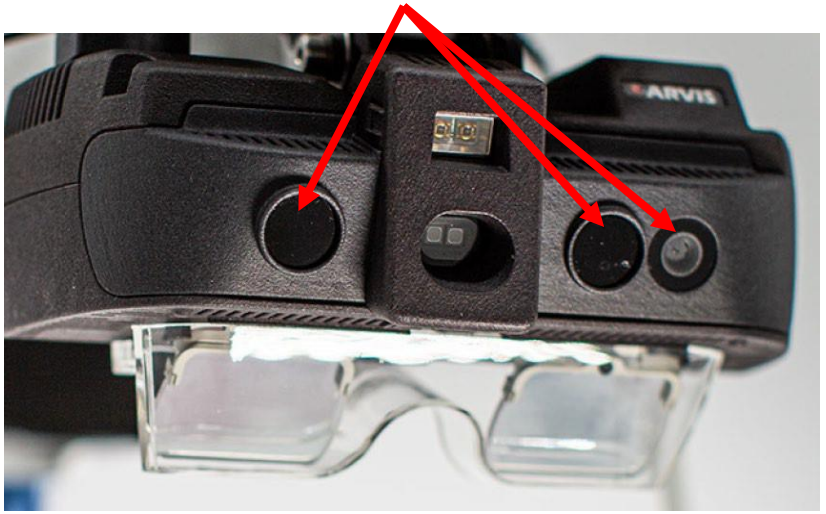
Elektronické hardvérové komponenty, ktoré tvoria systém **ARVIS**, sú okulár, pásová súprava, batéria a nabíjačky. Elektronické hardvérové komponenty sú opätovne použiteľné.

- Nabíjačky nie sú určené na použitie na operačnej sále.
- Okulár neposkytuje ochranu očí. Ak existuje možnosť, že sa do ovzdušia dostane krv alebo iné nečistoty, používateľovi sa odporúča nosiť na ochranu bežne predávaný štít na tvár. Ak existuje pravdepodobnosť znečistenia, používateľovi sa ďalej odporúča nosiť bežne predávaný chirurgický plášť alebo tógu.

Pri vhodnom oblečení by elektronické komponenty systému **ARVIS** nemali vyžadovať časté čistenie, ale v prípade potreby ich možno čistiť podľa uvedeného postupu.

- Vyberte batériu **ARVIS** a vypnite počítačový modul **ARVIS**.
- Počas jednej minúty utierajte roztokom izopropylalkoholu (70 - 99 %) a handričkou bez vlákien. Dodržiavajte všetky pokyny na štítku pre izopropylalkohol.
- Nepoužívajte abrazívne kefky ani handry.
- Dbajte na to, aby ste nepoškriabali kryty kamier. Po vyčistení vizuálne skontrolujte každý kryt kamery a uistite sa, že na ňom nie sú žiadne škrabance alebo zvyšky.
- Dávajte pozor, aby sa cez chladiace otvory nedostali do okulára nadbytočné tekutiny.
- Neponárajte. Nesterilizujte. Pred používaním nechajte úplne vyschnúť.
- Nepoužívajte fenolové dezinfekčné prostriedky, pretože môžu poškodiť kryty okulárov alebo puzdier pásovej súpravy.

Kryty kamier

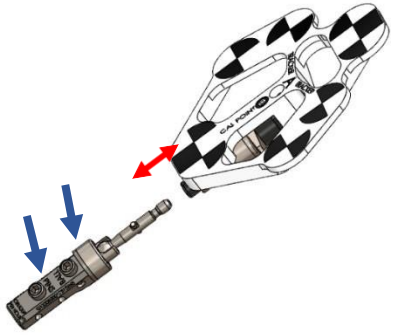


Pokyny na čistenie nástrojov

Nástroje ARVIS sa môžu používať opakovane. Pred prvým použitím a po každom použití všetky nástroje vyčistite a sterilizujte.

