

ARVIS® Hip & Knee Surgical Navigation Instructions for Use



WARNING: This document should always be used in conjunction with the ARVIS® Hip and Knee Surgical Technique Guides P/N IN-28170, IN-28180, or IN-28190 or P/N IN-16000 which contains additional product instructions. Access the Surgical Technique Guides at <https://enovis.com/medical-education/surgical/login> or <https://my.allego.com/>.

A printable copy of the IFU for this device can be located at www.enovis.com/ifu

Enovis Corporation.

www.enovis.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.
- The eyepiece includes a headlight, infrared emitter and Class I laser. The surfaces near the IR emitter, as well as other surfaces, may become hot during use. Touch only parts of the eyepiece intended for adjustment.
- The system contains magnets. 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, charger, 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 of 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 Enovis.
 - The computer module hosts a Mobile Device Management (MDM) tool that limits the function of the device to only those essential for use. MDM protects the user against potential cybersecurity risks. Do not attempt to remove or tamper with this capability.
 - If the computer module alerts the user that a security event has occurred, please discontinue use immediately and contact Enovis.
 - Do not attempt to enable Wi-Fi or cellular communication except as directed by Enovis.
 - Do not attempt to install or remove applications or store data.
 - Do not attach any devices to the USB port except as directed by Enovis.
 - Enovis recommends installing a password to restrict access to the computer module.
- The ARVIS™ system can be used with the optional ARVIS Screen Casting Kit (PN IN-21900) which includes a tablet. To maintain cybersecurity and correct operation of the tablet (if used), do not change settings on the provided tablet except as directed by Enovis.
 - The tablet hosts a Mobile Device Management (MDM) tool that limits the function of the device to only those

essential for use. MDM protects the user against potential cybersecurity risks. Do not attempt to remove or tamper with this capability.

- If the tablet alerts the user that a security event has occurred, please discontinue use immediately and contact Enovis.
- Do not attempt to enable Wi-Fi or cellular communication except as directed by Enovis.
- Do not attempt to install or remove applications or store data.
- Do not attach any devices to the USB port except as directed by Enovis.
- Enovis recommends installing a password to restrict access to the tablet.
- 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

Both the Gen 1 and Gen 2 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 Application Software. For Gen 2 systems, the Belt Pack also supplies power to the computer module.

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

ARVIS uses 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 measures the following parameters with the stated accuracy with 95% confidence in simulated use on benchtop fixtures.

Total Hip Arthroplasty

- Anteversion and inclination of the acetabular cup inserter within $\pm 3^\circ$
- Changes in leg length within $\pm 2\text{mm}$
- Sagittal plane pelvic tilt within $\pm 3^\circ$ for supine workflow

Knee Arthroplasty

- Coronal and sagittal plane resection angles within $\pm 2^\circ$
- Tibial resection depth within $\pm 2\text{mm}$
- Axial rotation of a tool relative to the femur within $\pm 2^\circ$

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

Total Hip Arthroplasty

- Anteversion and inclination of the acetabular cup angle within $\pm 10^\circ$, with 90% confidence
- Changes in leg length within $\pm 5.5\text{mm}$, with 95% confidence

Total Knee Arthroplasty

- Tibial coronal plane resection angle within $\pm 2^\circ$, with 90% confidence
- Tibial sagittal plane resection angle within $\pm 3^\circ$, with 90% confidence
- Tibial resection depth within $\pm 2.5\text{mm}$, with 90% confidence
- Femoral coronal plane resection angle within $\pm 3^\circ$, with 90% confidence
- Femoral sagittal plane resection angle within $\pm 3^\circ$, with 90% confidence

Unicompartmental Knee Arthroplasty (Transverse Resection)

- Coronal plane resection angle within $\pm 2^\circ$, with 90% confidence
- Sagittal plane resection angle within $\pm 3^\circ$, with 90% confidence

Principle of Operation

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 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

The ARVIS Surgical Navigation System 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 such as changes in leg length in Hip Arthroplasty. The system is compatible with straight acetabular impactors and with specific offset impactors, identified in the instructions for use, for which an adapter has been validated.

