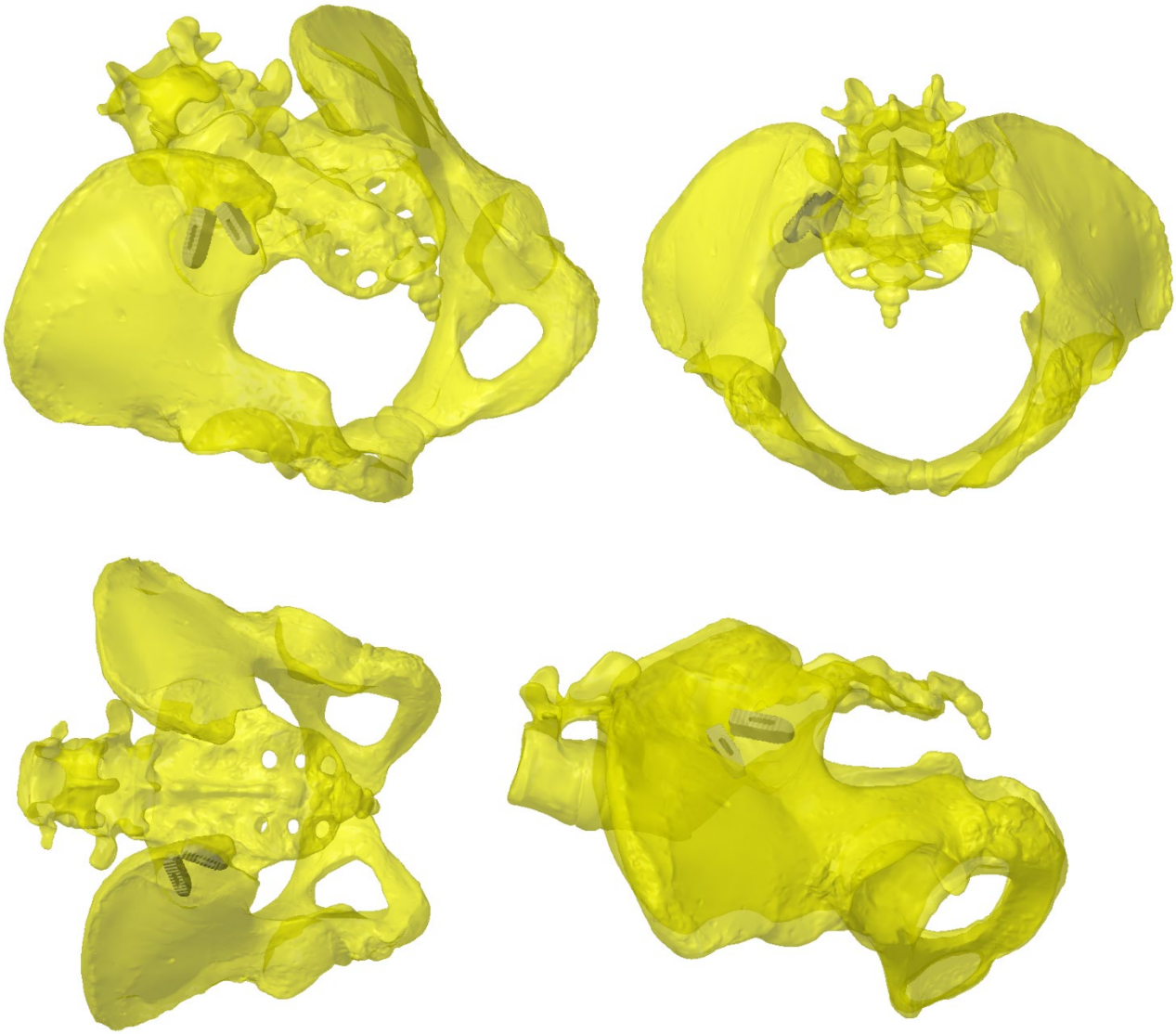
Zavation SIBI (Sacroiliac Bone Implant) System

Surgical Technique Guide



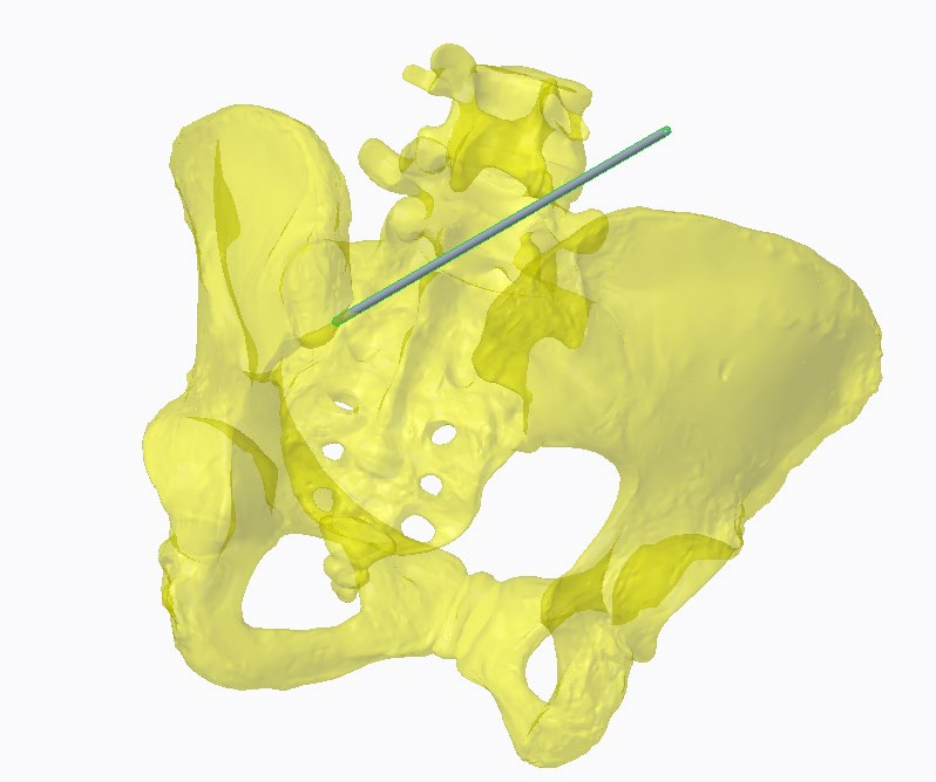
Device Description: The SIBI System consists of multiple handheld instruments used for insertion of a cortical bone wedge into the Sacroiliac joint. Subject instruments are intended for use only with Zavation pedicle or OCT screws.

