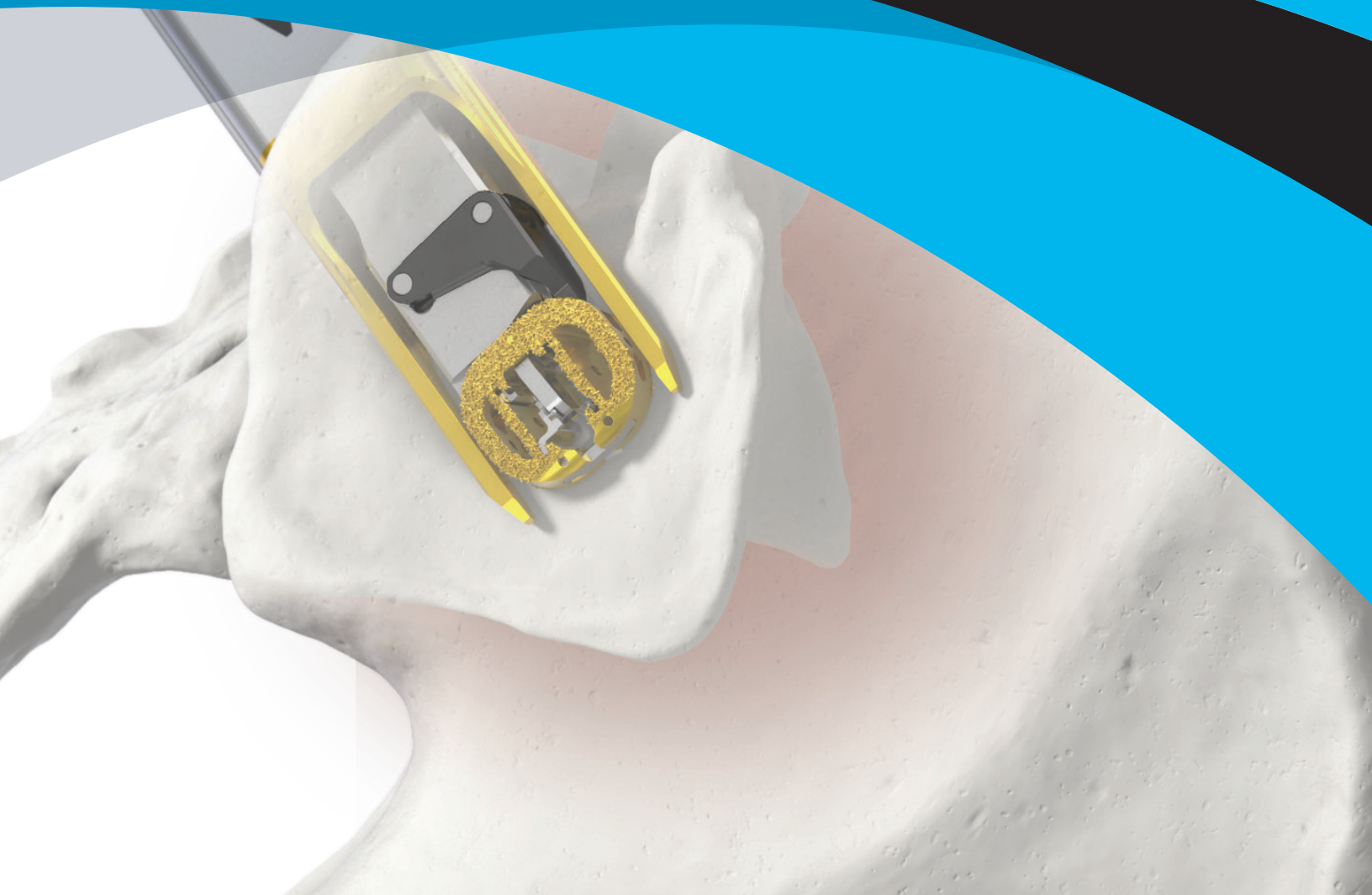
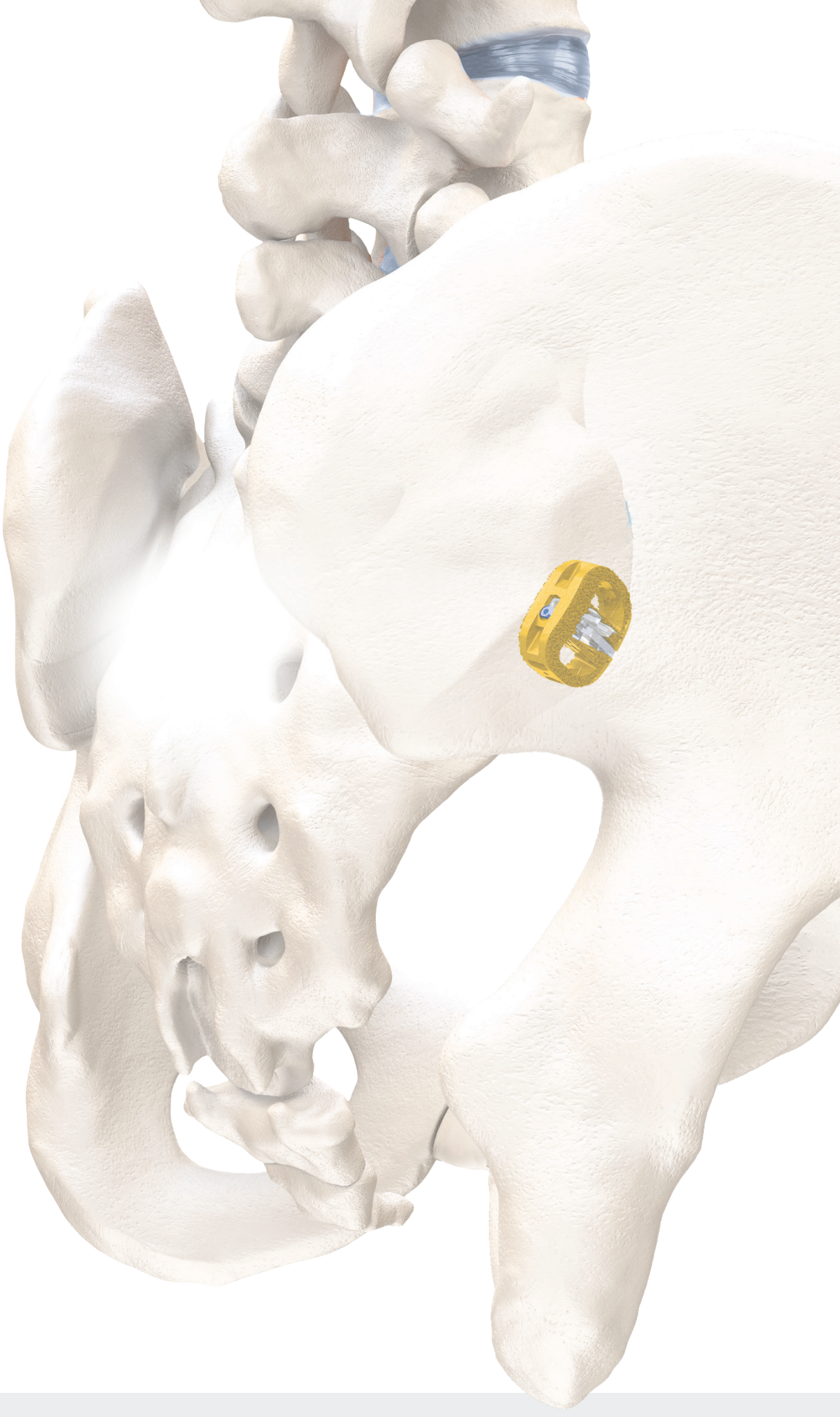
VYRSA™

# Nevro1™ Sacroiliac Transfixing and Fusion System Surgical Technique Guide





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# Product Information

## NON-STERILE PRODUCT

BEFORE USING THE PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

## DESCRIPTION

The Nevro1™ Sacroiliac Transfixing and Fusion System (Nevro1™) is a titanium fusion device that has a hollow chamber to permit packing with autogenous graft material to facilitate fusion. The superior and inferior surfaces of the device have a rough surface to help prevent movement of the device while fusion takes place. Additionally, the device has integrated fixation through superior and inferior transfixing anchoring plates.

These implants may be implanted via an open or MIS posterior approach. The Nevro1™ is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. The system is comprised of a Titanium Alloy (Ti-6Al-4V ELI) implant with integrated transfixing anchors.

The Nevro1™ implants are provided in 8 degrees of angle, 9, 11, 13 mm heights, 26 mm width and 23 mm depth. The titanium alloy implant also comes preassembled with integrated transfixing anchors.

## MATERIALS

The Nevro1™ device body is made from a 3D printed titanium alloy Ti-6AL-4V (Grade 23) per ASTM F3001-14. The internal device components (bridge, anchor plates, deployment ram, dowel pins and retention Blocking-Screw) are made of titanium (TAV) per ASTM F136.

## INDICATIONS FOR USE

The Nevro1™ Sacroiliac Transfixing and Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

## SURGICAL PROCEDURE

Please contact a customer service representative or company representative for the surgical procedure.

# Locating the SI Joint

With the patient in the prone position, DIRECT AP and LATERAL views are taken to identify the anatomy of the joint.

After the joint is identified and in the AP image frame, locate the Posterior Superior Iliac Spine (PSIS) and the Posterior Inferior Iliac Spine (PIIS).

Place a guide wire on the skin over the PSIS and take an image to properly locate it. Once located, mark a line across the PSIS. Repeat the same process to mark the PIIS.