Example orthopedic surgical procedures include but are not limited to:

- Total Knee Arthroplasty
- Unicompartmental Knee Arthroplasty: Tibial Transverse Resection
- Hip Arthroplasty

The ARVIS™ head mounted display is for displaying augmented reality visualization and information to the user intraoperatively. 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.

Contraindications

Knee Arthroplasty

- Significant loss of bone affecting identification of the required landmarks
- Severe osteoporosis at fixation site(s)
- Hip ankylosis or any other hip condition limiting range of motion of the hip to less than 10° abduction/adduction or flexion/extension
- Severe hip arthritis or any other disease of the hip causing it to no longer approximate a ball joint
- The presence of infection
- Any contraindication associated with knee arthroplasty surgery

Hip Arthroplasty

- Excessive soft tissue interference affecting identification of the required landmarks
- Severe osteoporosis at the fixation site(s)
- The presence of infection
- Any contraindication associated with hip arthroplasty surgery

Adverse Effects

Possible adverse effects include premature implant failure, dislocation or instability, decreased range of motion, limp, 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.

User Profile

The ARVIS system is to be used by orthopedic surgeons and operating room staff who perform hip arthroplasty and knee arthroplasty. Users should reference the ARVIS® Hip and Knee Surgical Technique Guides P/N's IN-28170, IN-28180, and IN-28190 for step-by-step product instructions. Training on product usage is available, and strongly recommended.

To arrange training, contact Enovis Corporation.

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




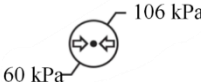










ARVIS is intended for patients undergoing orthopaedic surgery where rigid anatomic structures, such as the pelvis, femur, or tibia; can be identified and referenced.

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 |  | Storage Temperature |
|  | Consult <i>instructions for use</i> or consult electronic <i>instructions for use</i> |  | Pressure |
|  | Do not dispose in trash |  | Manufacturer |
|  | Non-Sterile |  | Date of manufacture |
|  | Humidity |  | Catalog Number |
| | |  | Serial Number |
| | |  | Lot Number |
| | |  | Caution |
| | |  | Medical device |

Hardware Information

ARVIS Hip & Knee Gap Balance Instrument Set

P/N IN-28000

| Catalog Number | Description |
|----------------|------------------------------------|
| IN-20010 | ARVIS Outer Case |
| IN-28010 | ARVIS Hip and Knee 3.0 Tray Insert |
| IN-28020 | ARVIS Hip and Knee 3.0 Tray Lid |
| IN-18600 | Trigger Stylus |
| IN-10200 | Reference Mount |
| IN-10400 | Tracker D |
| IN-10500 | Impactor V-Block Assembly |
| IN-10600 | Tracker B |
| IN-10800 | 3.5mm Hex Driver |
| IN-16300 | Tibial Slot Adapter |
| IN-16400 | Tracker A |
| IN-16100 | Tracker C |
| IN-14700 | Landmark Punch |
| IN-16200 | Femoral Slot Adapter |
| IN-18900 | Femoral AP Sizer Adapter |
| IN-20500 | Pin Driver |
| IN-28120 | Acetabular Impactor Tracker |
| IN-28050 | Tracker E |
| 804-33-005 | Adaptable Mount |
| IN-28110 | Enztec Adjustable Resection Guide |
| IN-28100 | Resection Guide Alignment Paddle |
| IN-28130 | Resection Check Tool, 3.0 |
| IN-28070 | Adjustable Bone Mount |
| 801-05-023* | DJO Empowr Knee™, 2mm Recut Guide |

