Record

360CAS - INSTRUCTIONS FOR USE

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1 PRODUCT OVERVIEW

The 360 Computer Assisted Surgery (360CAS) is a stereotaxic surgical navigation system for orthopaedic surgical procedures. The 360CAS is intended to be used as a planning and intraoperative guidance system with any manufacturer's implant in open or percutaneous orthopaedic surgical procedures. The 360CAS uses optical tracking technology that allows surgeons to map subject's morphology, navigate surgical instruments and implants and assess state of the joint throughout the surgery. The system consists of 360CAS navigation software, surgical instruments, spatial tracking components and accessories. 360CAS Knee is a navigation software for knee replacement surgery. The navigation software interfaces with the optical trackers which are attached to navigation instruments (e.g. pointer, bone fixator).

1.1 INTENDED USE

The 360CAS Knee is intended to be used as a planning and intraoperative guidance system in open or percutaneous image guided surgical procedures.

1.2 INDICATIONS FOR USE

The 360CAS Knee is intended to be used as a planning and intraoperative guidance system in open or percutaneous image guided surgical procedures.
The 360CAS Knee is indicated for patients undergoing orthopaedic surgery and where reference to a rigid anatomical structure, such as the femur, or tibia, can be identified.
The 360CAS Knee is indicated for the following surgical procedures:

- Total Knee Arthroplasty (TKA);
- For conditions of the knee joint in which the use of computer assisted surgery may be appropriate.

1.3 DEVICE DESCRIPTION

The 360CAS uses optical tracking technology that allows surgeons to map subject's lower limb morphology, navigate surgical instruments and implants and assess state of the joint throughout the surgery. The system consists of:

- 360CAS Navigation Software
    - 360CAS Knee
- Spatial Tracking Components
- Surgical Instruments
- Accessories

The navigation software interfaces with the optical Trackers which are attached to navigation instruments (e.g., pointer, bone fixator).

Figure 1 shows a representation of components and setup of the 360CAS system. In the operating theatre, the Accessories will be located outside of the sterile field while the Surgical Instruments will be used on the patient, in the sterile field.

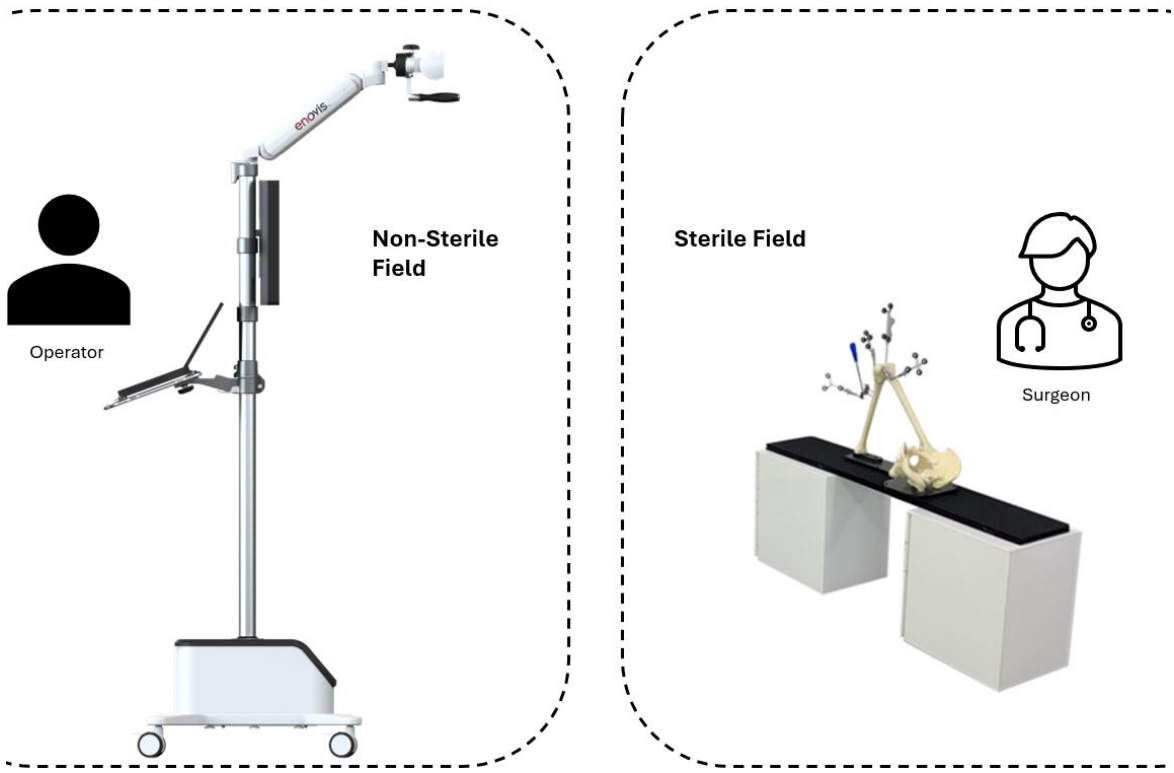


Figure 1: Representation of 360CAS system (not in intended environment)

The 360CAS includes the parts listed in **Table 2**.