Indications: The SIBI is intended for minimally invasive sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Surgical Technique

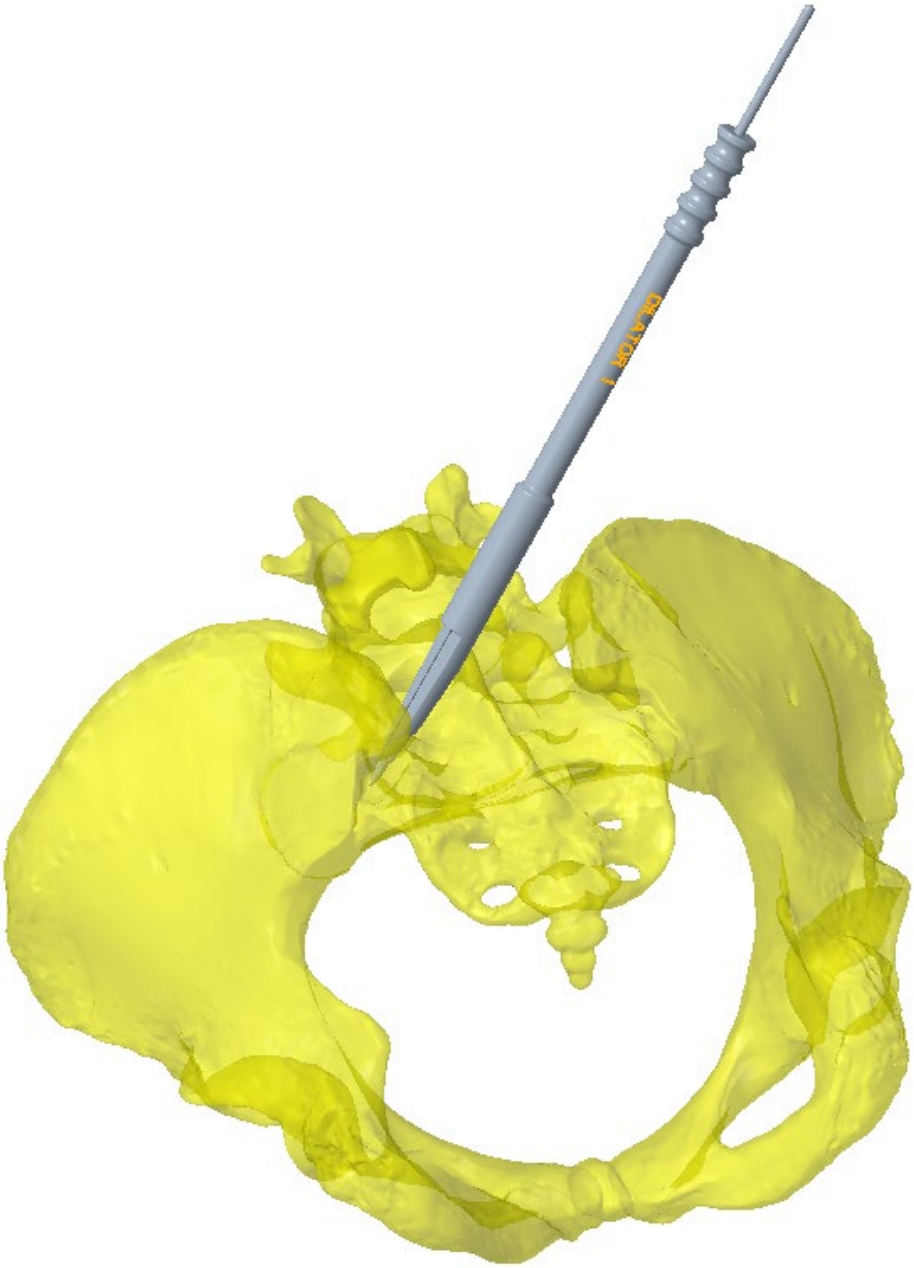
Step 1 – K-Wire Placement

After determining proper placement insert K-Wire to preferred depth in the joint. Note that the instruments of the SIBI system create a cavity 29mm deep into the joint.



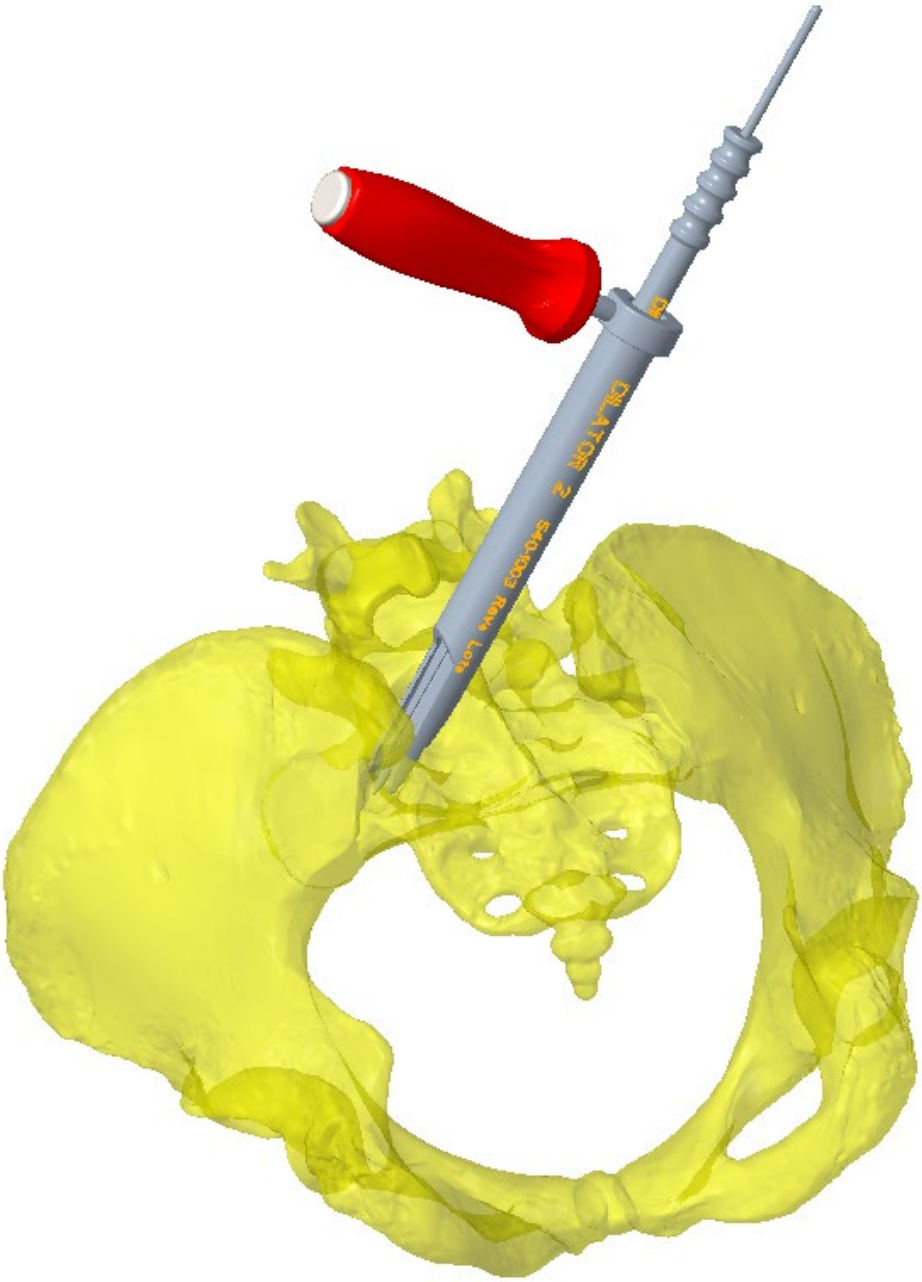
Step 2 – Dilator #1

Insert Dilator #1 over the K-Wire inserting the prongs of the dilator into the joint.