*Special order only

ARVIS Hip & Knee 2.0 Instrument Set

P/N IN-21200

| Catalog Number | Description |
|----------------|-----------------------------------|
| IN-20000 | Instrument Tray Base |
| IN-11000 | Instrument Tray Lid |
| IN-17200 | Pin Caddy |
| IN-17300 | Pin Caddy Lid |
| IN-18600 | Registration Stylus |
| IN-10200 | Reference Mount |
| IN-10400 | Tracker D |
| IN-10500 | Impactor V-Block Assembly |
| IN-10600 | Tracker B |
| IN-15900 | Impactor Adapter, DJO |
| IN-10800 | 3.5mm Hex Driver |
| IN-16300 | Tibial Slot Adapter |
| IN-20100 | Adjustable Mount, 1 |
| IN-20200 | Adjustable Mount, 2 |
| IN-20300 | Tibial Reference Mount, Left |
| IN-20400 | Tibial Reference Mount, Right |
| IN-21000 | Flex Jack |
| IN-15600 | Femoral Cutting Block |
| IN-19100 | Precision Adjustable Distal Guide |
| IN-16400 | Tracker A |
| IN-16100 | Tracker C |
| IN-15700 | Femoral Reference Mount, Left |
| IN-15800 | Femoral Reference Mount, Right |
| IN-14700 | Landmark Punch |
| IN-16200 | Femoral Slot Adapter |
| IN-19900 | Resection Check Tool |
| IN-18900 | Femoral AP Sizer Adapter |
| IN-20500 | Pin Driver |

ARVIS Gen 2 Electronic Hardware Components and Accessories - US

P/N IN-29200

| Catalog Number | Description |
|----------------|---------------------------------|
| IN-29001 | ARVIS Eyepiece Assembly, Gen 2 |
| IN-29002 | ARVIS Belt Pack, Gen 2 |
| IN-29003 | ARVIS Computer Module, Gen 2 |
| IN-29030 | ScreenCast Tablet, Gen 2 |
| IN-21904 | ARVIS Screen Cast Router |
| IN-12800 | ARVIS Battery |
| IN-13000 | ARVIS Battery Charger |
| IN-13800 | ARVIS Charger Power Supply |
| IN-29018 | ARVIS Cables Kit, Gen 2, Global |
| IN-29019 | ARVIS Wall Adapters Kit, US |
| IN-17700 | ARVIS Installation Kit |

Use only accessories supplied by the manufacturer.

ARVIS Gen 1 Electronic Hardware Components and Accessories - US

P/N IN-28150

| 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-13900 | ARVIS Charger Cord, USA |
| IN-15202 | Cable, USB-C 1m |
| IN-15201 | Wall Adapter, 25W, USA |
| IN-17700 | ARVIS Installation Kit |

Use only accessories supplied by the manufacturer.

Surgeon/Case-Specific ARVIS Accessories

| Catalog Number | Description |
|--|---|
| Gen 1 - Select one per surgeon preference₁ | |
| IN-17100 | ARVIS Headband |
| IN-17500 | FLYTE Mounting Kit |
| IN-21700 | T7 Adapter Kit |
| IN-21900 | ARVIS Screen Casting Kit (Tablet Control) |
| Gen 2 - Select one per surgeon preference | |
| IN-29100 | ARVIS Headband, Gen 2 |
| IN-29101 | FLYTE Mount Kit, Gen 2 |
| IN-29102 | T7 Mount Kit, Gen 2 |
| Select one or more per surgery (TKA, THA, UKA) | |
| 150-00-001 | Tech Knee Pack |
| 150-00-002 | Tech Ancillary Pack |
| 160-00-001 | Tech Hip Pack |

1. See IN-14001 for mounting instructions

Compatibility

- The ARVIS Gen 2 Electrical Hardware (IN-29200) is compatible with ARVIS Gap Balance instrument set (IN-28000) and has **limited capability** with ARVIS 2.0 instrument set (IN-21200).
 - The Gen 2 Electrical Hardware comes loaded with the Gap Balance software (v3.3.0 or later). The Gap Balance option must be turned off if using ARVIS 2.0 instrumentation.
- The ARVIS Gen 1 Electrical Hardware (IN-28150 or legacy IN-14100) is compatible with ARVIS 2.0 (IN-21200) and Gap Balance instrument sets (IN-28000).
 - It is recommended to use the Gap Balance software (v3.3.0 or later) when using the ARVIS Gap Balance instrument set. ARVIS Gen 1 Electrical Hardware kitted per IN-28150 comes loaded with the Gap Balance software, while ARVIS Gen 1 Electrical Hardware kitted per IN-14100 does not.
 - If using the Gap Balance software (v3.3.0 or later) with the ARVIS 2.0 instrument set, the Gap Balance option must be **turned off**.
- Surgical Techniques IN-28170, IN-28180, and IN-28190 describes use of ARVIS Gap Balance instrumentation (IN-28000) while surgical technique IN-16000 describes use of ARVIS 2.0 instrumentation (IN-21200). Consult the appropriate surgical technique based on the instrumentation available.
- Do not mix and match components of the ARVIS Gen 1 and Gen 2 Electrical Hardware unless directed by Enovis.