***Figures 1 and 3 show the target location of the Nevro1™ Implant.***

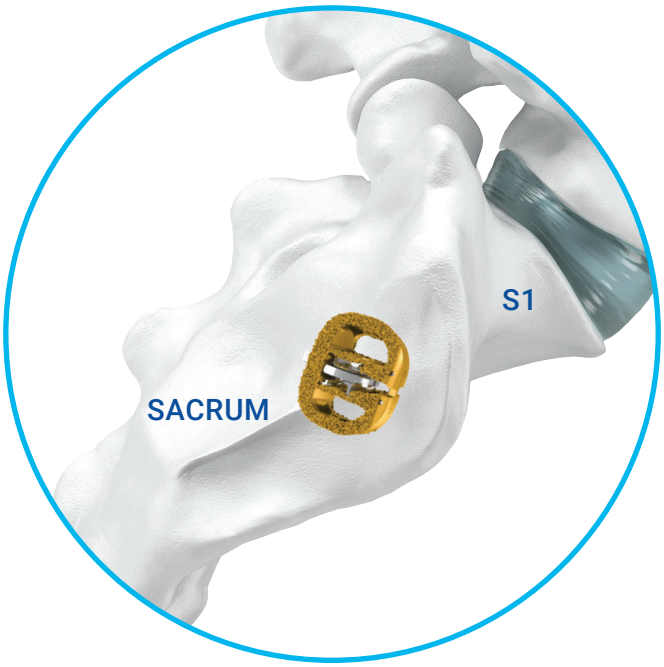



*Figure 1. Lateral view of the Nevro1™ Transfixing Implant.*

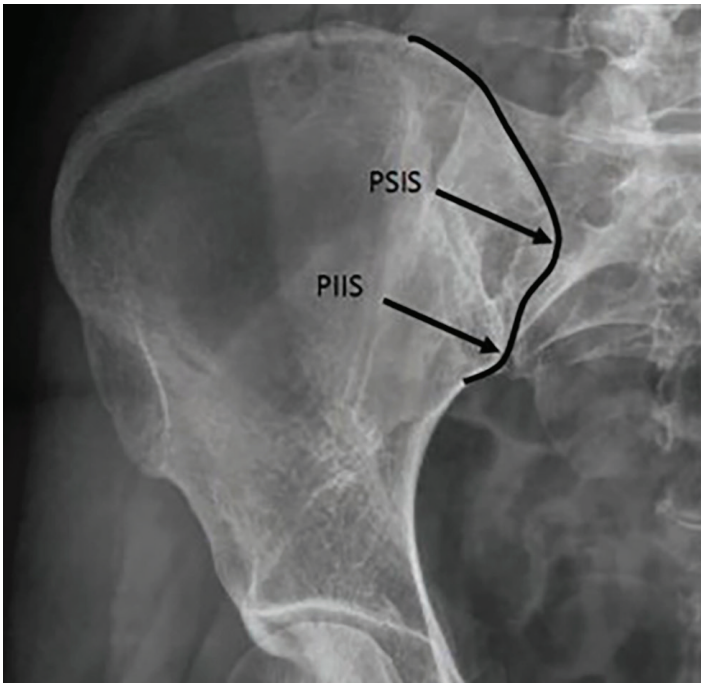



*Figure 2. Direct AP Image of the SI joint.*

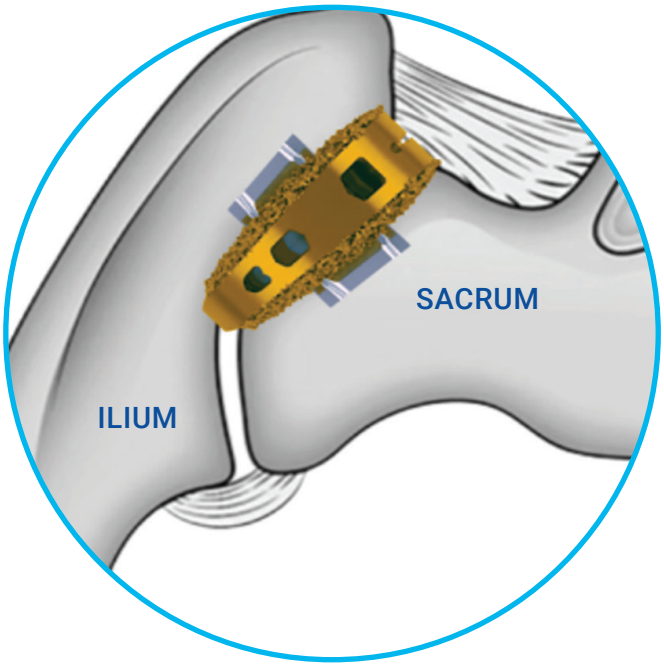



*Figure 3. AP view of the Nevro1™ Transfixing Implant.*

# Locating the SI Joint

Below are different views that aid in locating the SI joint.

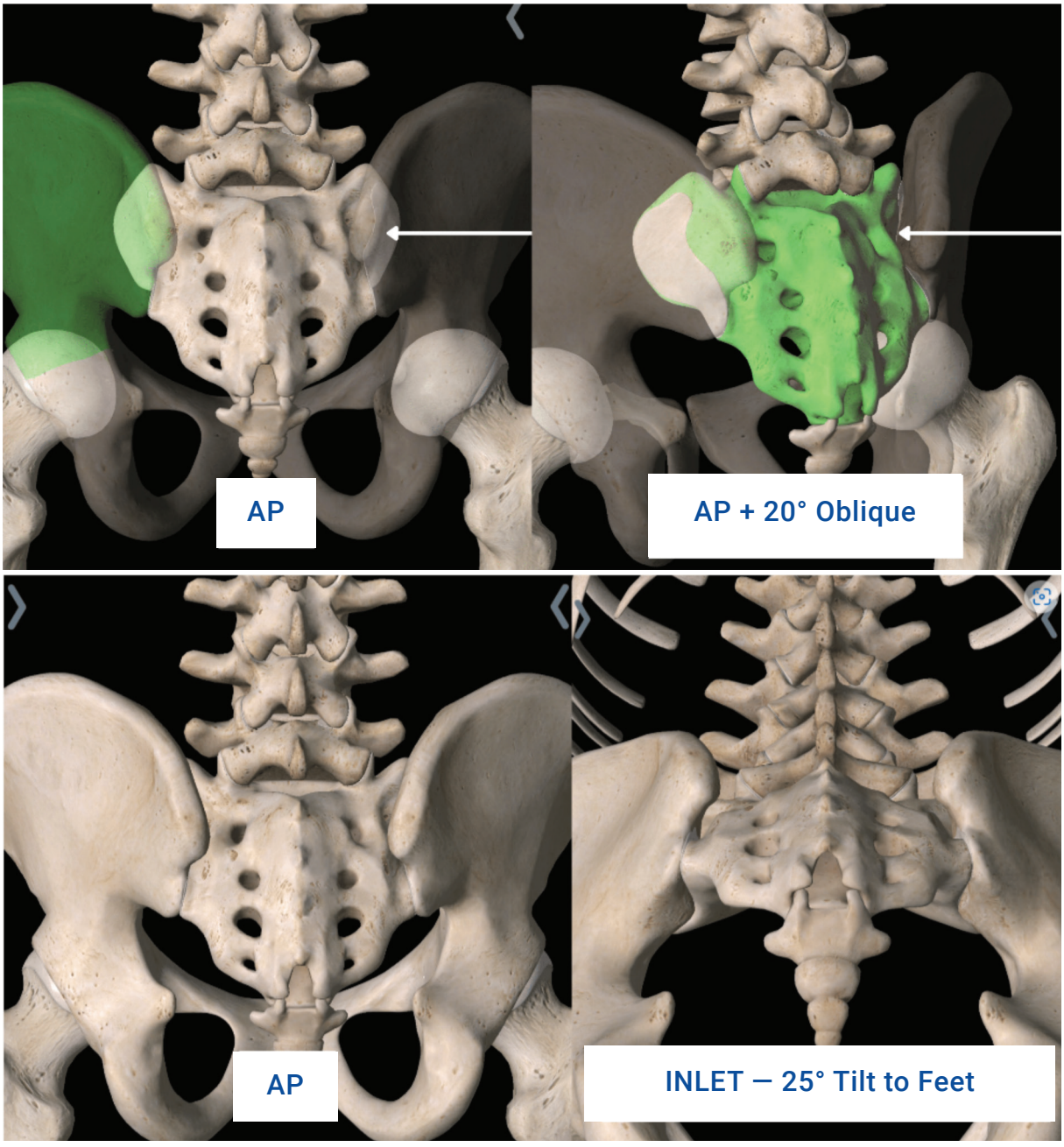



*Figure 4. Locating the SI joint from different approaches.*

# Marking the Joint Line

Once the PSIS and the PIIS are located, rotate the C-Arm 10°– 25° medially to obtain the best visualization of the SI joint. Lay the guide wire on the skin, align the wire with the angle of the joint from the PSIS to the PIIS, and mark the joint line.

Make an approximately 3cm long incision along the marked joint line.

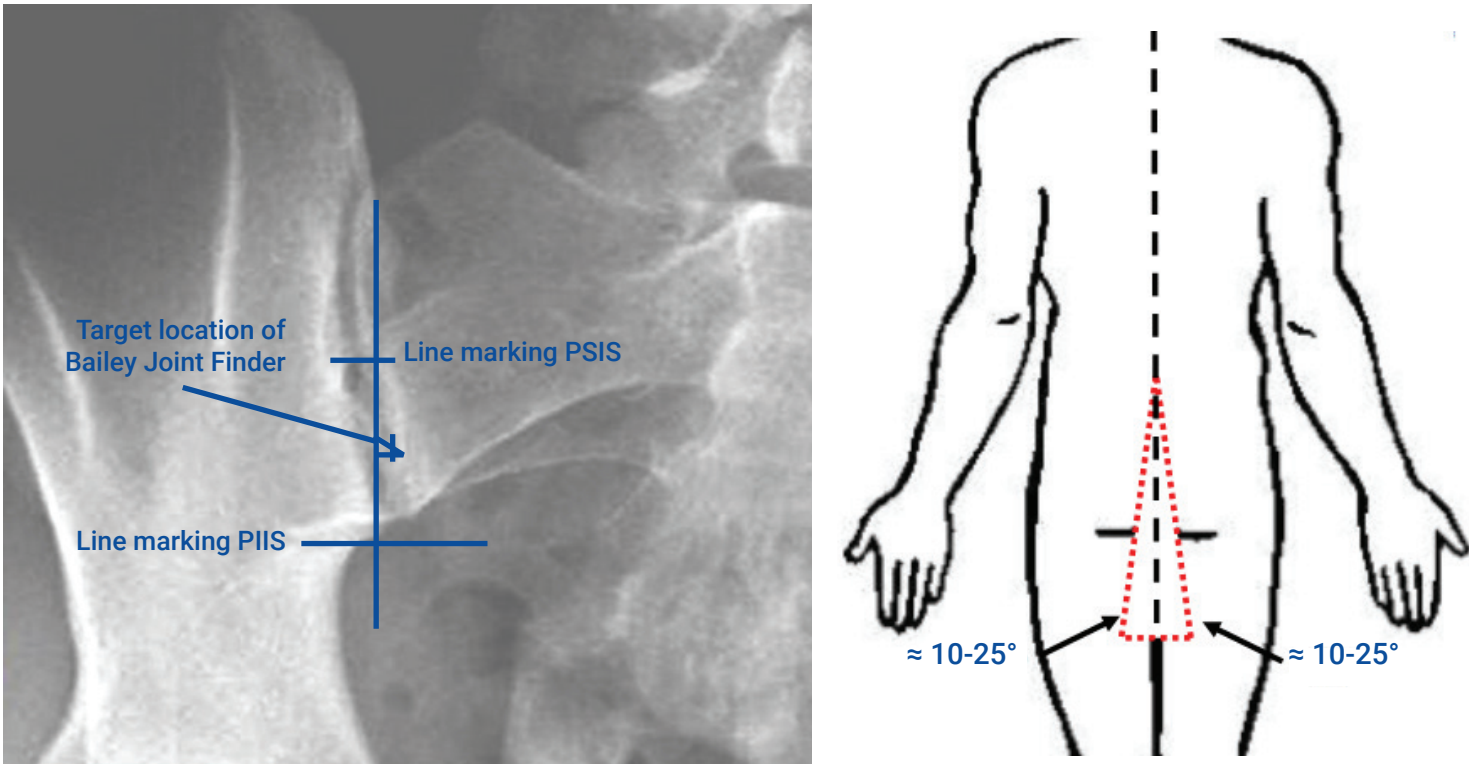



*Figure 5. The target locations for the incision and the Bailey Joint Finder.*

# Bailey Joint Finder Insertion

Attach the Bailey Joint Finder (VYPR-130-002) to the Palm Handle (VY-101-001). Insert the Bailey Joint Finder into the SI joint. Once the Bailey Joint Finder is properly aligned, advance it with a Mallet (VY-104-098), while checking advancement with imaging.

