Attention Operating Surgeon
**IMPORTANT Please read carefully before using this product**

**GENERAL DOCUMENT OVERVIEW**
This document contains general instructions for use of the OPS™ Femoral Patient Specific Instruments (PSI).
The Corin OPS™ Femoral PSI, consisting of guides and bone models, are patient specific devices designed to fit, or represent, the patient's anatomy for use in Total Hip Arthroplasty.

**DESCRIPTION**
The Corin Optimized Positioning System (OPS™) Femoral consists of Femoral Patient Specific Instruments (PSI) and reusable instrumentation. The Femoral Patient Specific Instruments include a Femoral Guide and an optional Trial Femoral Head (Bone Model).

The Femoral Guide is shape-matched to the patient's femoral anatomy and provides a guide for the femoral neck osteotomy during total hip arthroplasty.

The Corin OPS™ Femoral PSI is available in two variants:

- Dislocating Femoral Guide (Suitable for the posterolateral approach): The dislocating Femoral Guide is designed to sit on the posterior aspect of the femoral head when the femoral head is exposed by intraoperative dislocation.
- In-situ Femoral Guide (Suitable for the direct anterior approach): The in-situ Femoral Guide is designed to sit on the anterior head-neck junction of the proximal femur when the femoral neck is exposed intraoperatively with the femoral head located within the acetabulum.

**Indications for Use**
The Corin OPS™ Femoral is intended to be used as a patient-specific surgical instrument to assist the surgeon in delivering a target femoral neck osteotomy, based on a pre-operative plan with implant sizing, type and placement.

The Corin OPS™ Femoral is intended to be used with OPS™ Insight (K192656), Corin OPS™ Plan (K171847,K183038) and the compatible components. The dislocating Femoral Guide is intended for use with the posterolateral surgical approach and the in-situ Femoral Guide is intended for use with the direct anterior surgical approach.

The Corin OPS™ Femoral PSI is intended for single use only.

**MATERIAL**
The Corin Optimized Positioning System™ Femoral Patient Specific Instruments are made of polyamide (Nylon 12).

**PATIENT SPECIFIC INSTRUMENT IDENTIFIERS**
A unique identifier is indicated on each guide and model within the PSI. This alphanumeric code links the PSI unambiguously to the patient case and is specified on the device labelling. In the event of a bilateral surgery, the unique identifier will be issued for each side separately. Before using the guide, check the unique identifier for readability and confirm that it corresponds with the identifier listed on the device labelling.

**CONTRAINDICATIONS**
The Corin OPS™ Femoral is contraindicated for:

- Patients in which total hip arthroplasty is contraindicated
- Patients with insufficient bone structure or quality, which may not allow for rigid attachment of instruments
- Other disorders that affect hip anatomy and bony landmark recognition

**WARNINGS AND PRECAUTIONS**
1. Use of this device is restricted to registered orthopaedic surgeons. This device should only be used in a sterile operating room of a hospital.
2. The surgeon should be familiar with the appropriate surgical technique(s) specific to the joint replacement implants utilised in conjunction with the Patient Specific Instruments.
3. Errors of operative technique and improper positioning or inadequate assembly of OPS™ Femoral components may result in limb length discrepancies and/or failure to implant the femoral components in the desired position.
4. The OPS Femoral is not intended for anterolateral approach.
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. Store the Patient Specific Instruments in a properly cleaned and dry place.
7. The Patient Specific Instruments need to be used within the specified expiry date. The Patient Specific Instruments expiry date is 6 months from the date of CT.
8. The Patient Specific Instruments shall be properly cleaned before sterilization.
9. Open, clean and sterilize immediately prior to use.
10. The Patient Specific Instruments should not be modified or altered in any way.
11. The Patient Specific Instruments' specific identifier, implant system and reference markings are to be checked for readability and confirmed by the surgeon before use.
12. The Patient Specific Instruments 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 patient imaging, the Patient Specific Instruments should not be used.
14. Do not use if the Patient Specific Instruments are broken, cracked, or if loose powder is present.
15. In case a Patient Specific Instrument is dropped, the device should carefully inspected for any cracks or fracture to ensure it has not been damaged. The PSI should only be used after second sterilization if there was no cracking/fracture observed in the PSI (for example due to dropping).
16. Patient Specific Instruments are suitable for up to two sterilization cycles. Instruments should not be sterilized more than twice.
17. The patient specific Femoral Guide is designed to fit patient anatomy. Do not use the patient specific Femoral Guide if full surface contact is not achieved between the Femoral Guide and the underlying patient's anatomy.
18. 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 pin, the surgeon should use the standard surgical technique for performing the femoral neck osteotomy without the use of the OPS™ Femoral.
19. The site should be washed prior to closure to avoid incidental debris remaining in the wound.
20. All trial, packaging, and instrument components must be removed prior to closing the surgical site; do not implant.
21. 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.
22. Errors of operative technique and improper positioning of OPS™ Femoral Patient Specific Instruments may affect accuracy of the delivered osteotomy level.
23. Ensure the Femoral Guide maintains its position on the patient anatomy while performing the osteotomy.

**CLEANING AND STERILIZATION INSTRUCTIONS**

The Patient Specific Instruments, designed for single use, 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 |

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

- Method: Moist-Heat Sterilization
- 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 Instruments are not tested with these techniques and do not claim to be "pyrogen free".

**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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