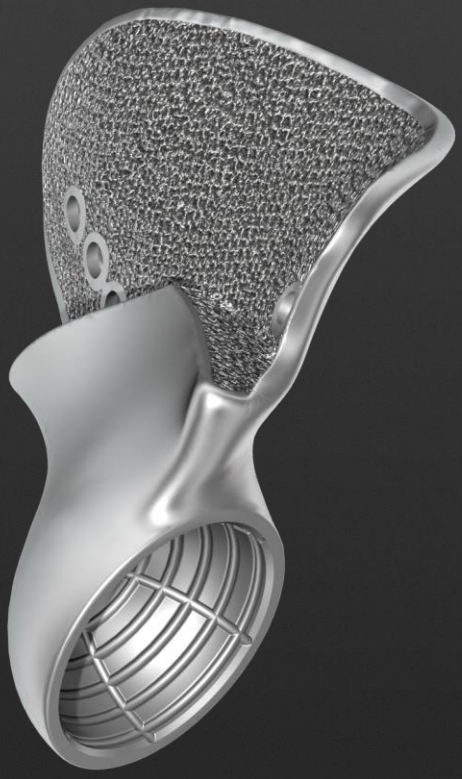
My3D® Personalized Pelvic Reconstruction System

Surgical Technique



ONKOS SURGICAL

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Incision and Hardware Removal

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

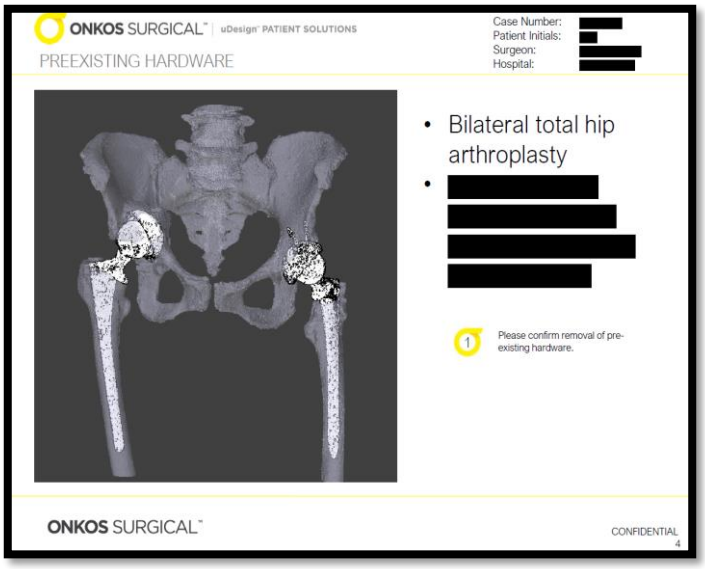


Figure 1: Example in situ hardware section of surgical plan.

2. If applicable, remove any existing hardware according to the surgical plan.

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

Placement of Resection Instrumentation

3. Referring to the case specific anatomic model(s), place the single use resection instrument(s) on the patient ensuring proper fit (location and orientation) as outlined in the surgical plan.
   - Dissect 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 resection instruments 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.
4. Referencing the surgical plan, using smooth trocar tip pins at the specified diameter, mechanically fasten single use resection instrument(s) 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 that sterile, 3.2mm smooth trocar tip pins are available from Onkos (PN: PN-32090-04N).

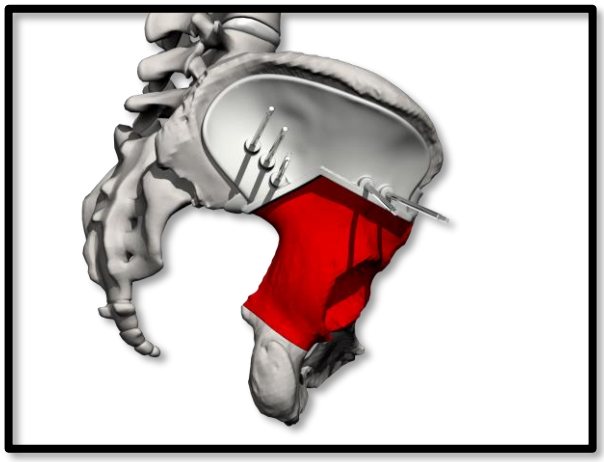


Figure 3: Example of patient-matched resection plan.

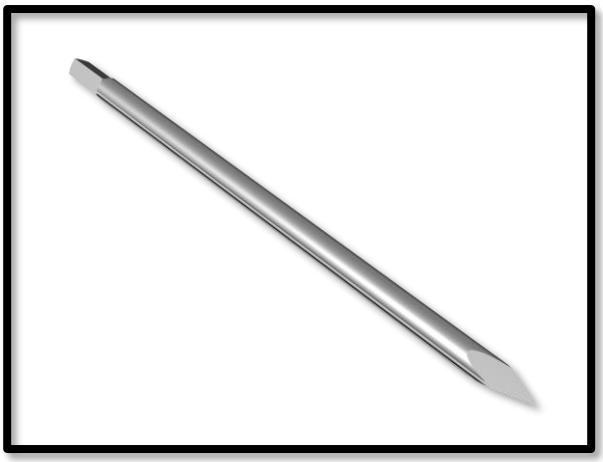


Figure 4: Trocar Tipped Smooth Fixation pin.

