Attention Operating Surgeon
IMPORTANT Please read carefully before using this product

MD

GENERAL DOCUMENT OVERVIEW
This document contains instructions for use for the Patient Specific Instruments (PSIs) of the Corin Optimized Positioning System™ (OPS™) delivery systems, including the OPS™ Acetabular Delivery System and the OPS™ Femoral Delivery System. The PSIs consist of guides and bone models that fit, or represent, the patient's anatomy and assist in the alignment of components during Total Hip Arthroplasty (THA).

The PSIs are intended to be used in conjunction with reusable instruments specifically designed for this purpose. Refer to OPT-REC-RA-58 for the surgical technique for safe use of OPS Instruments. For instruction specific to the reusable instrumentation, refer to OPT-REC-RA-57 *Reprocessing of Reusable Instruments* for the OPS™ Acetabular Delivery System and refer to OPT-EXD-RA-15 *Instrument Care, Cleaning and Sterilisation Instructions* for OPS™ Femoral Delivery System.

A Patient Specific Visualisation (PSV) Report is part of the device labelling and provides the surgeon with a 3D visualisation of the PSI guides and bone models. The PSV is provided to the surgeon in a portable document format (PDF).

OPS™ ACETABULAR DELIVERY SYSTEM
DESCRIPTION
Corin OPS™ Acetabular Delivery System consists of a patient specific Acetabular Guide and corresponding Bone Model (Trial Acetabulum) (replica of the patient's acetabulum, into which the guide fits), as well as associated reusable instrumentation.

The Acetabular Guide is shape-matched to the patient's acetabular anatomy and uses reference lasers together with the reusable instrumentation to provide a guidance system to achieve a pre-operatively defined orientation of the acetabular component. Refer to OPT-REC-RA-58 for the surgical technique for safe use of the system. The planned cup orientation is defined by the compatible pre-operative planning tools used by the surgeon. The system is suitable for use when there is clear axial access to the patient's acetabulum e.g., as is standard practice for Direct Anterior, Posterolateral and Anterolateral surgical approaches.

The OPS Acetabular Delivery System has been demonstrated to deliver a more accurate cup orientation than conventional freehand techniques. More accurate reproduction of the planned cup orientation aids in reducing the rates of dislocation and edge loading.

INTENDED USE AND INDICATIONS FOR USE
The Corin OPS Acetabular Delivery System is intended to be used as a patient specific surgical instrument to assist the surgeon in achieving a planned acetabular cup orientation. The Patient Specific Guides and Bone Models are intended for single use only.

The Corin OPS Acetabular Delivery System is indicated for use in primary THA, where a target acetabular cup orientation has been established using a compatible Corin pre-operative planning tool.

CONTRAINDICATIONS
The Corin OPS™ Acetabular Delivery System are contraindicated for:
•Patients in which THA is contraindicated
•Patients with insufficient bone structure or quality, which may not allow for rigid attachment of instruments
•Cases where a pre-operative plan cannot be established

⚠ **WARNING AND PRECAUTIONS**
1. Ensure that the focal points from the two laser components converge at the same point. Non-convergence of the laser focal points can lead to inaccurate results in obtaining the pre-operatively desired acetabular cup orientation.
2. Movement of the patient or pelvis may alter the focal point of the reference laser and will introduce error in terms of obtaining the pre-operatively determined orientation of the acetabular cup.
3. Ensure the Acetabular Guide maintains its position within the patient acetabulum while setting the reference laser. Any movement may impact the achieved cup orientation.
4. Removal of osteophytes from the acetabulum may impact the fit of the Acetabular Guide and lead to unpredictable results.
5. All soft tissue should be removed from the contact area between the patient's acetabulum and the guide to ensure the guide can be seated properly.
6. The position of the Acetabular Guide within the patient's anatomy must match the position of the guide in the Trial Acetabulum. Note that the correct position of the support arms of the guide are marked in the Trial Acetabulum.
7. The orientation of the guide is defined by the pre-operative plan. Final decisions regarding choice of implant and component positioning/alignment should be made according to the surgeon's standard technique.

OPS™ FEMORAL DELIVERY SYSTEM
DESCRIPTION
Corin OPS™ Femoral Delivery System consists of patient specific instruments; including a femoral cutting guide (Femoral Guide) and an optional replica proximal femoral bone model (Trial Femoral Head), and reusable surgical instruments; including headed fixation pins and associated driver.

The Femoral Guide is shape-matched to the patient's femoral anatomy and provides a guide for the femoral neck osteotomy during THA. The femoral pins can be used to rigidly fix the Femoral Guide to the patient anatomy. It is essential to use Corin approved femoral pins for this purpose. The planned femoral resection is defined by the compatible pre-operative planning tools used by the surgeon.

