Product overview and surgical technique
Overview

Every patient moves differently¹ and their total hip replacement should be optimized to account for this.

The orientation of the acetabular cup is one of the most important factors under the surgeon’s control², and acetabular cup orientation has a significant effect on device performance, including patient outcomes, impingement, edge loading, bearing wear, osteolysis and loosening³⁻⁴.

There remains two key issues with THR today:

1. What is the target for a well orientated cup?
2. Are we able to achieve that orientation?

Clinical issue

Safe zones
There have been various attempts to define a ‘safe zone’ for the orientation of an acetabular cup, and increasing evidence to suggest that one generic zone is not applicable⁵⁻⁷⁻⁸⁻⁹.

Pelvic tilt
Pelvic tilt is an important consideration for a patient’s physiological profile, and the arc of pelvic motion in some patients can be as mobile as 70° and in others as stiff as 5° during functional activities¹⁰. This can have significant impact on the functional orientation of the acetabular cup.

Clinical solution

What is the optimal cup orientation for an individual patient?
OPS™ is a state-of-the-art technology platform that delivers potential target orientations unique for each individual. These target orientations are calculated from a pre-operative patient specific analysis, which accounts for the patient’s physiological profile throughout a range of daily activities.
Intra-operative tools

It is inherently difficult to position the cup during surgery and achieving a target position is a considerable challenge in THR. It has been shown that up to 50% of surgeries miss the intended orientation and the chance of hitting a target to within $5^\circ$ can be as low as 21.5%.

Clinical solution

How is the optimized position delivered during surgery?

Once the target orientation for a specific patient has been decided, a unique guide is produced for the individual. The planned orientation is built into the axis of the guide which is used intra-operatively with a simple laser system to allow the surgeon to deliver on the planned cup orientation.

The following surgical technique outlines this procedure.
Optimizing your practice

The Corin OPS™ is a state-of-the-art pre-operative planning technology and delivery system, designed to enable you to deliver on an optimized acetabular cup orientation for each of your patients.

Functional safe zone

Every patient moves differently, and a total hip replacement should be optimized to account for this. OPS™ is designed to identify and deliver a personalized implant orientation based on the functional movement profile of each patient.
Operative technique

1. Laser canister assembly
The lasers are supplied non-sterile and are not suitable for sterilisation. The laser 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 the 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.

⚠️ Please consult the laser unit safety instructions for the correct handling protocol.

2. Pelvic construct preparation
Assemble the pelvic screw onto the T-handle inserter and place percutaneously in the iliac crest. Ensure the screw is rigidly fixed into bone.

⚠️ The ability of the screw to remain fixed is critical to achieving the intended orientation.

⚠️ Do not use screw for tissue retraction.
3. Assessment of guide and model
Place the guide into the acetabular model. There are five reference markings on the acetabular model to assist with locating the guide.

a. The transverse plane is marked on the back of the acetabular model
b. The identification of where the guide arms will sit
c. A projection of the rim of the acetabular component at the planned orientation
d. A reference line along the top of the fossa which is parallel to the transverse plane
e. A reference line perpendicular to d
For further visual confirmation refer to the electronic report.

4. Acetabular preparation
Remove the fat pad and remnants of the ligamentum teres from the acetabular fossa. Ensure the thin layer of cartilage is removed from the fossa lip. Identify where the arms of the guide will sit within the acetabulum and ensure all cartilage has been removed from these areas.

5. Guide insertion
Place the guide assembly into the acetabulum and apply a superomedial pressure to ensure it is rigidly stable.

Note: Ensure the guide is fully seated in the fossa.

6. Laser introducer
Attach a laser to the end of the curved guide handle. Holding the guide firmly in place, slide the curved guide handle into the guide.
7. Laser alignment
Attach a laser canister onto the adjustable clamp. Lower the assembly onto the pelvic post and secure with dial. Lower the assembly onto the pelvic screw.

Adjust the alignment of the pelvic laser to converge with the acetabular guide laser as projected on the ceiling or wall and secure with dial.

Note: Ensure that the pelvic laser setting is not accidentally altered between alignment and cup impaction.

8. Acetabular reaming
Ream the acetabulum as per the routine technique.

Note: It is recommended to remove pelvic laser assembly from pelvic screw during reaming.
9. Identification of target orientation

After reaming place the pelvic laser assembly back onto the pelvic screw. The orientation of the pelvic reference laser is dependent on the position of the pelvis and therefore, it is extremely important to limit the movement of the patient and pelvis during the procedure to maintain the location of the reference focal point on the wall or ceiling of the operating theatre. Any movement of the patient and pelvis or of the focal point of reference laser will introduce error in terms of obtaining the pre-operatively determined acetabular cup orientation and therefore affect the accuracy of the device.

10. Cup impaction

Screw a laser canister into the magnetic impactor adaptor and attach to the end of the cup introducer. Place the cup in the acetabulum and adjust the orientation until the laser converges with the pelvic laser on the ceiling or wall. Remove the laser adaptor from the end of the inserter and impact. The laser adaptor can be repeatedly attached and removed between mallet blows to control alignment deviation during impaction.

Note: Ensure the laser adaptor and pelvic laser assembly are always removed during impaction.

Note: It may be helpful to impact lightly to achieve purchase in the desired orientation before full impaction.
Compatibility guide

**Trinity™ shell outer diameter**
- 44mm
- 46mm
- 48mm
- 50mm
- 52mm
- 54mm
- 56mm
- 58mm
- 60mm
- 62mm
- 64mm
- 66mm
- 68mm

**Taper size**
- 01
- 02
- 03
- 04
- 05

**Polyethylene liner**
- (UHMWPE*, HXLPE and ECiMa™)
  - 28mm
  - 32mm

**Polyethylene liner**
- (HXLPE and ECiMa™ only)
  - 36mm
  - 40mm

*UHMWPE liners in taper 1 size 28mm and taper 2 size 32mm are not approved for use in the USA
**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 and two patient specific reports: Functional Hip Analysis (FHA) report and Patient Specific Visualisation (PSV) report. The FHA report presents information pertaining to the functional orientation of the acetabular cup of the hip replacement based on patient specific kinematics. The PSV report provides 3D models for visualisation of the acetabular component of the hip replacement in the planned orientation, as well as the patient specific instrumentation.

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.

Corin OPS™ can be used with the Trinity Acetabular System (K093472, K110087, K111481, K122305, K123705, K130128, K130343 and K131647) and the respective compatible components.

**Indications for use**

The Corin Optimized Positioning System™ (OPS) is intended to be used as a patient specific surgical instrument to assist in the alignment of components during total hip arthroplasty.

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 pre-operative X-rays and CT scans.

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.

Corin OPS™ is intended for use with 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

- 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.
- 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).
- Patient specific guides are suitable for up to two sterilization cycles. Guides should not be sterilized more than twice.
- 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.
- 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.
- The Guide’s patient specific identifiers are to be checked for readability and confirmed by the surgeon before use.
- 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.
- 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.
- 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.
- Ensure that the patient is adequately strapped such that the position of the patient and pelvis does not move during the procedure.
- 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.
- The Patient Specific Guides are custom made and must only be used for the individual identified on the packaging and on the part.
- 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.
- The Patient Specific Guides need to be used within the specified expiry date.
- Store Patient Specific Guides in a properly cleaned and dry place.
- The instrument should be properly cleaned before sterilization.
- Open, clean and sterilize immediately prior to surgery.
- Do not use if the Patient Specific Guide is broken, cracked, or if loose powder is present.
- The Patient Specific Guides should not be modified or altered in any way.
- 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.
- 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. 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...
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