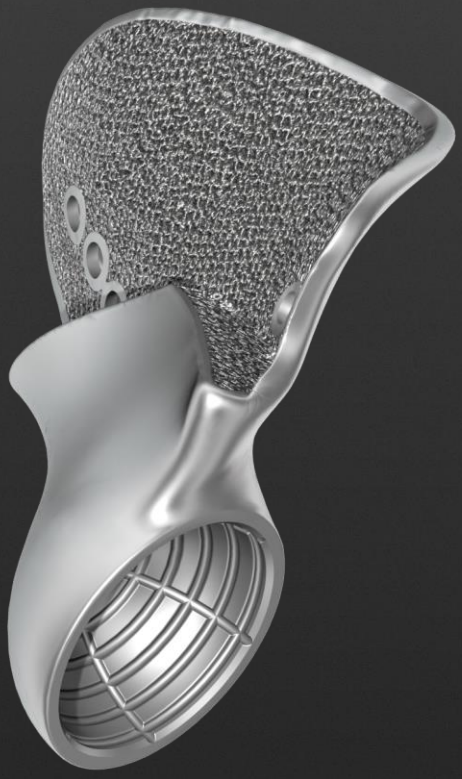
My3D® Personalized Pelvic Reconstruction System

Surgical Technique



ONKOS SURGICAL

Table of Contents

Refer to document CORP 08.09.22 - My3D Pelvis Tray Layout Guide for a full listing of implant and instrument set requirements, images, and part listings.

Incision and Hardware Removal

1. Incise the patient and expose the surgical site according to the surgical plan/ surgical approach (Figure 1).

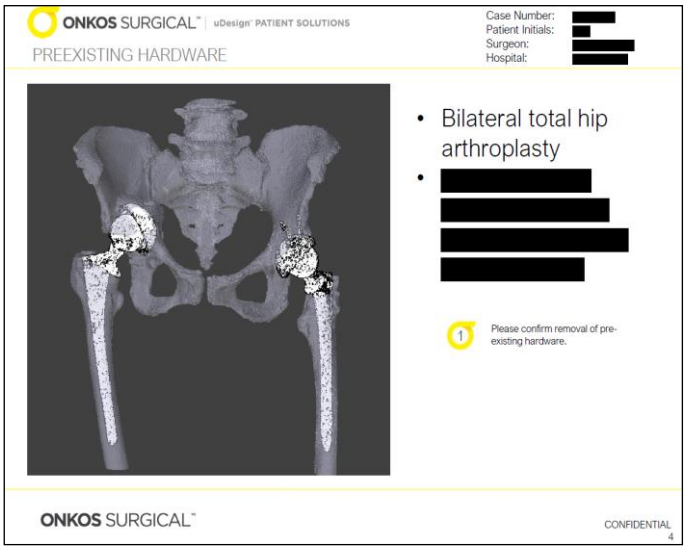


Figure 1: Example in situ hardware section of surgical plan.

2. If applicable, remove any existing hardware according to the surgical plan using the **Screw Extractor** and the **Quick Connect T Handle**. (Figure 2).

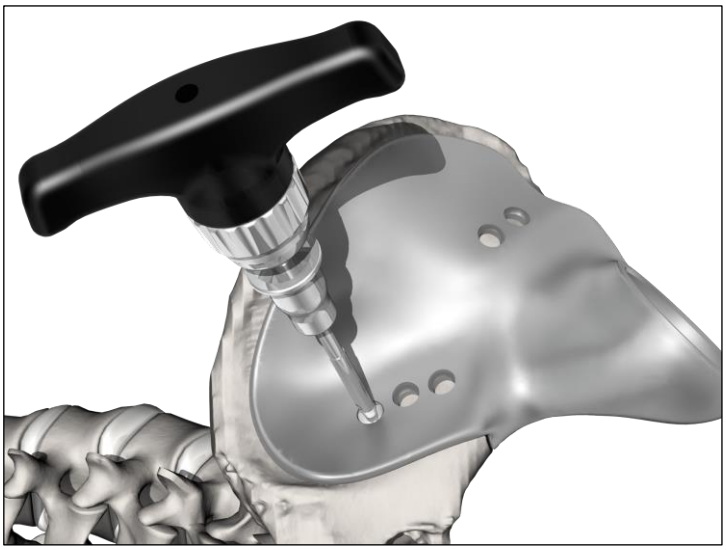


*Figure 2: **Screw extractor** can be used to remove pre-existing hardware.*

Placement of Resection Instrumentation

3. Confirm the size and fit of the resection guide(s) with the specific anatomic model(s). Place the **Single Use Resection Guide(s)** on the **Patient Model** ensuring proper fit (location and orientation) as outlined in the surgical plan.

4. Begin the pelvic implant prep surgical process by dissecting necessary soft tissues within the resection instrument footprint for proper placement on bone surface.
   - Measurements to landmarks: Reference the surgical plan to confirm placement of **Single Use Resection Guide(s)** relative to anatomical landmarks via the provided measurements.
   - Duplicate guides may be used along with the anatomic models to visualize the correct placement of the guide relative to the host bone.
5. Referencing the stated pin placements on the surgical plan (Figure 3). Using **3.2mm Smooth Trocar Tip Pins** at the specified diameter, mechanically fasten single use resection instrument(s) (either reaming trials or cutting guides) to the host bone through the provided fixation features. Ensure the device is stable and does not move from the placed position throughout the process.
   - Note: Sterile, **3.2mm Smooth Trocar Tip Pins** are available from Onkos (Figure 4)
   - Note: Only smooth walled trocar tipped fixation pins may be used. Threaded pins and fluted pins are not compatible with the plastic 3D printed patient specific instrumentation.

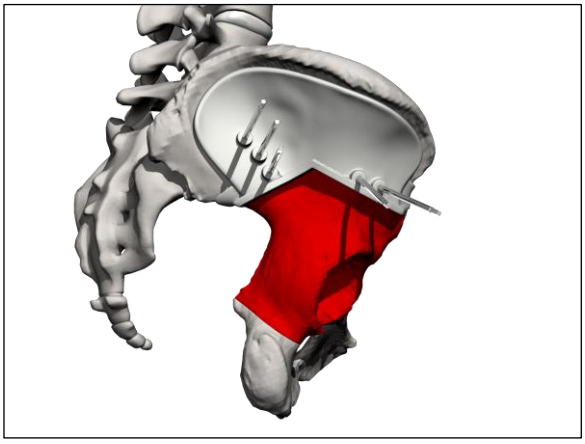


Figure 3: Example of patient-matched resection plan.

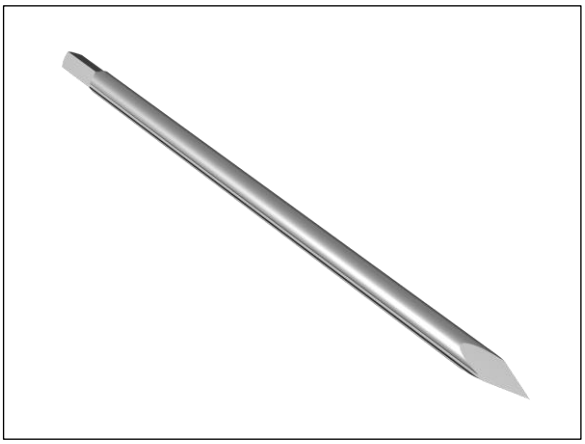


*Figure 4: **3.2mm smooth trocar tip pin***

Performing the Bone Preparation – Cutting Guides

6a. Perform the bone cutting using appropriate surgical saw blade(s) thickness(es)/width(s) and or reamer diameters according to the surgical plan (Figure 5).

- Always consider the planned trajectory for the given resection and the effect on overall accuracy, downstream device fit, potential for surgical delays and potential damage to sensitive structures.
- If during use, the **Single Use Resection Guide(s)** appear unstable or vibrate out of position, either add another fixation device (i.e. smooth trocar tip pin) or use an assistant with a set of forceps to apply pressure to the guide.
- Note: for guide(s) that contain a forceps-interfacing feature, this may be used to keep the guide(s) secure during use.