Performing the Bone Preparation

5. Perform the bone preparation using appropriate surgical saw blade(s) thickness(es)/ width(s) and or reamer diameters according to the surgical plan being mindful of 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 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.

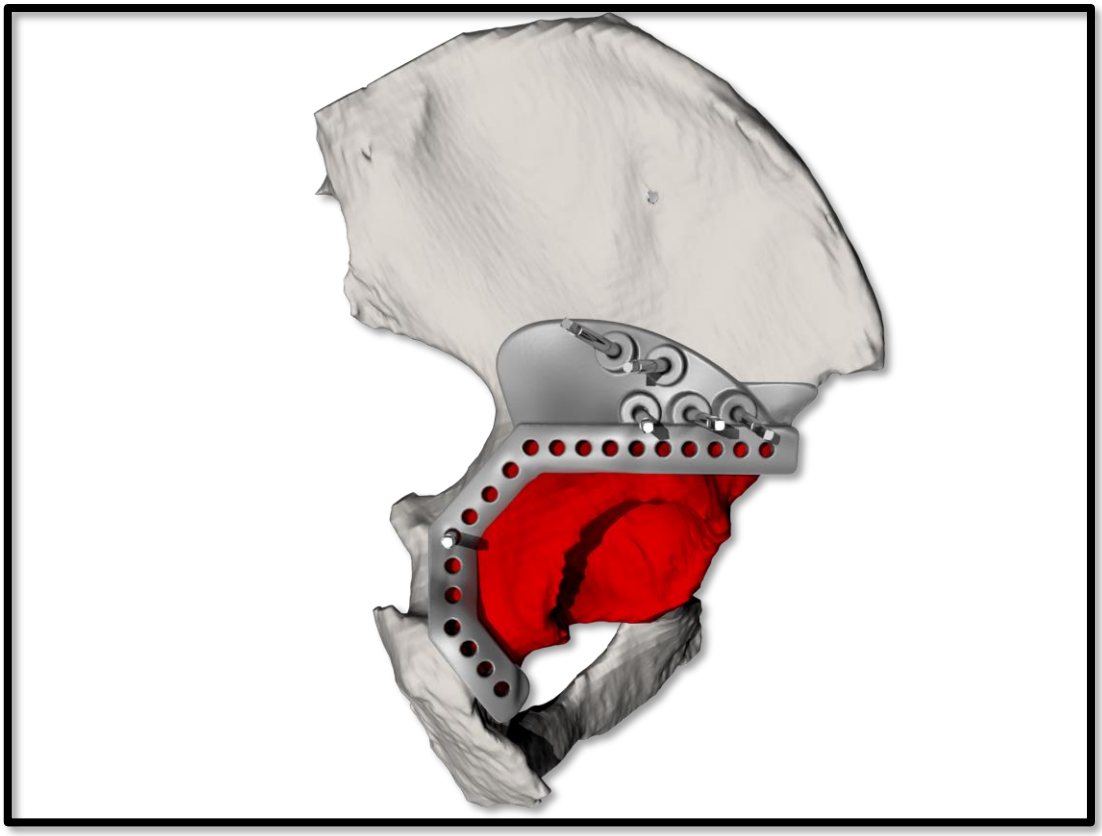


Figure 5: Example Hybrid Iliac Resection Guide with Point-to-point resection. Shown in situ with fixation pins in place.

Bone Preparation (Continued)

Reaming:

- Referring to the surgical plan and the patient anatomy, determine the correct reamer size to initiate reaming.
- 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 Trocar Pins to secure the modular trial to the bone.

Figure 6: Acetabular Reamer.

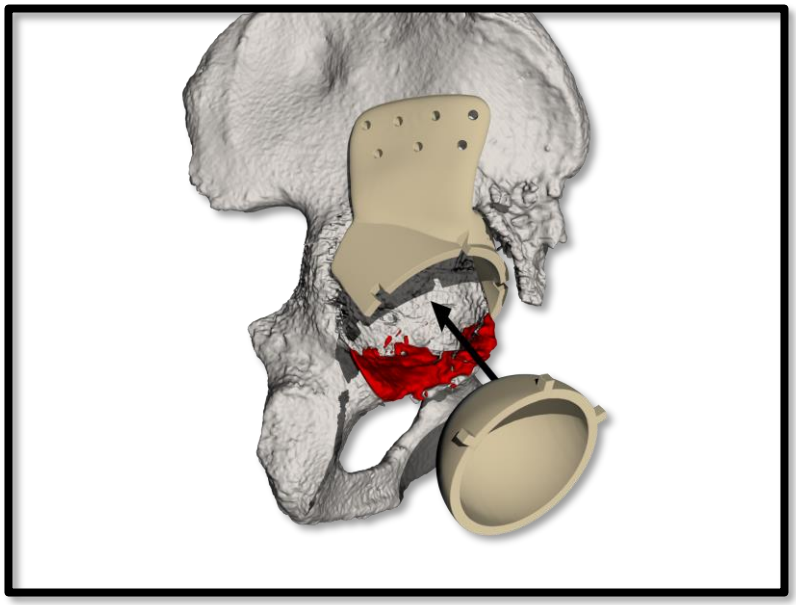


Figure 7: Use of Modular Acetabular Reaming Trial.