1. Po použití čo najskôr vyčistite nástroje a nedovoľte, aby znečistené nástroje zaschli. Pred čistením ponorte alebo použite vlhké uteráky alebo špongie namočené v destilovanej alebo deionizovanej vode, aby zostali vlhké.

2. Rozoberte prístroje na komponenty uvedené v tabuľke „Komponenty súpravy prístrojov **ARVIS** “.
    a. Oddeľte sledovacie zariadenie od držiaka.
    b. Uvoľnite obe upínacie skrutky v mechanickom držiaku IN-23000.



3. Nástroje opláchnite pod tečúcou studenou úžitkovou vodou (z vodovodu), aby ste odstránili hrubé nečistoty.
    a. Počas oplachovania aktivujte všetky pohyblivé časti nástrojov a použite mäkkú kefku so štetinami na pomoc pri odstránení hrubých nečistôt.
4. Úžitkovou vodou (z vodovodu) prepláchnite lúmeny a iné ťažko dostupné miesta nástrojov.
5. V prípade potreby sa môže použiť ultrazvuková čistička.
6. Vložte nástroje do automatickej umývačky dielov na spracovanie.
7. Spustite automatickú umývačku s nasledujúcimi parametrami:
    a. Pred umývaním oplachujte 2 minúty studenou vodou z vodovodného kohútika.
    b. Oplachujte 2 minúty horúcou vodou z kohútika a enzymatickým čistiacim prostriedkom pripraveným podľa pokynov výrobcu.
    c. Oplachujte 5 minút vodou s teplotou 43 °C (nominálna), deionizovanou vodou alebo vodou z reverznej osmózy.
    d. Sušte 7 minút pri teplote 90 °C (nominálne).
8. Po vyčistení by sa mali nástroje (demontované, ak je to potrebné) vizuálne skontrolovať. Pri neúplne vyčistených nástrojoch by sa mali zopakovať všetky kroky čistiaceho procesu.

    Poznámka: Pri nástrojoch s pohyblivými časťami alebo nástrojoch určených na intraoperačné spojenie s iným nástrojom sa odporúča používať mazivá rozpustné vo vode.

Sterilizácia opakovane použiteľných nástrojov v autokláve

- Zabalené pred použitím vákua, 4 minúty pri teplote 270 °F (132 °C). Čas sušenia je 75 minút*. Použite obal schválený agentúrou FDA alebo sterilnú bariéru. (Validácia je založená na používaní produktu Halyard Health H400.)
- Rozbalené pred použitím vákua („Flash“), 4 minúty pri teplote 270 °F (132 °C).

    *Okrem predpísaného času sušenia sa odporúča dodatočné 30-minútové ochladenie po vybratí zo sterilizačnej komory, aby sa zaistilo, že sú pomôcky bez kondenzácie a inej vlhkosti.

Odporúčaný sterilizačný proces bol overený tak, aby sa dosiahla úroveň zabezpečenia sterility (10^{-6}), ak boli diely vyčistené podľa vyššie uvedených pokynov. Iné parné cykly a postupy čistenia neboli vyhodnotené a musí ich kvalifikovať používateľ.

Účinná sterilizácia je založená na dôkladnom čistení a sušení. V opačnom prípade sa ohrozí proces sterilizácie a spracovaný nástroj sa stane nevhodným na klinické použitie.

Likvidácia

Žiadnu časť tohto systému nevyhadzujte do odpadu. Komponenty zlikvidujte v súlade s miestnymi predpismi a štandardnými postupmi pre nakladanie s odpadom v zdravotníckom zariadení.

Skladovanie a preprava

Teplota: -30 až 50 °C; Vlhkosť: Relatívna vlhkosť 10 až 90 % ; (bez kondenzácie); Tlak: 60 kPa až 106 kPa.

Zaobchádzajte opatrne.