The parts listed in **Table 2** are provided NON-STERILE to the hospital and are REUSABLE. The parts must be PROCESSED and REPROCESSED before each use according to **Section 8.**

1.4 COMPATIBILITY WITH MEDICAL DEVICES

The following components must be arranged by the operating hospital for use with the 360CAS prior to surgery:

1. **Schanz Pins**
   The apertures of the Pin Guide and Bone Fixators can be used with pins of diameter between 3.2mm and 4mm and length of at least 110mm.

2. **Steinmann Pins**
   The apertures of the ASM Cut block and ASM horseshoe fixations can only be used with pins which have a diameter of 3.2mm.

3. **Implant systems for Component planning feature**
   - Enovis Empowr Knee System (#K143242, #K171991, #K170573)

4. **Cutting Blocks**
   The 360CAS Knee Resection Plane Tool is designed to be used with cutting blocks with slot dimensions in the range of 1.3mm and 1.5mm. Additional to the 360CAS ASM Cut Block provided, suggested cut blocks below are part of supported implant systems listed above:

Table 1: 360CAS – Cutting Block Compatibility	
Implant system	**Cut block**
Enovis Empowr	• distal femur cut block (800-05-003) • tibia cut block (801-05-074) • 4-in1 cut block, size 2-11 (800-05-082 – 800-05-091)

1.5 USAGE ENVIRONMENT

The 360CAS is a stereotaxic intraoperative guidance system that is used in operating rooms. The system consists of parts that can be reused, such as the software, tracking system, accessories, and surgical instruments.

1.6 TRAINING

To promote safe and appropriate use, before using the 360CAS, it is recommended that users participate in training delivered by 360 Med Care.

1.7 SYSTEM ACCURACY

The 360CAS displays distance measurements to within ±2 mm and angular measurements to within ±1°.

2 USER/PATIENT SAFETY

2.1 CONTRAINDICATIONS

The 360CAS is contraindicated for:

- Patients for which TKA is contraindicated
- Insufficient bone structure or quality, which may not allow for rigid attachment of instruments
- Use in an MRI environment. The 360CAS is MR unsafe.

2.2 CLINICAL CONSIDERATIONS

Although not contraindicated, surgeon discretion is advised in the following circumstances:

- Existing femoral or tibial osteotomy
- Suspected or actual infection
- Existing implanted hardware
- Severe deformities of the femoral or tibial bone

2.3 POTENTIAL ADVERSE EFFECTS

There are currently no known side-effects or adverse effects of using the 360CAS. However, as the 360CAS is used for total knee joint replacement surgery, known possible adverse effects related to knee joint replacement surgery include:

- Dislocation or subluxation due to improper positioning or muscle and fibrous tissue laxity.
- Loosening or migration of components due to trauma and/or loss of fixation.
- Accelerated wear of the polyethylene articulating surfaces. Such wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Accelerated wear shortens the useful life of the prostheses and leads to early revision surgery to replace the worn components.
- Histiocytic granuloma formation and osteolysis around the implant due to wear debris
- Fracture of the implant as the result of strenuous activity, improper alignment, inadequate fixation or extreme duration of service.
    - Urological complications, especially urinary retention and infection.
    - Other complications associated with general surgery, drugs or ancillary devices used,

blood, etc.

Intraoperative and early postoperative complications can include:

- Damage to blood vessels;
- Temporary or permanent neuropathies;
- Traumatic arthrosis of the joint from Intraoperative positioning of the extremity.
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial Infarction;
- Hematoma;
- Delayed wound healing;
- Infection;

Late postoperative complications can include:

- Patellar dislocation or subluxation due to soft tissue imbalance or component malalignment;
- Aggravated problems of the hip or ankle of the affected limb or contralateral extremity by muscle deficiency;
- Bone fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
- Compression fracture of the proximal tibia by trauma or excessive loading, particularly in the presence of poor tibial bone density;
- Periarticular calcification or ossification, with or without impediment to joint mobility;
- Inadequate range of motion due to improper selection or positioning of components, bony impingement and periarticular calcification.
- Excessive joint pressures and pain with ambulation due to excessive scarring of the joint capsule and surrounding tissues.
- Infection

Potential adverse effects related to navigated orthopaedic surgery include:

- Bone fracture at the pin site
- Infection at the pin site

2.4 WARNINGS

Read and understand this information. Familiarization with the 360CAS prior to its use is important. Contact your 360 Med Care representative for more detailed information.

The 360CAS System is intended to be used by trained and qualified orthopaedic surgeons. The software components of the 360CAS are intended to be operated by trained and qualified operator.

The Navigation Cart is intended to be located outside of the sterile operating field and is not intended to be in contact with the patient during use.