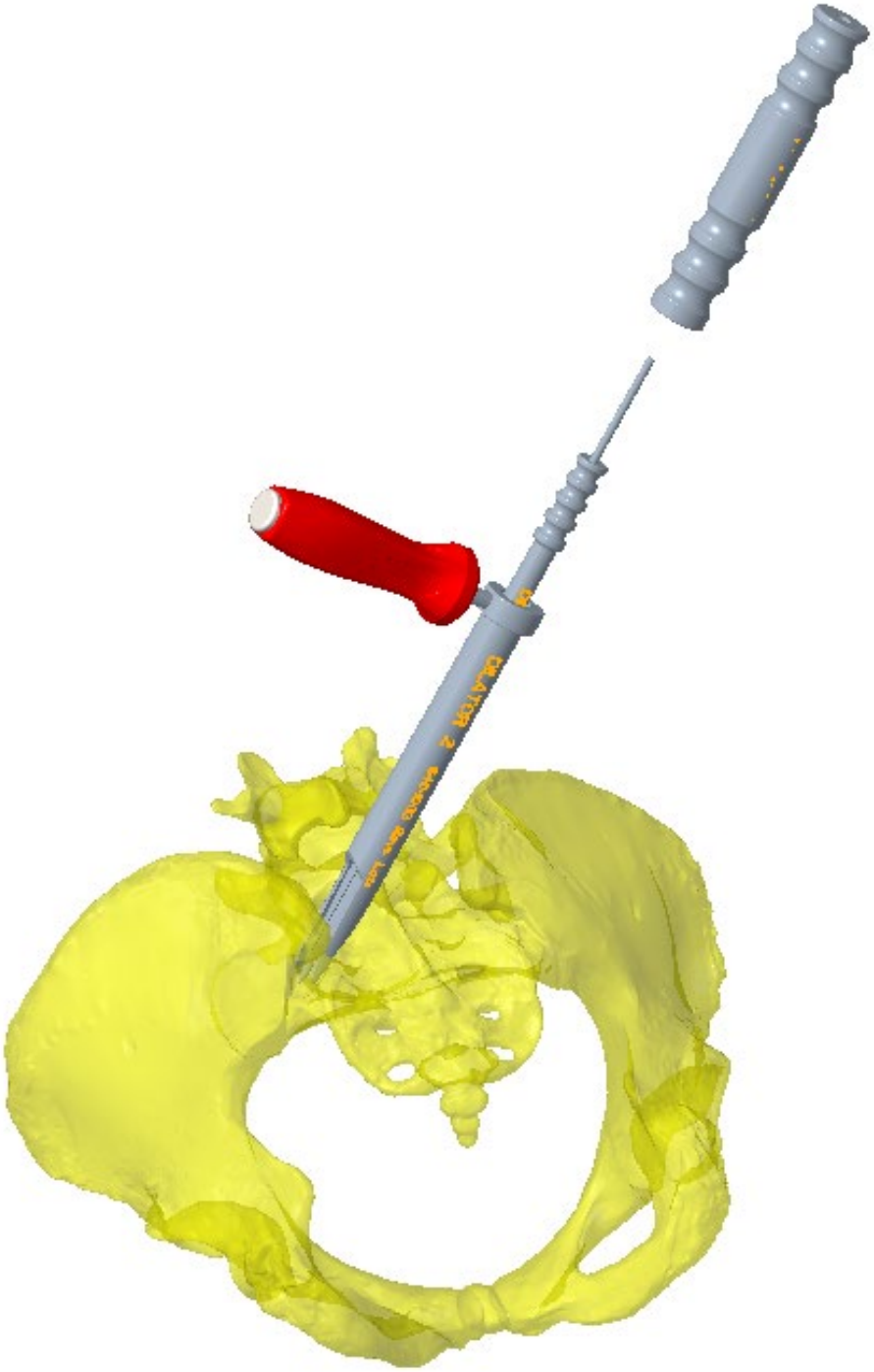


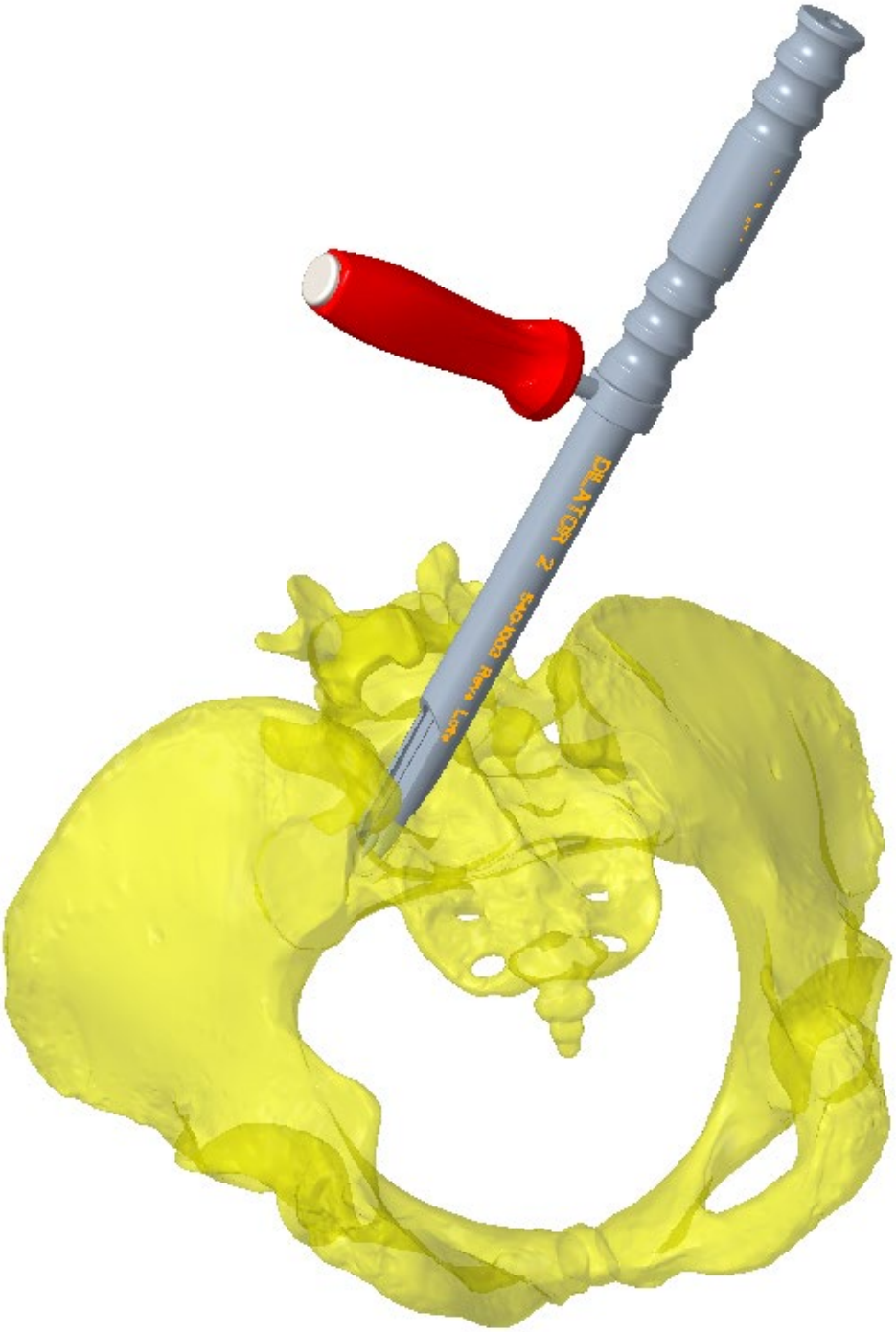
Step 3 – Inserter Dilator #2

Insert Dilator #2 over Dilator #1 inserting its prongs into the joint and advancing until the dilator bottoms on the sacrum and/or ilium bones