- 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 Trial ring. Once cup can be fully seated, adequate reaming has been performed to seat implant.

Bone Preparation (Continued)

Planar resections (sagittal saw):

- Refer to the surgical plan to confirm proper saw blade thickness(es) and width(s) and perform the resection(s).

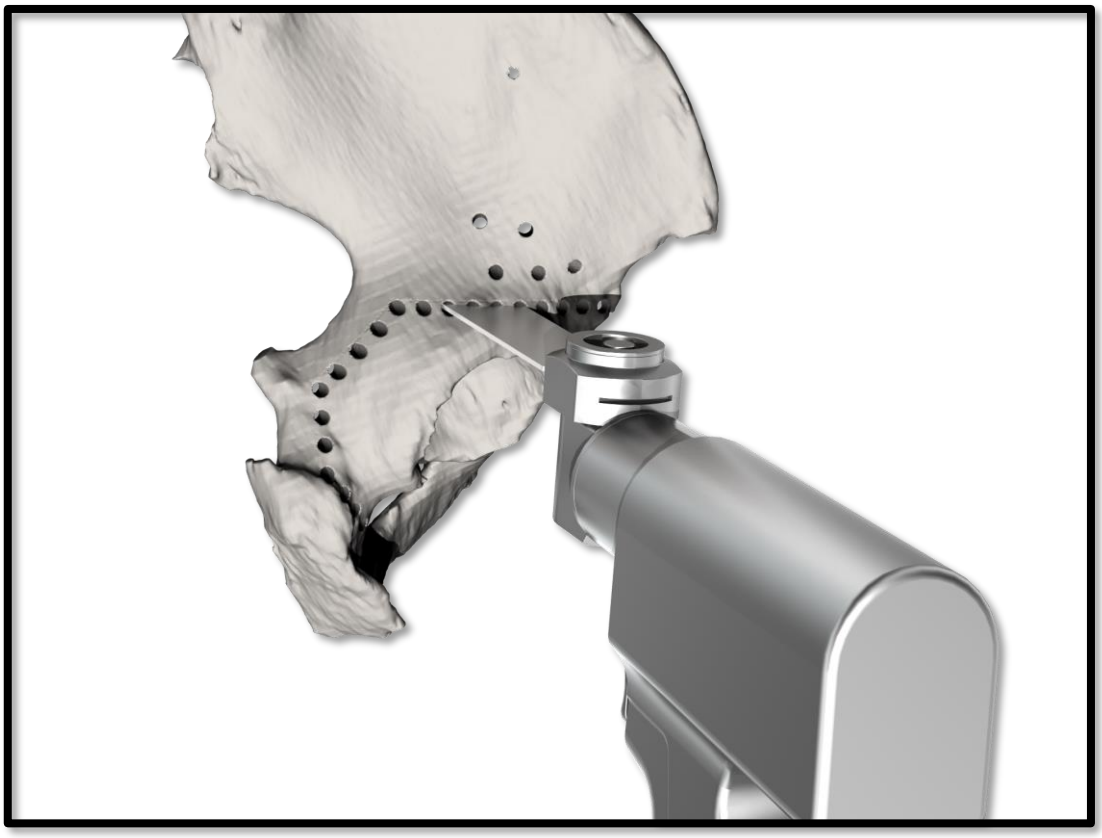


Figure 8: Use a saw to complete the resections using the guides.

Point-to-Point resections:

- Refer to the surgical plan to confirm the proper Trocar Tip 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

Bone Preparation (Continued)

6. After completing the bone preparation per the surgical plan, check that resected surfaces match the surgical plan. Use a rasp or rongeurs to smooth any surface as needed. 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.

