Attention Operating Surgeon
IMPORTANT Please read carefully before using this product

DESCRIPTION
The Corin Optimized Positioning System (OPS™) consists of software and hardware components to assist the surgeon in the alignment of components during Total Hip Arthroplasty.

The software component assists the surgeon in **determining a patient specific target orientation** for the acetabular cup through a pre-operative patient specific analysis: OPSInsight™ (K192656) or OPS Functional Hip Analysis (FHA) (K190834), as selected by the surgeon. A Patient Specific Visualisation (PSV) Report is also provided to allow 3D visualization of the Patient Specific Instruments (PSI) Guides and Bone Models.

The hardware components assist the surgeon in **delivering the target orientation** through the use of a Patient Specific Guide and bone model (replica of the patient's acetabulum, into which the guide fits), and associated reusable instrumentation.

The Corin OPS™ is only for use with the Trinity Acetabular System and the respective compatible components.

MATERIAL
Polyamide

INDICATIONS FOR USE
The Corin Optimized Positioning System (OPS™) is intended to be used as patient-specific surgical instrument to assist in the alignment of components during total hip arthroplasty. The Corin OPS™ is intended to assist in the orientation of the acetabular cup intra-operatively using anatomical landmarks of the pelvis that are clearly identifiable on preoperative X-rays and CT imaging scans.

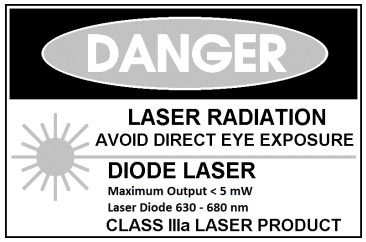
The Corin OPS™, including the Patient Specific Guide, is intended for use with the Corin Trinity™ Acetabular System (K093472, K110087, K111481, K122305, K123705, K130128, K130343 and K131647) for total hip arthroplasty.
The Corin Optimized Positioning System is intended for use with the Direct Anterior or Posterolateral surgical approaches.
The Patient Specific Guides are intended for single use only.

CONTRAINDICATIONS
The Corin OPS™, including the Patient Specific Guide, is contraindicated for:
- Patients in which total hip arthroplasty is contraindicated
- Patients with significant orthopaedic deformities, (e.g. fused knee, hip or ankle) anatomical disruption or distortion of the pelvis
- Patients who are unable to comply with imaging requirements
- Patients currently receiving ionising radiation treatment or scans for other medical conditions
- Patients with insufficient bone structure or quality, which may not allow for rigid attachment of instruments
- Other disorders that affect pelvic anatomy and bony landmark recognition
- Patients with active infection
- Any other implant system apart from the Corin Trinity™ Acetabular System referenced above.

WARNINGS AND PRECAUTIONS
1. Ensure that the focal points from the two laser components converge at the exact same point. Non-convergence of the laser focal points can lead to inaccurate results in obtaining the pre-operatively desired acetabular cup orientation.
2. In case the guide is dropped, the device should be carefully inspected for any cracks or fracture to ensure the guide has not been damaged. The guide should only be used after second sterilization if there was no cracking/fracture observed in the guide (for example due to dropping).
3. Patient specific guides are suitable for up to two sterilization cycles. Guides should not be sterilized more than twice.
4. In the event of any kind of hardware failure, including cracking/fracture/breakage of the guide (for example, due to dropping of the guide) or intraoperative loosening of the pelvic screw, the surgeon should use the standard surgical technique for the Trinity™ Acetabular System without the use of Optimized Positioning System.
5. The user should be aware of possible allergic reactions to materials used in the instrument. The patient should be informed on this matter by the user.
6. The Guide's patient specific identifiers are to be checked for readability and confirmed by the surgeon before use.
7. Use of this device is restricted to registered orthopaedic surgeons. This device should only be used in a sterile operating room of an accredited hospital.
8. Device is single use only. Do not attempt to re-clean or re-sterilize this product for anyone other than the originally-intended patient. After use, this product may be a potential biohazard.
9. Errors of operative technique and improper positioning or inadequate assembly of Optimized Positioning System components may result in limb length discrepancies and/or failure to implant the acetabular component in the desired orientation.
10. Ensure that the patient is adequately strapped such that the position of the patient and pelvis does not move during the procedure.
11. Any movement of the patient, pelvis or the focal point of the reference laser will introduce error in terms of obtaining the pre-operatively determined orientation of the acetabular cup and therefore affect the accuracy of the device.
12. The Patient Specific Guides are custom made and must only be used for the individual identified on the packaging and on the part.
13. If the patient's anatomy has changed significantly since the time of the X-rays and CT imaging scans, the Patient Specific Guides should not be used.
14. The Patient Specific Guides need to be used within the specified expiry date.
15. Store Patient Specific Guides in a properly cleaned and dry place.
16. The instrument should be properly cleaned before sterilization.
17. Open, clean and sterilize immediately prior to surgery.
18. Do not use if the Patient Specific Guide is broken, cracked, or if loose powder is present.
19. The Patient Specific Guides should not be modified or altered in any way.
20. The surgeon should be familiar with the appropriate surgical technique(s) specific to the joint replacement implants utilized in conjunction with the Patient Specific Guides.
21. All trial, packaging, and instrument components must be removed prior to closing the surgical site; do not implant.

