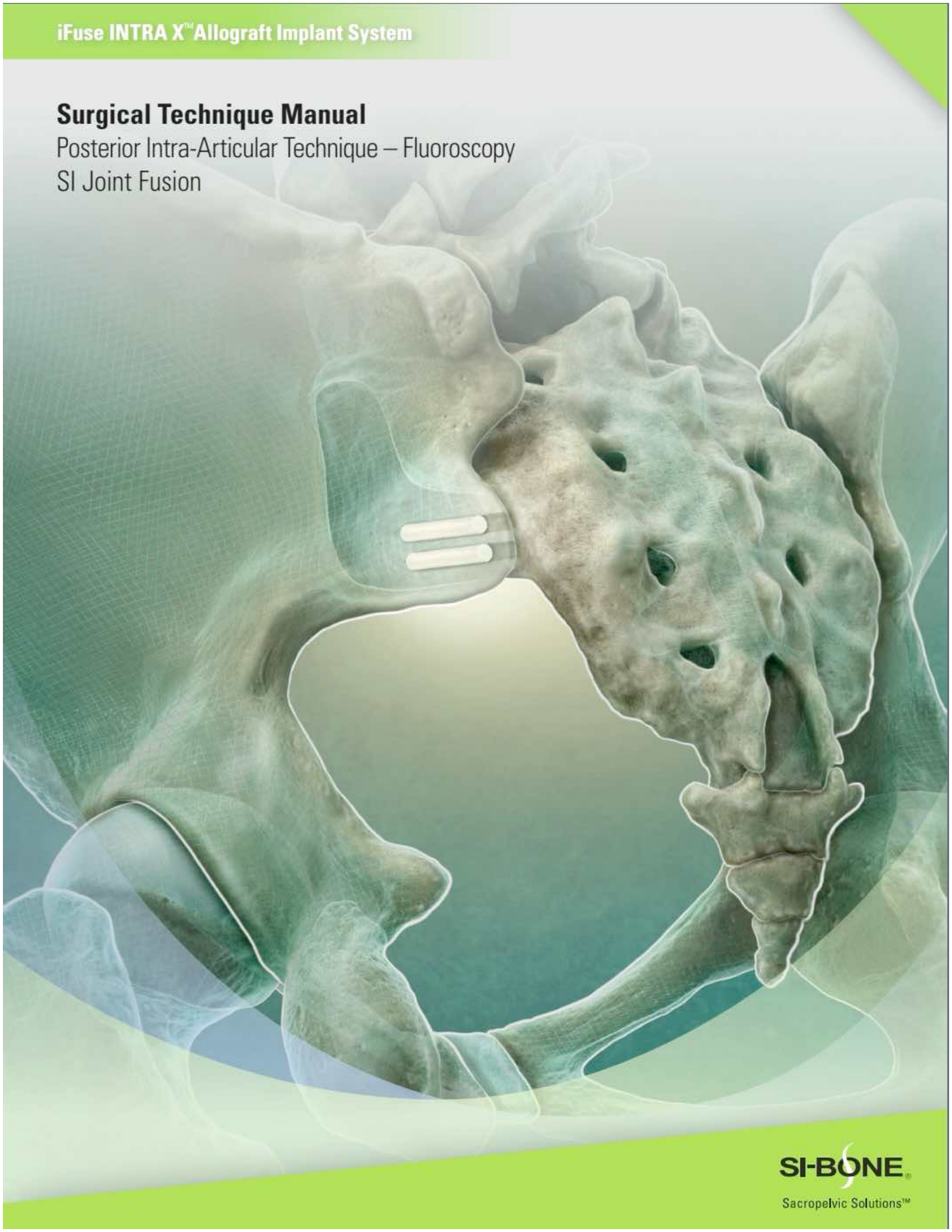
# Surgical Technique Manual

## Posterior Intra-Articular Technique – Fluoroscopy
## SI Joint Fusion



SI-BONE®
Sacropelvic Solutions™

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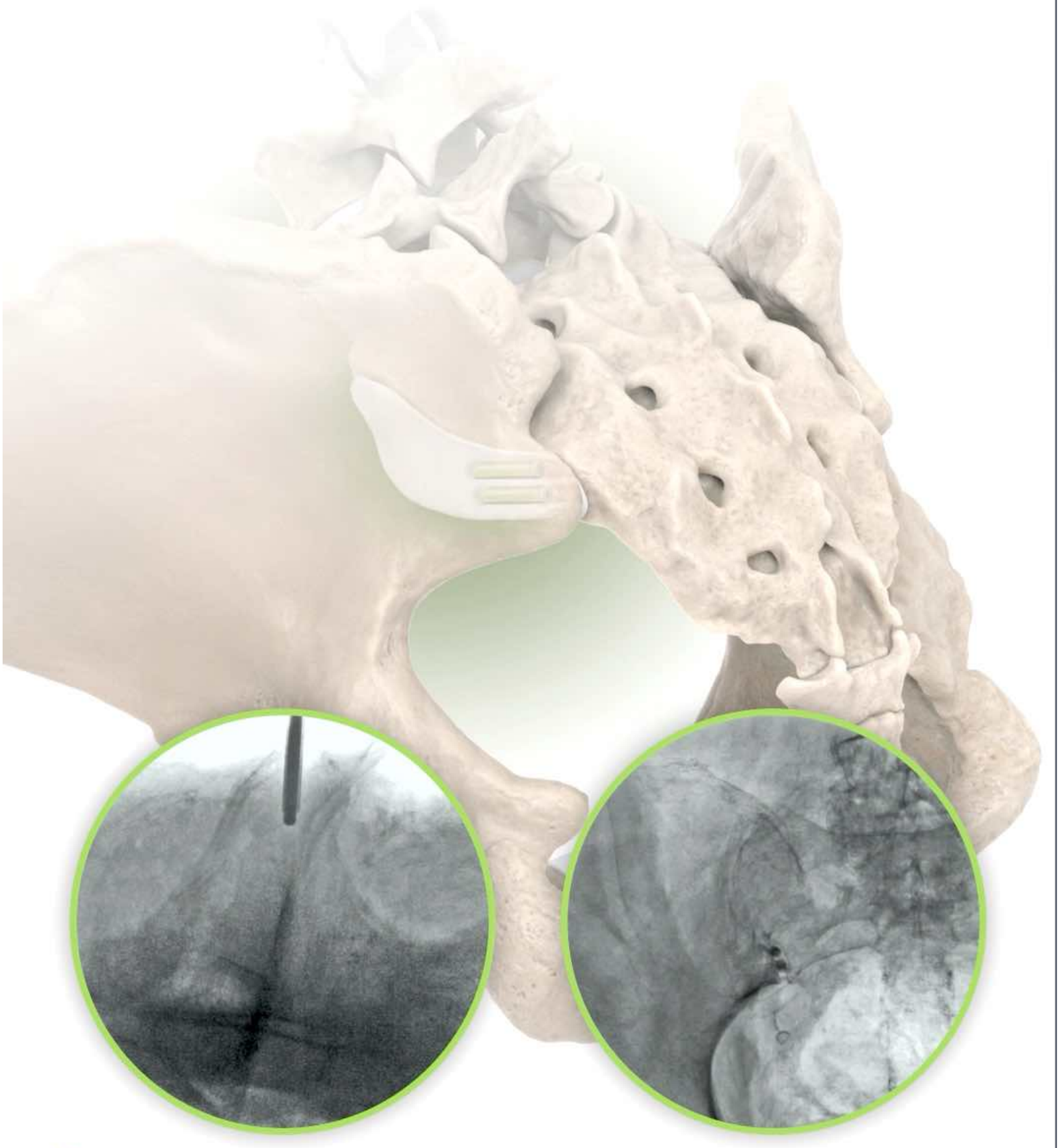
# iFuse INTRA X™ Allograft Implant System



# iFuse INTRA X™ Allograft Implant System



- Lateral, Inlet, and INTRA views promote repeatable placement of the allograft into the intra-articular portion of the joint.
- Single-use instruments are terminally sterilized and procedure-ready.
- Minimally invasive technique uses a single percutaneous incision.
- Two cylindrical dowels provides biomechanical stability in the joint.