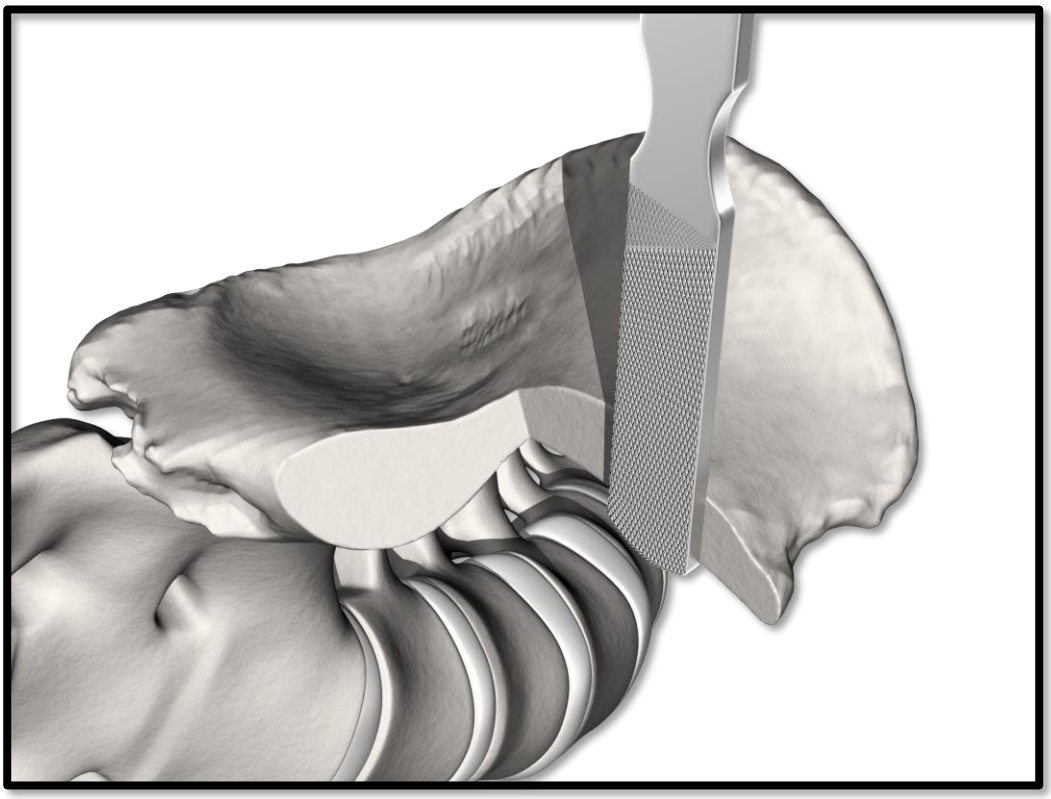


Figure 9: Rasp any sharp corners and or to adjust fit.

Implant Trialing

7. With the resections complete, use the provided implant trial while referencing the anatomic model to confirm the accuracy of the bone preparation. The anatomic model 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 trial.

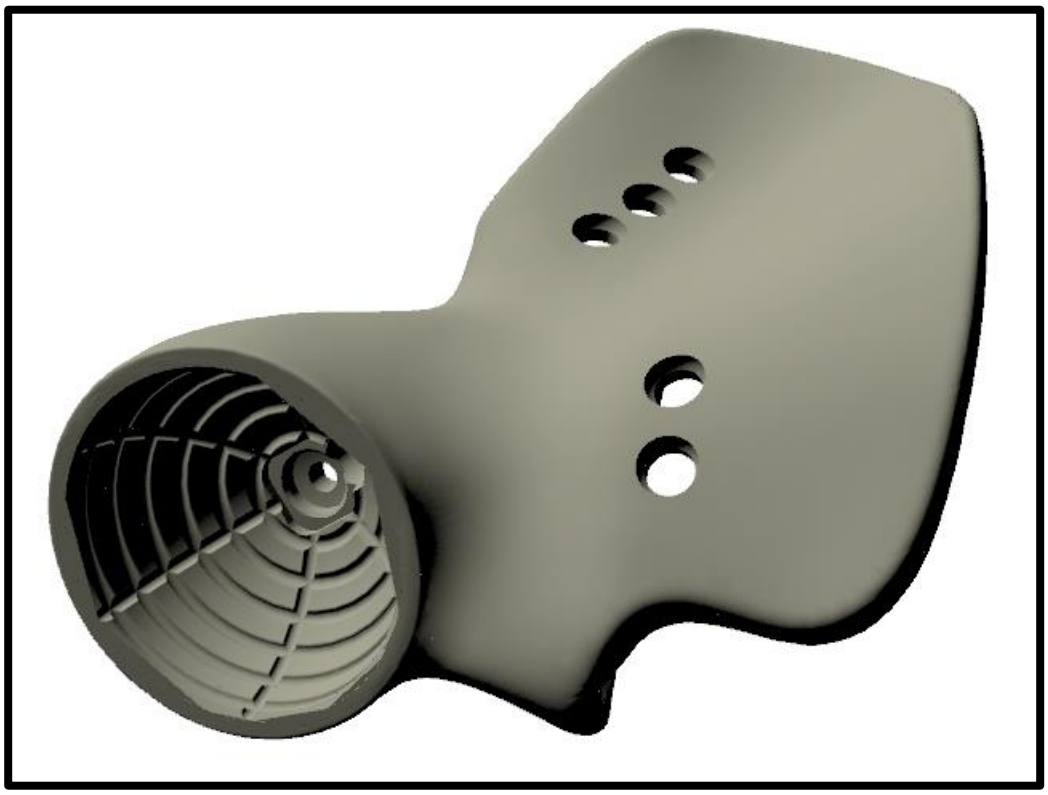


Figure 10: Example Implant Trial.

Implant Trialing (Continued)

8. On the back table, securely fasten the inserter handle to the definitive implant and introduce it into the patient.

Figure 11: Pelvic Inserter Handle

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.