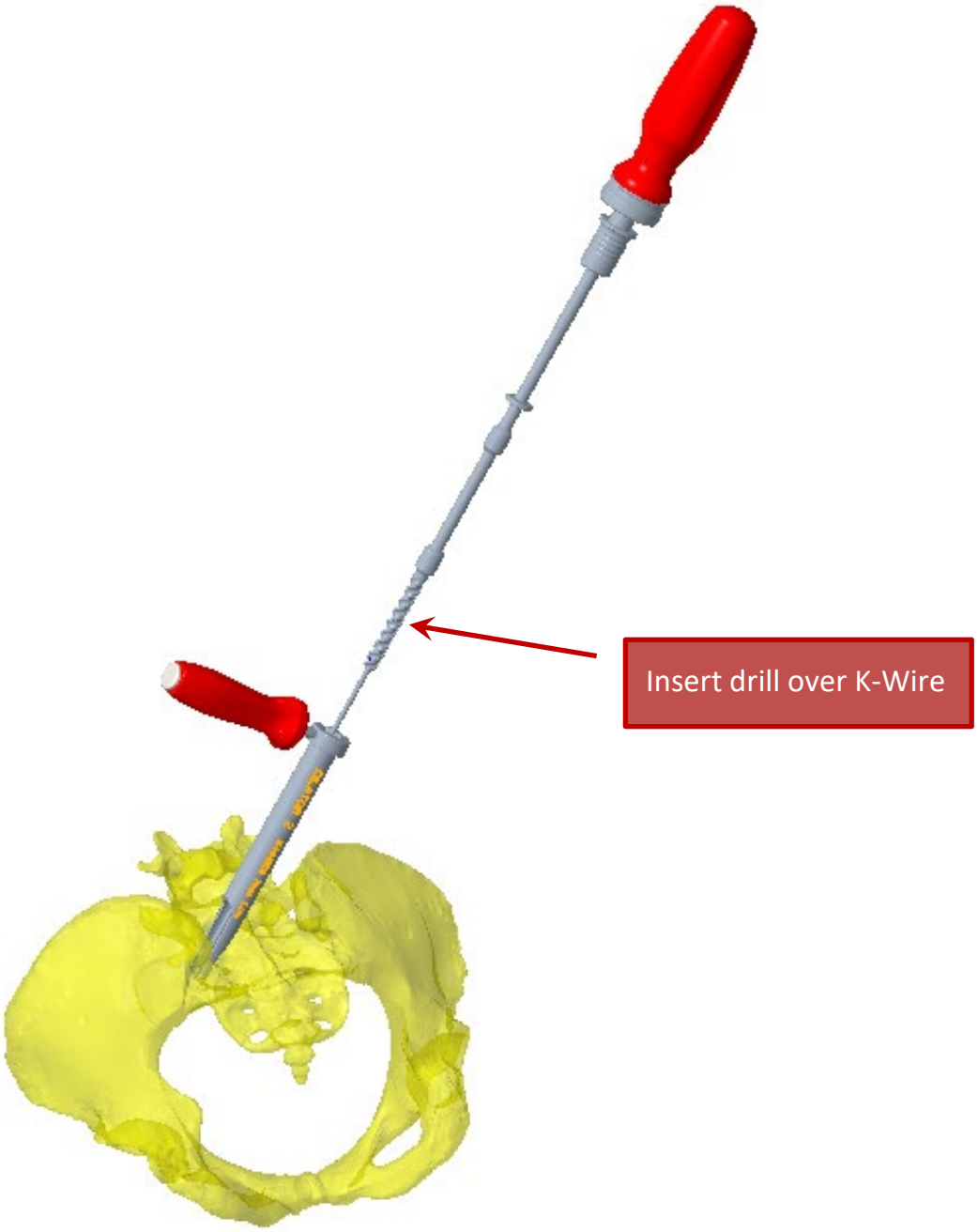
A Tamp is available to advance Dilator #1 and Dilator #2 if necessary.