Performing procedures with the 360CAS other than those specified in these instructions and KIC-REC-RA-621 *360CAS Knee Surgical Technique* or outside of its intended use will compromise the navigation accuracy.

Before using any component compatible with the 360CAS, read and understand the instructions. Failure to comply may result in patient and/or health care staff injury or damage to the 360CAS components.

DO NOT modify the 360CAS or any component or accessory. Failure to comply may result in patient and/or health care staff injury.

To prevent the Navigation Cart from tipping over, do not lean against the Navigation Cart, overload or add any weight to the Navigation Cart. Do not use any part of the 360CAS for loading, transport or storage unless otherwise specified. Failure to comply may lead to product damage and malfunction.

This 360CAS may cause radio interference or may disrupt the operation of nearby equipment. The system itself may be interfered by other nearby equipment or mobile HF equipment (e.g., cellular phone). Do not use the 360CAS stacked or adjacent other devices. It may be necessary to take mitigation measures, such as re-orienting or relocating the 360CAS or shielding the location. Do not enable Wi-Fi or Bluetooth transmitting functions during use of the 360CAS. For EMC technical specifications of the system refer to the related **Section 6** in this IFU.

To avoid the risk of electric shock, the 360CAS must only be connected to a mains supply with protective earth.

To ensure the safe disconnection of the system from the mains supply, never position the system so that it is difficult to access the plug of the main power cable or the power outlet.

The system must always be connected to mains power during use.

Do not access external networks using ethernet cables or Wi-Fi connections. The laptop is to be operated in flight mode **only.**

For cybersecurity reasons, 360CAS User is not able to modify system settings, including enabling Wi-Fi or external connections. For technical issues, please contact authorized technical support at compliance@360med.care

Pay attention to your surroundings when logging in to the 360CAS Laptop. 360CAS must only be used within a safe hospital area.

Ensure to use only the laptop provided by 360 Med Care. Ensure that the laptop is being charged during use. Only use the laptop charger provided to power the laptop during use.

If any one of the 360CAS components sterile packaging is compromised, the compromised component must be disregarded and reprocessed as per the cleaning and sterilisation instructions in **Section 8** of the IFU**.**

360 Med Care has not validated other sterilization methods and cannot ascertain safety and effectiveness of such methods. It is the responsibility of the reprocessing entity to ensure adherence to the instructions provided in **Section 8** of the IFU.

The 360CAS displays distance measurements to within ±2 mm and angular measurements to within ±1°. This is the 360CAS expected accuracy. Actual accuracy depends on various factors including patient registration.

Do not apply excessive force when using any one of the 360CAS instruments as there is a risk of fracturing or breaking the instrument

The 360CAS solely provides assistance to the surgeon and does not substitute or replace the surgeon's experience and/or responsibility during its use

If the 360CAS shuts down unexpectedly, restart the Laptop and/or Spatial Tracking System. If the problem persists, contact a 360 Med Care representative.

All 360CAS components must be returned to 360 Med Care for repair and maintenance. If the 360CAS or one of its components becomes damaged, contact a 360 Med Care Representative.

Assess navigational accuracy repeatedly throughout a procedure when using 360CAS e.g., reconfirm accuracy by positioning the Pointer tip on an identifiable anatomical landmark and compare it to the actual position of the actual Pointer tip displayed. If the 360CAS does not appear accurate, abandon use.

3 STORAGE AND HANDLING CONDITIONS

The 360CAS Surgical Instruments, 360CAS Navigation Cart and the parts it houses will be delivered to CSSD for cleaning and sterilisation, as appropriate, prior to surgery.
CSSD are to process the 360CAS Surgical Instruments as per the instructions in the IFU prior to surgery. Instruments undergoing STERRAD® sterilisation should not exceed 56°C/133°F.

NOTE: The 360CAS Navigation Cart MUST be set up by a 360 Med Care Surgical Representative prior to cleaning the navigation cart by CSSD for surgery. Contact 360 Med Care if any further assistance is required.

3.1 360CAS – SURGICAL INSTRUMENTS

The surgical instruments of the 360CAS should be stored in surgical instrument trays when not in use to prevent damage to fragile instruments. Items should be stored in a limited access location, protected from sunlight, heat and moisture. Prior to sterilisation, inspect all instruments for visible damage or debris. Damaged instruments must not be used.

3.2 360CAS – NAVIGATION CART

The Navigation Cart, and the parts that it houses, should be stored in a limited access location, protected from sunlight, heat and moisture. Ensure that the Laptop is powered off after every use.

4 OPERATING INSTRUCTIONS

For instructions relating to use of 360CAS for specific surgical workflows, please refer to:

- KIC-REC-RA-621 *360CAS Knee Surgical Technique*
- KIC-REC-RA-607 *360CAS Navigation System Software Release Notes*

4.1 360CAS NAVIGATION CART SETUP

1. Extend the top half of the cart using the hinge. Be careful to restrain the camera arm while doing so. Secure the top half with the knob provided.
2. Place Laptop Table onto the support frame, and secure with knob provided.
3. Slide Monitor, onto the support frame.
4. Place the Camera Mount arm onto Support.
5. Secure Camera to Camera Mount arm's camera attachment and secure from above with the knob provided. Adjust as appropriate.