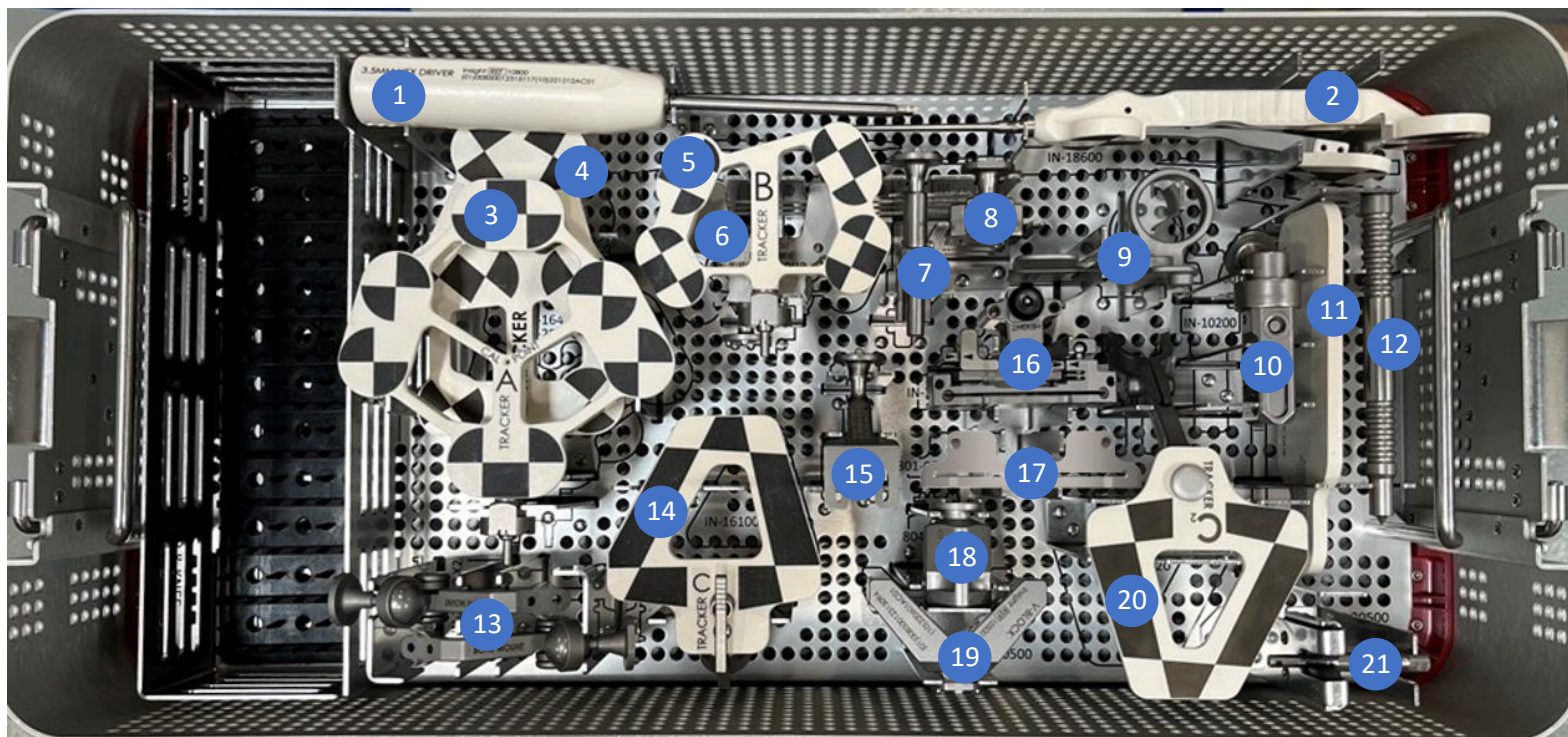
Gen 2 Electrical Hardware (IN-29200) Compatibility

| | 2.0 Instrument Set (IN-21200) | Gap Balance Instrument Set (IN-28000) |
|-------------------------------------|-------------------------------------|---|
| V3.3.0 or later Software | Gap Balance must be turned 'Off' | Optimized |