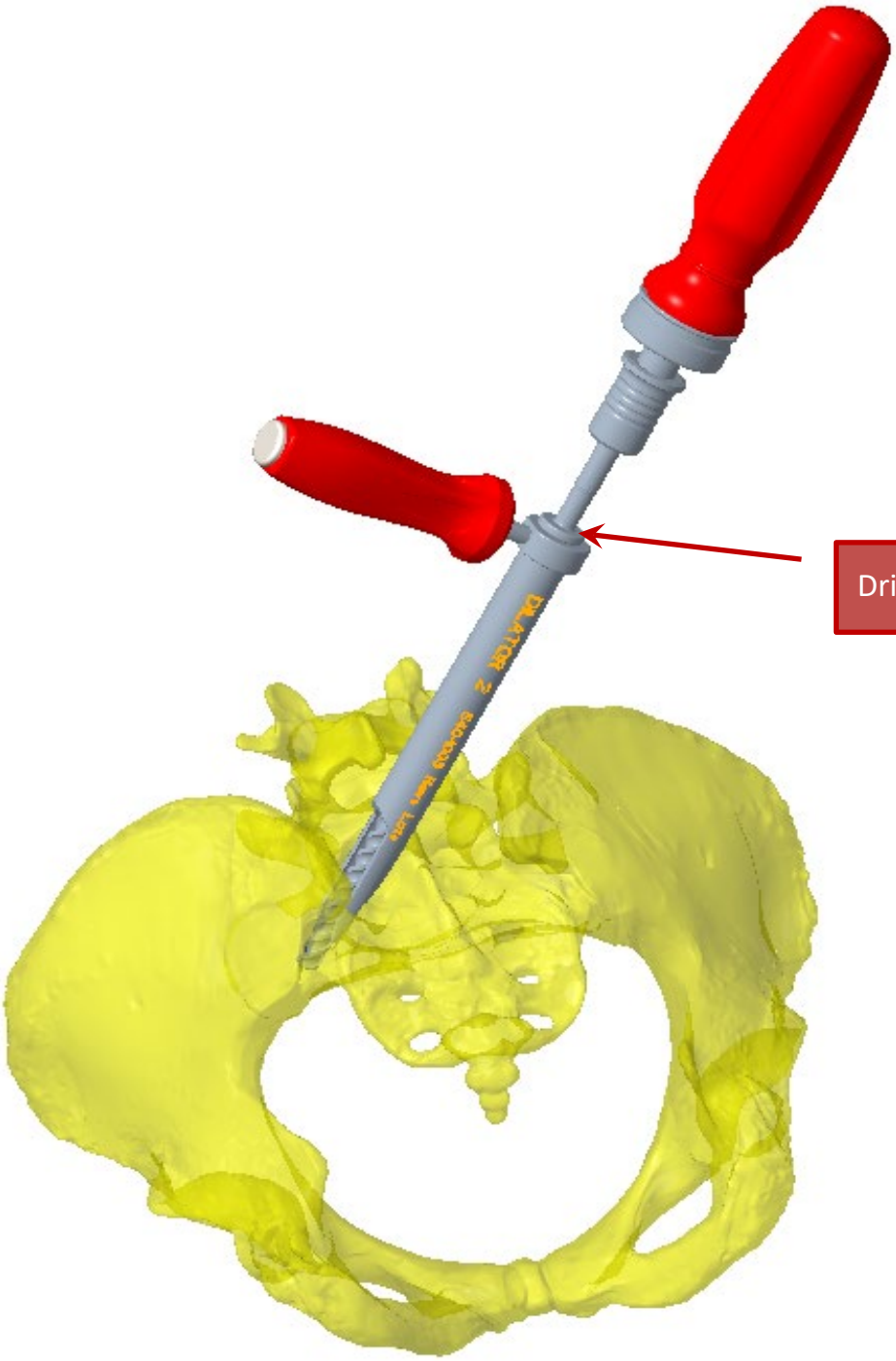



DELTOR 2

Step 4 –Drill to prepare implant cavity

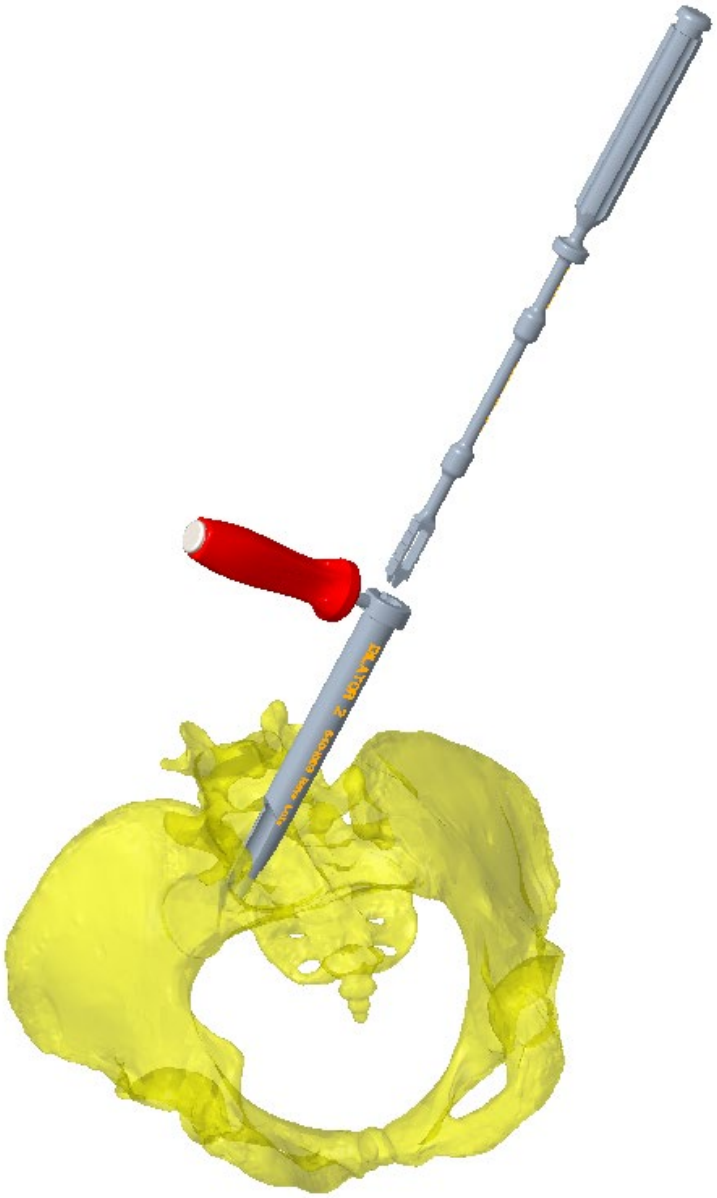
Remove Dilator #1. Inserter the Drill over K-Wire and through Dilator #2. Drill until the drill stop contacts Dilator #2 as shown.

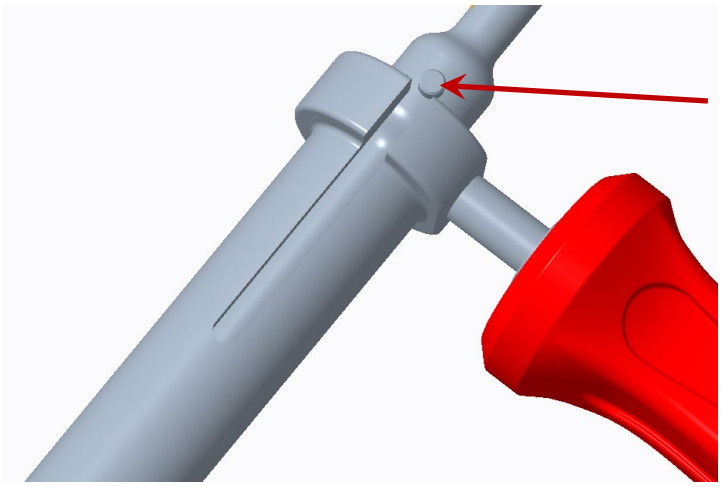



Drill stop contacting Dilator

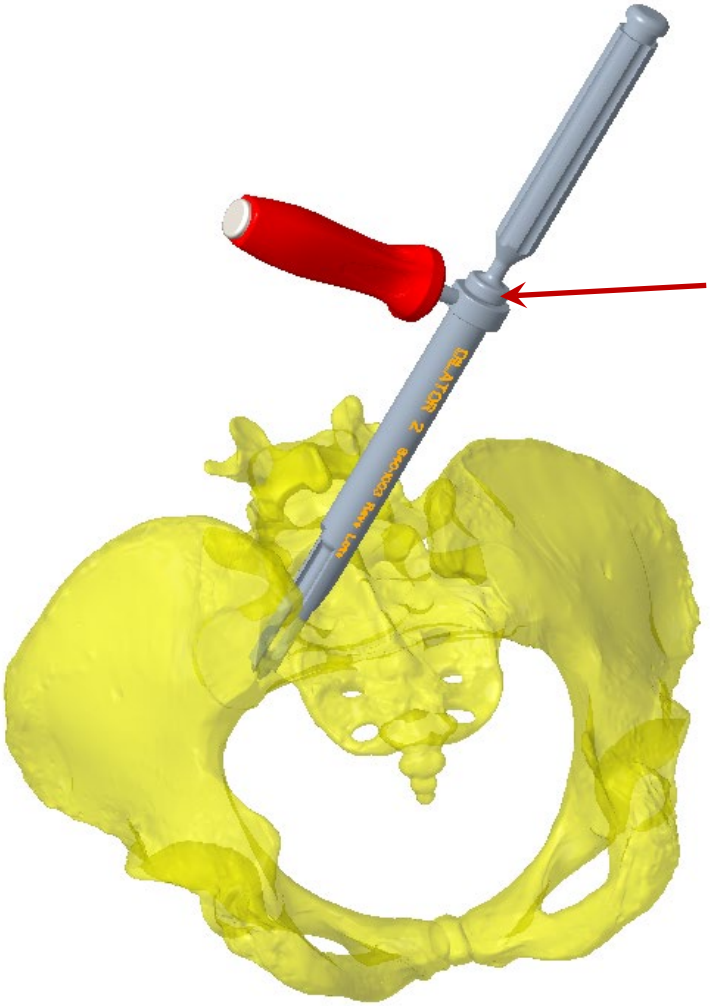
Step 5 – Chisel

Remove the Drill and K-Wire. Insert Chisel into Dilator #2. Align pin on the Chisel with Dilator #2 as shown. Tamp chisel until the stop on the chisel contacts the Dilator #2 as shown. Remove Chisel. A Slap Hammer is available if needed to aid in removing the Chisel