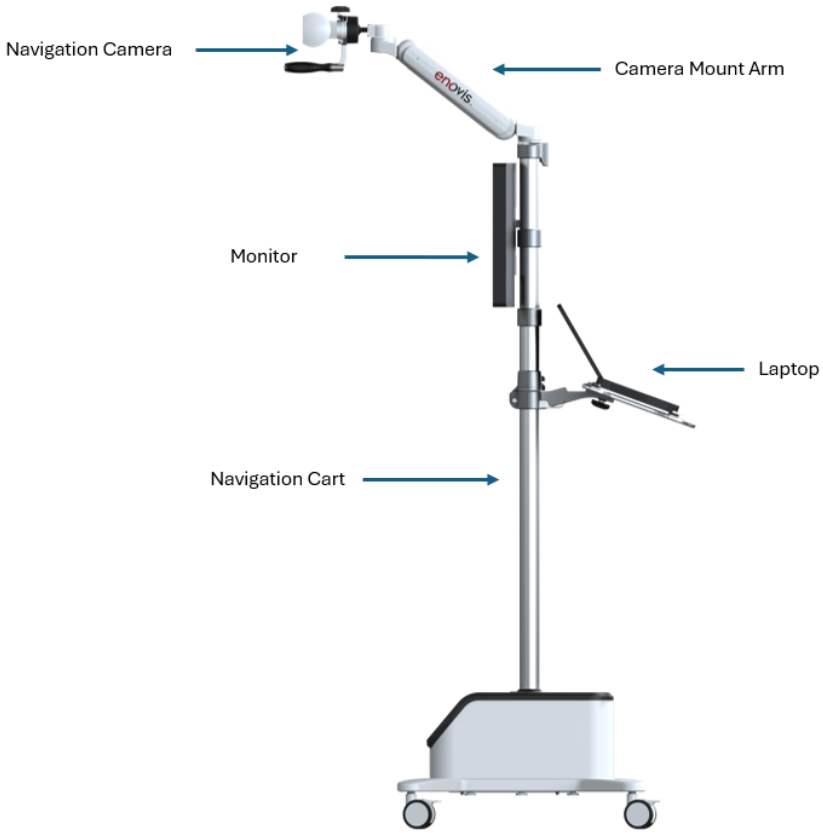


Figure 2: 360CAS Navigation Cart Assembled

NOTE Ensure CAS Cart wheels are locked to prevent any unwanted movement during use.

NOTE Ensure the Camera Mount adjustments are securely locked to prevent unwanted movement during use.

6. Connect the ethernet cable to the ethernet port on the Navigation Camera.
7. Connect the ethernet cable to the LAN port at the rear of the laptop.
8. Ensure a solid green LED light is visible on the front of the camera.
9. Connect the USB-C cable from the Monitor to the Laptop
10. Connect the power input cable to the laptop USB-C port
11. Connect the Navigation cart to the mains supply and switch on.

NOTE Ensure the Navigation camera cables are assembled correctly, safely and securely.

5 ELECTRICAL SAFETY

The 360CAS is Class I Medical Electrical Equipment and has been tested to and is compliant with AS/NZS 3551:2012 Management Programs for Medical Equipment.

6 ELECTROMAGNETIC COMPATIBILITY

The 360CAS Navigation System has been fully tested in accordance with IEC 60601-1-2. Its intended use environment is a professional healthcare facility.

Disturbances to the 360CAS Navigation System when in use may result in:

1. Loss of Tracker visibility
2. Loss of Navigation Camera operation
3. Unexpected shut down of the system

If any one of the disturbances occurs, refer to KIC-REC-RA-621 *360CAS Knee Surgical Technique* to troubleshoot.

Use of the 360CAS Navigation System adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the 360CAS Navigation System and other equipment should be observed to verify they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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 360CAS Navigation System, including cables specified by 360 Med Care. Otherwise, degradation of the performance of this equipment could result.

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

NOTE: All cables provided have been tested for use with the 360CAS Navigation System. Any cable that appears faulty shall be replaced by 360 Med Care. Contact 360 Med Care to remove and replace the defective cable to ensure the 360CAS Navigation System performs as intended.

NOTE: Maintenance of the 360CAS Navigation System electrical components shall be performed by 360 Med Care operators. Do not attempt to perform any maintenance.

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.

The 360CAS system has been tested to comply with IEC 60601-1-2 {ed 4.0} for electromagnetic compatibility, refer to compliance and guidance in the tables below.