As with all surgical procedures and implants, there are risks and considerations associated with surgery and use of the iFuse INTRA X Allograft Implant System. For complete information on contraindications, warnings, precautions, and potential risks, refer to 503004 iFuse INTRA X Allograft *Instructions For Use* and 503005 iFuse INTRA X Instruments *Instructions For Use*.

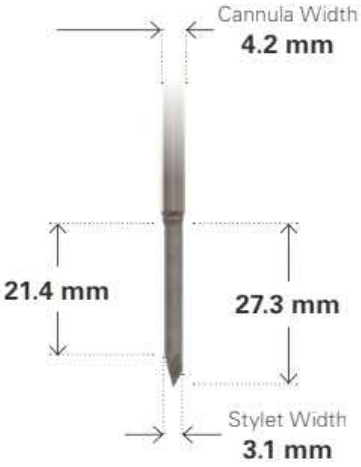
# iFuse INTRA X: Specifications


| Specifications | |
|---|---|
| Diameter | 3.5 mm |
| Length | 20 mm |

| Part Numbers | |
|---|---|
| Allograft Implant | 3520BD |

***PRECAUTIONS:***

- *Refer to the product insert for proper handling of the Allograft.*


| Specifications | |
|---|---|
| Stylet Length | 129 mm |
| Stylet Width | 3.1 mm |
| Cannula Length | 100 mm |
| Cannula Width | 4.2 mm |

| Part Numbers | |
|---|---|
| 8 Gauge Bone Access Needle | 501979 |

### Pre-Op Planning

A CT is recommended for pre-op planning. Check for anatomic abnormalities or preexisting hardware that may conflict with the trajectory of the allograft.

### Patient Set-Up

- Jackson and flat imaging tables are common.
- One or two C-arms may be used – usually one is sufficient.
- If a flat table is used, place towel rolls transversely under the chest and waist, and pillows under the feet to relax hip and knee joints **(Figure 1).**
- The patient should be in a "spine neutral" position as well as having the SI joint in a neutral position without extreme flexion or extension of hips.

### Patient Positioning

This procedure is performed in the prone position.

### Care of Instruments and Allografts

Inspect the packaging to ensure a sterile barrier was maintained, the tamper-evident seals are intact, and there is no damage to the instrumentation or allografts. Verify that the instruments and allografts are within the expiration date on the label.