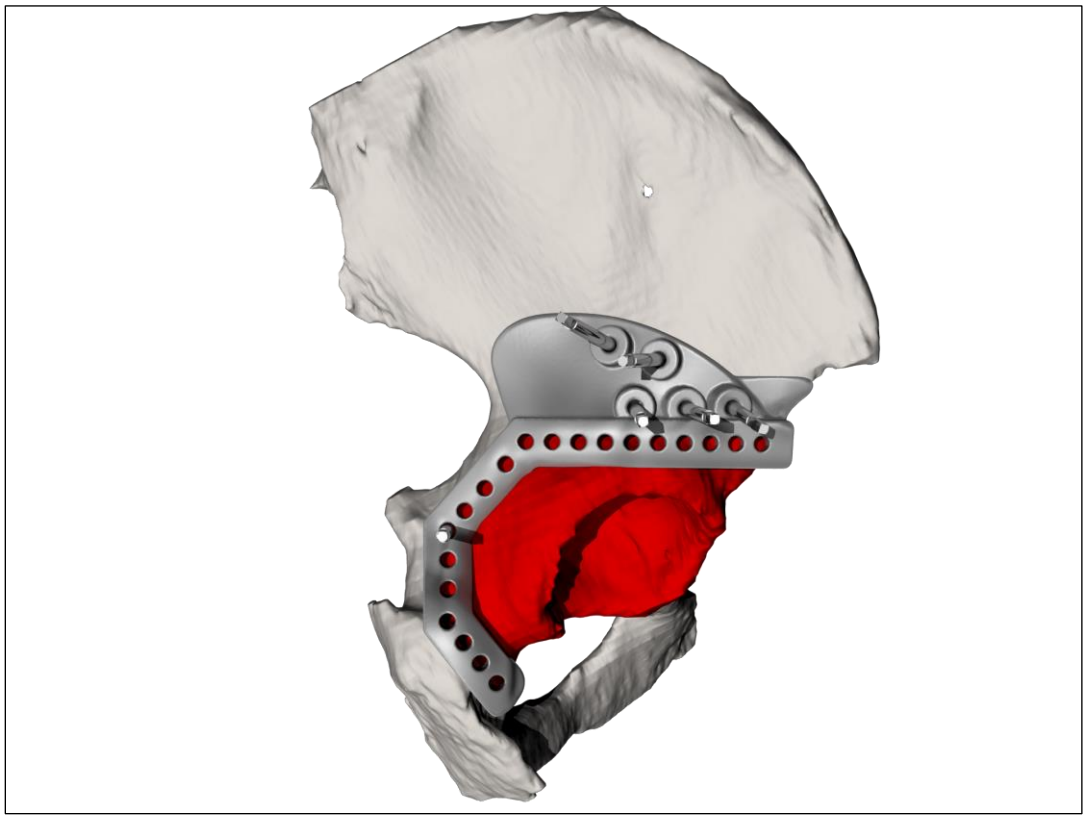


*Figure 5: Example Hybrid Iliac **Resection Guide** with Point-to-point resection. Shown in situ with fixation pins in place.*

Note: Point-to-Point resections:

- Refer to the surgical plan to confirm the proper fixation pin diameter.
- Sequentially drill the bone through all provided holes
- Remove the guide when complete
- Use the calibrated markings on the drill in order to limit the depth during drilling of the point-to-point resection guide

Performing the Bone Preparation – Reaming Guides

6b. Referring to the surgical plan and the patient anatomy, determine the correct reamer size to initiate reaming (Figure 6).

- Based on intraoperative assessment, continue reaming the acetabulum in progressive sizes according to the surgical plan.
- After reaming the acetabulum, place the modular trial on the bone and use **3.2mm smooth trocar tip pins** to secure the **Modular Trial Cup** to the bone (Figure 7).
- The **Modular Trial** is intended to isolate variables of flange fit and cup fit to ensure enough bone is reamed for implant cup. Place **Modular Trial Cup** within **Modular Reaming Trial** ring. Once cup can be fully seated, adequate reaming has been performed to seat implant.

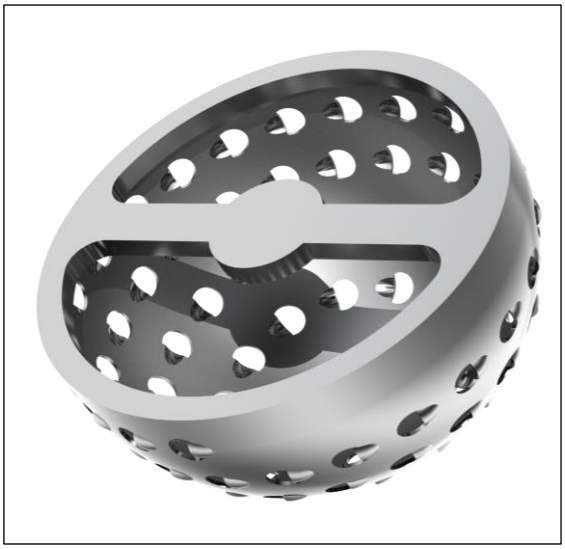


Figure 6: Acetabular Reamer.

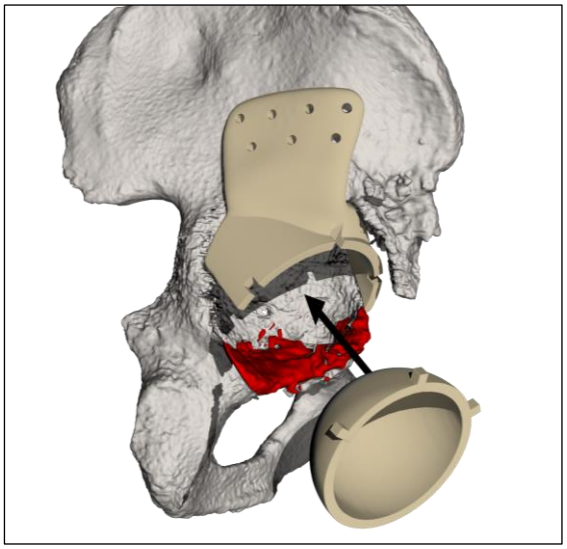


*Figure 7: Use of **Modular Trial Cup** and **Modular Reaming Trial**.*

Bone Preparation - Adjustments

7. After completing the bone preparation per the surgical plan, check that resected surfaces match the surgical plan. **Anatomic Models** can be used for this purpose.

8. Use a rasp or rongeurs to smooth any surface as needed (Figure 8). For ‘point-to-point’ style resection guides, use an instrument of your choice (gigli saw, reciprocating saw, sagittal saw, osteotome, etc..) to connect the perforations.

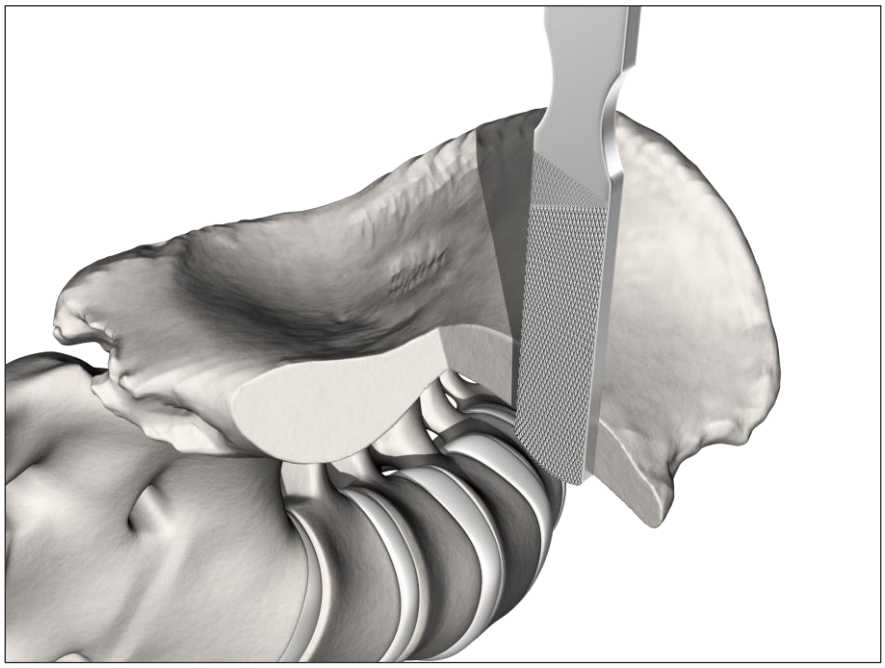


Figure 8: Rasp any sharp corners and or to adjust fit.