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

Implant Trialing (Continued)

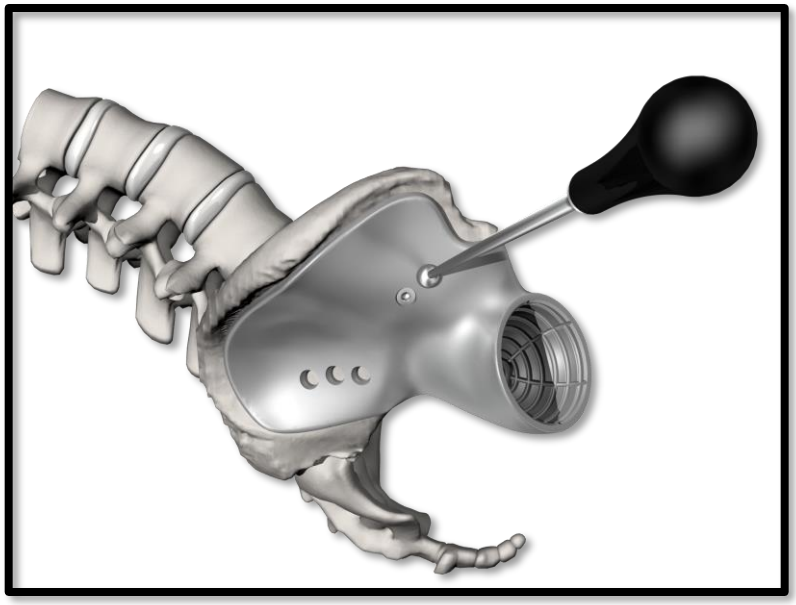


Figure 13: Ball Pusher Instrument may be used to hold down implant while fixating screws into the flange, or to adjust the location of the implant on the bony anatomy.

Figure 14: Use of ball pusher instrument to hold down implant while a bone screw is fixated into the iliac table.

Implant Trialing (Continued)

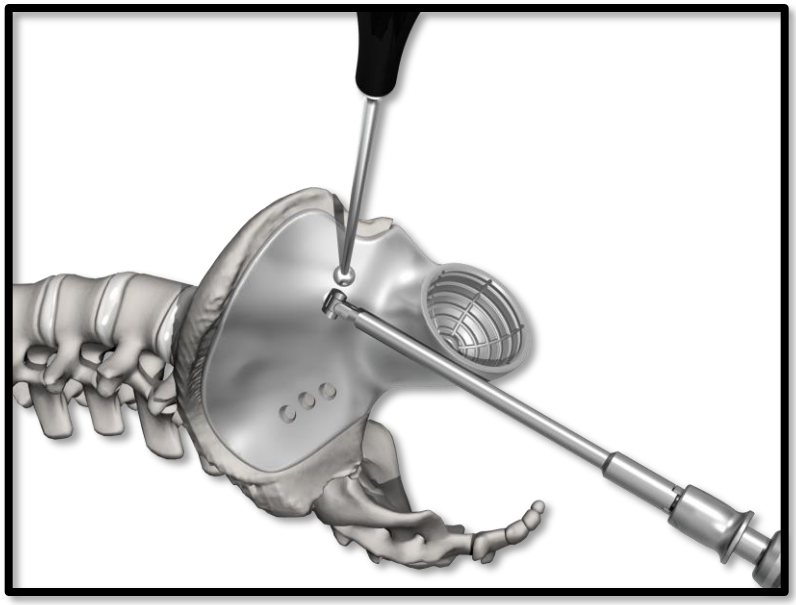


Figure 15: Use of ball pusher instrument used while a bone screw is inserted with a screwdriver with U Joint attachment.

Figure 16: Use of ball pusher instrument in conjunction with spherical impactor assembled onto the pelvic inserter handle which may also be used to aid in implant placement and positional adjustment.

Screw Hole Preparation

9. Using the screw drill guide, place the drill guide into the screw hole of the pelvic implant being sure to respect the trajectory established in the surgical plan. 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, calibrated long,). Either under power or by hand, perform the pre-drill operation for all screw holes per the surgical plan.

    - Note for cases involving resection guides, the fixation holes used on the guide(s) may serve a dual purpose as pre-drill 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.