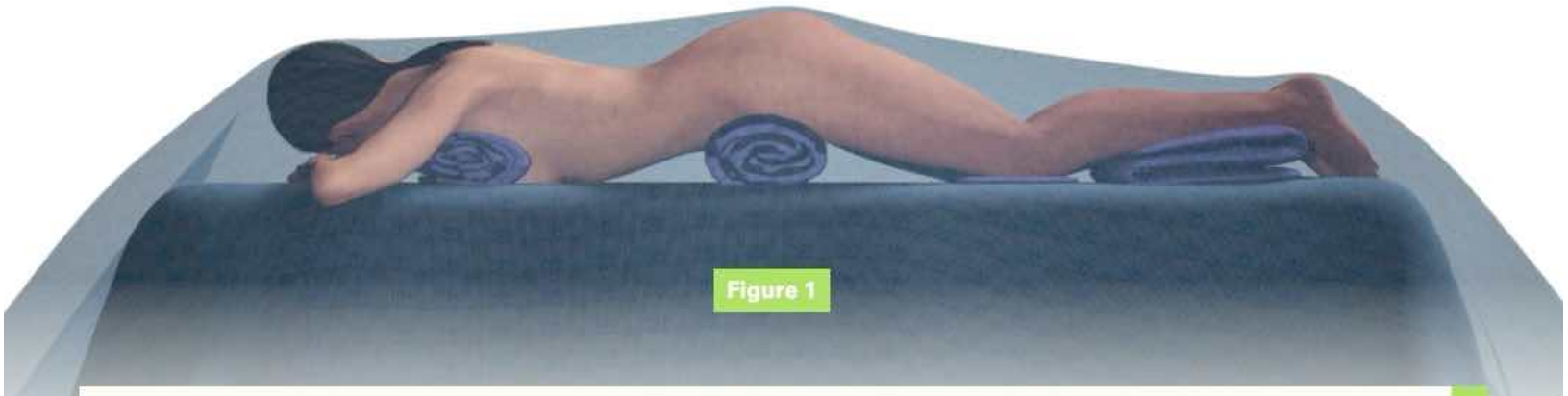


Figure 1

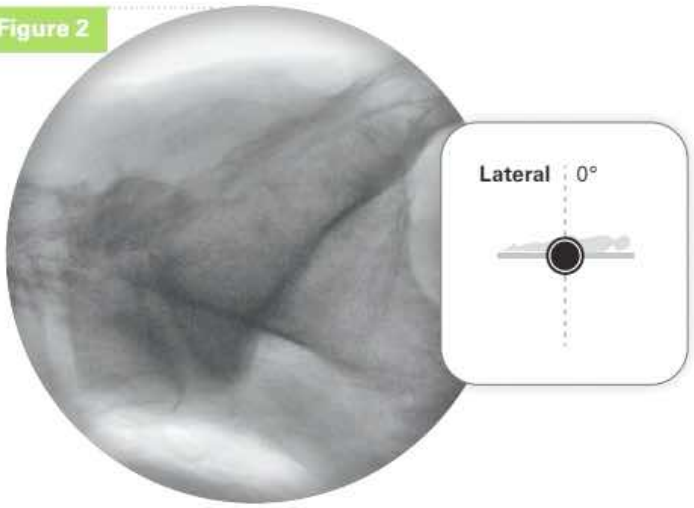
***PRECAUTIONS:***

- *This manual is provided for reference only. The procedure should be adjusted based on patient characteristics and the physician's judgment. Instruments not shown in this manual may be used at the physician's discretion.*
- *Ensure all instruments are present prior to beginning the procedure.*
- *Breakage, slippage or misuse of instruments or Allograft may cause injury to the patient or operative personnel.*
- *Excessive loads, such as excessive torque, tensile or compression load applied to long handle insertion tools can damage the instruments, especially when the instrument is docked in the bone.*
- *Position C-arm to minimize interference with instruments throughout the procedure.*
- *Host bone material may adhere to the instruments which may result in binding or adherence of instruments to each other or to the Allograft.*

### Lateral View

First align the alar lines by superimposing the left and right iliac cortical densities. Next, align the sciatic notches using C-arm swivel or "wig-wag." Proper alignment of the lateral view is critical for this procedure. The sciatic notches should remain superimposed throughout the procedure.

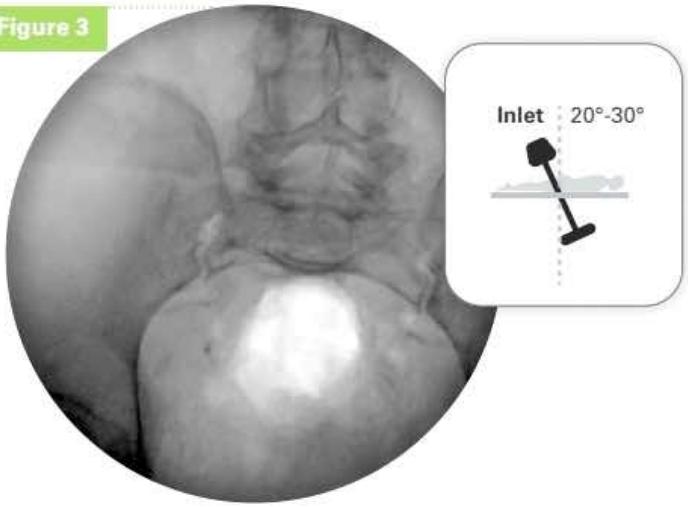
Figure 2




### Inlet View

The inlet view is an anterior-to-posterior view to optimize visualization of the ventral cortex of the S1 sacral body. The fluoroscope is tilted toward the feet until the dense cortical line of the S1-S2 vestigial disc directly overlies the dense cortical line of the sacral promontory. The beam in this view should line up with the anterior cortex of the S1 sacral body.