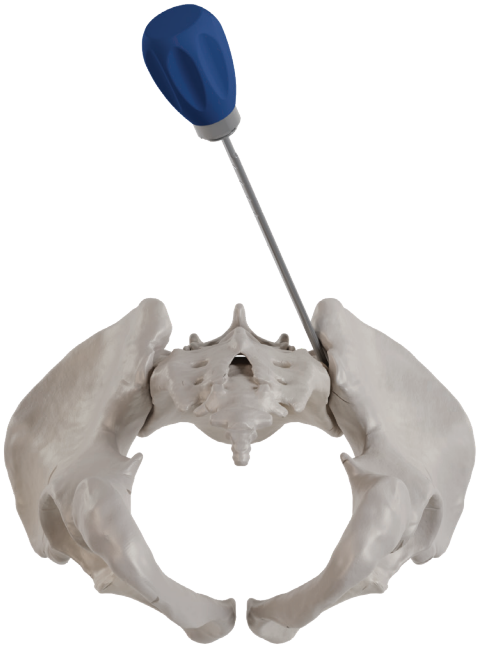
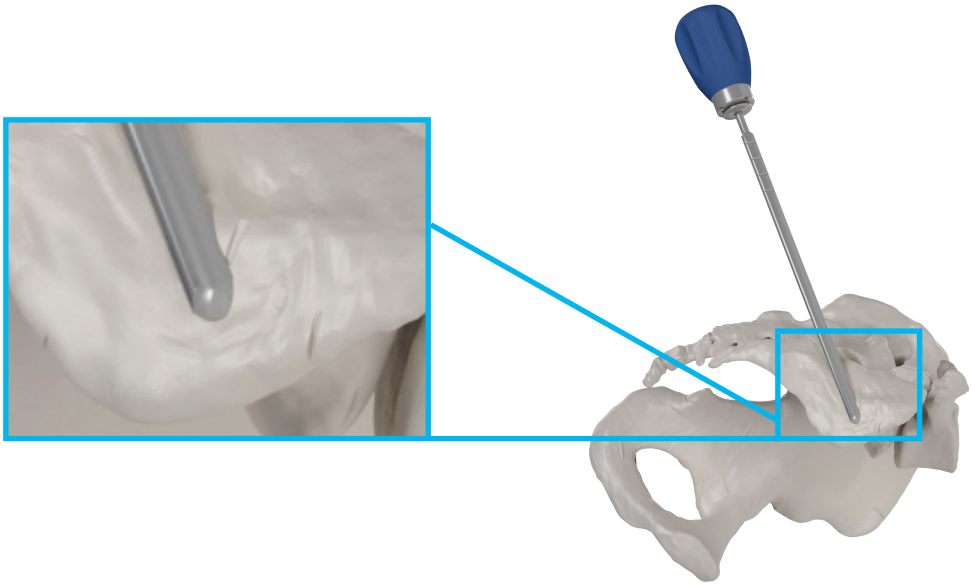


*Figure 6. This cephalad view shows the approximate medial/lateral angulation of the Bailey Joint Finder.*

*Figure 7. This lateral view shows the approximate cephalad/caudal angulation of the Bailey Joint Finder.*



# Dilator Insertion

Remove the Palm Handle from the Bailey Joint Finder.

Slide the Dilator (VYV1-131-104) over the Bailey Joint Finder.

Advance the Dilator into the SI joint with the Utility Tool (VYV1-133-001) and a Mallet until the Dilator tip is aligned with the Bailey Joint Finder tip.

The Utility Tool will aid in advancing the Dilator without advancing the Bailey Joint Finder.

The top of the Dilator will align with the “0” mark on the Bailey Joint Finder when their tips are aligned. Confirm placement of the Dilator with imaging.

*Figure 9. Using the Utility Tool to advance the Dilator over the Bailey Joint Finder.*


*Figure 10. The approximate final location of the Dilator in the joint space with correct alignment to the Bailey Joint Finder.*

# Bailey Joint Finder Removal

Use the small window on the side of the Utility Tool to remove the Bailey Joint Finder.


*Figure 11. Removal of the Bailey Joint Finder using the Utility Tool*

# Working Cannula Insertion

Slide the Working Cannula (VYV1-134-001) over the Dilator ensuring the “SACRUM” and “ILIUM” laser markings face the matching sides of the joint.

Using the Utility Tool and a Mallet, advance the Working Cannula into the SI joint until the Working Cannula tips are aligned with the Dilator tip.

The Utility Tool will aid in advancing the Working Cannula without advancing the Dilator.

The top of the Working Cannula will align with the “0” mark on the Dilator when the distal tips of the instruments are aligned in the joint space. Confirm placement of the Working Cannula with imaging.

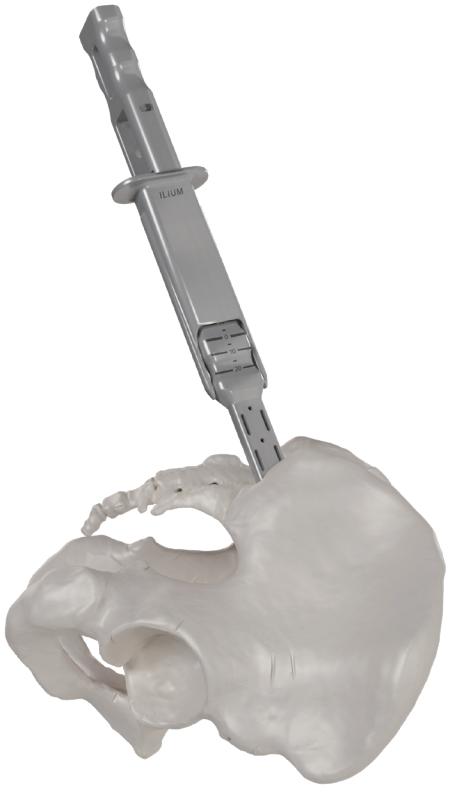



*Figure 12. Insertion of the Working Cannula using the Utility Tool over the Dilator.*


*Figure 13. The approximate location of the Working Cannula in the joint space aligned correctly with the Dilator.*

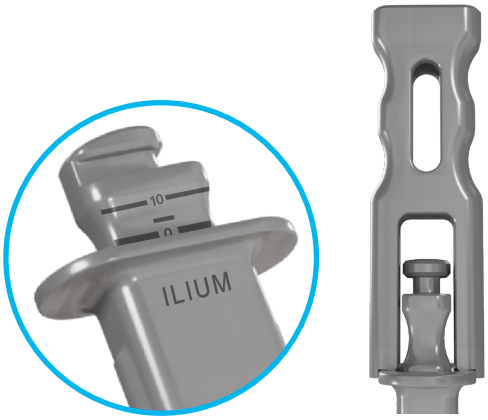



*Figure 14. The laser marking on the Dilator denotes the approximate depth of the Working Cannula once fully inserted (left). The Utility Tool should be used in the orientation shown (right) during insertion.*

# Dilator Removal

Remove the Dilator from the Working Cannula. Use a Slap Hammer (VY-100-05-0180 or VY-105-001) as necessary.

**NOTE:** When removing the Dilator, firmly hold on to the Working Cannula to avoid disrupting its placement in the SI joint.

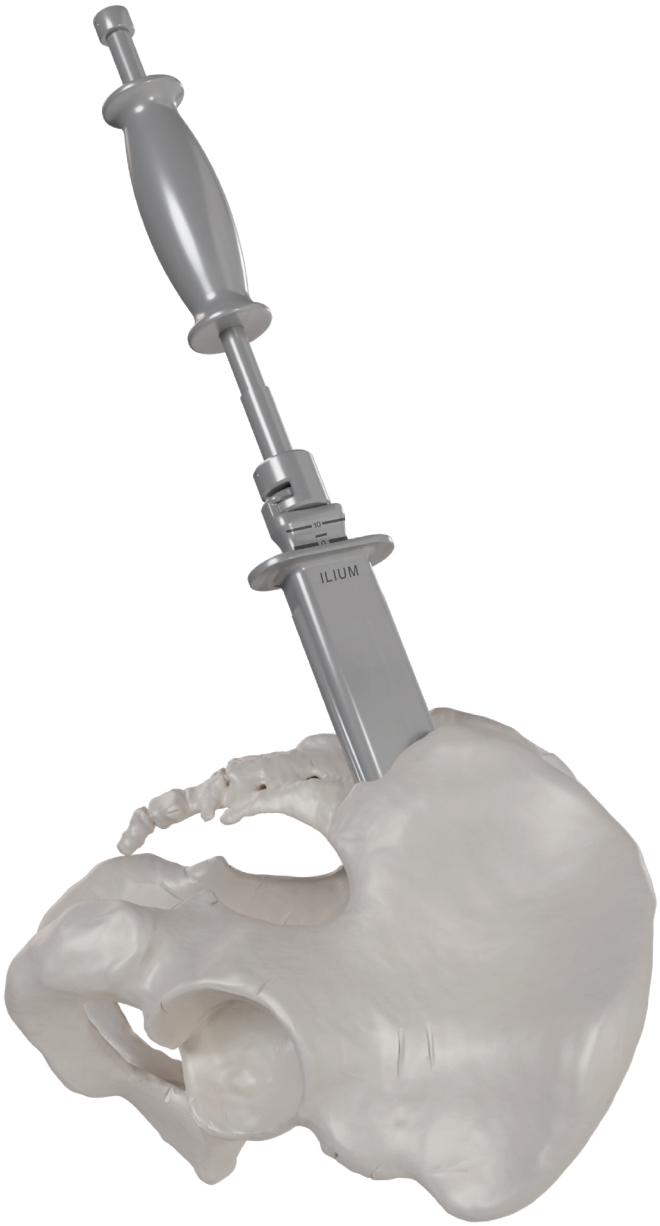



***Figure 15. Removal of the Dilator using a Slap Hammer.***

# Drill Guide Insertion

Slide the Drill Guide (VYV1-135-001) into the Working Cannula. The Drill Guide can be inserted in either orientation.