Údržba

Pred každým použitím skontrolujte, či nástroje nie sú opotrebované alebo poškodené. Venujte zvláštnu pozornosť stavu značiek sledovacieho zariadenia a prispôsobeniu rozhraní medzi sledovacími zariadeniami a držiakmi sledovacích zariadení. Aj keď nástroje systému nemajú obmedzený čas používania a očakáva sa, že vydržia dlho, poškodené alebo opotrebované nástroje sa musia vymeniť. Používanie poškodených nástrojov môže viesť k chybnej navigácii.

Dodržujte pokyny na správnu kontrolu, čistenie a sterilizáciu (ak je to relevantné) komponentov systému. Nie je potrebná žiadna ďalšia údržba. Nevykonávajte servis ani úpravy žiadneho komponentu systému.

Akákoľvek časť, ktorá neplní svoju určenú funkciu, by sa mala nahlásiť výrobcovi kvôli vyriešeniu.

Záruka

Na výrobok sa vzťahuje záruka na bezchybnosť materiálu a spracovania.

Elektrická bezpečnosť

Toto zariadenie bolo testované a vyhovuje limitom EMC podľa normy IEC 60601-1-2. Tieto limity sú navrhnuté tak, aby poskytli primeranú ochranu proti škodlivej interferencii v typických zdravotníckych inštaláciách. Zariadenie generuje, využíva a môže vyžarovať rádiofrekvenčnú energiu. Ak nie je nainštalované a nepoužíva sa v súlade s týmito pokynmi, môže spôsobiť škodlivé rušenie iných zariadení v okolí. Nie je však zaručené, že sa pri určitých typoch inštalácií nevyskytne rušenie. Ak toto zariadenie spôsobí škodlivé rušenie iných zariadení, čo sa dá určiť vypnutím a zapnutím zariadenia, používateľ by sa mal pokúsiť opraviť toto rušenie prijatím jedného alebo viacerých z nasledujúcich opatrení:

- Zmeňte orientáciu alebo premiestnite prijímacie zariadenie.
- Zvýšte vzdialenosť od tohto zariadenia.
- Požiadajte o pomoc spoločnosť Insight Medical Systems alebo jej autorizovaného zástupcu.

FCC ID: SH6MDBT42Q Toto zariadenie je v súlade s časťou 15 pravidiel FCC. Prevádzka podlieha nasledujúcim dvom podmienkam: (1) Toto zariadenie nesmie spôsobovať škodlivé rušenie a (2) toto zariadenie musí prijať akékoľvek rušenie vrátane rušenia, ktoré môže spôsobiť neželanú prevádzku.

Prevádzkové podmienky: Teplota: 15-25 °C; Vlhkosť: 20 - 80 % (RH) bez kondenzácie; Tlak: 70 - 106 kPa.

Varovanie: Táto pomôcka je určená na veľmi špecifické úlohy. Použitie v prostredí s EM poruchami mimo možností tejto pomôcky môže ohroziť výsledok operácie.

Varovanie: Táto pomôcka nie je určená na používanie vedľa iných zariadení alebo na ukladanie na seba. Je potrebné vyhnúť sa používaniu zariadenia vedľa alebo v stohu s inými zariadeniami, pretože to môže spôsobiť nesprávnu prevádzku.

Varovanie: Používanie batérií, výpočtových modulov alebo káblov iných, než poskytuje spoločnosť Insight Medical Systems, môže viesť k zvýšeniu elektromagnetických emisií alebo k zníženiu elektromagnetickej odolnosti tohto zariadenia a spôsobiť jeho nesprávne fungovanie.

Varovanie: Prenosné RF komunikačné zariadenia (vrátane periférnych zariadení, napríklad káblov antén či externých antén) nepoužívajte vo vzdialenosti menej ako 30 cm od ktorejkoľvek časti prístroja* vrátane káblov, ktoré špecifikoval výrobca. V opačnom prípade môže dôjsť k zhoršeniu výkonu tohto zariadenia.