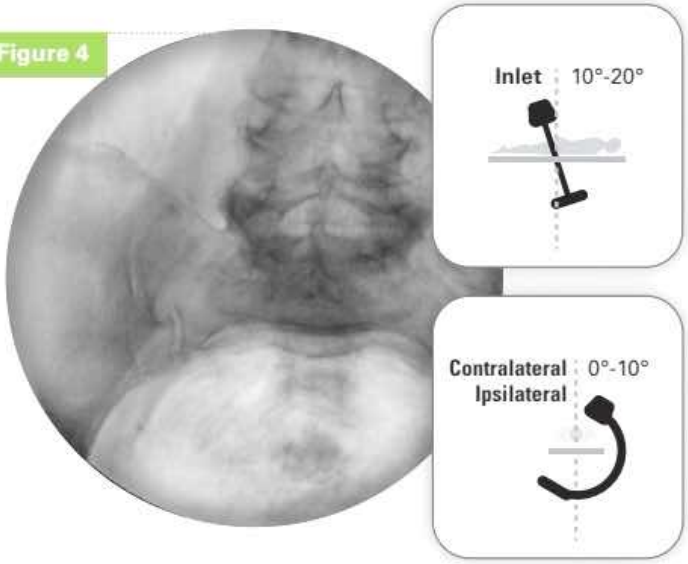
Figure 3




### INTRA View (Inlet -10° Oblique)

The INTRA View is -10° cephalad from the inlet view and slightly oblique (typically within 5°) ipsilateral or contralateral. The beam in this view will optimize visualization of the posterior aspect of the inferior limb of the articular SI joint. The posterior aspect of the inferior limb of the articular SI joint is the medial joint in this view.

Figure 4



### Obtaining the INTRA View

- Oblique the C-arm towards the midline from the operative SI joint from the inlet -10° view.
- Begin at a minimum of -5° obliquity and move towards the midline slowly, looking for the posterior portion of the inferior limb of the SI joint to be most open. The green highlighted portion of the joint in **Figure 7** and white oval in **Figure 8** indicate the aspect of the SI joint we are optimizing in this view.
- If the posterior portion of the inferior limb of the SI joint does not open up after moving from -5° to +5° obliquity, increase the obliquity to -10° and try again.

***NOTE:***

- *As you continue to oblique the C-arm towards the midline past where the posterior aspect of the joint is "optimized" you will see that the posterior and the anterior aspects of the inferior articular limb are superimposed and only one joint line is visible. This is too much obliquity and the C-arm should be obliqued back towards the operative joint (laterally) until the posterior aspect of the joint is "optimized".*
- *If you oblique past 10°, the SI joint may open a second time. This is the ventral or anterior portion of the joint and if the Bone Access Needle is placed here, the Allograft may not be in the articular portion of the joint.*
- *If the patient is not in a spine neutral position then the needed obliquity may be greater. Check that the spinous processes in the inlet view are aligned.*