Note: v3.1.0 Software is not available on Gen 2 Eyepiece

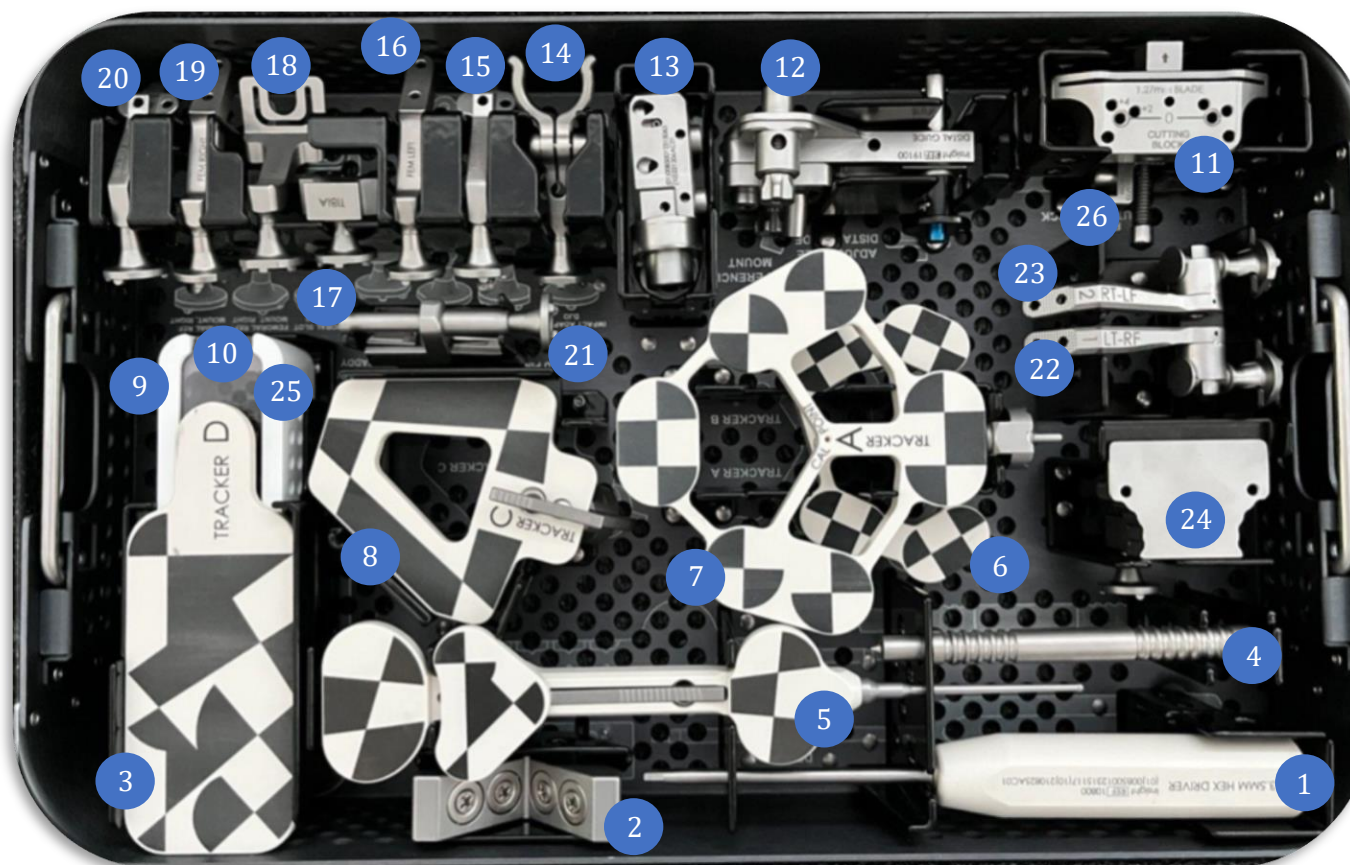
Gen 1 Electrical Hardware (IN-28150/IN-14100) Compatibility

| | 2.0 Instrument Set (IN-21200) | Gap Balance Instrument Set (IN-28000) |
|-------------------------------------|-------------------------------------|---|
| V3.3.0 or later Software | Gap Balance must be turned 'Off' | Optimized |
| V3.1.0 Software | Optimized | Compatible |