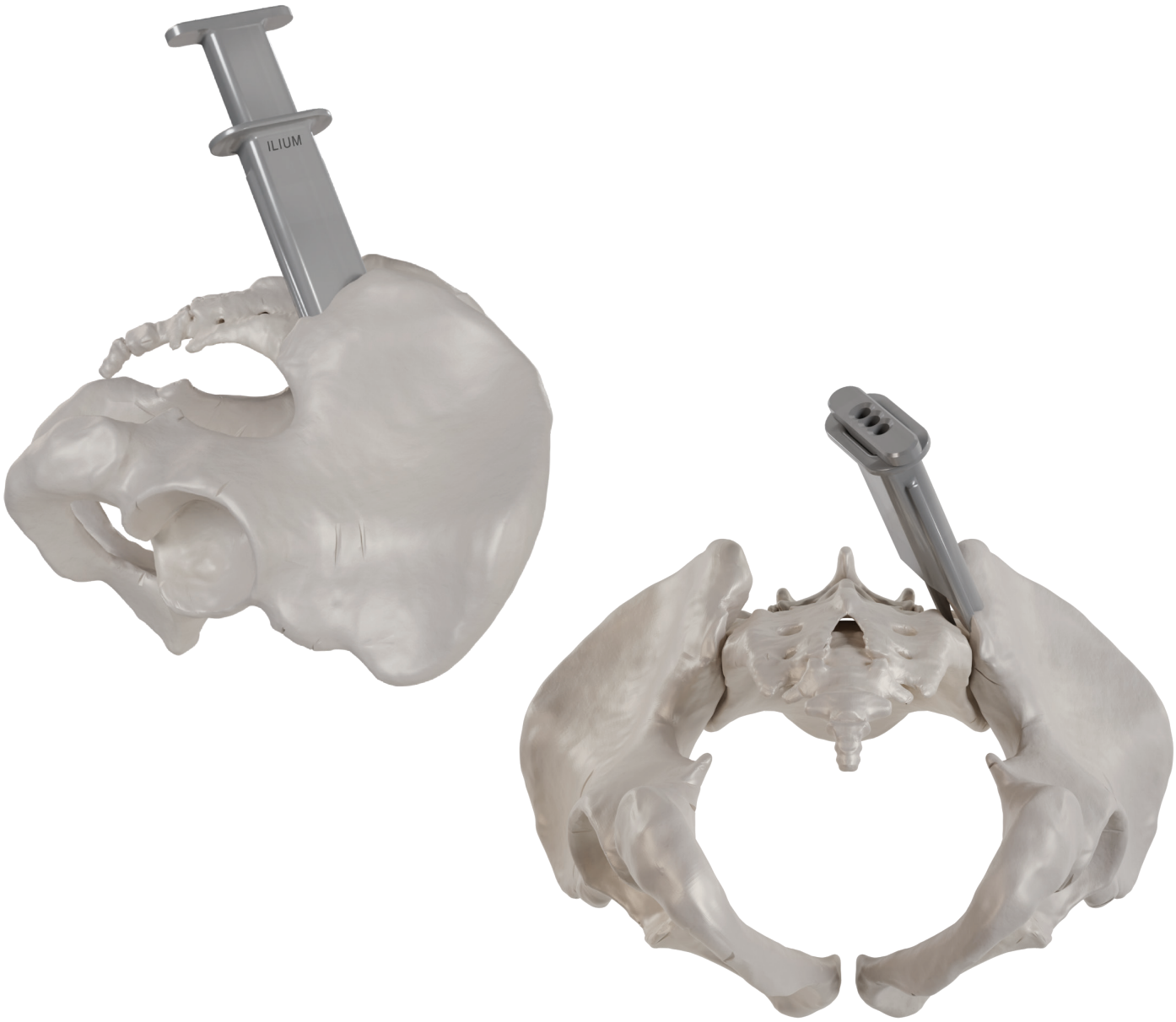



*Figure 16. Insertion of the Drill Guide into the Working Cannula.*

# Drill Bit Insertion and Tissue Removal

Attach the Ratcheting T-Handle (VY-100-34) to the Drill Bit (VYV1-125-132 or VYV1-125-142 or VYV1-125-152).

Using imaging, advance the Drill Bit into each of the three cannulas of the Drill Guide while rotating the Drill Bit clockwise until the tip of the Drill Bit is aligned with the tips of the Working Cannula.

**NOTE:** The 152mm Drill Bit allows for drilling up to 20mm past the Working Cannula tips before it reaches the depth stop. When fully seated against the depth stop, the 152mm Drill Bit extends 20mm distal of the Working Cannula tips. If further Drill Bit advancement past the Cannula Tips is desired, use of imaging is recommended.


*Figure 17. Insertion of the Drill Bit into the Drill Guide.*

# Box Chisel Insertion

Remove the Drill Bit and the Drill Guide.

Insert the Box Chisel (VYV1-136-090) into the Working Cannula. Using a Mallet, impact the proximal face to advance the Box Chisel distally until the tip of the Box Chisel is aligned with the tips of the Working Cannula.

The top of the Working Cannula will align with the “0” mark on the Box Chisel when their tips are aligned. Confirm the placement of the Box Chisel with imaging.

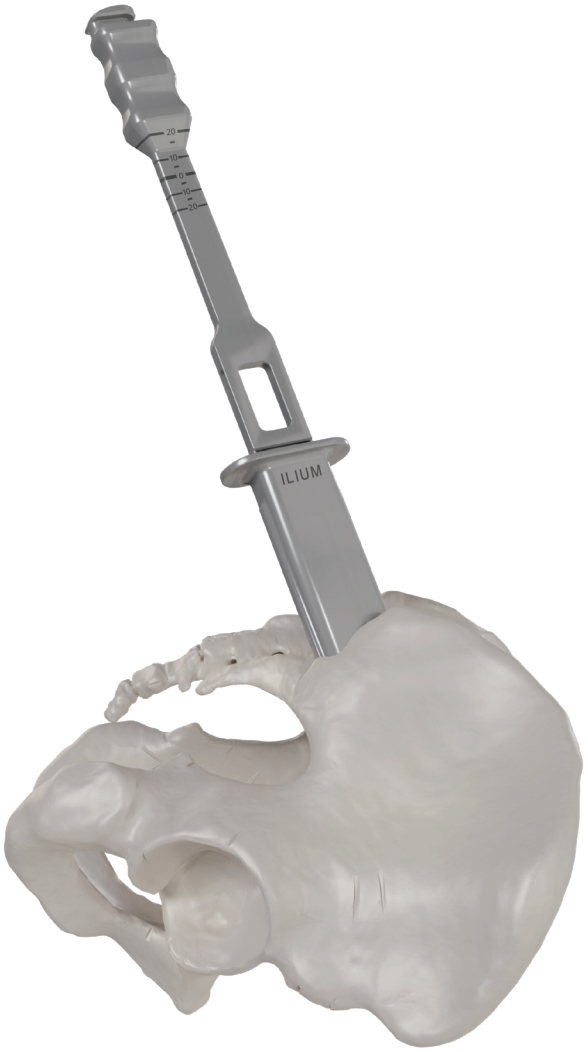



*Figure 18. Insertion of the Box Chisel into the Working Cannula.*


*Figure 19. Box Chisel fully seated in the Working Cannula, showing “0” aligned with edge of the Working Cannula.*

# Box Chisel Removal

Remove the Box Chisel using a Slap Hammer as necessary.


*Figure 20. Removal of the Box Chisel using a Slap Hammer.*

# Trial Insertion

Advance the 9mm Trial Rasp (VYV1-137-090) into the Working Cannula until its tip aligns with the tips of the Working Cannula. Use a Mallet as necessary. Confirm the placement of the Trial Rasp with imaging.

If the trial feels snug inside the SI joint, then implant a 9mm device. If the trial feels loose in the SI joint, then implant an 11mm device.

Next, remove the Trial. Use a Slap Hammer as necessary.


*Figure 21. Insertion of the Trial Rasp into the Working Cannula.*


*Figure 22. The Trial Rasp fully seated in the Working Cannula, showing "0" aligned with edge of the Working Cannula.*


*Figure 23. Removal of the Trial Rasp using a Slap Hammer.*

# Implant Insertion

Assemble the Inserter (VYV1-103-121) following the steps in the Pre-Procedure Setup section.

Remove the Shipping Lug (VYV1-504-07) before attaching the Inserter to the Nevro1™ Transfixing Implant (VYV1-2326-0809 or VYV1-2326-0811).

Load the Implant onto the Inserter by engaging the fixed distal jaw of the Inserter (non-coated) with the recessed shoulder of the Implant. Rotate the Inserter Knob (VYV1-103-121-03) clockwise to engage the articulating Inserter jaw (black) with the other recessed shoulder of the Implant. To ensure correct orientation of the Implant, align the black articulating jaw of the Inserter with the blue Blocking-Screw of the Implant - “Black to Blue”.

**NOTE:** Confirm all the Inserter components are assembled accurately including the Knob and the Drive Linkage (VYV1-103-121-04) before attaching the Nevro1™ Transfixing Implant to the Inserter. Ensure the Implant is properly attached to the Inserter prior to use. To disengage the articulating Inserter jaw, rotate the Inserter Knob counterclockwise. Exercise caution while handling the Implant; the Implant consists of rough titanium surfaces which may catch the handler’s gloves.

*Figure 24. Removal of the Shipping Lug prior to Implant Attachment to the Inserter*

*Figure 25. Proper alignment of the Inserter jaws to Implant, “Black to Blue”.*

# Implant Insertion

Insert the Implant with the Inserter through the Working Cannula and use imaging to advance until the tip of the Implant is aligned with the tips of the Working Cannula.

**NOTE:** The top of the Working Cannula will align with the “0” mark on the Inserter when the bottom of the Implant aligns with the Working Cannula tips.

*Figure 26. Target placement of the Implant, aligned with the distal tips of the Working Cannula.*


*Figure 27. Insertion of the Implant through the Working Cannula.*

# Deploying the Transfixing Implant Anchors

When the desired position of the Implant has been confirmed with imaging, insert the Anchor Deployment Ram (VYV1-103-123) into the center cannula of the Inserter until it touches the Implant Ram. Thread the Anchor Deployment Ram clockwise to secure it to the Implant Ram until finger tight.

Use a Mallet to impact the head of the Anchor Deployment Ram until the head is fully seated against the Inserter.

**NOTE:** Ensure the Anchor Deployment Ram is contacting the Inserter head without leaving space between them.

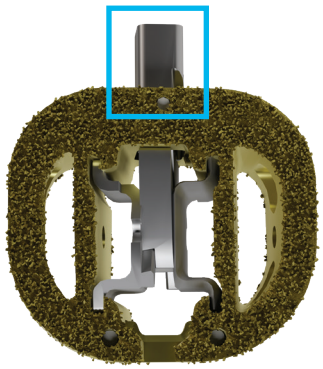


*Figure 28. The Implant Ram*

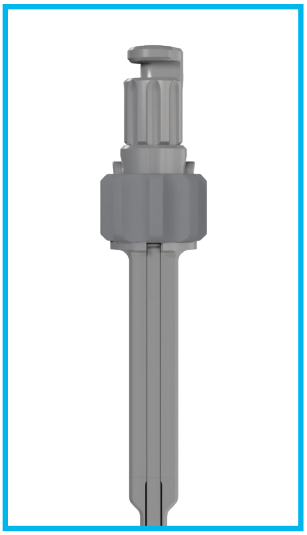


*Figure 30. Deployment of Implant Anchors.*

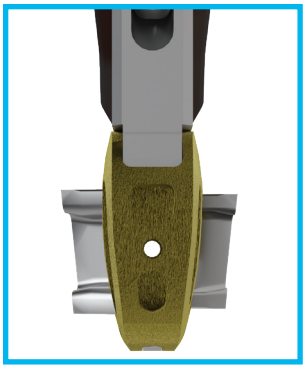


*Figure 31. Implant Anchors fully deployed.*

*Figure 29. Anchor Deployment Ram fully Impacted into the Inserter.*

# Removal of the Anchor Deployment Ram

Using continuous gentle axial pressure on the Anchor Deployment Ram, unthread counterclockwise to remove the Anchor Deployment Ram from the Inserter.