9. Use pulsed lavage to remove any debris from the surgical site before proceeding.

Implant Trialing

10. Place the provided **Implant Trial** (Figure 10) within the defect and then within the **Patient Model** to confirm the accuracy of the bone preparation. The **Implant Trial** is a 1:1 replica of the implant and is intended to fit securely with no toggle.
    - If the fit does not appear correct, ensure the dissection of soft tissue structures and resection of bone were both performed according to the surgical plan.
    - It is not recommended to predrill screw holes through the **Implant Trial**.

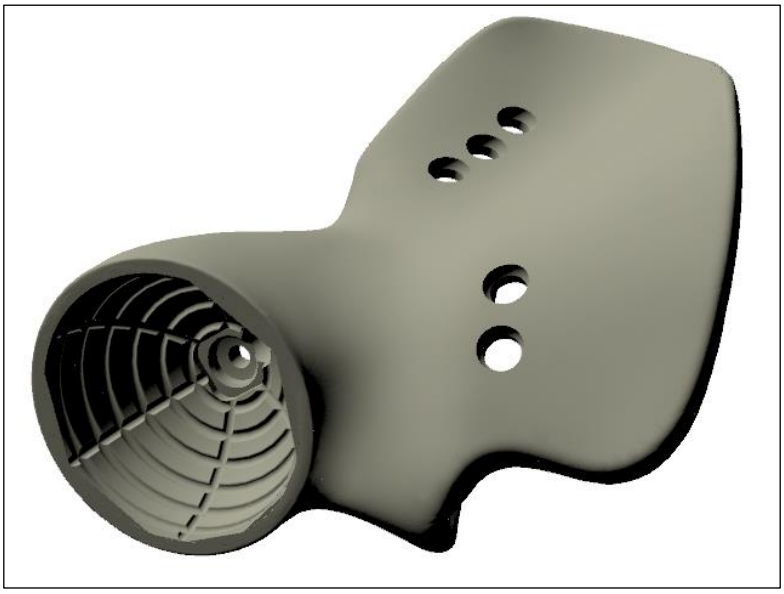


*Figure 10: Example **Implant Trial**.*

Implant Insertion

11. There are two options for guiding the cup during implant insertion:
    - If the implant includes a threaded apical hole (also referred to as a dome hole)
        - On the back table, securely fasten the Inserter Handle (Figure 11) to the definitive implant and introduce it into the patient (Figure 12).
        - Mobilize soft tissue as necessary to ensure the device fits according to the surgical plan.
        - If necessary, the implant can be fit to the provided anatomic model(s) to verify the correct location.
    - If the implant does not include a threaded apical hole, the Pelvic Impactor Tip can be assembled onto the Inserter Handle to act as an impactor and guide within the cup (Figure 13).

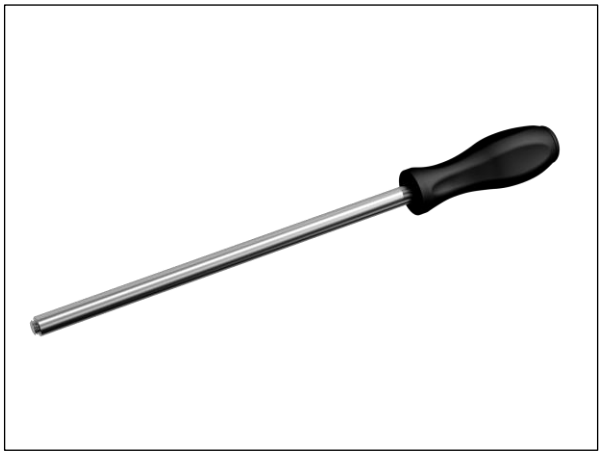


*Figure 11: **Inserter Handle***

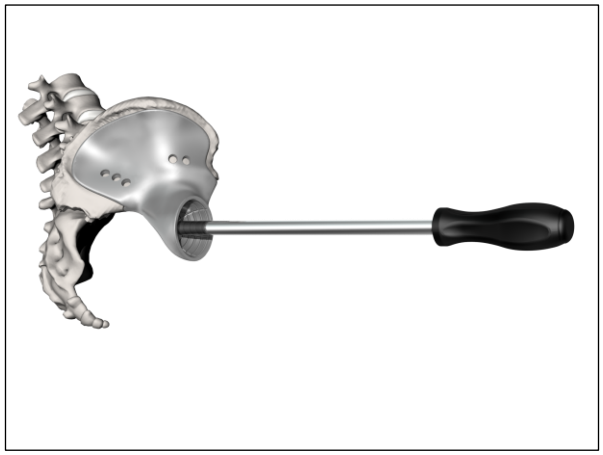


*Figure 12: **Inserter Handle** used to place the Pelvic Implant.*

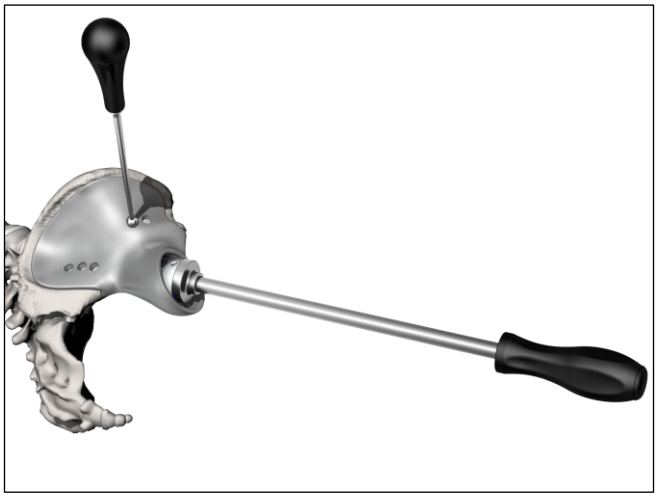


*Figure 13: The **Ball Pusher Instrument** can be used in conjunction with the **Pelvic Impactor Tip** assembled onto the **Pelvic Inserter Handle** to aid in implant placement and positional adjustment.*

Implant Insertion

12. The **Ball Pusher Instrument** can be used to help provide provisional fixation of the implant to the iliac table. Press the ball pusher tip into a flat, iliac screw hole to hold down implant while fixating screws into the flange, or to adjust the location of the implant on the bony anatomy (Figure 14-15).