Figure 5

Figure 6

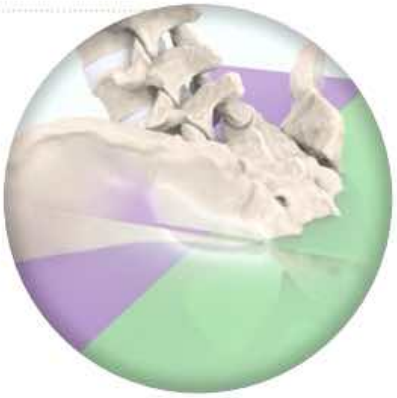


Figure 7

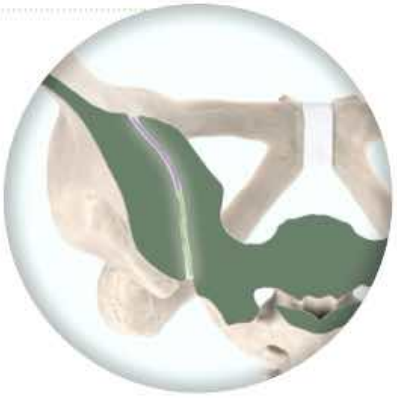
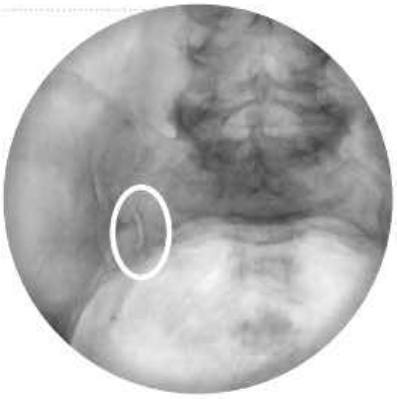


Figure 8



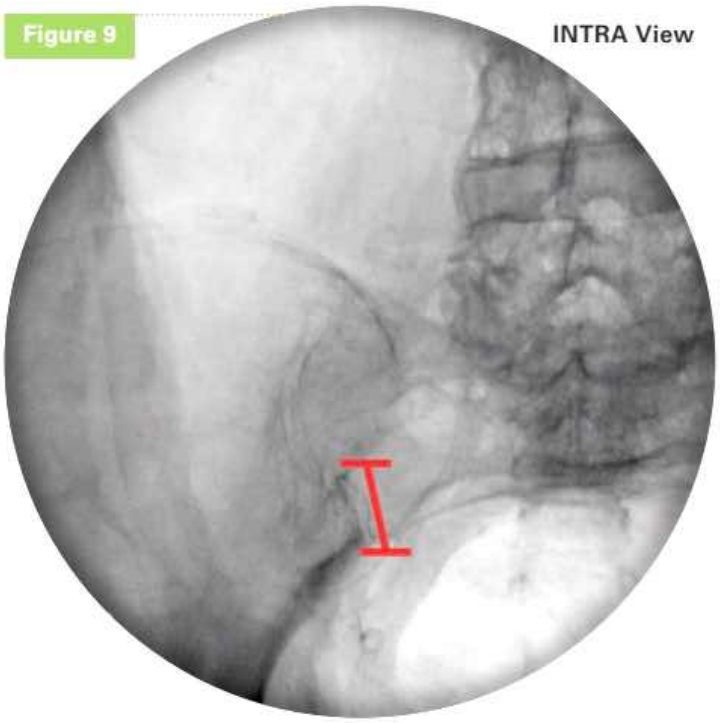
### Skin Marking

In the INTRA View, localize the inferior aspect of the joint by placing an 8 Gauge Bone Access Needle on the skin **(Figure 9).**

Mark where the medial joint meets the pelvic brim. Trace a 2 cm line posteriorly along the joint.

- Mark the ventral aspect of the joint. This is where the joint meets the pelvic brim.
- Mark the dorsal aspect of the joint approximately 2 cm above the first marking.
- Connect these two lines while tracing posteriorly along the joint.