**NOTE:** Continuous axial pressure (downward into the Inserter) on the Anchor Deployment Ram ensures that the Implant Anchors remain fully deployed during removal of the Anchor Deployment Ram.

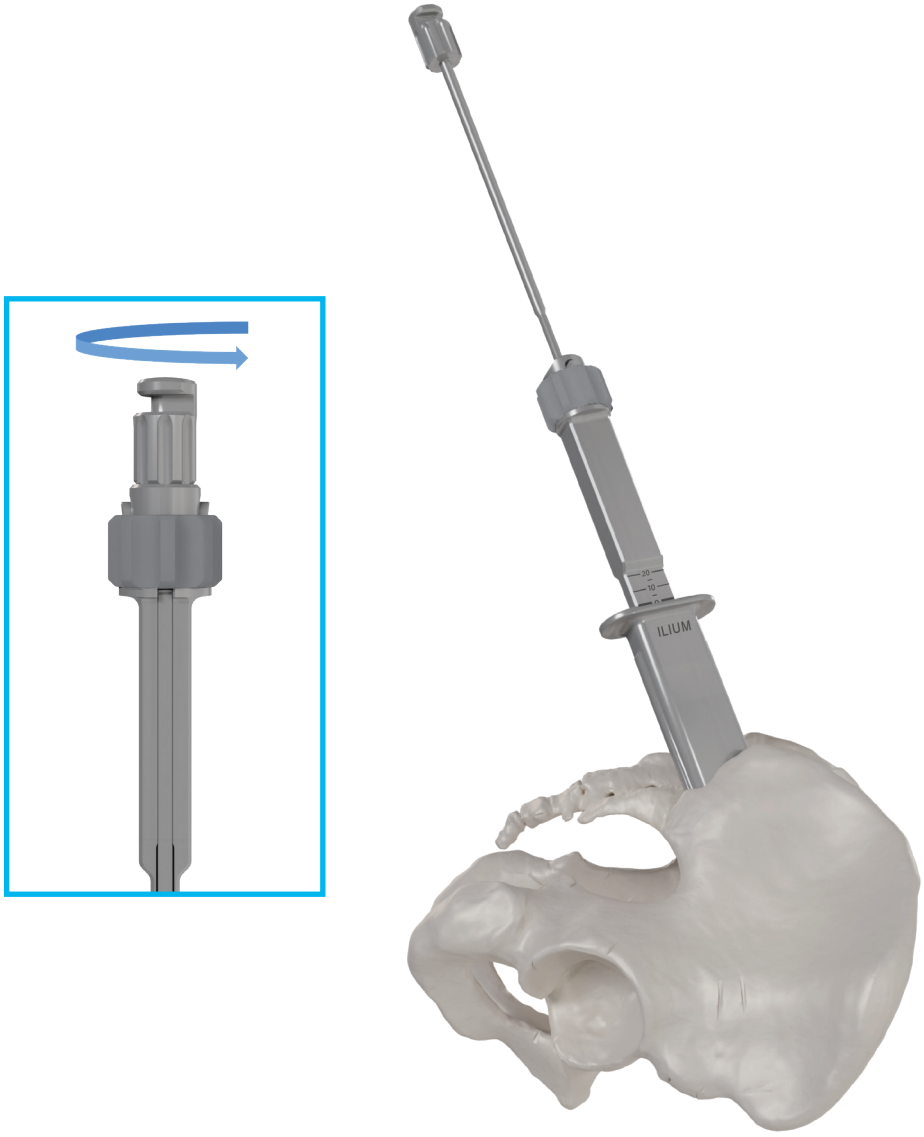



*Figure 32. Removal of the Anchor Deployment Ram.*

# Locking the Transfixing Implant Anchors

Attach the 0.8 Nm Torque-Limiting Handle (VYV1-100-001) to the T10/AO Locking Driver (VYV1-103-125). Insert the Locking Driver through the offset-cannula in the Inserter.

Once the Locking Driver reaches the Implant's Blocking-Screw, rotate clockwise until the handle clicks.

The "click" from the handle on the Locking Diver indicates the 0.8 Nm torque is reached.

After the blue Blocking-Screw has been locked in place, remove the Locking Driver from the Inserter.

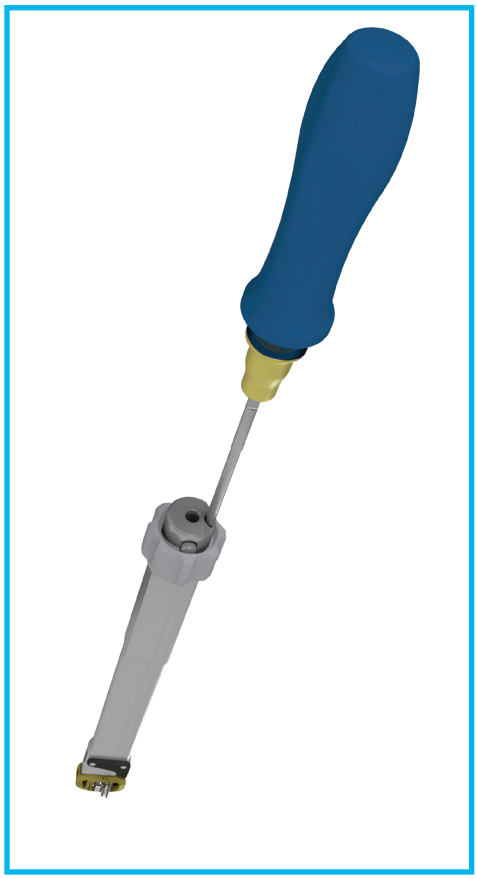


*Figure 33. Insertion of the Locking Driver through the Inserter's offset-cannula.*

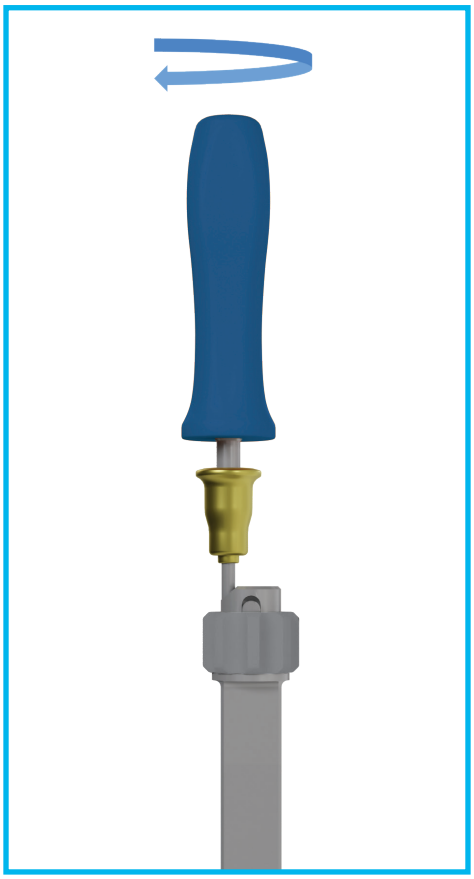


*Figure 34. Use clockwise rotation of the Locking Driver to actuate the Implant Blocking-Screw.*

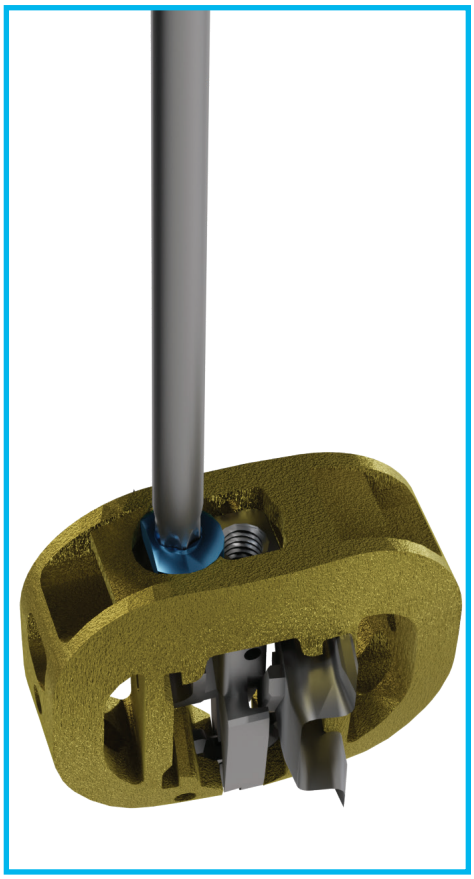


*Figure 35. The Blocking-Screw should fully cover the Implant Ram when fully rotated.*

# Inserter Removal

Disengage the Inserter's articulating jaw from the Implant by rotating the Knob counterclockwise. Separate the Inserter from the Implant, and remove it from the Working Cannula.

## IMPLANT CONFIRMATION

Confirm that the Transfixing Implant Anchors have deployed using imaging. Visually confirm the Implant's Blocking-Screw is over the Implant Ram. The round section of the blue Blocking-Screw should be sitting over top of the gray Implant Ram.

Next, remove the Working Cannula and finger dissect to confirm the Implant's placement.

Close the surgical site.