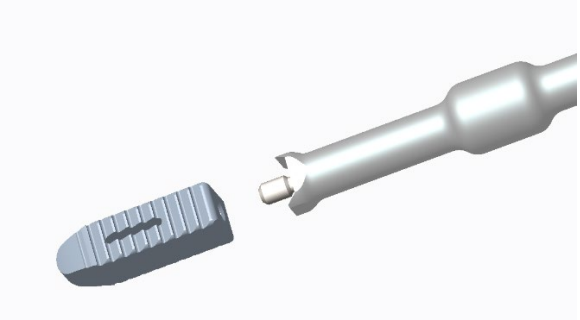
Pin aligned to slot

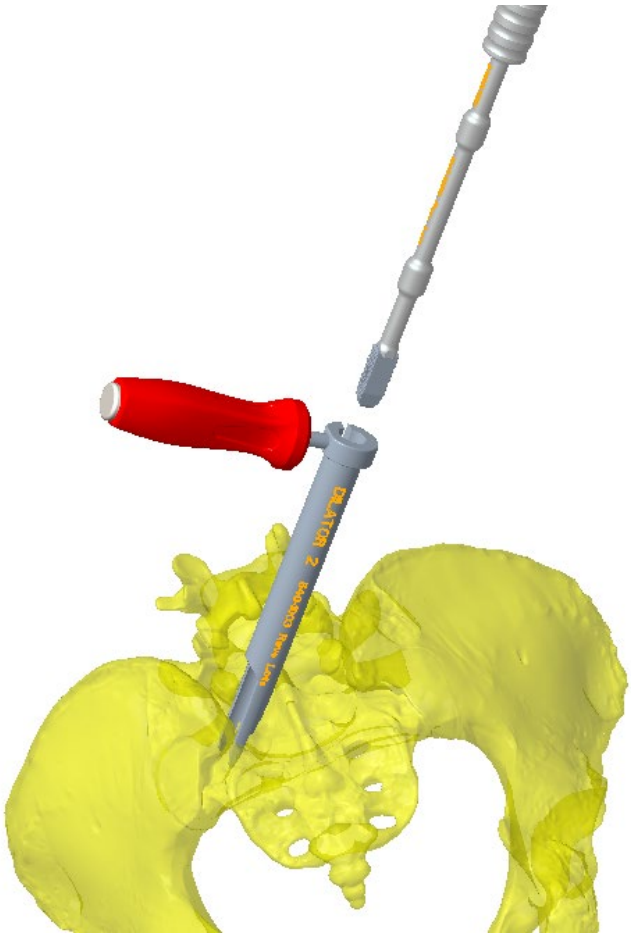


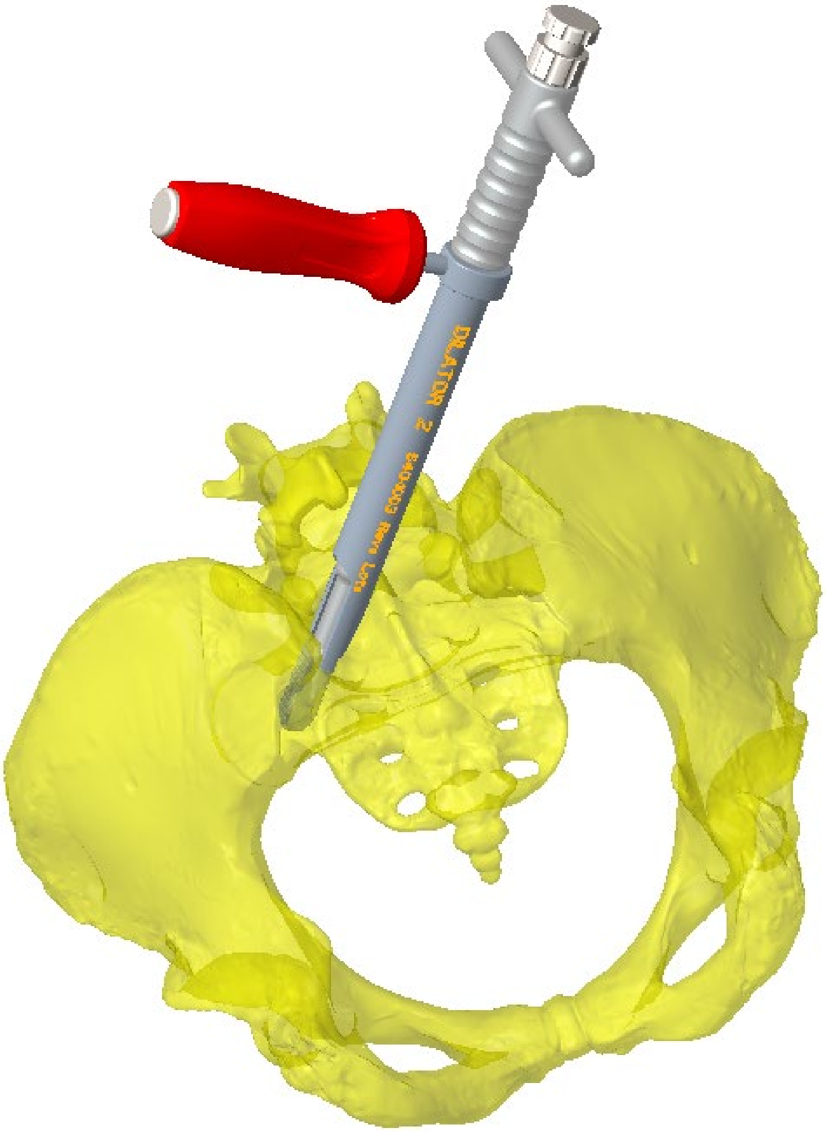
Chisel stop contacting Dilator

Step 6 – Insert Cortical Bone Wedge

Attach Bone Wedge to the inserter. Insert wedge through Dilator #2 until bottomed, ensuring that the implant is aligned as shown with teethed surfaces contacting the Sacrum and Iliac bones. Remove inserter.