13. Screws can be inserted with either **3.5mm Hex Driver, 3.5mm Universal Hex, Flexible Modular shaft, or Rigid Modular shaft attached to the Ratcheting Straight Handle.**

*Figure 14: Use **Ball Pusher Instrument** to hold down implant while a bone screw is fixated into the iliac table, using a straight inserter.*

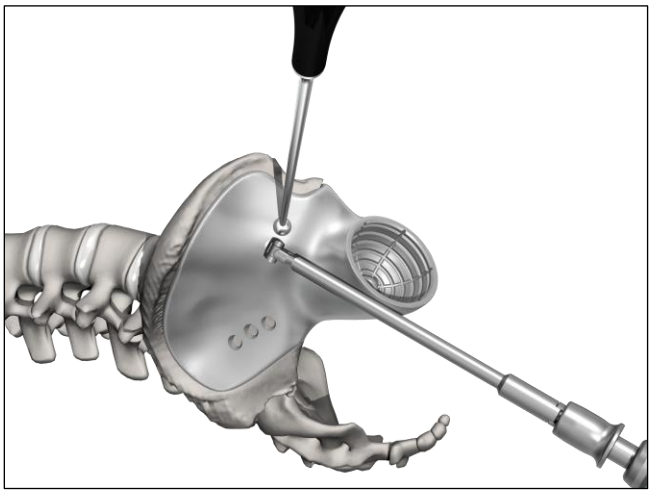


*Figure 15: Use **Ball Pusher Instrument** to hold down implant while a bone screw is fixated into the iliac table, using a **U-joint inserter**.*

Screw Hole Preparation

Please refer to Appendix A: Locking Screw Technique if any locking screws were planned as part of the design of the implant.

14. To drill the screw holes, use the **Non-Locking Drill Guide** and the desired length drill bits (either 25mm, 50mm, or 200mm).
    - If using the **25mm** or **50mm Drill Bits**
        - Assemble the drill bit to the desired Modular Shaft (**Flexible Modular Shaft** or **Rigid Modular Shaft**) and attach to power.
        - Reference the forecasted screw length according to the surgical plan.
        - Place the short barrel end of the **Non-Locking Drill Guide** to the implant and proceed to place the drill through that hole. Drill until fully seated or until desired depth is reached.
        - When the 25mm or 50mm drill bit is fully seated, the nominal depth will be measured from the tip of the drill to the underside of the **Non-Locking Drill Guide** barrel (Figures 16-17)

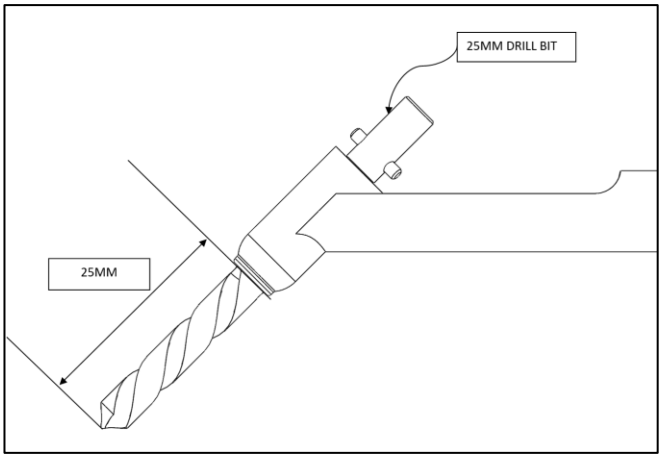


*Figure 16: Short Side of **Non-Locking Drill Guide** Measurements with 25mm Drill*

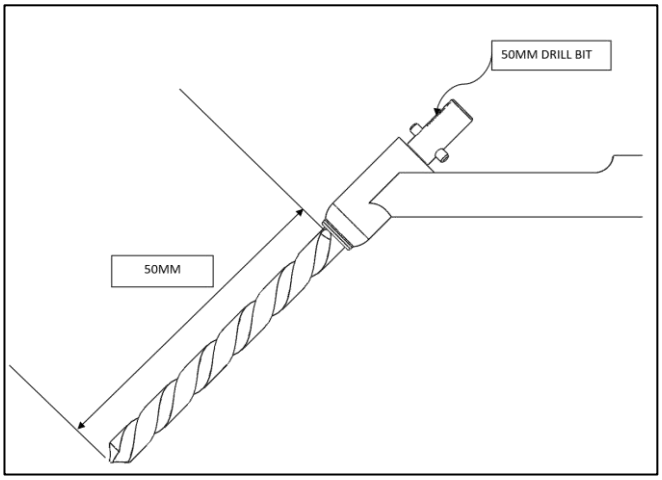


*Figure 17: Short Side of **Non-Locking Drill Guide** Measurements with 50mm Drill*

Screw Hole Preparation

- If using the 200mm drill bit:
    - Assemble the 200mm drill bit to power using its AO connection.
    - Reference the forecasted screw length according to the surgical plan.
    - Place the longer barrel end of the **Non-Locking Drill Guide** to the implant (Figure 18) and proceed to place the drill through that hole and drill until:
        - Desired depth is reached based on tactical feedback **AND**
        - The visual depth check is confirmed by ***checking the depth measurement on the drill shaft and subtracting 20mm (as marked on the drill guide barrel to account for the additional depth of the drill guide, Figure 19).***
- **Note:** All Ø4.3mm drills are calibrated in length relative to the short side of the **Non-Locking Drill Guide.** If using the **200mm drill** with the short side of the **Non-Locking Drill Guide**, the markings on the drill represent the effective drill depth (without subtracting 20mm). (Figure 20)
- **Note:** The various combinations of available drill bits and inserter shafts and handles are shown on page 14 (Figures 21-22) and page 17 (Figures 27-29).
- **Note:** The depth markings on the 200mm drill may only be used to measure hole depth on holes that do not pass through both cortices.
- **Note:** For cases involving resection guides, the fixation holes used on the guide(s) may serve a dual purpose as pre-drilled holes for the screws that fasten the implant; if using these existing holes, ensure they are correctly aligned with the associated screw hole location in the implant.
- **Note:** While the cancellous bone screws are 6.5mm in diameter, the drill to prepare for them is 4.3mm in diameter, which is marked on the drill guide.

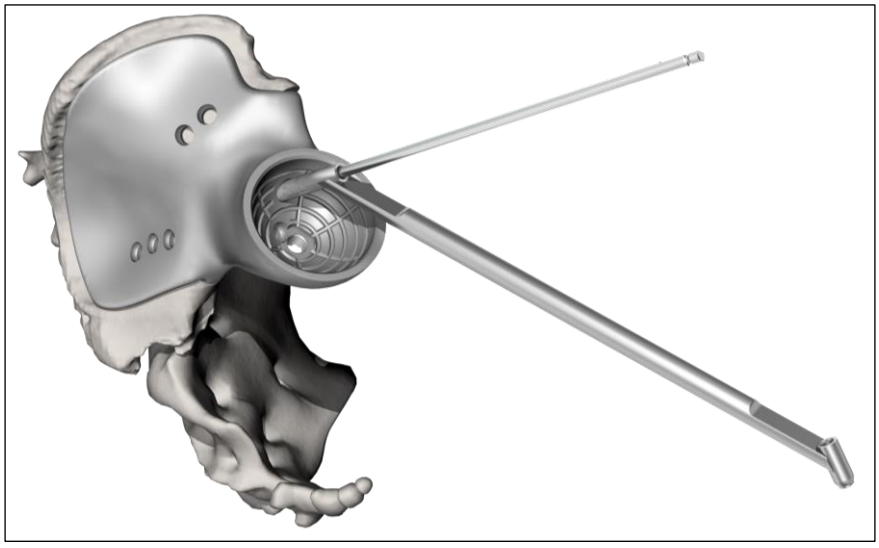


*Figure 18: Predrilling of posterior column through-cup screws; long end of **Non-Locking Drill Guide** matches planned trajectory.*