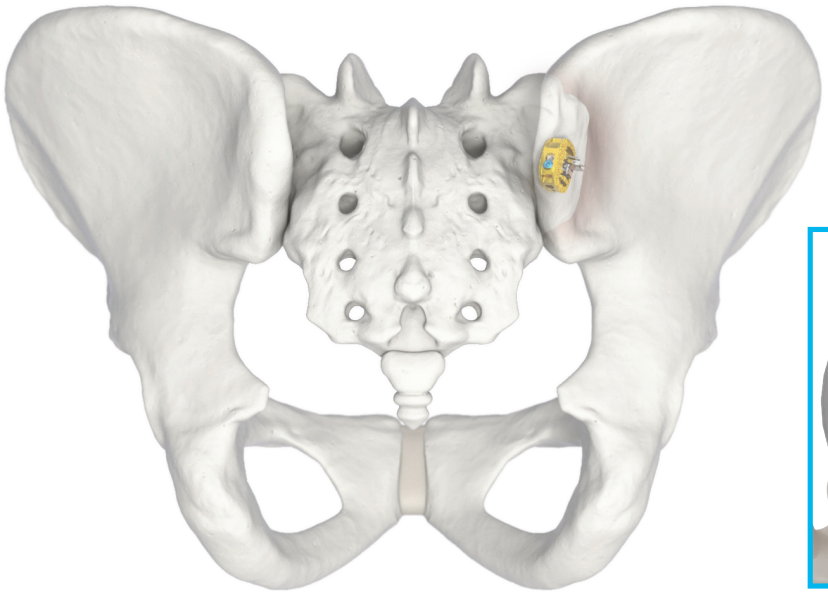


*Figure 36. The target location of the Nevro1™ Transfixing Implant.*

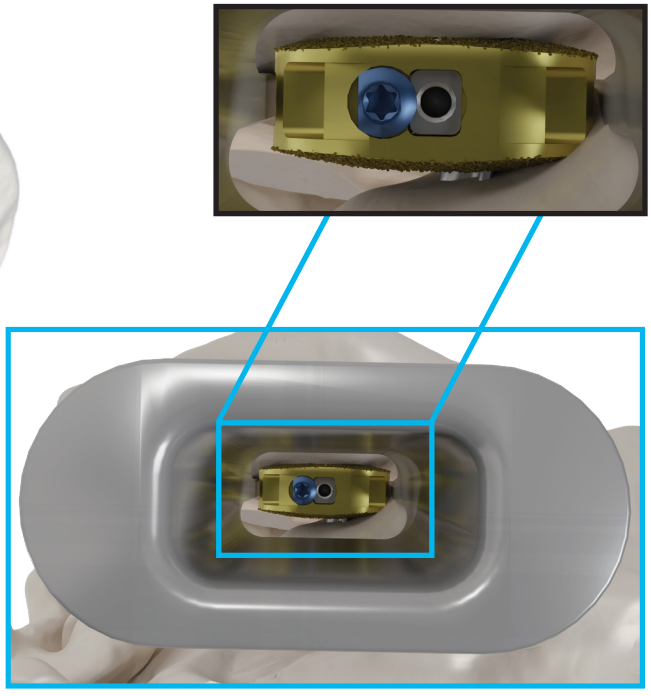


*Figure 37. Visually confirm the Implant's Blocking-Screw coverage.*

# Nevro1™ Removal Technique

To remove the Nevro1™ Transfixing implant from the SI joint, insert the T10/AO Locking Driver attached to the 0.8 Nm Torque-Limiting Handle into the Implant's blue Blocking-Screw. Turn the Torque-Limiting Handle counterclockwise, about half a turn, until the Blocking-Screw is no longer covering the Implant Ram to allow the Implant Ram to move freely.

Visually confirm the Implant's Blocking-Screw is not covering the Implant Ram.

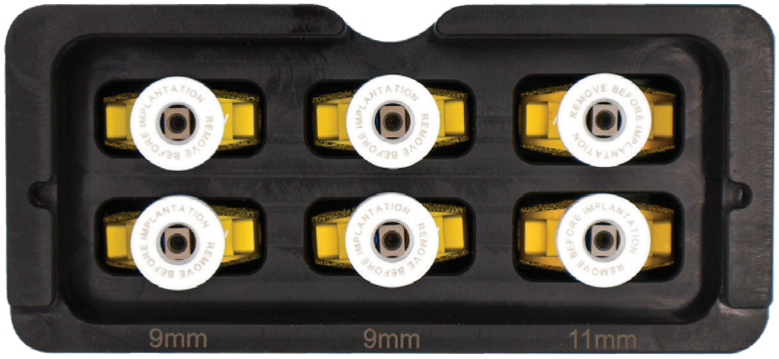
Thread the Anchor Deployment Ram into the Implant Ram, turning clockwise until finger tight.

Using a Slap Hammer, gently backslap the Anchor Deployment Ram until the Transfixing Implant Anchors retract. Continue to use the Slap Hammer to firmly pull out the Implant from the joint space.

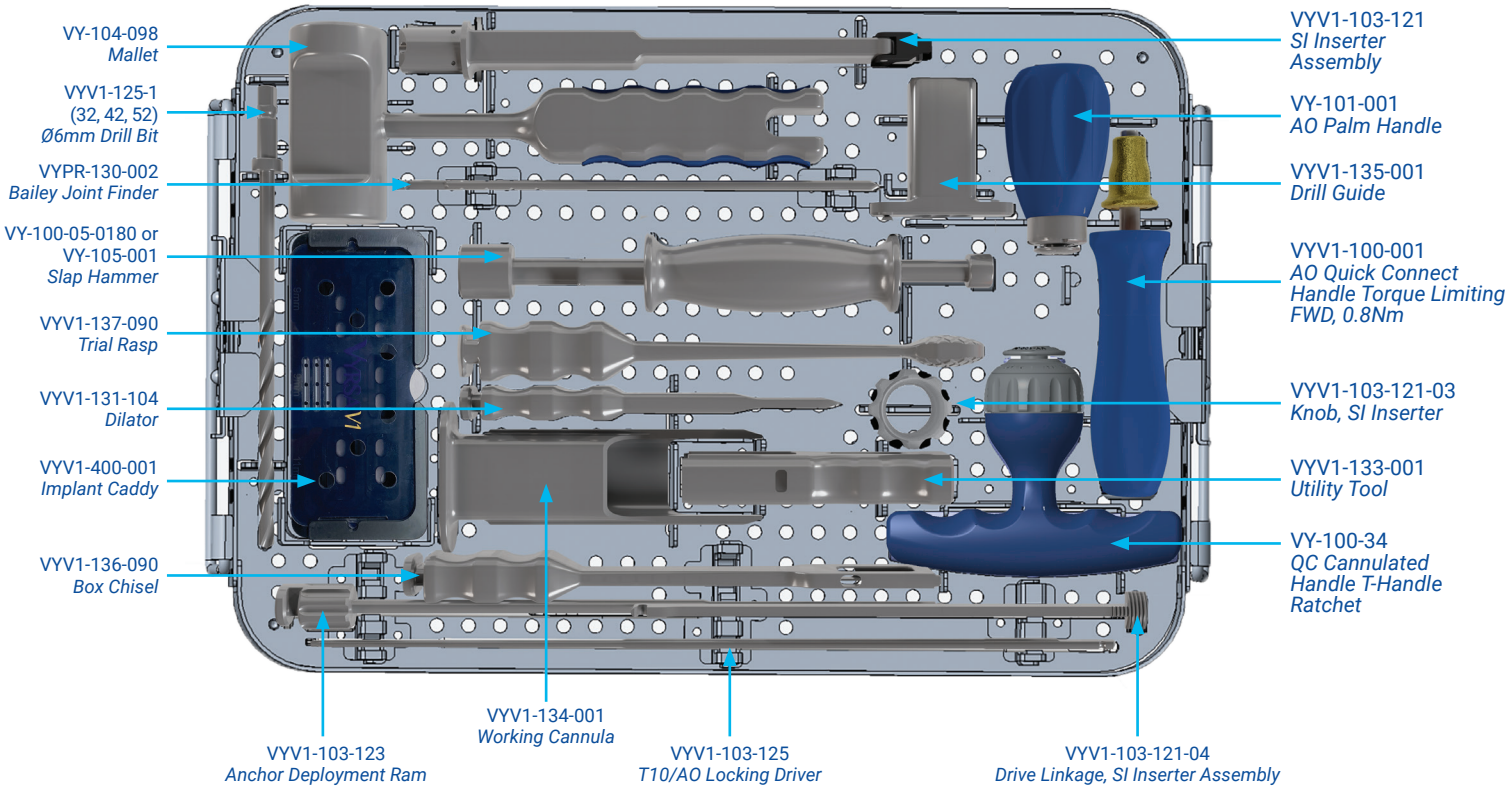
*Figure 38. Use a Slap Hammer and the Anchor Deployment Ram to remove the Nevro1™ Transfixing Implant by engaging it with the Implant Ram.*

# Trays

## NEVRO1™ IMPLANT CADDY




## NEVRO1™ INSTRUMENT TRAY



# Set Contents

| Part number | Description | Quantity |
|---|---|---|
| VYV1-2326-0809 | V1 Transfixing Implant 8°, 23mm x 26mm x 9mm | 4 |
| VYV1-2326-0811 | V1Transfixing Implant 8°, 23mm x 26mm x 11mm | 2 |
| VYV1-2326-0813 | V1 Transfixing Implant 8°, 23mm x 26mm x 13mm | See Note |
| VYPR-130-002 | Bailey Joint Finder | 1 |
| VY-101-001 | AO Palm Handle | 1 |
| VYV1-131-104 | Dilator | 1 |
| VYV1-133-001 | Utility Tool | 1 |
| VYV1-134-001 | Working Cannula | 1 |
| VYV1-135-001 | Drill Guide | 1 |
| VYV1-125-1(32, 42, 52) | Ø6mm Drill Bit, 132mm, 142mm or 152mm | 1 |
| VY-100-34 | QC Cannulated Handle - T-Handle Ratchet | 1 |
| VYV1-136-090 | Box Chisel | 1 |
| VYV1-137-090 | Trial Rasp | 1 |
| VYV1-103-121 | SI Inserter Assembly | 1 |
| VYV1-103-121-04 | Drive Linkage, SI Inserter | 1 |
| VYV1-103-121-03 | Knob, SI Inserter | 1 |
| VYV1-103-123 | Anchor Deployment Ram, SI Inserter | 1 |
| VYV1-103-125 | T10/AO Locking Driver, SI Inserter | 2 |
| VYV1-100-001 | AO Quick Connect Handle Torque Limiting FWD, 0.8 Nm | 1 |
| VY-100-05-0180 or VY-105 | Slap Hammer Assembly or Small Slap Hammer Assembly | 1 |
| VY-104-098 | Mallet | 1 |
| VYV1-400-001 | Implant Caddy | 1 |
| VYV1-500-001 | VYRSA™ - 3/4 Case Lid | 1 |
| VYV1-501-001 | V1 - Instrument Tray | 1 |

**NOTE:** This Surgical Technique Guide and the Instruments provided are not compatible with the Nevro1™ Transfixing 8°, 23mm x 26mm x 13mm Implant. Please contact VYRSA™ Technologies if you would like to set up a case using the 13mm Implant.

# Instructions for Use (IFU)

## NEVRO1™ SACROILIAC TRANSFIXING AND FUSION SYSTEM

### Instructions For Use

**PATIENT SELECTION**
The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome.

**CONTRAINDICATIONS**

1. Contraindications may be relative or absolute. Nevro1™ components are contraindicated in the following patient situations:
2. Deformities.
3. Tumor resection.
4. Infection local to the operative site and/or signs of local inflammation.
5. Failed previous fusion.
6. Suspected or documented allergy or intolerance to the component materials.
7. Any condition not described in the indications for use.

**WARNINGS**

Inspect implant prior to use. Do not use if implant is damaged.

Correct selection of the implant is extremely important. The potential for satisfactory joint fusion is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present a limitation on the size, shape and strength of the implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand the unsupported stress of a full weight bearing indefinitely.

Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation devices are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree of success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also cause early failure. Patients should be fully informedof the risks of implant failure.

Mixing metals can cause corrosion. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of which can lead to fatigue fracture and the amount of metal compounds released into the body system will also increase.  Internal fixation devices, such as rods, hooks, wires, etc., which come in contact with other metal objects, therefore must be made from like or compatible metals.