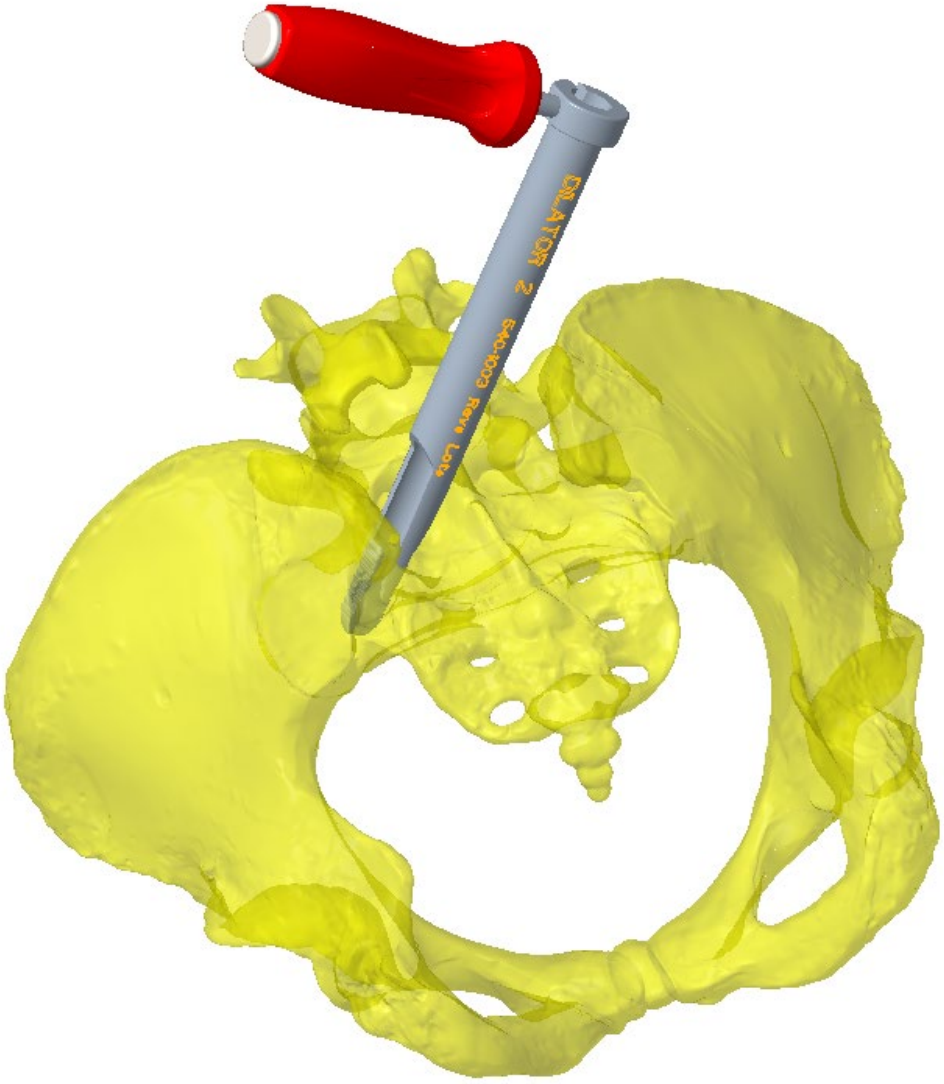





DILATOR 2

Step 7 – Remove Inserter

Remove inserter by loosening the stylus in a counterclockwise direction until the implant is released.

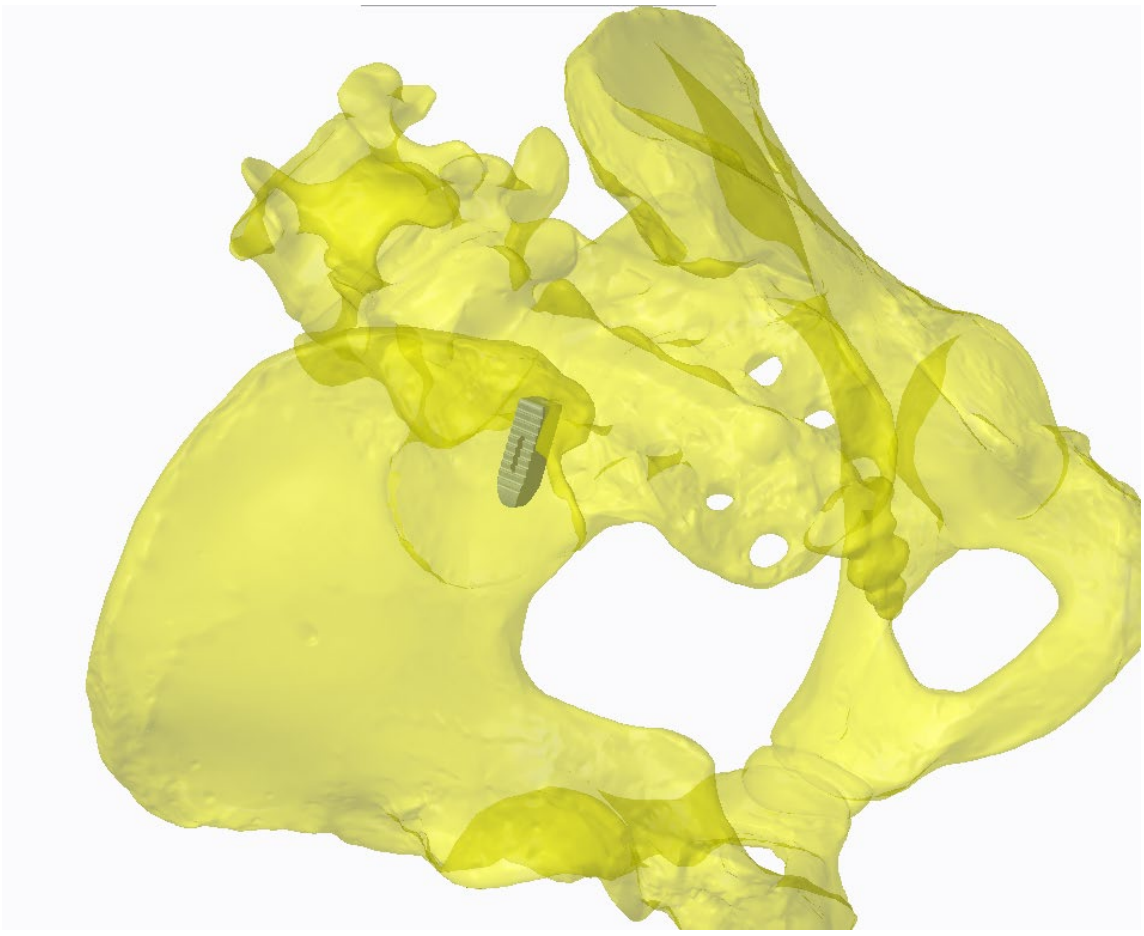


Step 8 – Grafting material

With the Inserter removed and Dilator #2 still in place, grafting material can be placed through the dilator and packed on top of the implant.

Step 9 – Remove Dilator #2

Remove Dilator #2 by pulling out of joint and incision.



Part#	Description	Tray Qty
540-1000	Inserter	1
540-1001	K-Wire	2
540-1002	Dilator 1	1
540-1003	Dilator 2	1
540-1004	Tamp	1
540-1007	Drill	1
540-1010	Box Chisel	1
std	Straight Ratchet Handle (cannulated)	1
100-1008	Slap hammer	1
Z-1034	Mallet	1

Materials: The SIBI System patient contacting materials are Stainless Steel.