The Femoral Guide and Trial Femoral Head are patient specific devices available in two variants:
- Dislocating Femoral Guide is suitable for the posterolateral and anterolateral approaches and is designed to sit on the femoral head (extending down the proximal femur as required), when the femoral head is exposed by intraoperative dislocation.
- In-situ Femoral Guide is suitable for the direct anterior and anterolateral approaches and is designed to sit on the anterior aspect of the proximal femur where the femoral head-neck junction is exposed intraoperatively while the femoral head remains located within the acetabulum. Due to the smaller profile of the In-Situ Guide and limited access to the proximal femur, a Trial Femoral Head is provided for each case as a reference of the patient's anatomy.

The OPS Femoral Delivery System has been demonstrated to deliver a more accurate osteotomy than conventional freehand techniques. More accurate reproduction of the planned osteotomy aids in more precise restoration of leg length and offset.

INTENDED USE AND INDICATIONS FOR USE
Corin OPS™ Femoral Delivery System 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 compatible pre-operative planning tool. The Patient Specific Guides and Bone Models are intended for single use only.

The Corin OPS™ Femoral Delivery System is indicated for use in primary THA, where a target femoral neck osteotomy has been established using a compatible pre-operative planning tool.

CONTRAINDICATIONS
The Corin OPS™ Femoral Delivery System are contraindicated for:
•Patients in which THA is contraindicated
•Patients with insufficient bone structure or quality, which may not allow for rigid attachment of instruments
•Cases where a pre-operative plan cannot be established

⚠ **WARNING AND PRECAUTIONS**
1. Failure to follow the operative technique and/or achieve proper positioning of the PSI may result in sub-optimal osteotomy level.
2. Ensure the guide maintains its position on the patient anatomy while performing the osteotomy.
3. Osteophytes on the proximal part of the femur should not be removed before positioning the guide.
4. The femoral guide has been designed to be used with a standard surgical sawblade of up to 1.5mm thickness. Thicker sawblades could result in a more distal than intended osteotomy.
5. The surgical sawblade should run parallel and flush along the distal part of the guide during femoral resection else a sub-optimal osteotomy level may be achieved.
6. The femoral guide may include a step cut blocker that indicates a step cut is required to avoid cutting the greater trochanter.
7. The osteotomy level of the guide is defined by the preoperative plan. Final decisions regarding choice of implant and component positioning/alignment should be made according to the surgeon's standard technique.
8. Use of non Corin approved femoral pins can result in unintentional injury to anatomical structures below the femoral head.

GENERAL INFORMATION FOR OPS™ ACETABULAR and FEMORAL DELIVERY SYSTEMS

MATERIAL
The Corin OPS™ Acetabular Delivery System and OPS™ Femoral Delivery System PSIs are made of polyamide.

EXPECTED DEVICE LIFETIME
The OPS™ Acetabular Delivery System and OPS™ Femoral Delivery System PSIs are single use, non-sterile instruments which have a shelf-life of six months post the date of the pre-operative imaging on which they are based.

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.

⚠ **GENERAL 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) (OPT-REC-RA-58) specific to the joint replacement implants utilised in conjunction with the PSI.
3. Errors of operative technique and improper positioning or inadequate assembly of OPS™ components may result in limb length discrepancies and/or failure to implant the acetabular and femoral components in the desired orientation and position.
4. 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.
5. Store the PSI in a properly cleaned and dry place.
6. The PSI need to be used within the specified expiry date.
7. The PSI shall be properly cleaned before sterilisation.
8. The device must be cleaned and sterilised prior to use.
9. The PSI should not be modified or altered in any way.
10. The PSI's specific identifier, implant system and orientation (if applicable) are to be checked for readability and confirmed by the surgeon before use. If these cannot be confirmed, the PSIs should not be used.
11. The PSI's reference markings used for indicating anatomical references are to be checked for readability and confirmed by the surgeon before use. If these cannot be confirmed, the PSIs should not be used.
12. The PSI must only be used for the individual identified (Case ID#) on the packaging and on the part for whom the pre-operative planning has been carried out. Use on a different patient will lead to unpredictable hip replacement outcomes.
13. If the patient's anatomy has changed significantly since the time of the X-rays and CT imaging scans, the PSI should not be used.
14. Do not use if the PSI are broken, cracked, or if loose powder is present.
15. PSI are not suitable for more than one sterilisation cycle and should not be re-sterilised.
16. The patient specific guide is designed to fit patient anatomy. Do not use the patient specific guide if full surface contact is not achieved between the guide and the underlying patient's anatomy. The PSV report can be used to visualise the intended guide fit.
17. 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 implant system without the use of the OPS™ Delivery System.
18. The PSI may be subject to abrasive forces during normal use that can generate debris. The site should be washed prior to closure to avoid incidental debris remaining in the wound.
19. All trial, packaging, and instrument components must be removed prior to closing the surgical site; do not implant.
20. Device is single use only. Do not attempt to re-clean or re-sterilise this product. After use, this product may be a potential biohazard and must be disposed of appropriately according to the hospital's procedure of biohazard waste disposal.
21. Any serious incident that has occurred in relation to the device should be reported to Corin and the National Regulatory Authority of the region in which the user and/or patient is established.