Poznámka: Toto zariadenie je v dôsledku svojich EMISNÝCH charakteristík vhodné na použitie v priemyselných oblastiach a nemocniciach (CISPR 11 triedy A). Ak sa toto zariadenie používa v obytnom prostredí (pre ktoré sa bežne vyžaduje CISPR 11 triedy B), nemusí poskytovať dostatočnú ochranu rádiofrekvenčnej komunikácie. Môže byť potrebné, aby používateľ prijal zmierňujúce opatrenia, napríklad premiestnením alebo zmenou orientácie zariadenia.

Poznámka: Toto zariadenie bolo testované z hľadiska elektromagnetickej odolnosti a preukázalo sa, že si zachováva základný výkon (chyba sledovania ≤5 mm) pri vystavení očakávaným úrovniam elektromagnetických rušení (ďalej definovaných v nasledujúcich tabuľkách). Systém má interné softvérové kontroly kvality, ktoré zastavujú postup v pracovnom procese. Ak sa používateľovi opakovane nepodarí postúpiť za krok v pracovnom postupe, mal by sa najprv uistiť, že dodržiava správnu chirurgickú techniku a že nič neblokuje okulár. Ak používateľ stále nie je schopný pokračovať, musí prestať používať pomôcku.

Poruchy systému ARVIS pri používaní môžu spôsobiť:

- Strata viditeľnosti sledovacieho zariadenia
- Strata funkčnosti okulára ARVIs
- Neočakávané vypnutie systému

Systém ARVIS je napájaný z batérie, čím sa upravujú platné testy odolnosti EMC. V tejto častisú uvedené testy emisií a odolnosti, ktoré sa vzťahujú na systém ARVIS, pozostávajúci z okulára, pásovej súpravy, batérie a zostavy kábla USB, ktoré používateľ nosí počas operácie.

POKYNY A VYHLÁSENIE VÝROBCU – ELEKTROMAGNETICKÉ EMISIE		
Systém ARVIS je určený na použitie v nižšie špecifikovanom elektromagnetickom prostredí. Zákazník alebo používateľ systému ARVIS musí zaistiť, aby sa používal v takomto prostredí.		
TEST EMISIÍ	**SÚLAD**	**ELEKTROMAGNETICKÉ PROSTREDIE - USMERNENIE**
RF emisie podľa normy CISPR 11	Skupina 1	Produkt ARVIS používa RF energiu iba na interné funkcie (s výnimkou zámernej komunikácie). RF emisie sú veľmi nízke a je nepravdepodobné, že by spôsobili rušenie blízkych elektronických zariadení.
RF emisie podľa normy CISPR 11	Trieda A	Výrobok ARVIS je vhodný na použitie vo všetkých iných ako domácich prostrediach.
RF emisie podľa normy IEC 61000-3-2	–	
RF emisie IEC 61000-3-3	–	

USMERNENIA A VYHLÁSENIE VÝROBCU – ELEKTROMAGNETICKÁ ODOLNOSŤ			
Systém ARVIS je určený na použitie v nižšie špecifikovanom elektromagnetickom prostredí. Zákazník alebo používateľ systému ARVIS musí zaistiť, aby sa používal v takomto prostredí.			
TEST ODOLNOSTI	**ÚROVEŇ TESTU IEC 60601**	**ÚROVEŇ ZHODY**	**ELEKTROMAGNETICKÉ PROSTREDIE - USMERNENIE**
Elektrostatický výboj (ESD) IEC 61000-4-2	+/- 8 kV kontakt +/- 15 kV vzduch	+/- 8 kV kontakt +/- 15 kV vzduch	Musia sa prijať bežné preventívne opatrenia proti elektrostatickému výboju, vrátane použitia v priestoroch bez podláh pokrytých syntetickým materiálom. Relatívna vlhkosť vzduchu musí byť aspoň 20 %.
Elektrické rýchle prechodné javy/skupiny impulzov IEC 61000-4-4	Nevzťahuje sa na systém ARVIS napájaný z batérie		
Prepätie IEC 61000-4-5	Nevzťahuje sa na systém ARVIS napájaný z batérie		