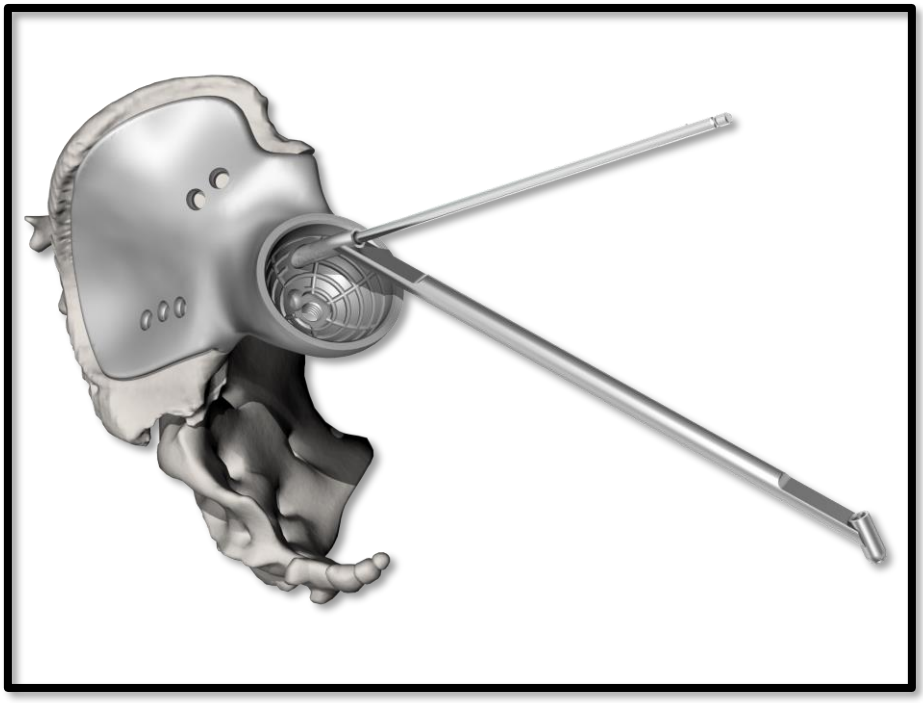


Figure 17: Predrilling of posterior column through-cup screws; long end of drill guide matches planned trajectory.

Screw Hole Preparation (Continued)

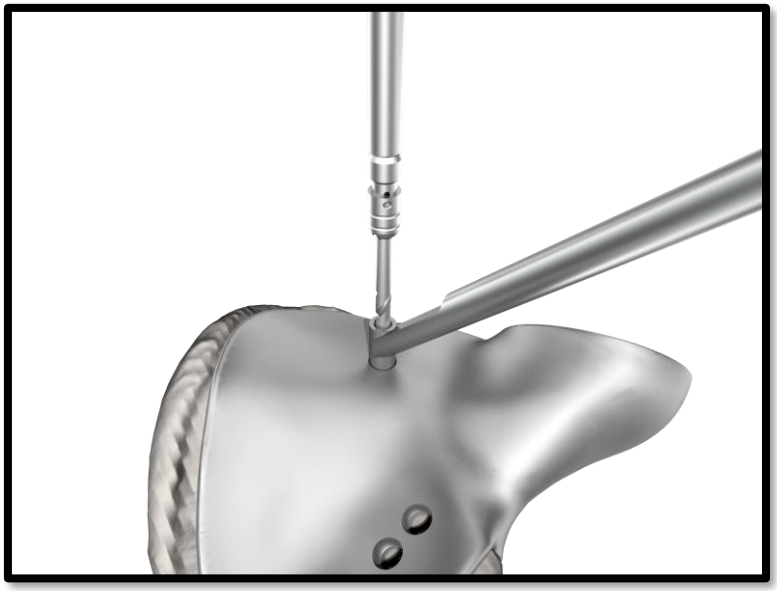


Figure 18: Drill guide with straight bayonet drill adaptor.

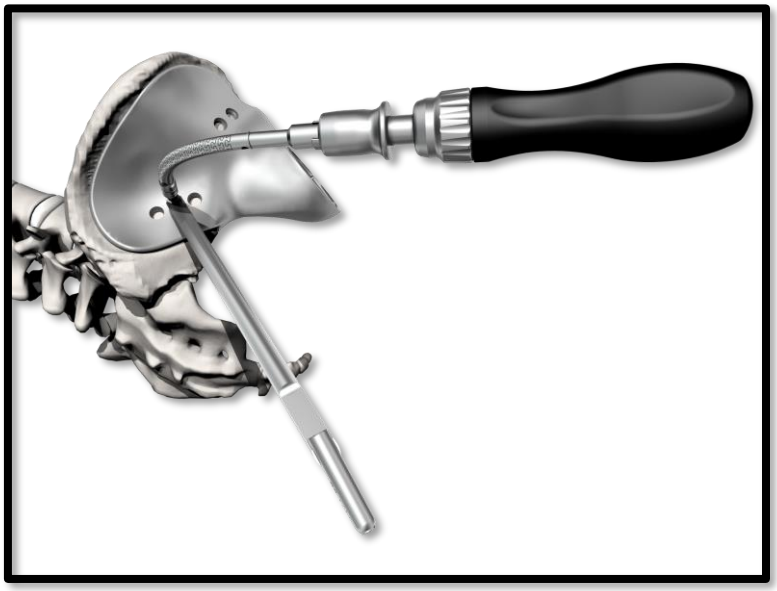


Figure 19: 25mm bayonet drill with flexible driver and drill guide can be used to predrill holes in ischium, pubis, or any other area where a straight drill cannot easily access.