Screw Hole Preparation

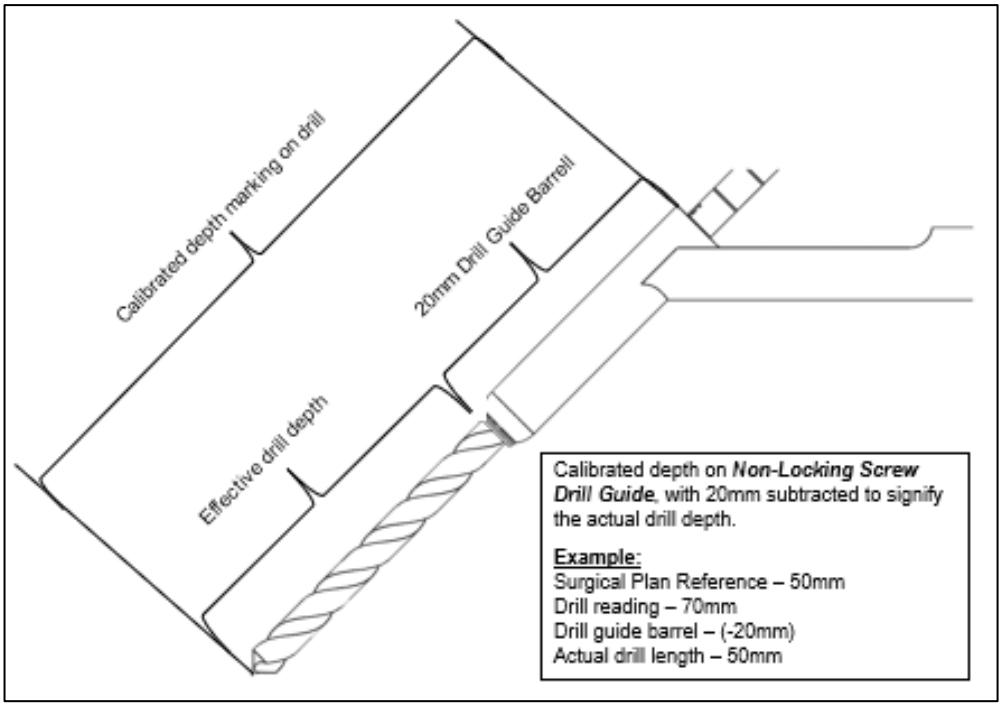


*Figure 19: Long Side of **Non-Locking Drill Guide Measurements** with 200mm Drill*

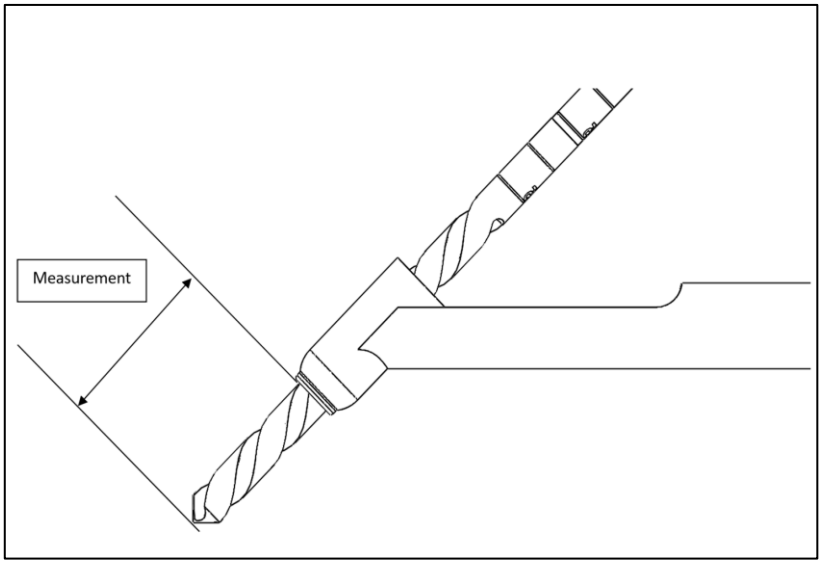


*Figure 20: Short Side of **Non-Locking Drill Guide Measurements** with 200mm Drill*

Screw Hole Preparation – Drill Inserter Options

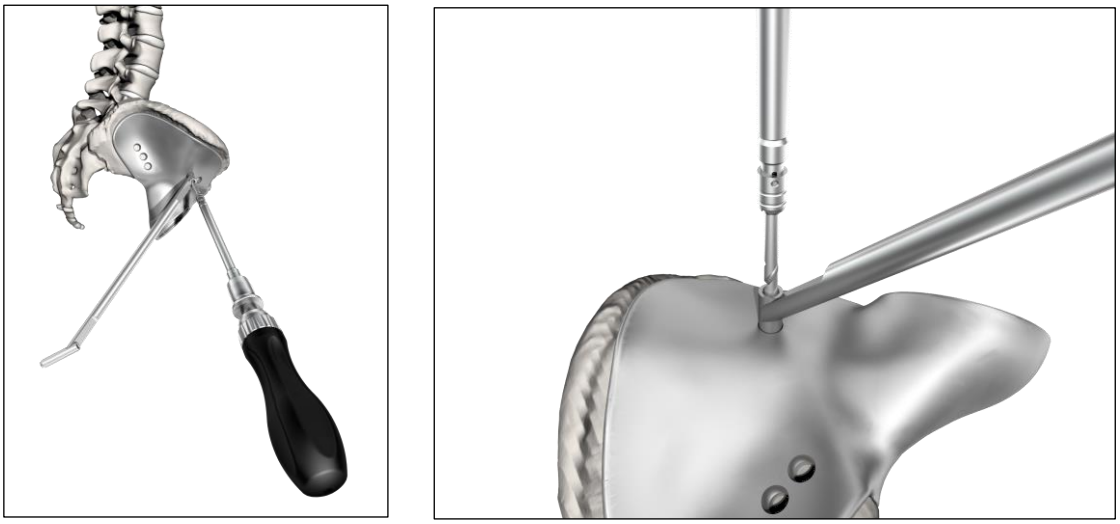


Figure 21: ***Non-Locking Drill Guide*** *with* ***Straight Bayonet Drill Adaptor.***

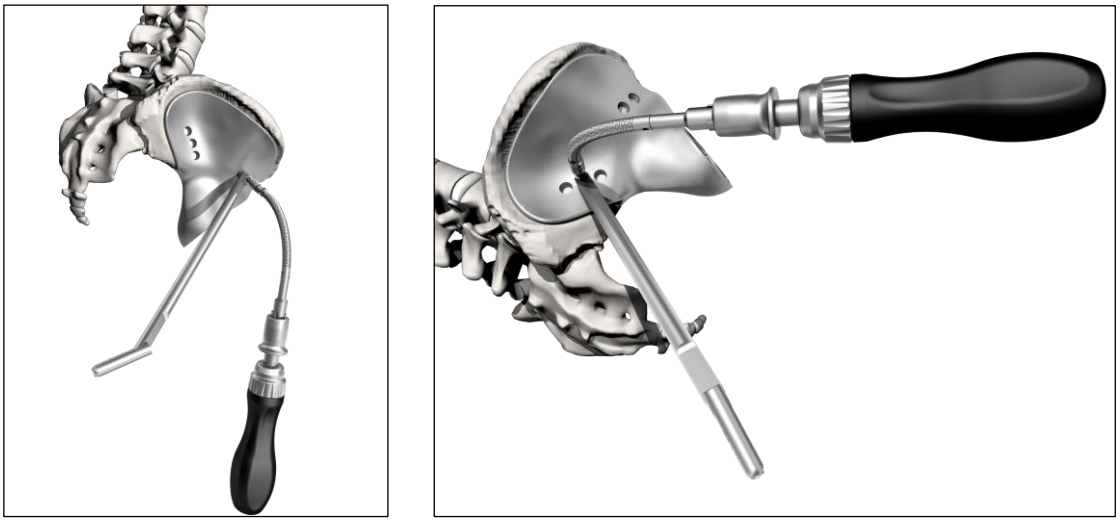


Figure 22: ***25mm Bayonet Drill*** *with* ***Modular Flexible Driver*** *and* ***Non-Locking Drill Guide*** *can be used to predrill holes in ischium, pubis, or any other area where a straight drill cannot easily access.*

Screw Depth Confirmation

15. Before inserting a screw, verify the depth using the Depth Gauge. Measure the screw lengths with the implant in situ. For implants containing deep countersinks and measured with the **Rigid 45°, 120mm Depth Gauge,** the following practices may be followed:
    - (Figures 23-24): Using either the **Fixed Angle Depth Gauge** or the **Flexible Depth Gauge**, measure the depth of the screw hole to the outside of the implant. Subtract the countersink depth from the measured length to determine the screw length. Countersink depths are identified in the surgical plan