P/N IN-28000 ARVIS Hip & Knee Instrument Gap Balance Set
(Cover Removed)

- | | |
|-------------------------------------|---------------------------------------|
| 1. 3.5mm Hex Driver | 12. Landmark Punch |
| 2. Trigger Stylus | 13. Adjustable Bone Mounts |
| 3. Tracker A | 14. Tracker C |
| 4. Tracker E | 15. Femoral Slot Adapter |
| 5. Tracker B | 16. Enztec Adjustable Resection Guide |
| 6. Resection Check Tool, 3.0 | 17. DJO Empowr Knee™, 2mm Recut Guide |
| 7. Femoral AP Sizer Adapter | 18. Adaptable Mount |
| 8. Tibial Slot Adapter | 19. Impactor V-Block Assembly |
| 9. Resection Guide Alignment Paddle | 20. Acetabular Impactor Tracker |
| 10. Reference Mount | 21. Pin Driver |
| 11. Tracker D | |



P/N IN-21200 ARVIS Hip & Knee Instrument 2.0 Set (Cover Removed)

1. 3.5mm Hex Driver
2. Impactor V-Block Assembly
3. Tracker D
4. Landmark Punch
5. Registration Stylus
6. Tracker B
7. Tracker A
8. Tracker C
9. Pin Caddy
10. Pin, 4mm X 115mm (in caddy)
11. Femoral Cutting Block
12. Precision Adjustable Distal Guide
13. Reference Mount
14. Impactor Adapter, DJO
15. Tibial Reference Mount, Left
16. Femoral Reference Mount, Left
17. Tibial Slot Adapter
18. Femoral Slot Adapter
19. Femoral Reference Mount, Right
20. Tibial Reference Mount, Right
21. Femoral AP Sizer Adapter
22. Adjustable Mount, 1
23. Adjustable Mount, 2
24. Resection Check Tool
25. Pin Driver (in caddy)
26. Flex Jack

Electronics Cleaning Instructions

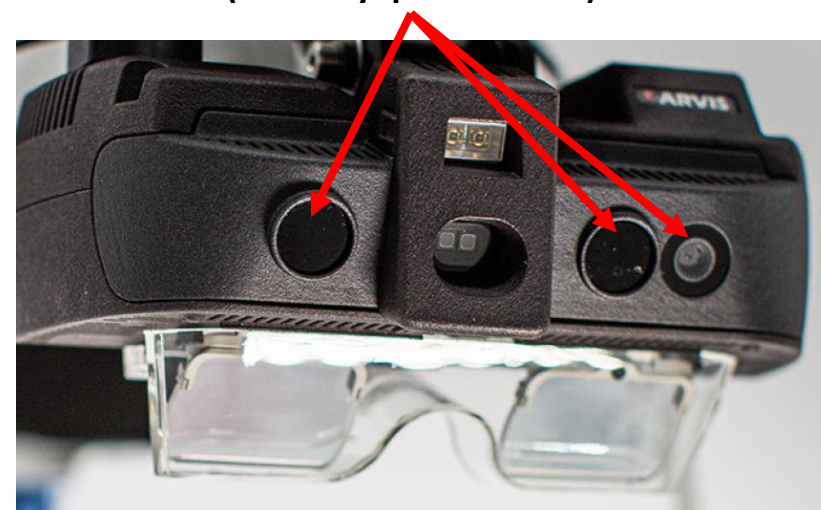
The electronic hardware components comprising the ARVIS system are the Eyepiece, Belt Pack, Battery, and Charger. The electronic hardware components are re-usable.

- The Charger is 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.