Electromagnetic Emissions		
The 360CAS Navigation System is intended for use in the electromagnetic environment specified below. The customer or user of the 360CAS Navigation System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF Emissions CISPR 11	Group I	The 360CAS Navigation System uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference to nearby electronic equipment.
RF Emissions CISPR 11	Class A	The 360CAS Navigation System is suitable for use in all establishments other than domestic and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Electromagnetic Compatibility			
The 360CAS Navigation System is intended for use in the electromagnetic environment specified below. The customer or user of the 360CAS Navigation 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	±8kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient / Burst IEC 61000-4-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line(s) to line(s) ±2kV for line(s) to earth	±1kV line(s) to line(s) ±2kV for line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment
Voltage Dips and Interruptions IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° and 70 % U_T; 25/30 cycles	Complies Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 360CAS Navigation System requires continued operation

Electromagnetic Compatibility			
The 360CAS Navigation System is intended for use in the electromagnetic environment specified below. The customer or user of the 360CAS Navigation System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic Environment – Guidance**
	Single phase: at 0° 0 % U_T; 250/300 cycle	Complies Complies	during power mains interruptions, it is recommended that the 360CAS Navigation System powered from an uninterruptable power supply.
Power Frequency IEC 61000-4-8 (50Hz / 60Hz)	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.
NOTE: U_T is the a.c. mains voltage prior to Application of the test level.			

Electromagnetic Immunity			
The 360CAS Navigation System is intended for use in the electromagnetic environment specified below. The customer or user of the 360CAS Navigation 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	3 V; 0,15 MHz to 80 MHz, 6V in ISM bands between 0,15 MHz and 80MHz, 80% AM at 1 kHZ	6 V_{rms}	Refer to warnings above regarding use of portable RF communications equipment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz-2.7 GHz	3 V/m	

7 DEVICE DISPOSAL

7.1 SURGICAL INSTRUMENTS

In the event that any one the 360CAS surgical instruments requires disposal, please clean and sterilise the component(s) requiring disposal as per IFU **Section 8** and contact 360 Med Care. Contact details can be found in **Section 10** of the IFU.

7.2 NON-SURGICAL COMPONENTS

In the event that any one of the 360CAS non-surgical components e.g., 360CAS Laptop requires disposal, please notify 360 Med Care (contact details can be found in **Section 10**) and follow jurisdiction specific electrical waste disposal procedures.

8 CLEANING AND STERILISATION

Clean and sterilise the instruments of the 360CAS according to **Table 2**

Only use reprocessing procedures described in this IFU. Other procedures could result in material damage, corrosion, fatigue, breakage, or decrease the weight bearing capability of the instrument.

Inspect instruments Pre- and Post-operatively to ensure no damage or signs of fatigue corrosion.

Inspect Trackers for hairline cracks prior to sterilisation.

Sterilize the Fiducials according to the specified STERRAD® instructions in the IFU. DO NOT sterilize the Fiducials by steam autoclaving. Steam sterilization is likely to damage the Fiducials by melting components.

Fiducials can only be cleaned using manual cleaning methods.

Table 2: 360CAS – Cleaning and Sterilisation of Non-Sterile Instruments / Components

	Item Code	Instrument	Cleaning Method	Sterilisation Method	360CAS Knee
Instrument Trays	**KIC-DND-0102**	**CAS Small Instruments Tray**	Automated	Steam	X
	KIC-DND-0103	**CAS General Instruments Tray**	Automated	Steam	X
	KIC-DND-0126	**CAS Instruments Tray – SET-0015**	Automated	Steam	X
	KIC-DND-0125	**CAS STERRAD® Fiducial Caddy**	Manual	STERRAD®	X
	KIC-DND-0147	**360CAS Enovis Single Knee Tray**	Automated	Steam	X
Surgical Instruments	KIC-DND-0004	Male Bone Fixator	Automated	Steam	X
	KIC-DND-0024	Pin Guide	Automated	Steam	X
	KIC-DND-0025	Gimbal Array Mount 0°	Automated	Steam	X
	KIC-DND-0026	Gimbal Array Mount 90°	Automated	Steam	X
	KIC-DND-0028	UTC 2 Gimbal Stem	Automated	Steam	X
	KIC-DND-0068	CAS Flex Driver	Automated	Steam	X
	KIC-DND-0069	Bone Fixator	Automated	Steam	X
	KIC-DND-0076	4mm Hex Driver Long	Automated	Steam	X
	KIC-DND-0100	ASM Cut Block	Automated	Steam	X
	KIC-DND-0100-1	-ASM Cut Jig	Automated	Steam	X
	KIC-DND-0100-2	-ASM Adjustment Jig	Automated	Steam	X
	KIC-DND-0100-3	-ASM Fixation Frame	Automated	Steam	X
	KIC-DND-0104-A	ASM Horseshoe Fixation A	Automated	Steam	X
	KIC-DND-0104-B	ASM Horseshoe Fixation B	Automated	Steam	X
	KIC-DND-0105	Universal Horseshoe Fixation	Automated	Steam	X