Contraindications: Contraindications for the SIBI System are similar to those of other systems of similar design, and include, but are not limited to:
1. Patients with probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities.
4. Use with components from other systems.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any other medical or surgical condition which would preclude the potential benefit of surgery.
7. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
8. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
10. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not described in the indications for use.

Potential Adverse Events: Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and include, but are not limited to:
1. Early or late loosening of any or all the components.
2. Breakage of any or all the components.
3. Foreign body (allergic) reaction.
5. Infection.
6. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
7. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
8. Loss of bladder control or other types of urological system compromise.
9. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
10. Fracture, micro-fracture, resorption, damage, or penetration of any bone.
11. Non-union (pseudarthrosis), delayed union, mal-union.
12. Cessation of any potential growth of the operated portion of the spine.
13. Inability to perform the activities of daily living.
14. Death.
Note: Additional surgery may be necessary to correct some of these anticipated adverse events

Warnings and Precautions

As with any surgical system, the SIBI System should be used by experienced surgeons with specific training in the use of the system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. Appropriate selection, placement and fixation of the components are critical factors.

Patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients should be advised of this fact and warned of the potential consequences. Patients with previous surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery.
Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through corporate sales representatives.

Preoperative:
1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.

3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. The type of implant to be used for the case should be determined prior to beginning the surgery.
7. All parts should be cleaned and sterilized before use.

Intraoperative:
1. Extreme caution should be used around the spinal cord and nerve roots. Damage to these structures will cause loss of neurological function.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
4. Caution should be taken in handling the implants; Damage to the implants may affect their performance.
5. Implants should not be reused under any circumstances.

Postoperative:
Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:
1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity.
3. During explantation, care should be taken to avoid damaging the implant and surrounding tissue as little as possible. The explanted device should be cleaned and disinfected using the instructions provided for cleaning/disinfection of instruments. Information on the procedure and patient should be retained to assist in any investigation.
4. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.

Pre-Cleaning/Cleaning and Sterilization Procedure Recommended for Reusable Instruments (and Trays):
For safety reasons, reusable instruments must be pre-cleaned, cleaned and sterilized before use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following table.

Sterilization trays should be thoroughly cleaned using either the Automated or Manual procedure that is detailed below for instruments. It is acceptable to skip the ultrasonic cleaner step for the sterilization trays if the inspection criteria provided below are acceptable for the tray.

Cautions: Long, narrow cannulations and blind holes require particular attention during cleaning.	
Limitations on reprocessing: Repeated processing has minimal effect on these instruments. End of life is determined by wear and damage due to use.	
1-Point of use: Remove all visual soil with disposable cloth/paper wipe. Soiled instruments must be kept moist to prevent soil from drying. If the instruments cannot be soaked immediately place a moist towel around them until they can be cleaned.	
2-Containment and transportation: Avoid damage and minimize time before cleaning	
3-Preparation for cleaning: None of the instrument require disassembly prior to cleaning other than disassemble removable handles that are left attached to the drill, tap and screw drivers and remove drills, taps and awl that are left in the drill guides. (note that these items are normally stored in their dedicated tray already disassembled).	
4 Thoroughly clean instruments per one of the following (Manual or Automated)	
Manual	**Automated**
4.1 Pre-Cleaning-Manual:	**4.1 Pre-Cleaning-Automated:** Automated washing shall be conducted in a validated washer-disinfector.

<table>
<tr><td>Prepare a pH neutral, enzymatic detergent soak per the instructions of the enzymatic solution manufacturer.
Soak the instrument for a minimum of 15 minutes. Actuate any mechanisms and slide moving parts to the extreme positions to ensure the cleaning solution contacts all the surfaces.
Change the soak solution if the solution becomes visibly soiled.
While still in the soak solution, use a soft brush the remove all exterior soil. Thoroughly scrub any grooves, slots, threads, teeth, ratchets, or hinges. Use an appropriate size cleaning brush to thoroughly brush the entire length of any internal lumens a minimum of five times per lumen
Rinse instruments thoroughly with warm (approximately 35-40°C) critical water, such as reverse osmosis, distilled, and/or deionized water, taking care to flush all lumens or crevices, for at least one minute, until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until water runs clear</td><td>An example of a validated cycle used for cleaning validation includes:
Wash 45ºC 4 minutes dose pump 4 (detergent) 5mL
Wash 60ºC 3 minutes
Rinse with unheated critical water, such as reverse osmosis, distilled, and/or deionized water 1 minute.
Rinse 60ºC 1 minute</td></tr>
<tr><td>4.2 Cleaning-Manual:
Prepare a fresh pH neutral enzymatic cleaning solution and sonicate the instruments and subassemblies for a minimum of 15 minutes in an ultrasonic bath. After sonication, rinse instruments again under running critical water, such as reverse osmosis, distilled, and/or deionized water for a least one minute until water runs clear. Use a tubing attachment to the water outlet in order to direct the rinse flow into any lumens, crevices, grooves, or slots and flush them completely until the water runs clear.
Dry the exterior of the instruments with a clean, soft cloth. Use clean compressed air or 70% isopropyl alcohol to dry any lumens or crevices where water may become trapped.</td><td>4.2 Washer Disinfector:
Automated washing shall be conducted in a validated washer-disinfector.

An example of a validated cycle used for cleaning validation includes:
Thermal Disinfection A_0 93ºC
A_0 value: $A_0$3000
Dry 123ºC air 14 minutes</td></tr>
<tr><td colspan="2">Inspection:
Visually inspect each disassembled device to ensure all visible blood and soil has been removed. If not visually clean repeat step 4 above until clean or appropriately dispose of device if unable to get visually clean.
Check disassembled instruments with long slender features for distortion.
Inspect the disassembled devices for any cracking, pitting, or other signs of deterioration</td></tr>
<tr><td colspan="2">Packaging: Instruments are loaded into dedicated instrument trays. Wrap the trays using appropriate FDA cleared wrap.</td></tr>
<tr><td colspan="2">Sterilization: See sterilization procedure</td></tr>
<tr><td colspan="2">Storage: Control environment</td></tr>
</table>

Additional information: When sterilizing multiple instruments/trays in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.
Manufacturer contact: Contact local representative or call customer service at 601-919-1119

Sterilization: The SIBI System should be sterilized by the hospital using the recommended cycle:
Do not stack trays in the chamber.

Method	Cycle	Temperature	Minimum Exposure Time	Drying Times
Steam	Gravity	270°F (132°C)	15 Minutes	15 Minutes
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes

Instrument Maintenance: Lubricate hinges, threads and other moving parts with a commercial water-based surgical grade instrument lubricant (such as instrument milk) to reduce friction and wear. Follow lubricant manufacturer's instructions.

Product Complaints: Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Zavation Medical Products, LLC, 3670 Flowood Drive., Flowood, MS 39232, USA, Telephone: 601-919-1119.

Further Information: A recommended surgical technique for the use of this system is available upon request from Zavation Medical Products, LLC, 3670 Flowood Drive., Flowood, MS 39232, USA, Telephone: 601-919-1119.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.