Correct handling of the implant is extremely important. Excessive torque, when applied to long-handled insertion tools can cause splitting or fracture of the implants. When an implant is impacted or hammered into place, the broad surface of the insertion tool should be carefully seated fully against the implant. Impaction forces applied directly to a small surface of the implant could cause fracture of the implant. Split or fractured implants should be removed and replaced.

# Instructions for Use (IFU)

Proper implant selection and patient compliance with post-operative precautions will greatly affect the surgical outcome. Patients who smoke have been shown to have an increased level of non-unions. Therefore, these patients should be advised of this fact and warned of the potential consequences.

## PRECAUTIONS

### Procedural:

The implantation of the Nevro1™ should be performed only by experienced healthcare professionals with specific training in the use of this implant system as this is a technically demanding procedure presenting a risk of serious injury to the patient.

The healthcare professional must confirm that all necessary implants and instruments are on hand for the planned surgical procedure. The implant components should be handled and stored carefully and protected from any damage including corrosive environments. They should be carefully unpacked and inspected for any damage.

The implants and instruments must be cleaned and sterilized before use.

Based on the fatigue testing results, the healthcare professional should consider unilateral/bilateral implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

Implant blocking screw must completely cover the front face of the ram. Visually confirm final placement of the blocking screw after rotation to prevent the ram from backing out.

### Post-Procedural:

The patient must be adequately instructed as to the risks and limitations of the implant as well as postoperative care and rehabilitation.

The patient should be instructed in the limitation of physical activities which would place excessive stresses on the implant or cause a delay of the healing process. The patient should also be instructed in the use of any required weight bearing or assist devices as well as in the proper methods of ambulation, climbing stairs, getting in/out of bed or other daily activities while minimizing rotational and bending stresses.

The components of this system are designed to be used with VYRSA™ Technologies instruments and should not be used with components of any other system or manufacturer.

## POSSIBLE ADVERSE EFFECTS

While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials that are placed within the body to support potential fusion of the sacroiliac joint. However, due to the many biological, mechanical, and physiochemical factors that affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
Possible adverse effects include, but are not limited to the following:

- Bending, loosening or fracture of the implants or instruments.
- Implant material sensitivity, or allergic reaction to a foreign body (including possible tumor formation).
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Nerve damage due to surgical trauma or presence of the device.

# Instructions for Use (IFU)

- Vascular damage could result in catastrophic or fatal bleeding.
- Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
- Fracture of bony structures.
- Reflex sympathetic dystrophy.
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which might result in skin breakdown and/or wound complications.
- Nonunion or delayed union.
- Infection.
- Nerve or vascular damage due to surgical trauma (including loss of neurological function, radiculopathy, and paralysis) gastrointestinal, urological and/or reproductive system compromise (including sterility, impotency and/or loss of consortium).
- Pain or discomfort.
- Hemorrhage of the blood vessels and/or hematomas.
- Malalignment of anatomical structures (including loss of proper spinal curvature, correction, reduction and/or height).
- Bursitis.
- Bone graft donor site pain.
- Inability to resume normal daily living activities.
- Reoperation or revision.
- Paralysis.
- Death.

## Warnings and Precautions:

The devices should only be used by healthcare professionals who have been trained in the use of this device. Information on laboratory and clinical training, as well as additional brochures with a detailed description of proper surgical technique, may be obtained from VYRSA™ Technologies. See the Nevro1™ Surgical Technique Guide for instructions on the implant procedure.

Infection may occur immediately following implant fixation, fusion, or a long time afterwards due to transient bacteremia such as caused by dental treatment(s), endoscopic examination, or any other minor surgical procedure. To avoid infection at the implant fixation, or fusion site, it may be advisable to use antibiotic prophylaxis before and/or after such procedures.

Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fixation and/or fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.

If the implant has been in place for enough time for bone to have grown into the implant, removal may not be feasible.

Do not reuse implants; discard used, damaged, or otherwise suspect implants.

Single use only. Reuse of devices labeled as single use (implants, drills, tacks, trial rods, etc.) could result in injury or reoperation due to breakage or infection.

All implants are intended for SINGLE USE ONLY. Any used implant should be discarded. Even though the device may appear undamaged, it may have small

defects and internal stress patterns that may lead to fatigue failure.

The safety, efficacy and performance of the system have been established for conditions in which the system is used as intended and when used as identified in the Indications for Use. Performance of the system has not been evaluated for use that is contrary to the intended use, indications for use or for use that is contraindicated. Failure to use the system as indicated could detrimentally affect the performance of its components.

### MRI Safety Information:

The Nevro1™ has not been evaluated for safety in the MR (Magnetic Resonance) environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Nevro1™ in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

### IMPLANT CARE

Implants can either be shipped contained within a caddy or individually packaged, non-sterile. Care should be taken when handling the implants to avoid damaging the implant.

If an implant was shipped individually packaged, it should be carefully transferred to its appropriate caddy for sterilization and storage. All implants will be provided non-sterile.

All implants must be thoroughly inspected for any debris prior to sterilization. This includes prior to initial use. Implants are single-use, and not to be reprocessed. If any biologic material is found on the implant, remove the implant from the set. This implant is not to be used. If any debris or other material is present, contact a VYRSA™ Technologies representative using the information listed at the end of this document.

Implants should always be contained in their appropriate caddy for sterilization.

Implants are identified by both catalog numbers and lot numbers, listed on the implant itself, and additionally on the packaging if received individually packaged. These numbers should be recorded when used in surgery, or when calling for a replacement. Catalog number and lot numbers provide traceability to VYRSA™ Technologies and are crucial in the event of any necessary medical device reporting.

### SINGLE USE ONLY

**NOTE: Implants are single-use only and not to be reprocessed.**

### CLEANING

### MANUAL CLEANING OF INSTRUMENTS AFTER USE

1. Use utility/tap water to rinse instrument(s) for a minimum of 1.5 minutes to remove gross debris. Do not use hot water.
2. Continue to rinse with the utility/tap water until gross debris is removed.
3. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument surfaces.
4. Mix enzymatic cleaning solution per the manufacturer's label instructions.
5. Tube (lumen) portion of instrument(s) must be filled with cleaning solution during soak.
6. Soak in cleaning solution for a minimum of 4 minutes.
7. Mix a separate detergent bath using enzymatic cleaning solution per the manufacturer's label instructions in an ultrasonic unit.
8. Fully immerse the instrument(s), in an open

position/disassembled, under the surface of the cleaning solution ensuring the cleaning solution can be reached to all instrument(s) surfaces.

9. Sonicate the instrument(s) for a minimum of 5 minutes.
10. Prepare a separate (3rd) detergent bath using enzymatic cleaning solution per the manufacturer's label instructions.
11. Fully immerse the devices into cleaning solution and using a soft-bristled or medium non-metal bristle brush, remove all visible soil and debris from the surfaces.
12. Brush difficult to reach areas such as lumens/ cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
13. If all debris is not removed, repeat brushing and flushing.
14. Flush device with deionized water, or equivalent, by placing the device under the water flow for a minimum of 3x.
15. Actuate parts, if applicable 3x, under running deionized water, or equivalent.
16. Rinse lumens, tubes, or cannula under running deionized water, or equivalent, 4x.
17. Use heat or lint-free cloth to dry devices following final rinse.

**AUTOMATED CLEANING FOR INSTRUMENTS AFTER USE**

1. Use utility/tap water to rinse instrument(s) for a minimum of 1.5 minutes to remove gross debris. Do not use hot water.
2. Continue to rinse with the utility/tap water until gross debris is removed.
3. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument surfaces.
4. Mix enzymatic cleaning solution per the manufacturer's label instructions.
5. Tube (lumen) portion of instrument(s) must be filled with cleaning solution during soak.
6. Soak in cleaning solution for a minimum of 4 minutes.
7. Mix a separate detergent bath using enzymatic cleaning solution per the manufacturer's label instructions in an ultrasonic unit.
8. Fully immerse the instruments, in an open position/disassembled, under the surface of the cleaning solution ensuring the cleaning solution can be reached to all instrument(s) surfaces.
9. Sonicate the instruments for a minimum of 5 minutes.
10. Prepare a separate (3rd) detergent bath using enzymatic cleaning solution per the manufacturer's label instructions.
11. Fully immerse the devices into cleaning solution and using a soft-bristled or medium non-metal bristle brush, remove all visible soil and debris from the surfaces.
12. Brush difficult to reach areas such as lumens/ cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
13. If all debris is not removed, repeat brushing and flushing.
14. Load the instrument(s) into the appropriate washer-disinfector.

# Instructions for Use (IFU)

Select the cycle which reflects the following parameters:

### AUTOMATIC WASHER

| Phase | Recirculation Time (min) | Temperature | Detergent Type & Concentration |
|---|---|---|---|
| Pre-wash 1 | 01:00 | Cold tap water | N/A |
| Wash 1 | 05:00 | 43°C tap water (Set point) | Enzymatic detergent per washer instructions |
| Rinse 1 | 01:00 | Warm tap water | N/A |
| Pure Water Rinse | 01:00 | 43°C deionized water | N/A |
| Dry Time | 10:00 | 90°C | N/A |

### INSPECTION

All devices must be inspected for remaining soil or cleaning solution. The cleaning steps must be repeated until the device is free from soil and cleaning solution. STERILIZATION FOR IMPLANTS AND INSTRUMENTS Warning: VYRSA™ Technologies does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded. Open and/or disassemble instrument(s) if applicable, so the steam can reach all instrument surfaces.

To achieve a sterility assurance level of SAL 10-6, VYRSA™ recommends the following parameters:

| **Method** | **Steam** | **Steam** |
|---|---|---|
| **Cycle** | Gravity Displacement (Wrapped) | Pre-vacuum (Wrapped) |
| **Preconditioning Pulses** | N/A | 4 |
| **Temperature** | °132C (°270F) | °132C (°270F) |
| **Exposure Time** | 15 minutes | 4 minutes |
| **Drying Time** | 45 minutes | 45 minutes |
| **Open Door Drying Time** | 15 minutes | 15 minutes |

Note: An FDA Cleared Wrap must be used.