Screw Depth Confirmation

10. 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 (DG-45120-04N), the following practices may be followed:

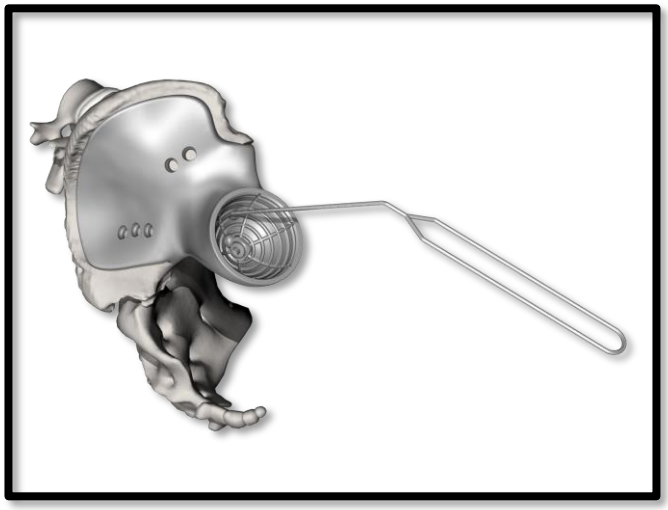


Figure 20: Use of fixed angle depth gage to measure required screw length.

Figure 21: Use of Flexible Depth Gage to measure holes in harder to access locations.

Method 1: 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.

Method 2: Insert the variable angle drill guide (DG-CX020-04N) into the screw hole. Using the depth gauge, measure the depth of the hole to the end of the drill guide. Subtract the length of the drill guide (18mm for short side, 38mm for long side) to determine screw length.

Screw Insertion

11. 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. Care should be taken not to overtighten the screw such that screw purchase is lost.

Figure 22: Use of forceps to hold screw head while inserting with inline ratcheting modular handle and flexible bayonet driver (Left). Use of forceps to hold screw head while inserting with inline ratcheting modular handle and universal joint 3.5mm hex driver (Right).

Figure 23: Use of ratcheting inline handle with straight 3.5mm Hex Driver to insert screw through the cup.

Screw Insertion (Continued)

Figure 24: Schematic of interchangeable instruments with the modular handle.

Figure 25: Schematic of interchangeable instruments with the bayonet connector.

Figure 26: 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)

Summary of Drivers

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

The Instrument Kit Provides:

- 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

Screw Insertion (Continued)

For situations where insertion of the screw is difficult, screw taps in various lengths are available to remove additional removal and ease screw insertion.

Figure 28: Modular bayonet tap assembled to the flexible bayonet driver (Left). 180mm AO tap assembled to the ratcheting AO T-handle (Right).

POLARCUP™ Cementation

12. After all screws are securely fastened, 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

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.