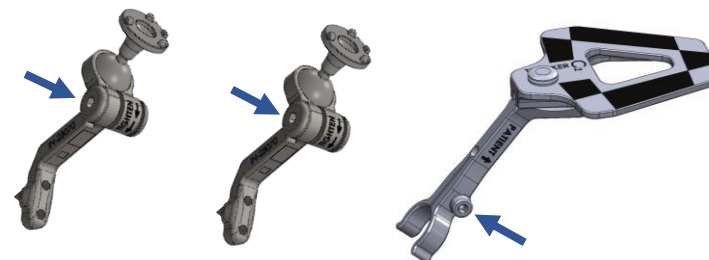
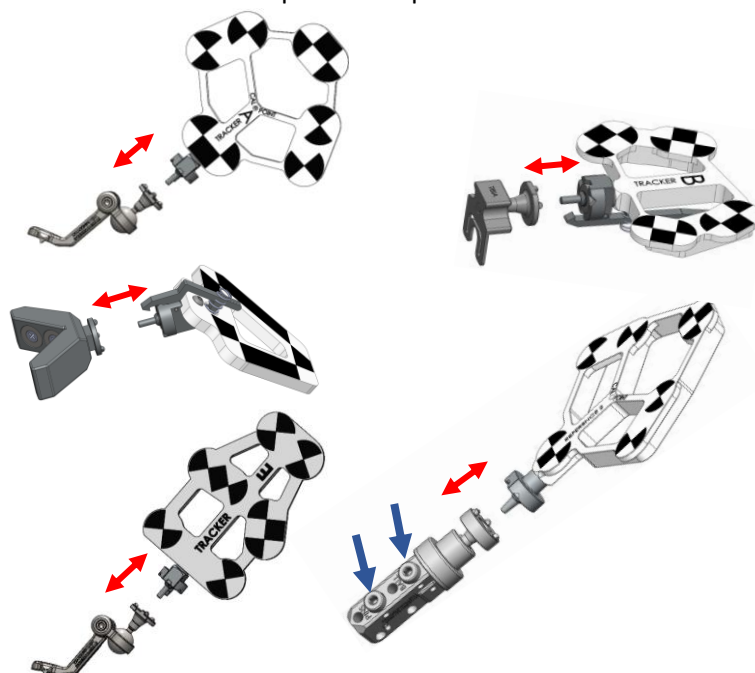
**Camera Covers
(Gen 1 eyepiece shown)**



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” tables.
 - a. Separate all trackers from reference mounts or adapters to which they may be coupled.
 - b. Separate slot adapters from cutting blocks.
 - c. Loosen the clamping screws in Reference Mount IN-10200, in the Adjustable Bone Mounts IN-28070, and in the Acetabular Impactor Adapter IN-28120.



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). Use an FDA-cleared wrap or sterile barrier. (Validation is based on use of Halyard Health H400.) Dry times are as follows:
 - 45 minutes* for instrument set IN-28000
 - 75 minutes* for instrument set IN-21200
- 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°C 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, cutting guides, and tracker adapters. 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 Enovis 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 Enovis 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 | | | |
|---|---|------------------|---|
| 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 | <p>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.</p> <p>Recommended separation distance $d = 2.3 \cdot (P)^{1/2}$</p> <p>$d = 2.3 \cdot (P)^{1/2}$ 800 MHz to 2.7 GHz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> |

| 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.

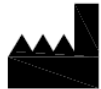
| Nearby Transmitter's EIRP (W) | Minimum Separation Distance (m) |
|-------------------------------|---------------------------------|
| 10 | 1.33 |
| 1 | 0.42 |
| 0.1 | 0.13 |
| 0.01 | 0.04 |

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 International | CE CB |
| Electromagnetic Emissions | Europe USA | EN55011, EN55032, level B FCC15 class B |
| Electromagnetic Immunity | ESD Immunity Electromagnetic field immunity EFT / Burt Surge Conducted Immunity Magnetic Fields Voltage dips, short instrumentations & voltage variations Immunity characteristics | EN/IEC61000-4-2 EN/IEC61000-4-3 EN/IEC61000-4-4 EN/IEC61000-4-5 EN/IEC61000-4-6 EN/IEC61000-4-8 EN/IEC61000-4-11 EN55024 |

Further Information

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



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