USMERNENIA A VYHLÁSENIE VÝROBCU – ELEKTROMAGNETICKÁ ODOLNOSŤ			
Systém ARVIS je určený na použitie v nižšie špecifikovanom elektromagnetickom prostredí. Zákazník alebo používateľ systému ARVIS musí zaistiť, aby sa používal v takomto prostredí.			
TEST ODOLNOSTI	**ÚROVEŇ TESTU IEC 60601**	**ÚROVEŇ ZHODY**	**ELEKTROMAGNETICKÉ PROSTREDIE - USMERNENIE**
Poklesy napätia, krátke prerušenia a kolísanie napätia na vstupných napájacích vedeniach IEC 61000-4-11	Nevzťahuje sa na systém ARVIS napájaný z batérie		
Frekvencia napájania (50/60 Hz) Magnetické pole IEC 61000-4.8	30 A/m	30 A/m	Magnetické polia frekvencie napájania by mali zodpovedať úrovniam typického umiestnenia v typickom komerčnom alebo nemocničnom prostredí.
Vedené RF IEC 61000-4-6	Nevzťahuje sa na systém ARVIS napájaný z batérie		
Vyžarované RF IEC 61000- 4-3	3 V/m 80 MHz až 2,7 GHz	3 V/m	Prenosné a mobilné RF komunikačné zariadenia sa nesmú používať bližšie k akejkoľvek časti produktu ARVIS (vrátane káblov), než je odporúčaná vzdialenosť vypočítaná z rovnice vzťahujúcej sa na frekvenciu vysielača. Odporúčaná vzdialenosť $d = 2,3*(P)^{1/2}$ $d = 2,3*(P)^{1/2}$ 800 MHz až 2,7 GHz kde P je maximálny výstupný výkon vysielača vo wattoch (W) podľa výrobcu vysielača a d je odporúčaná odstupová vzdialenosť v metroch (m). Intenzity polí z pevných RF vysielačov, ako bolo stanovené podľa elektromagnetického prieskumu pracoviska, by mali byť nižšie ako úroveň zhody v každom frekvenčnom rozsahu.

ODPORÚČANÉ VZDIALENOSTI OD BLÍZKYCH VYSIELAČOV	
Systém ARVIS je určený na použitie v elektromagnetickom prostredí, v ktorom sú vyžarované RF rušivé signály pod kontrolou. Zákazník alebo používateľ systému ARVIS môže pomôcť predchádzať elektromagnetickému rušeniu dodržiavaním minimálnej vzdialenosti medzi prenosnými a mobilnými RF komunikačnými zariadeniami (vysielačmi) a systémom ARVIS, ako sa odporúča nižšie, podľa maximálneho výstupného výkonu komunikačných zariadení.	
EIRP blízkeho vysielača (W)	**Minimálna vzdialenosť (m)**
10	1,33
1	0,42
0,1	0,13
0,01	0,04

Okrem systému ARVIS napájaného z batérie je k dispozícii aj podporné zariadenie na prípadné nabíjanie batérie ARVIS. Toto podporné zariadenie nie je súčasťou operačného prostredia a počas chirurgického zákroku nie je potrebné. Podporné zariadenie bolo testované podľa noriem uvedených v tejto tabuľke.