LASER SAFETY WARNINGS AND PRECAUTIONS
- Class IIIa lasers are utilised in the Optimized Positioning System.
- Laser units and batteries are SINGLE USE and are not suitable for re-use.
- Clean before use. Refer to LASER ASSEMBLY AND USE instructions.
- DO NOT sterilize the laser units.
- Laser radiation is harmful to the eye, avoid direct eye exposure.
- Laser protection eyewear should be worn to prevent eye injury.
- Do not point the laser beam at anyone's eyes.
- Do not shine onto reflective surfaces.
- Use lasers only for the purpose stated in the OPS surgical technique.
- To prevent misuse, please ensure lasers are disposed after use.

- Refer to the laser unit safety instruction.
- This device requires the use of diode lasers



LASER ASSEMBLY AND USE

The lasers are supplied non-sterile and are not suitable for sterilization. The lasers must be housed in the sterile laser canister assembly provided.

To ensure the sterile field is not breached the following procedure is recommended prior to use:

1. While wearing gloves, wipe the external surfaces of the laser with isopropyl alcohol (70% w/w). Use caution when cleaning as fluid ingress may damage the laser unit.
2. Inside the sterile field, operating theatre personnel present the laser canister ready to accept the laser.
3. Theatre personnel outside of the sterile field pass the laser into the sterile field and carefully place the laser into the laser canister, avoiding any contact with personnel or instruments inside the sterile field.
4. Once the laser is inserted into canister, the canister cap is screwed on securely by personnel within the sterile field. The laser should now be permanently on, and the laser dot should be visible across the theatre with the naked eye.

Two laser canister assemblies are required for the OPS procedure. An additional canister assembly is supplied as a spare in case of breach to sterility.

ADVERSE REACTIONS

Complications can potentially occur following any joint replacement surgery. The following complications have occurred in some patients after their hip joint replacement surgery.

1. Infection, venous thrombosis, pulmonary embolism, cardiovascular disturbances, vascular or nerve injury, osteolysis, periarticular ossification, allergy and/or pain following the procedure.
2. Introduction of foreign materials can result in an inflammatory response or allergic reaction.
3. Wound dehiscence.
4. Nerve damage.

See also possible Adverse Effects associated with total hip replacement in general and those associated with the hip replacement system utilized in conjunction with the Patient Specific Guides.

STERILITY AND CLEANING

Patient Specific Guides

The Patient Specific Guides, single use instruments, are provided to the hospital non-sterile and should be cleaned and sterilized according to the Corin cleaning instructions supplied.

Cleaning

The patient specific instruments can be cleaned using manual cleaning and/or automated cleaning in a washer/disinfector with manual pre-cleaning and ultrasonic cleaning. Use only validated washer-disinfector machines and cleaning agents, following the manufacturers' instructions for use, warnings and recommended cycles. Load patient specific instruments carefully into a wire basket. Place instruments with concave surfaces facing down to prevent pooling of water.

Manual Cleaning

Step	Cleaning Instructions
1	Prepare the neutral or near neutral (pH 7-9.5) detergent and/or enzymatic cleaner according to the manufacturer's recommendations. The detergent or enzymatic cleaner must be non-abrasive, and be low-foaming.
2	Immerse the device in the prepared detergent and allow to soak for 3 minutes.
3	Scrub the device using an appropriate size soft-bristled nylon brush, paying particular attention to crevices and other hard to reach areas ensuring that non-visible contaminations are present.
4	Remove the device from the solution and rinse under ambient temperature running water (deionized (DI) or purified water (PURW)) for at least 2 minutes
5	Dry the device using a clean, soft, lint-free cloth. The cloths used should be absorbent and not disintegrate during use

Manual pre-cleaning

Step	Minimum	Cleaning instructions
1	1 minute	Rinse the guide or model under running cold tap water.
2	2 minutes	Manually clean the guide or model in a newly-made enzymatic cleaner or detergent solution
3	1 minute	Rinse the guide or model using cool to lukewarm running tap water. Use a syringe, pipette or water pistol to flush cylinders, slots, and other hard-to-reach areas
4	15 minutes	Clean the guide or model ultrasonically per manufacturer's recommended temperature (usually 32°-60°C or 90°-140°F) and specially formulated detergents. Follow manufacturer's recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners and medical equipment.
5	2 minutes	Rinse the guide or model using DI or PURW. Use a syringe, pipette, or water pistol to flush cylinders, slots, and other hard-to-reach areas.