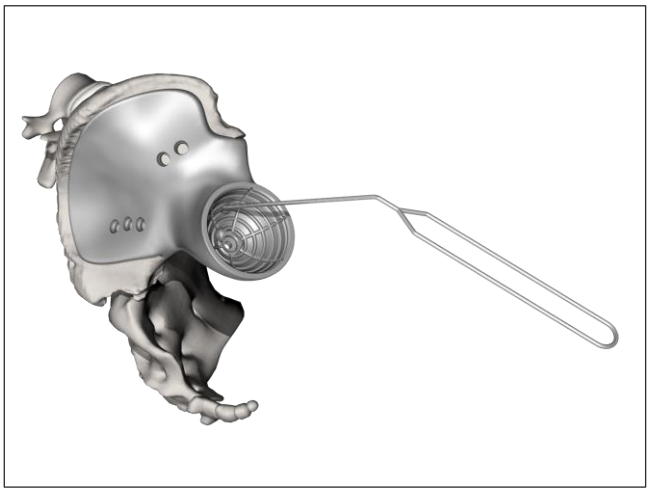


*Figure 23: Use of **Fixed Angle Depth Gauge** to measure required screw length.*

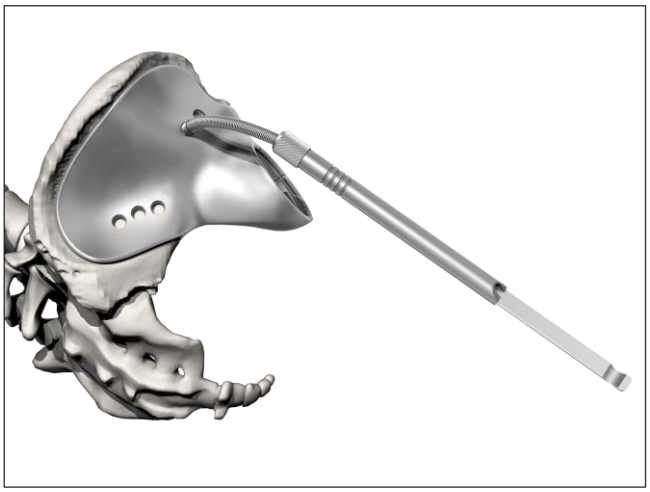


*Figure 24: Use of **Flexible Depth Gauge** to measure holes in harder to access locations.*

Screw Insertion

16. Using the **Screw Forceps**, introduce the correct length screw into the associated pre-drilled hole. To ensure the implant is stable and in the correct position, have an assistant firmly hold the implant in place throughout the screw insertion process. Under hand power only, use one of the driving instruments listed below to drive the screw such that the spherical head is flush with the seat in the implant. Support the screw with screw forceps when introducing into the implant (Figure 25-26). Care should be taken not to overtighten the screw such that screw purchase is lost.

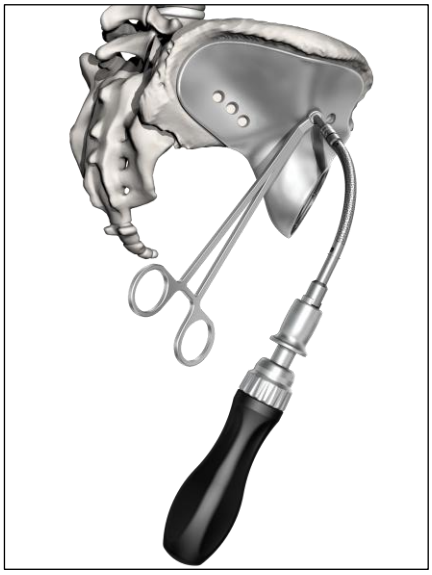


*Figure 25: Use of **Screw Forceps** to hold screw head while inserting with **In-line Ratcheting Modular Handle** and **Flexible Bayonet Driver** (Left). Use of **Screw Forceps** to hold screw head while inserting with **In-line Ratcheting Modular Handle** and **Universal Joint 3.5mm Hex Driver** (Right).*

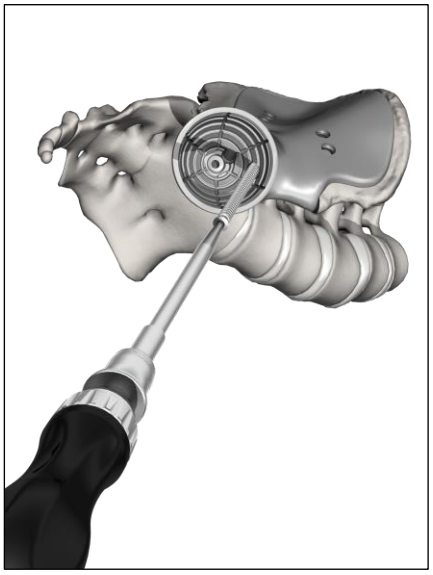


*Figure 26: Use of **In-line Ratcheting Modular Handle** with **Straight 3.5mm Hex Driver** to insert screw through the cup.*

Screw Insertion (Continued)

Figure 27: Schematic of interchangeable instruments with the modular handle.

Figure 28: Schematic of interchangeable instruments with the bayonet connector.

Figure 29: Schematic of the interchangeability of the AO connector.

Modular Handle options
- Ratcheting straight handle

Modular Shaft options
- Rigid: bayonet quick connect
- Flexible: bayonet quick connect, 3.5mm hex modular working ends
- Bayonet quick connect 3.5mm

Non-modular options
- Straight 3.5mm hex driver
- Universal joint 3.5mm hex driver

Screw Insertion (Continued)

The Instrument Kit Provides (Figure 30):

- Two straight instruments and two angled instruments
- Two monolithic instruments and two modular instruments
  (Plus torque limiting driver)
- Bayonet connectors can work with drivers, taps, and drills
- Monolithic drivers provide more rigidity for driving screws when direct access and surgical exposure permits

Flexible Driver With Bayonet		
Straight Driver with Bayonet		 
U-Joint Hex Driver		
Straight Hex Driver		

Figure 30: Summary of Drivers and Modular Tips

Screw Insertion (Continued)

Note: For situations where insertion of the screw is difficult, **Screw Taps** in various lengths are available to further prep the bone and to ease screw insertion (Figure 31).