* VYRSA™ Technologies has validated the above sterilization cycles and has the data on file. The validated sterilization parameters are compliant with the full cycle validation approach per ANSI/AAMI/ISO 17665-1, Annex D. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

# Instructions for Use (IFU)

## SYMBOLS

| Symbol | Definition | Reference |
|---|---|---|
|  | Catalogue Number-Indicates the manufacturer's catalogue number to that the medical device can be identified | ISO 15223-1:2021 Symbol 5.1.6 |
|  | Batch code-Indicates the manufacturer's batch code so that the batch or log can be identified | ISO 15223-1:2021 Symbol 5.1.5 |
|  | Do not re-use-Indicates a medical device that is intended for one single use only | ISO 15223-1:2021 Symbol 5.4.2 |
|  | Non-sterile-Indicates a medical device that has not been subjected to a sterilization process | ISO 15223-1:2021 Symbol 5.2.7 |
|  | Prescription Only-Caution: Federal law restricts this device to sale by or on the order of a physician | FDA 801.15(c)(1)(i)(F) |
|  | Consult Instructions for Use-Indicates the need for the user to consult the instructions for use | ISO 15223-1:2021 Symbol 5.4.3 |
|  | Manufacturer-Indicates the medical device manufacturer | ISO 15223-1:2021 Symbol 5.1.1 |
|  | Unique Device Identifier (UDI)-Indicates a carrier that contains unique device identifier information | ISO 15223-1:2021 Symbol 5.7.10 |
|  | Date of Manufacture-Indicates the date when the medical device was manufactured | ISO 15223-1:2021 Symbol 5.1.3 |

## FOR FURTHER INFORMATION

If further information on this product, or the Surgical Technique Guide, is needed please contact VYRSA™ Technologies at the number listed below:

Manufactured by:
VYRSA™ Technologies
501 Allendale Rd, Suite 101B
King of Prussia, PA 19406
Phone: (484) 427-7060

# Pre-Procedure Setup

## ASSEMBLING THE INSERTER

Slide the Drive Linkage (VYV1-103-121-04) under the pin of the Inserter (VYV1-103-121). Hold the black articulating jaw in a closed position.

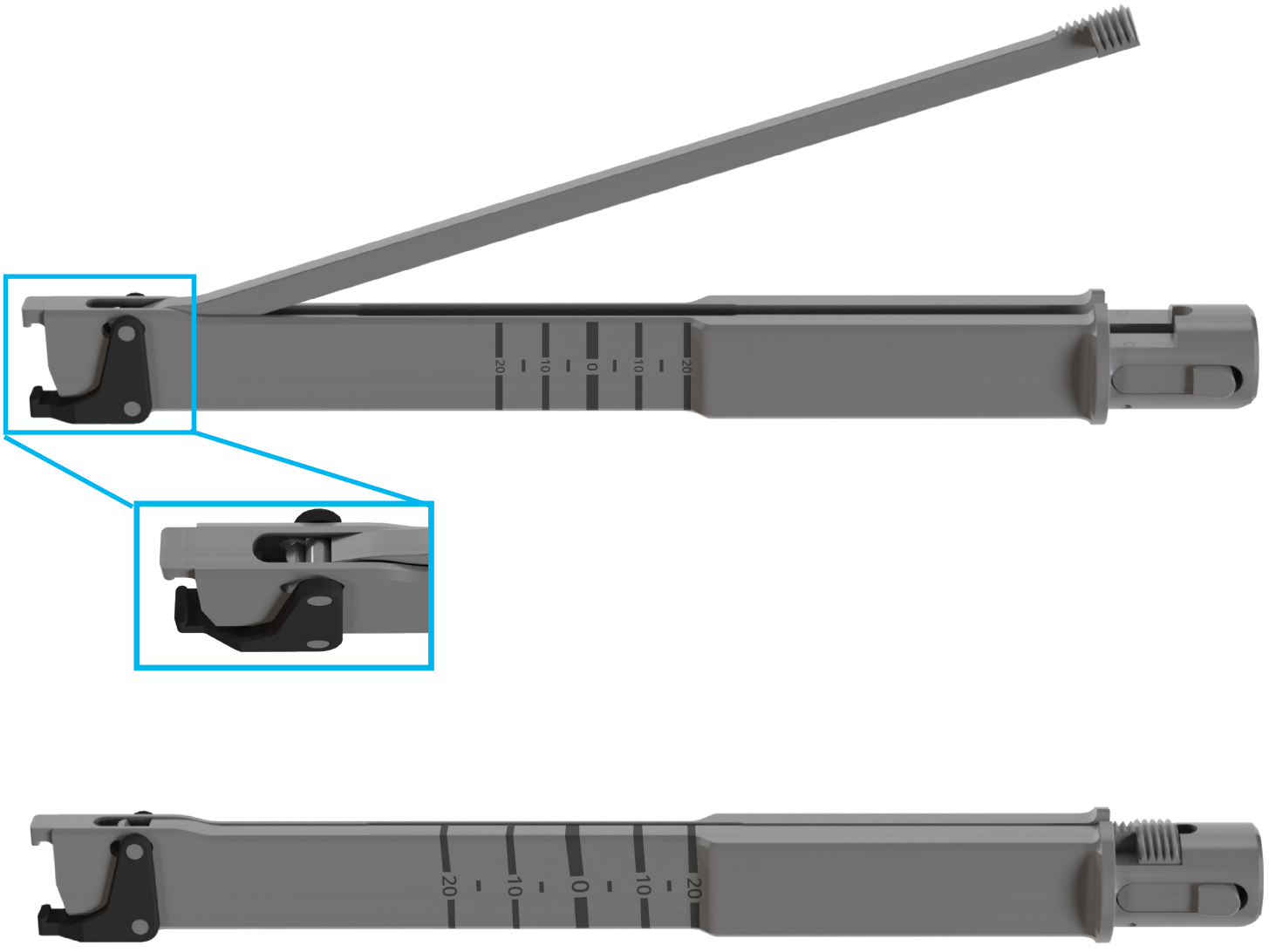



*Figure P.1. Assembling the Drive Linkage with the Inserter.*

# Pre-Procedure Setup

Hold down the buttons on both sides of the Inserter and slide the Knob (VYV1-103-121-03) over the buttons.

**NOTE:** Ensure the Knob's "Assemble" arrow faces towards the Inserter's articulating jaw.

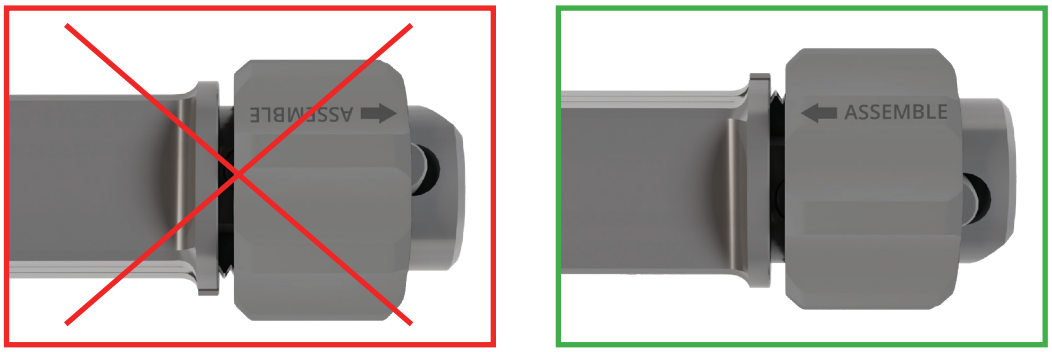



*Figure P.2. The correct direction to assemble the Knob onto the Inserter.*

Push and thread the Knob clockwise until it is finger tight. The Knob should screw completely over the Drive Linkage threads. Then, turn the Knob counterclockwise until the black articulating clamp is opened.

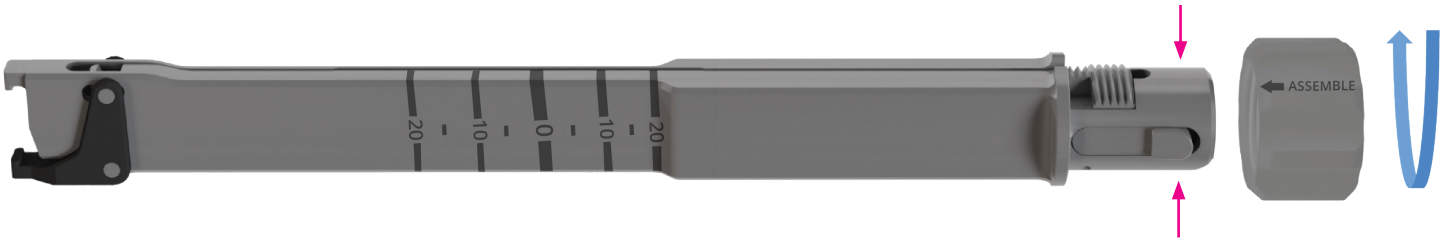



*Figure P.3. Assembling the Knob while holding down the buttons on both sides, then rotating it clockwise over the threads.*


*Figure P.4. This figure shows the Inserter completely assembled.*

# Post-Procedure Cleanup

In order for all the instruments and handles to be cleaned and sterilized properly, they need to be disassembled, including the Inserter.

## DISASSEMBLING THE INSERTER

Press and hold the buttons on both sides of the Inserter.

Turn the Knob counterclockwise until it separates from the Inserter.

Remove the Drive Linkage from the Inserter.

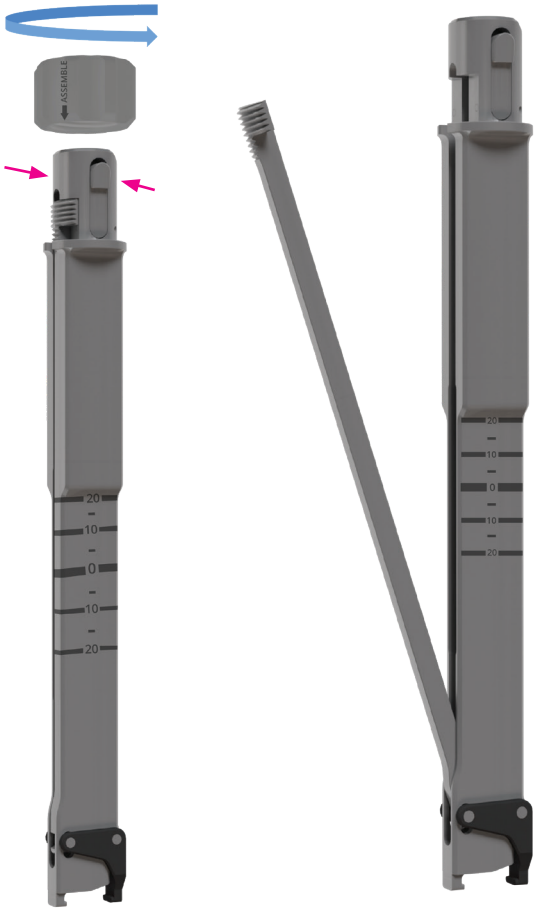



*Figure P.5. Detaching the Knob (left) and the Drive Linkage (right) from the Inserter.*

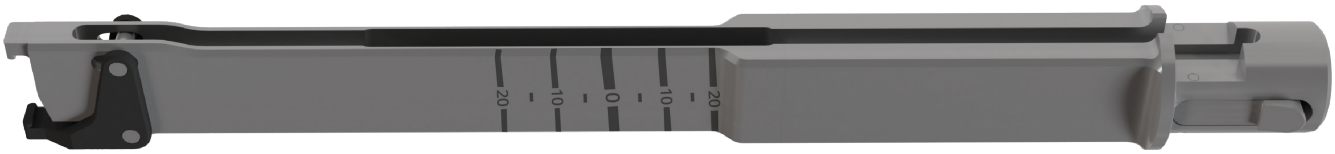



*Figure P.6. Disassembled Inserter.*

# Notes

# Notes

# Notes

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