	Item Code	Instrument	Cleaning Method	Sterilisation Method	360CAS Knee
	KIC-DND-0106	UTC Click Stem	Automated	Steam	X
	KIC-DND-0107	Array	Automated	Steam	X
	KIC-DND-0108	Array	Automated	Steam	X
	KIC-DND-0109	Array	Automated	Steam	X
	KIC-DND-0110	Pointer	Automated	Steam	X
	KIC-DND-0120	Resection Plane 90	Automated	Steam	X
	KIC-DND-0142	Action Pointer	Automated	Steam	X
	KIC-DND-0113	Fiducial	Manual	STERRAD®	X
	KIC-DND-0123	Fiducial Wrench	Manual	STERRAD®	X
	KIC-DND-0145	Empowr Sizer UTC Adaptor	Automated	Steam	X
	KIC-DND-0235	Empowr 4-in-1 Drill Guide	Automated	Steam	X
Accessories	KIC-DND-0077	Navigation Cart	Manual	N/A	X
	KIC-DND-0078	Laptop	Manual	N/A	X
	KIC-DND-0112	Navigation Camera	Manual	N/A	X
	KIC-DND-0082	Monitor	Manual	N/A	X

8.1 PREPARATION OF 360CAS FOR FIRST USE AND REPROCESSING

8.1.1 POINT OF USE

After use (within 30 minutes post-operatively), remove gross soil using absorbent paper wipes.

8.1.2 TRANSPORT TO PROCESSING AREA

1. Avoid mechanical damage by ensuring that heavy devices do not get mixed with delicate ones.
2. Pay particular attention to sharp edges, both to avoid personal injury and prevent damage to the reusable instruments.
3. Transport the reusable instruments to the point where cleaning is to be performed as soon as practical in closed or covered containers to prevent risk of unnecessary contamination. If transfer to the processing area is likely to be delayed, consider covering the instruments with a damp cloth to avoid drying of soil.

8.1.3 PREPARATION FOR CLEANING

360CAS Instruments are to be disassembled prior to cleaning.

8.1.3.1 TRACKER TOOLS DISASSEMBLY

1. Holding the Tracker UTC, use two fingers to pull the tab in an upwards direction away from the Tracker post to compress the spring.
2. While the spring is in a fully compressed position, remove the Tracker UTC from the Tracker Post.

Figure 3: Disassembly of Resection Plane Tool

8.1.3.2 BONE FIXATOR DISASSEMBLY

Each Bone Fixator is to be disassembled prior to cleaning.
When Bone Fixator (KIC-DND-0069) is used:

1. Using the Flex Driver (KIC-DND-0068), loosen both the Post Clamp screw, and the Pin clamp screw until the internal springs are disengaged allowing access to the internal mechanisms for flushing and rinsing.

When Male Bone Fixator (KIC-DND-00004) and Gimbals (KIC-DND-0025, KIC-DND-0026) are used:

1. Detach Gimbals (KIC-DND-0025, KIC-DND-0026) from the Male Bone Fixator (KIC-DND-00004) by pressing the button and pulling apart.
2. Using the 4mm Hex Driver Long (KIC-DND-0076), loosen the Gimbal (KIC-DND-0025, KIC-DND-0026) and remove the UTC 2 Gimbal Stem (KIC-DND-0028)

8.1.3.3 ASM CUT BLOCK DISSASSEMBLY

The ASM Cut Block assembly consists of 3 separate parts –

- ASM Cut Jig (KIC-DND-0100-1)
- ASM Adjustment Jig (KIC-DND-0100-2)
- ASM Fixation Frame (KIC-DND-0100-3)

1. Remove Horseshoe Fixation as appropriate.
2. Separate the Cut Jig from the Adjustment Jig by pressing in the button on the Adjustment Jig and pulling pieces apart.
3. Separate the Adjustment Jig from the Fixation Frame by using the 4mm Hex Driver Long to release the screw.

8.2 CLEANING – MANUAL METHOD (FIDUCIALS)

Cleaning and disinfection are achieved through enzymatic soak and scrub followed by sonication. Automated cleaning using a washer/disinfector without manual pre-cleaning is not recommended.

Refer to **Table 2** to verify the 360CAS Surgical Instruments which are processed using manual cleaning methods.