ADVERSE REACTIONS

Possible inflammatory response or allergic reaction to polyamide.

Complications can potentially occur following any hip replacement surgery. See also possible Adverse Effects associated with THA in general and those associated with the hip replacement system utilised in conjunction with the Patient Specific Instruments.

CLEANING AND STERILISATION INSTRUCTIONS

The Patient Specific Instruments, designed for single use, are provided to the hospital non-sterile and should be cleaned and sterilised according to the cleaning instructions supplied below.

CLEANING
The patient specific instruments can be cleaned using the manual and/or automated cleaning method described below.

Manual Cleaning

Step	Minimum	Cleaning Instructions
1 - Setup	N/A	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 - Soak	3 minutes	Immerse the device in the prepared detergent and allow to soak for 3 minutes.
3 - Scrub	N/A	Scrub the device using an appropriate size soft-bristled nylon brush, paying particular attention to crevices and other hard to reach areas ensuring that no visible contaminations are present. Frequently dip the device back in to the cleaning solution during cleaning
4 - Rinse	2 minutes	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	N/A	Dry the device using a clean, soft, lint-free cloth. The cloths used should be absorbent and not disintegrate during use.

Automated Cleaning

- The washer/disinfector manufacturer's instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfector. A washer/disinfector with approved efficacy (e.g., CE mark, FDA approval, and validation according to ISO 15883) should be used.
- Only agents with proven efficacy (FDA approved, VAH listed, or CE mark) should be used. As a large variety of cleaning agents and disinfectants exists around the globe, Corin does not recommend any specific brand.
- Alkaline enzymatic cleaning agents with low foaming surfactants are recommended.

Pre-cleaning instructions:

Step	Minimum	Cleaning Instructions
1 - Rinse	1 minute	Rinse in cold water (<43°C) until gross debris is removed. Thoroughly flush lumens, holes and other difficult-to-reach areas
2 - prepare	N/A	Place prepared cleaning agents in a sonication unit. Completely submerge device in ultrasonic bath with enzymatic detergent solution
3 - Sonicate	10 minutes	Sonicate for 10 minutes at 40-50 kHz.
4 - Rinse	1 minute	Remove device from solution and rinse with purified (demineralised) water for 1 minute in sink: thoroughly flushing out any crevices, lumens and other hard-to-clean areas.
5 - Inspect	N/A	If any visible soil remains, then brush gently to remove from the device and then repeat step 1 through 4

Automated cleaning instructions:

Step	Minimum	Cleaning Instructions
1 – Prewash	2 minutes	Prewash at ≥45°C with alkaline enzymatic detergent
2 – Cleaning cycle	5 minutes	Cleaning cycle at ≥55°C with alkaline enzymatic detergent
3 – Rinse	2 minutes	Rinse with purified water
4 – Disinfect	≥1 minute	Disinfection at 90°C with hot purified water for either (based on local requirements) a minimum of ≥1 minute until A_0 600 is reached, or up to ≥ 5 min until A_0 3000 is reached
5 - Dry	≥22 minute	Hot air drying at ≥100°C

STERILISATION

Single use instruments should be removed from their packaging prior to cleaning and sterilisation. The following sterilisation methods have been validated to provide a sterility assurance level of 10^{-6}:

Note: Sterilize in a steam autoclave conforming to BS EN 285:2015 at a holding temperature of 134°C to137°C for 3 minutes or 132°C for 4 minutes as per below table. Steam sterilization is validated to recognised consensus standard EN 17665-1:2006 and adheres to guidelines in AAMI TIR12:2010, ISO 17664:2004 and ISO 11138-3.

Cycle Type	Temperature	Minimum Exposure time	Minimum Dry Time	Minimum Cool Time
UK Prevacuum/ Pulsating Vacuum	134 - 137˚C / 273 - 279˚F	3 minutes	30 minutes	60 minutes
Prevacuum/ Pulsating Vacuum	132˚C / 270˚F	4 minutes	30 minutes	60 minutes

The single use instruments should be wrapped in two single layer wraps or one double bonded layer sterilisation wrap that is compatible with heavy instrument sets and steam sterilisation. This is required after cleaning and prior to sterilisation. The wrap should be CE marked or be FDA approved. Wrapping should be performed using the appropriate wrapping method (e.g. AAMI CSR wrapping technique). Ensure instruments are dry before sterilisation.

Ethylene Oxide (EtO) sterilisation and cold sterilisation techniques are not recommended. Patient Specific Instruments are not tested 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.
	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*
- Medical Device Regulation (EU) 2017/745
- 21 CFR FDA Code of Federal Regulations Title 21: Food and Drugs
- ISO 17665-1 Sterilization of health care products - Moist heat - Development validation and control of sterilization process

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