Automated cleaning in a washer/disinfector:

Step	Minimum	Cleaning instructions
Pre-wash	2 minutes	Cold tap water
Wash	10 minutes	Warm tap water (>40°C); use detergent
Neutralize	2 minutes	Warm tap water with neutralizer, if necessary
Rinse	2 minutes	Rinse with warm DI or PURW (>40°C)
Thermal disinfection	7 minutes	At minimum 94°C
Dry	40 minutes	At minimum 90°C

Sterilization

Single use instruments should be removed from their packaging prior to cleaning and sterilization. The following sterilization method has been validated, based on AAMI/ANSI/ISO guidelines and recommendations:

- Cycle: Pre-Vacuum (Pre-Vac)
- Temperature: 270° F (132° C)

- Exposure Time: 4 minutes
- Dry-Time: 30 minutes (minimum, in chamber)

Ethylene Oxide (EtO) sterilization and cold sterilization techniques are not recommended. Patient Specific Guides are not tested and do not claim to be "pyrogen free".

Re-useable Instruments

The re-usable instruments used with the Optimized Positioning System are supplied non-sterile and should be cleaned and sterilized according to the Corin cleaning instructions supplied.

After cleaning and prior to sterilization, the reusable device(s) should be double-wrapped or packaged in FDA-cleared CSR sterilization wraps or pouches. Wrapping should be performed using the appropriate wrapping method (e.g. AAMI CSR wrapping technique). The following sterilization method has been validated, based on AAMI/ANSI/ISO guidelines and recommendations:

- Cycle: Pre-Vacuum (Pre-Vac)
- Temperature: 270° F (132° C)
- Exposure Time: 4 minutes
- Dry-Time: 30 minutes (minimum, in chamber)

Ethylene Oxide (EtO) sterilization and cold sterilization techniques are not recommended.

The information contained in this package insert was current on the date it was issued but the package insert may have been revised after that date. To obtain a current package insert, please access via electronic portal.

Symbols Glossary

Symbol	Reference	Symbol Title	Description
	ISO 15223-1 Symbol 5.4.2	***Do not reuse***	Indicates a medical device that is intended for one use only, or for use on a single patient during a single procedure.
	ISO 15223-1 Symbol 5.2.8	***Do not use if package is damaged***	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1 Symbol 5.4.4	***Caution***	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 15223-1 Symbol 5.4.3	***Consult instructions for use***	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 Symbol 5.1.1	***Manufacturer***	Indicates the medical device manufacturer, as defined in EU Regulations 2017/745 and 2017/746.
	ISO 15223-1 Symbol 5.1.3	***Date of manufacture***	Indicates the date when the medical device was manufactured.
LOT	ISO 15223-1 Symbol 5.1.5	***Batch code***	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Symbol 5.1.4	***Use-by date***	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 Symbol 5.3.1	***Fragile, handle with care***	Indicates a medical device that can be broken or damaged if not handled carefully.
	ISO 15223-1 Symbol 5.3.4	***Keep dry***	Indicates a medical device that needs to be protected from moisture.
EC REP	ISO 15223-1 Symbol 5.1.2	***Authorised Representative in the European Community***	Indicates the authorised representative in the European Community.
	ISO 7000 Symbol 3725	***Importer [in the European Community]***	To indicate the entity importing the medical device into the locale.
CE 2797	Medical Device Regulation (MDR) – Annex V	***CE Mark***	CE marking of conformity accompanied by the identification number of the notified body (2797 = BSI Group, The Netherlands).
NON STERILE	ISO 15223-1 Symbol 5.2.7	***Non-Sterile***	To indicate that the device that is normally provided sterile in the same or similar packaging has not been sterilized.
	ISO 15223-1 Symbol 5.3.3	***Protect from heat and radiation***	To indicate that the contents of the package may deteriorate or be rendered totally unusable by heat or ionizing radiation and must be protected from these.
CH REP	ISO 15223-1 Symbol 5.1.2	***Authorised Representative in Switzerland***	Indicates the authorised representative in Switzerland.
MD	ISO15223-1 Symbol 5.7.7	***Medical Device***	Indicates the item is a medical device.
UK CA	MHRA Guidance, Regulating Medical Devices in the UK	***UKCA***	Indicates that the device has been UK Conformity Assessed.
	ISO15223-1 Symbol 5.7.2	***Patient Name***	Indicates the name of the patient.
	ISO15223-1 Symbol 5.7.5	***Health care centre or Doctor***	Indicates the address of the health care centre or doctor where medical information about the patient may be found.

Standards References

ISO 15223-1 *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*
ISO 7000 *Graphical symbols for use on equipment — Registered symbols*
21 CFR ***FDA*** *Code of Federal Regulations Title 21: Food and Drugs*

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