Bezpečnosť a EMC	**V kombinácii s dodávaným externým AC/DC napájacím zdrojom**	
Regulačné schválenia	Európa	CE
	Medzinárodné	CB
Elektromagnetické emisie	Európa	EN55011, EN55032, úroveň B
	USA	FCC15 trieda B
Elektromagnetická odolnosť	Odolnosť proti ESD	EN/IEC61000-4-2
	Odolnosť proti elektromagnetickému poľu	EN/IEC61000-4-3
	EFT/Burt	EN/IEC61000-4-4
	Prepätie	EN/IEC61000-4-5
	Odolnosť indukovaná vedením	EN/IEC61000-4-6
	Magnetické polia	EN/IEC61000-4-8
	Poklesy napätia, krátke prerušenia a zmeny napätia	EN/IEC61000-4-11
	Charakteristiky odolnosti	EN55024

Predoperačné plánovanie

Cieľom predoperačného plánovania pre ARVIS® Shoulder je definovať anatomické modely a referencie založené na CT, ako aj požadované polohy implantátov, ktoré sa použijú počas stereotaktickej chirurgie a pomôžu chirurgovi pri umiestňovaní ortopedických implantátov.

Prevádzkové pokyny

Plánovací softvér je založený na webe a nevyžaduje inštaláciu.
Na prihlásenie do platformy musí používateľ najprv zadať svoje používateľské meno a heslo. Ak chcete získať prístup k webovej stránke, prejdite na stránku https://www.precisionai.com.au/contact/.
Plánovací softvér pozostáva z niekoľkých stránok určených pre rôzne fázy procesu chirurgického plánovania.
Stránka s prehľadom operácií poskytuje prehľad všetkých chirurgických prípadov, ktoré sú k dispozícii pre daný účet.
Ak chcete začať s plánovaním a získať podrobnejšie pokyny, pozrite si Príručku chirurgickej techniky pre ramenný kĺb ARVIS® P/N 22000.

Vyhlásenie o ochrane osobných údajov

Všetky osobné údaje pacienta uložené v softvéri budú pred uložením deidentifikované. Žiadne osobné údaje pacientov nebudú zdieľané s tretími stranami. Všetky informácie zaslané tretím stranám budú pred odoslaním deidentifikované.

Varovania a bezpečnostné opatrenia

- Tento softvér smú používať iba vyškolené, kvalifikované osoby, ktoré sú oboznámené s pokynmi na používanie.
- Uistite sa, že sú dodržané minimálne systémové požiadavky, ako sú uvedené v tomto dokumente.

Balenie a označovanie

Tento softvér je založený na webe, preto sa naň nevzťahujú žiadne požiadavky na balenie. Každý používateľ však pred používaním softvéru dostane k dispozícii kópiu tohto návodu na používanie.

Kybernetická bezpečnosť

Softvér funguje v rámci zabezpečenej operačnej platformy, ktorá zahŕňa systémy na monitorovanie a identifikáciu zraniteľností a na zníženie prípadných rizík kybernetických útokov.

Systémové požiadavky

Minimálne a odporúčané systémové požiadavky na používanie plánovacieho softvéru sú nasledovné:

Minimálne systémové požiadavky pre webový prehliadač:

Google Chrome (v.107 alebo novšia) Mozilla Firefox (v.109.0 alebo novšia) Apple Safari (v.16 alebo novšia)

Operačný systém:

Microsoft Windows 8 alebo novší MacOS 10.x alebo novší

Rozlíšenie obrazovky:

1280 x 800

Internet:

Vyžaduje sa internetové pripojenie. Internetové pripojenie s rýchlosťou 10 Mb/s alebo vyššou Odporúčané systémové požiadavky

Webový prehliadač:
Google Chrome (verzia 107 alebo novšia)

Operačný systém:
Microsoft Windows 10 alebo 11 MacOS 12.x

Rozlíšenie obrazovky:
1920 x 1080

Legenda symbolov (plánovací softvér)

LOT	Číslo verzie softvéru
	Dátum vydania softvéru

Ďalšie informácie

Ak potrebujete ďalšie informácie o tomto produkte alebo chcete získať autorizáciu na vrátenie výrobku, obráťte sa na oddelenie služieb zákazníkom na čísle 1-800-456-8696 (Central Time 8:00 AM - 5:00 PM) v USA.

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EC REP

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