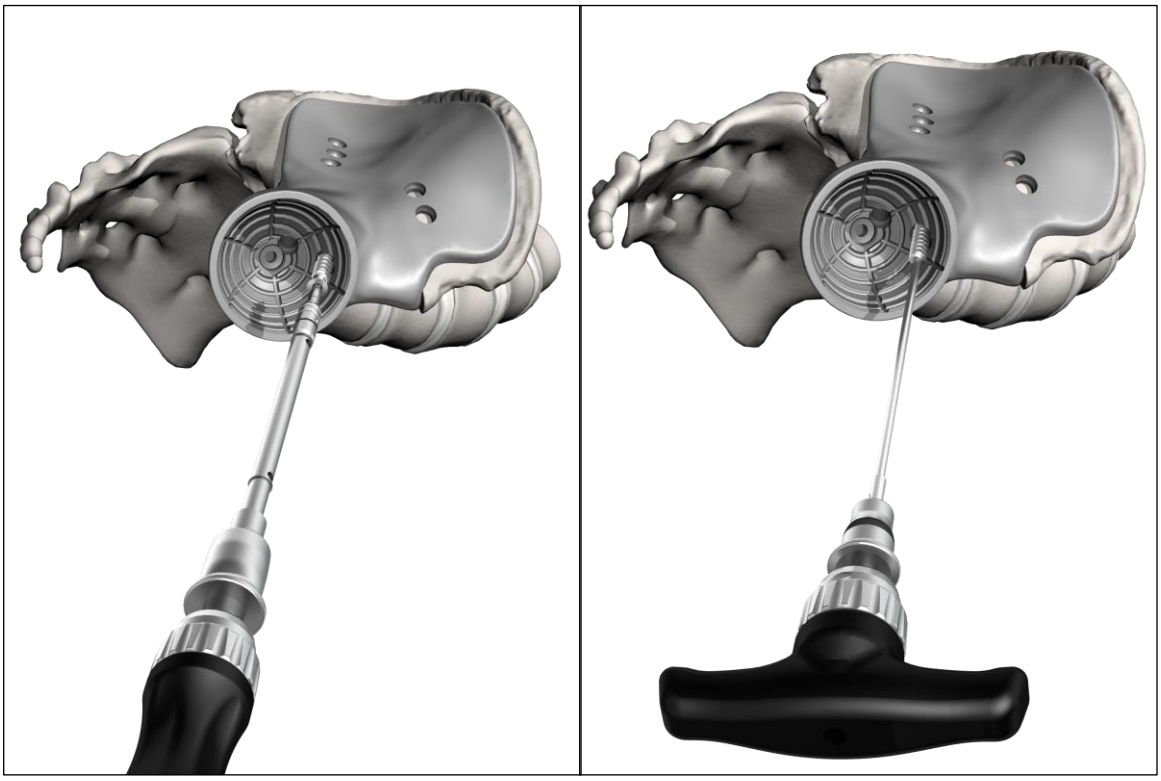


*Figure 31**: Modular Bayonet Tap** assembled to the **Flexible Bayonet Driver** (Left). 180mm AO tap assembled to the **Ratcheting AO T-handle** (Right).*

Apical Hole Plug Insertion (Optional)

17. Some implants are designed with a dome hole thread. If your implant was designed with a dome hole thread, it will be required to close the dome hole with an **Apical Hole Plug**.
    - After all screws are securely fastened, assemble the **Straight Hex Driver** or **Flexible Modular Shaft** + **3.5mm Hex Tip** to the **Straight Ratcheting Handle**. Press an **Apical Hole Plug** into the 3.5mm tip and advance into the apical hole in the implant. Thread it into place until fully seated.
    - Take care not to drop the Apical Hole Plug or to cross thread upon insertion.
    - Ensure that the Plug threads are aligned properly prior to seating.
    - **Tip:** When apical hole trajectory is difficult to reach, a 3.5mm hex driver bit may be assembled to the flexible modular driver. Screw Forceps can be used to aid in guiding the trajectory of the plug (Figure 32)

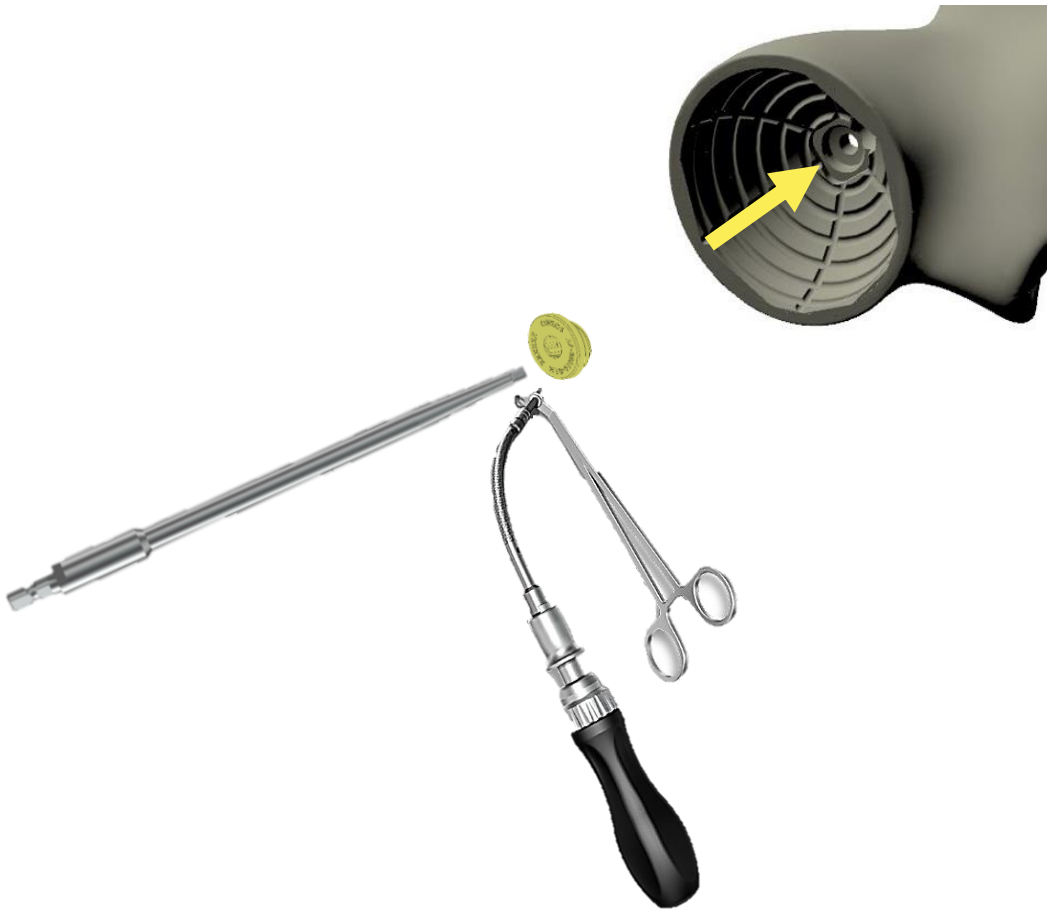


*Figure 32: Examples of driver, handle, and forceps configurations to insert an **Apical Hole Plug***

POLARCUP™ Cementation

18. Then, follow the applicable surgical technique to implant the compatible acetabular liner system and femoral system noting a cement mantle thickness of 2.5mm (per side) is required for Smith & Nephew POLARCUP™.

Final Adjustments

19. Should any screw become stripped, use the **Screw Extractor** instrument with the **AO Ratcheting T-Handle** to remove the screw and replace it with another screw (Figure 33).