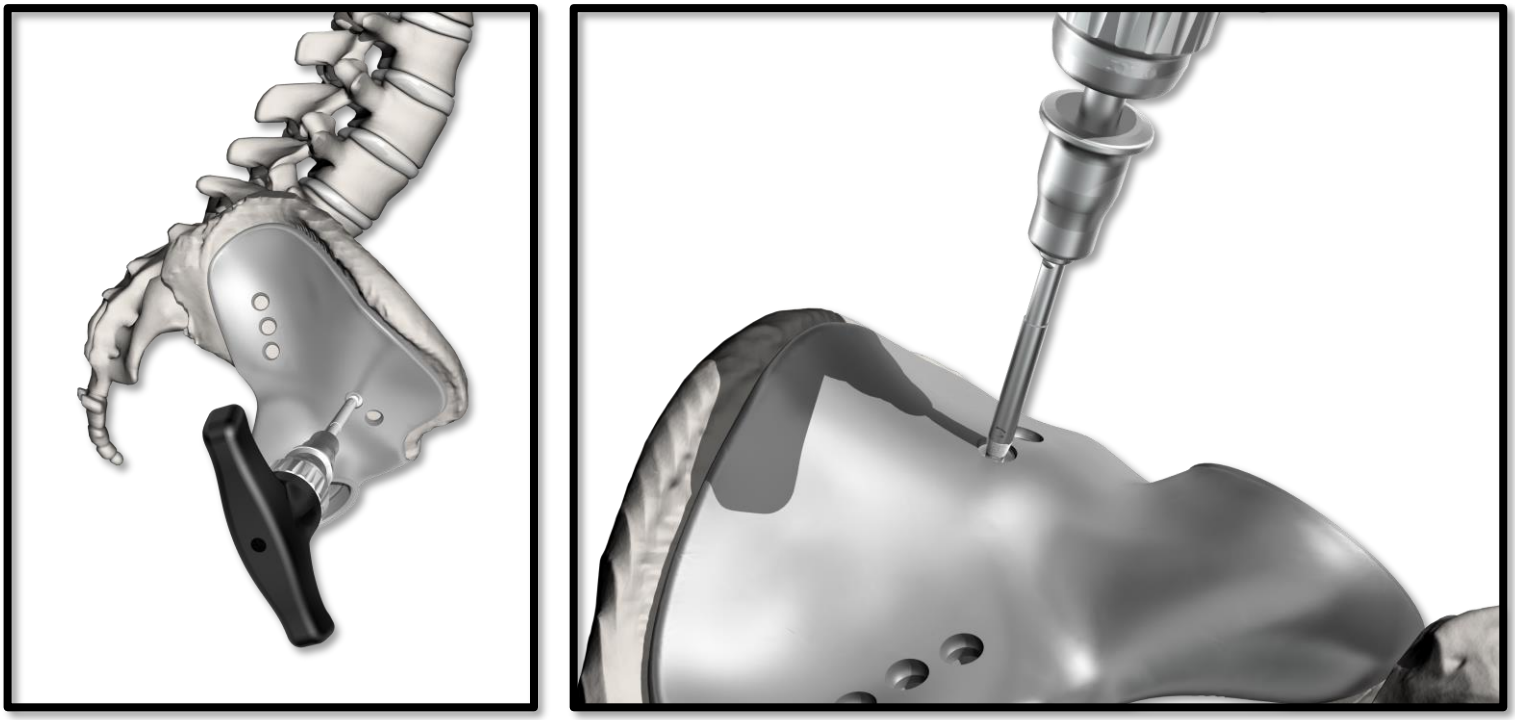
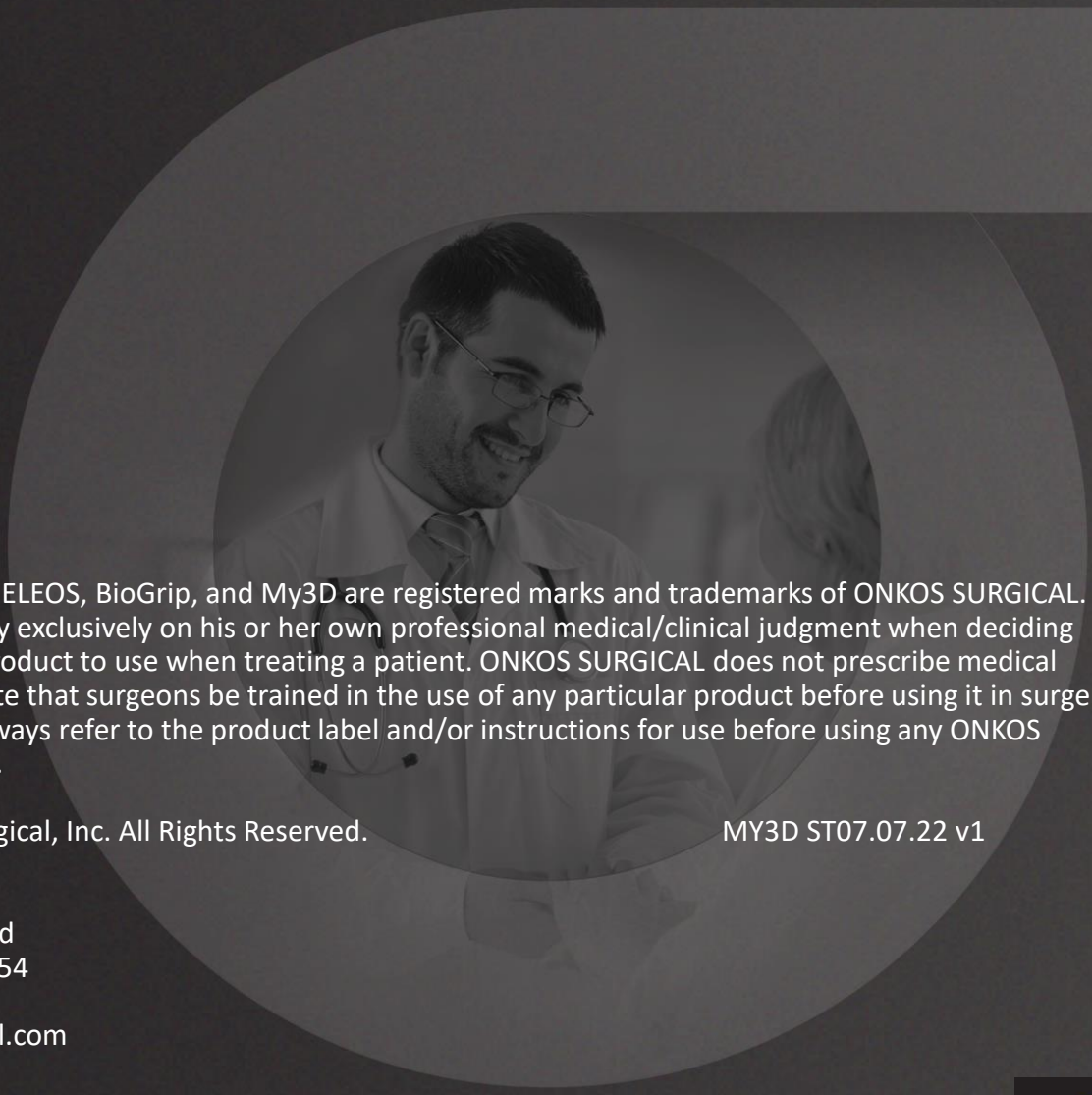


Figure 29: Use of Screw Extractor with the AO Ratcheting T-Handle.



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