1. Remove any inserted fiducials (KIC-DND-0113) from the Pointer and Arrays (KIC-DND-0107 Array, KIC-DND-0108 Array, KIC-DND-0109 Array, KIC-DND-0110 Pointer and KIC-DND-0142 Action Pointer) using the fiducial wrench (KIC-DND-0123).
2. Make sure only the fiducials (KIC-DND-0113) and the fiducial wrench (KIC-DND-0123) are present in the CAS STERRAD® Fiducial Caddy (KIC-DND-0125).
3. Store KIC-DND-0125 CAS STERRAD® Fiducial Caddy in an appropriate storage area as per the Storage and Handling Conditions outlined in this IFU.
4. Remove each component from the Fiducial Caddy as necessary. Completely submerge all components in enzyme solution and allow to soak for 20 minutes. Scrub using a soft-bristled, nylon brush (crevices, lumens, mated surfaces and other hard to clean areas should be attended) until all visible soil has been removed. Clean cannulations and holes using an appropriate brush ensuring that the full depth of the feature is reached. Hold the items low in the sink to limit the generation of aerosols during scrubbing.
5. Remove each component from solution and rinse in purified water (from one or any combination of the following: ultra-filter (UF), reverse osmosis (RO), deionised (DI) or distilled) for a minimum of 3 minutes. Thoroughly flush holes and other difficult to reach areas. Ensure that running water passes through the cannulations, and that blind holes are repeatedly filled and emptied.
6. Pour the prepared neutral pH cleaning solution into a sonication unit and completely submerge each component in the solution and sonicate for 10 minutes at 40-50 kHz.
7. Rinse each component in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
8. Repeat the sonication and rinse steps above.
9. Allow all components to air dry in **ambient** temperatures. To remove excess moisture from each component use a clean, absorbent and non-shedding wipe.
10. Inspect all components per **Section 8** of this IFU.

NOTE: If suggested cleaning, drying or storage temperature conditions are not maintained, please contact 360 representatives.

8.3 CLEANING – AUTOMATED METHOD (INSTRUMENTS)

1. Manual pre-cleaning:
    - IS NOT REQUIRED if the instruments do not have dried-on visible debris. Proceed to step 2.
    - IS REQUIRED if the instruments have dried-on visible debris. Follow the manual pre-cleaning steps below prior to proceeding to step 2.
        a. Rinse instruments under running cold tap water for a minimum of one (1) minute. Remove gross debris using a soft-bristled brush.
        b. Immerse and soak instruments for a minimum of five (5) minutes in enzymatic detergent. Use a soft-bristled nylon brush to remove visible debris from challenging design features. Actuate joints, handles and other movable device features to expose all areas to detergent solution, if applicable.
        c. Rinse instruments under running cold tap water for a minimum of one (1) minute, ensuring that running water passes through cannulations and that blind holes are repeatedly filled and emptied.
        d. Pour a prepared neutral pH cleaning solution into a sonication unit and completely submerge each instrument in the solution and sonicate for 10 minutes at 40-50 kHz.
        e. Rinse instruments in purified water for at least three (3) minutes.
        f. Visually inspect instruments. Repeat steps a-f until no visible soil remains on instruments.

    NOTE: Devices / Instruments must be removed from Instrument Trays or any other packaging for manual and/or automated cleaning procedures.

    NOTE: Do not conduct automatic cleaning for Fiducials and fiducial wrench from CAS STERRAD® Fiducial Caddy.

2. Prepare KIC-DND-0102 CAS Small Instruments Tray, KIC-DND-0142 Action Pointer, KIC-DND-0103 CAS General Instruments Tray, KIC-DND-0126 CAS Instruments Tray SET-0015, KIC-DND-0147 360CAS Enovis Single Knee Tray (empty, without 360CAS Surgical Instruments).
3. Transfer each instrument and instrument tray to the automatic washer.

    NOTE: Instrument trays and lids should be cleaned separately.
4. Select the cycle parameters as listed in **Table 3** below.

Table 3: Parts Washer Cleaning Parameters

Phase	Recirculation Time (Minutes)	Temperature	Detergent Type and Concentration (If Applicable)
Pre-Wash 1	02:00	Cold Tap Water	N/A
Wash 1	02:00	65°C/149°F Tap Water	Enzymatic Detergent
Rinse 1	05:00	43°C Tap Water	N/A
Thermal Disinfection	01:00	82.2°C/180°F RO/DI Water	N/A
Drying	07:00	115°C/239°F	N/A

8.4 CLEANING – MANUAL (NAVIGATION CART)

Manual cleaning is recommended for the Navigation Cart and all components housed within the Navigation Cart. Suggested cleaning suppliers for cleaning agents are listed in **Table 4** below.

DO NOT use solvents, lubricants, or other chemicals unless otherwise specified.

DO NOT allow moisture in any opening or on the power cables. Fluids/moisture may damage the electrical components. Spilling liquids on any electrical device attached to the system should warrant inspection by an authorised 360 Med Care service technician.

Table 4: Cleaning Agents		
Supplier	**Agent**	**Dilution**
Ecolab	Incidin®	2%
None	Isopropyl Alcohol	70%

1. Clean the whole surface of the Navigation Cart, Laptop, Monitor, only if required.
2. Carefully wipe all surfaces using a lint-free soft cloth dampened with a non-abrasive and mild detergent.
3. Do not use abrasive brushes or cloths when cleaning the Navigation Camera, Laptop or Monitor as these may scratch or otherwise damage the window.
4. Wipe the Navigation Camera, Laptop and Monitor with one of the approved cleaning solutions. Follow the manufacturers cleaning instructions.
5. Wipe the Navigation Camera window with a soft damp cloth to remove any residue left by the cleaner.
6. When the Navigation Camera is dry, confirm that the Navigation Camera lens is free from residue.