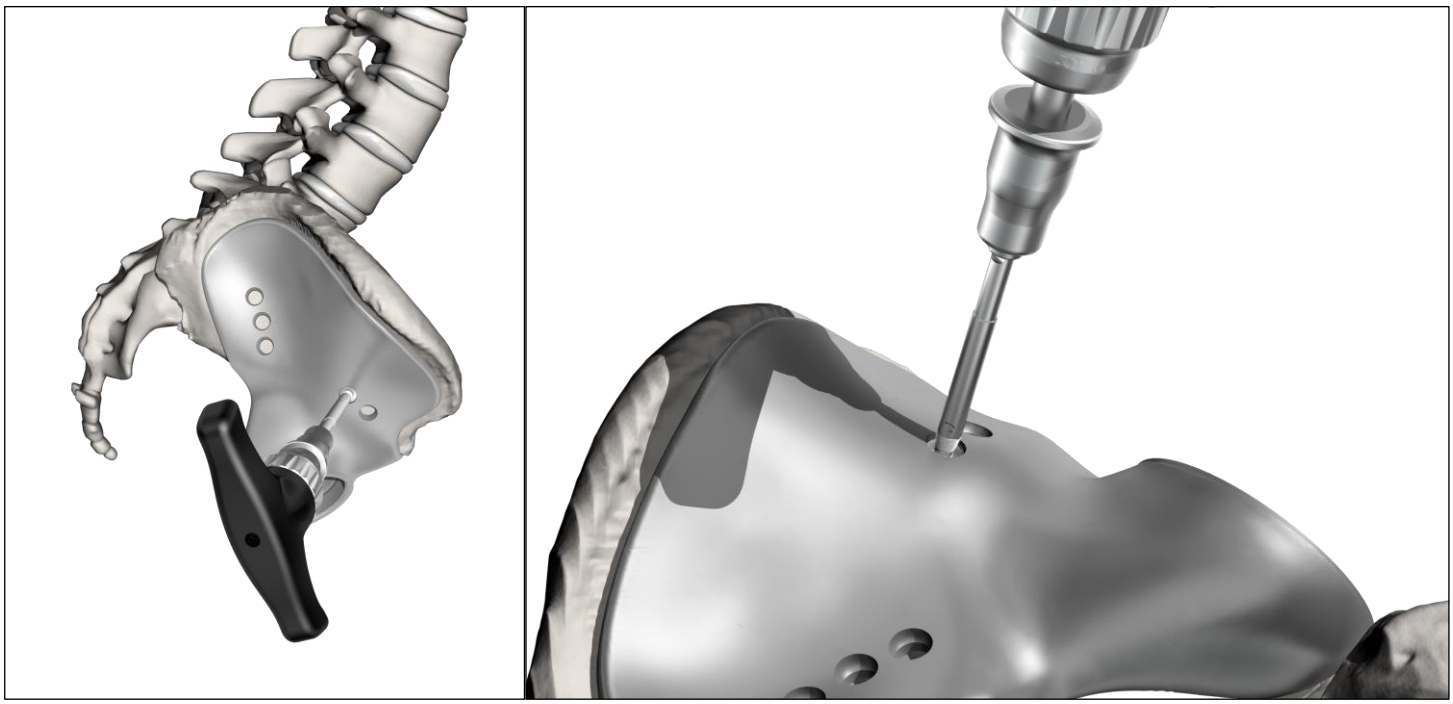


*Figure 33: Use of **Screw Extractor** with the **AO Ratcheting T-Handle.***

Appendix A: Locking Screw Technique

During preoperative planning, it can be requested, for any screw hole that crosses at least one cortex, that the screw hole be designed to accept a 5.0 mm fixed-angle locking screw.

- **Note that locking screw holes will not accept a 6.5mm cancellous screw.**

1. After bone preparation and implant trialing, prior to preparing for locking screws, first ensure the implant is seated on the bone in the correct position and orientation.
    - Note: If locking and compression screws are both being used on an implant, it is generally recommended to prepare for and insert any compression screws first for those screws to generate compression between the pelvic implant and the patient bone.

2. For each screw hole intended to be used with a locking screw, thread either the **40mm Long or 100mm Long Locking Screw Drill Guide** into the screw hole (Figure 34).

Figure 34: ***Locking Screw Drill Guide*** *Assembled to Pelvic Implant.*

Appendix A: Locking Screw Technique (Continued)

3. To ensure the implant is stable and in the correct position, firmly hold the implant in place throughout the drilling process. Depending on the need, multiple options of drill bits are available (modular straight & flexible, non-modular flexible, and calibrated long). Either under power or by hand, perform the pre-drill operation for all screw holes per the surgical plan (Figure 35).
   - Note that use of the drill guide is mandatory for screws to lock to the implant properly.
   - Note that while the locking screws are 5.0mm in diameter, the drill to prepare for them is 4.3mm in diameter, which is marked on the drill guide.

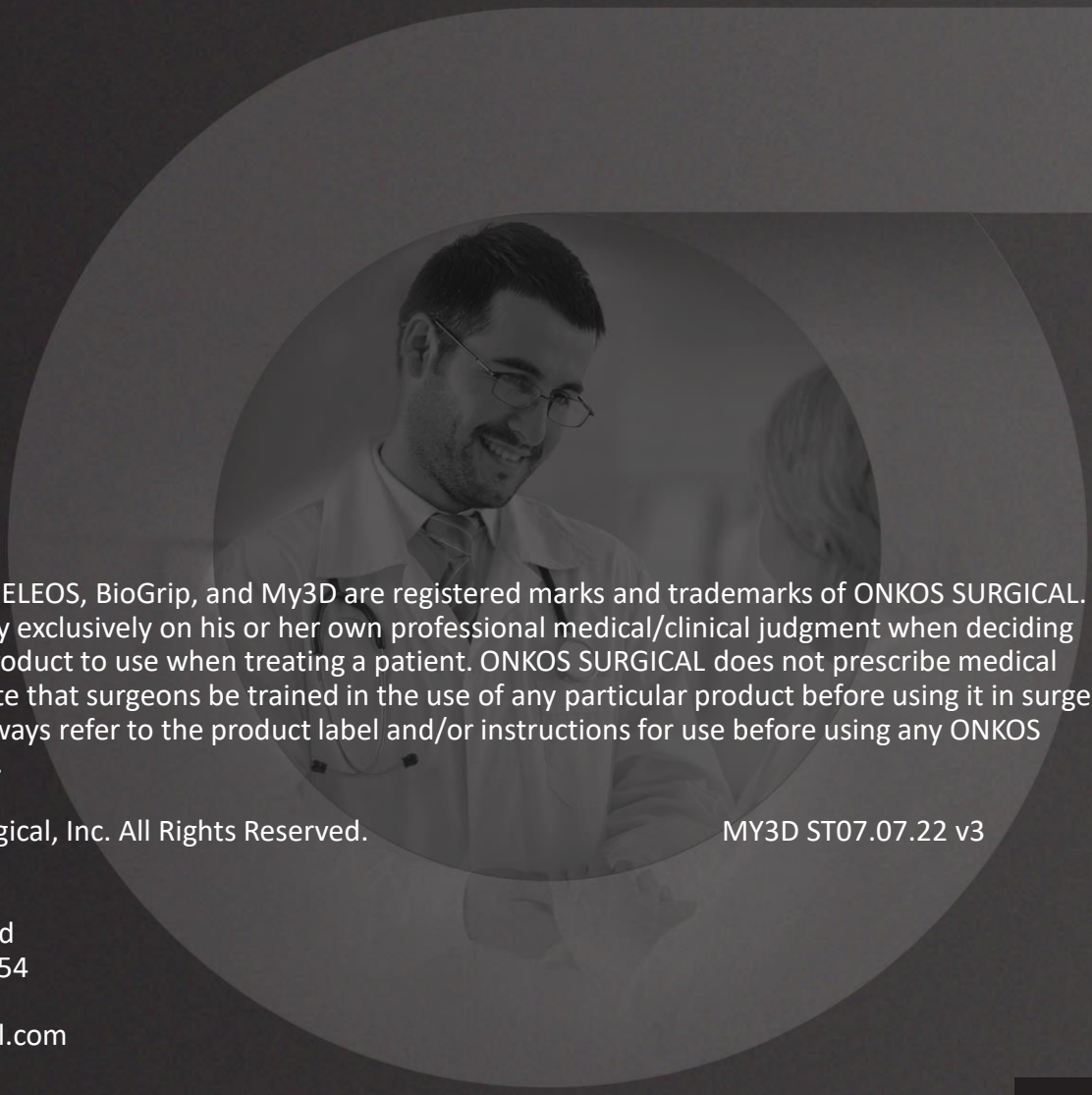
*Figure 35: Use of **Calibrated Drill Bit** with **Locking Screw Drill Guide**.*

Appendix A: Locking Screw Technique (Continued)

4. Before inserting a screw, verify the depth using the **Depth Gauge**. Measure the screw lengths with the implant in situ. Please refer to Page 15 (Figures 23-24) for suggested methods of confirming screw hole depth.

5. Using the **Screw Forceps**, introduce the correct length screw into the associated pre-drilled hole. To ensure the implant is stable and in the correct position, have an assistant firmly hold the implant in place throughout the screw insertion process. Under hand power only, use one of the driving instruments listed on Page 17 of the Surgical Technique (Figures 27-29) to drive the screw such that the tapered head is flush with the seat in the implant (Figure 36). Advance the locking screw until the head fully seats and the threads of the head are locked in place. Excessive force is not necessary to produce effective screw-to-implant locking. A T**orque-Limiting Inline ZSJ-Hall Handle** may be used, which would limit the applied torque to 4 N-m (approximately 35 in-lbs).

Figure 36: Cortical Locking Screw Threaded into Pelvic Implant.



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