Do not use abrasive brushes or cloths. Use only approved cleaners to clean and disinfect the navigation camera.

8.5 POST-CLEANING PARTS INSPECTION

8.5.1 360CAS SURGICAL INSTRUMENTS

1. After cleaning, visually inspect the 360CAS Surgical Instruments under good light conditions for remaining debris.
2. Visually inspect each one of the cleaned parts for corrosion, damaged surfaces, soil accumulation, recessed features and cracks etc. Pay particular attention to the Trackers for damaged surfaces or moisture behind window(s).
3. Functionally inspect each one of the cleaned parts for mating and smooth operation.
4. Repeat the cleaning procedure, if required.

The end of component service life is normally determined by wear and damage due to use. If any one of the visual or functional inspections are deemed to fail, the failed part(s) must be immediately removed from service and 360 Med Care must be contacted to replace the defective part.

The maximum number of applications possible for reusable medical device depends on factors such as method and duration of each use, and handling between uses.

Articulating surfaces should be lubricated regularly with standard medical grade lubricants to ensure smooth operation.

8.6 STEAM STERILISATION

1. Place clean 360CAS Surgical Instruments that require steam sterilisation according to **Table 2** in their instrument tray. Trays shall be wrapped in standard medical grade, steam sterilisation wrap using the AAMI double wrap method or equivalent. Label the contents of the wrapped tray using an indelible marker or sterilisation compatible label system.
2. Refer to the following **Table 5** for recommended minimum sterilisation parameters that have been validated by 360 to provide a 10^{-6} sterility assurance level (SAL).
3. The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned. Instruments must be disassembled and packaged in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.
4. Moist heat/steam sterilisation is the recommended and validated method for 360KS instrument sets.
5. The sterilising unit manufacturer's recommendations should always be followed. When sterilising multiple instrument sets in one sterilisation cycle, ensure that the manufacturer's maximum load is not exceeded.
6. Ethylene oxide (EO) or gas plasma sterilisation methods should not be used.
7. Local or national specifications may be followed where steam sterilisation requirements are stricter or more conservative than those listed in **Table 5** It is then the responsibility of the user to validate the specification.
8. Drying times vary according to load size and should be increased for larger loads.

Table 5: Steam Sterilisation Cycle Parameters		
Pre-vacuum Autoclave Cycle		
Temperature	**Exposure Time**	**Dry Time**
132°C / 270°F	4 minutes	30 minutes

8.7 STERRAD® STERILISATION

1. Place clean Fiducials and fiducial wrench in KIC-DND-0125 CAS STERRAD® Fiducial Caddy which is suitable for STERRAD®.
2. Wrap the instrument tray with one sheet of 2-ply sterilization wrap or two sheets or 1-ply sterilization wrap and place within the sterilization chamber.
3. The Fiducials and fiducial wrench are to be sterilized using STERRAD® 100NX sterilization systems.
4. The general processing instructions in the "STERRAD® 100NX Sterilization System Operator's Manual(s)" should be followed.
5. Perform sterilisation of the Fiducial Caddy with the Fiducials and fiducial wrench in it using STERRAD® 100NX Express cycle.

NOTE: If suggested cleaning, drying or storage temperature conditions are not maintained please contact 360 representatives.

8.8 POST-STERILISATION PARTS INSPECTION

1. After sterilisation, visually inspect the 360CAS Surgical Instruments under good light conditions for remaining debris.
2. Visually inspect each one of the sterilised parts for corrosion, damaged surfaces, soil accumulation, recessed features and cracks etc. Pay particular attention to the Trackers for damaged surfaces or moisture behind window(s).
3. Functionally inspect each one of the sterilised parts for mating and smooth operation.
4. Repeat the cleaning and sterilisation procedure, if required.

The end of component service life is normally determined by wear and damage due to use. If any one of the visual or functional inspections are deemed to fail, the failed part(s) must be immediately removed from service and 360 Med Care must be contacted to replace the defective part.

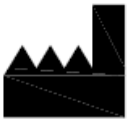
The maximum number of applications possible for reusable medical device depends on factors such as method and duration of each use, and handling between uses.

9 SYMBOLS

Symbols with a reference number in **Table 6** have been sourced from BS EN ISO 15223-1:2021 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – General Requirements.

Table 6: Symbols Glossary					
 5.1.7	Serial Number	**Rx ONLY**	Prescription Use	 5.3.4	Keep Dry
 5.1.5	Batch code	 5.2.8	Do not use if package is damaged	 5.1.1	Manufacturer
 5.4.4	Caution	 5.1.3	Date of manufacture	 5.4.3	Consult instructions for use
 5.1.6	Catalogue Number	 5.3.1	Fragile, handle with care	 5.3.2	Keep away from sunlight

10 MANUFACTURER CONTACT DETAILS



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

11 US SALE OF 360CAS

Caution: Federal law restricts this device to sale by or on the order of a physician.

This document is intended for the US market only.