Figure 9



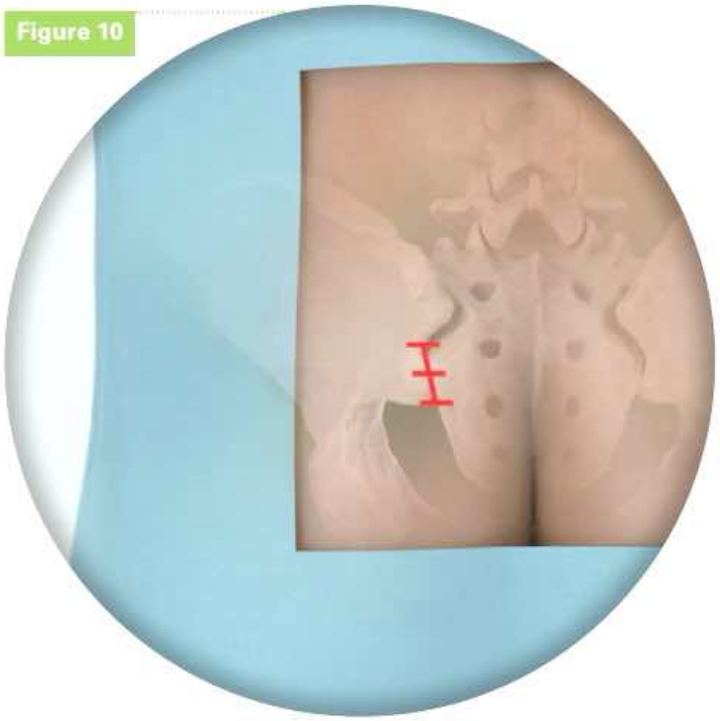

Mark at the center point of the skin marking line. **(Figure 10).**

### Incision

Make a percutaneous stab incision with a scalpel at the center marking. The skin will be mobile enough to move ventrally to place the first implant and dorsally to place the second implant.

> ***NOTE:***
> *Typically an 11-blade scalpel is used.*

Figure 10



The Assist is a combo tool containing both a Clamp and Lever **(Figure 11).**

Figure 11

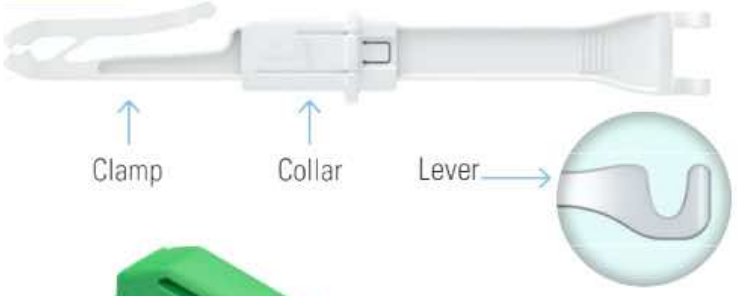
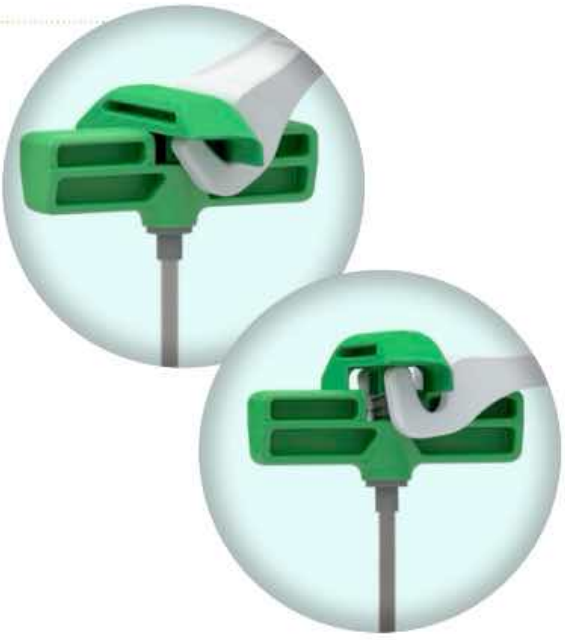



Figure 12

The Clamp is designed to allow the user to hold the Bone Access Needle while keeping their hand away from the radiation source. The collar is advanced into the Clamp to lock around the Bone Access Needle **(Figure 12).** Ensure the Bone Access Needle is clamped at a 90-degree angle to allow optimal engagement with the Clamp.

The Lever allows the user to remove the stylet from the Bone Access Needle after it is placed to depth in the joint. The hooks are placed in the cavities of the Bone Access Needle stylet **(Figure 13).**

Figure 13

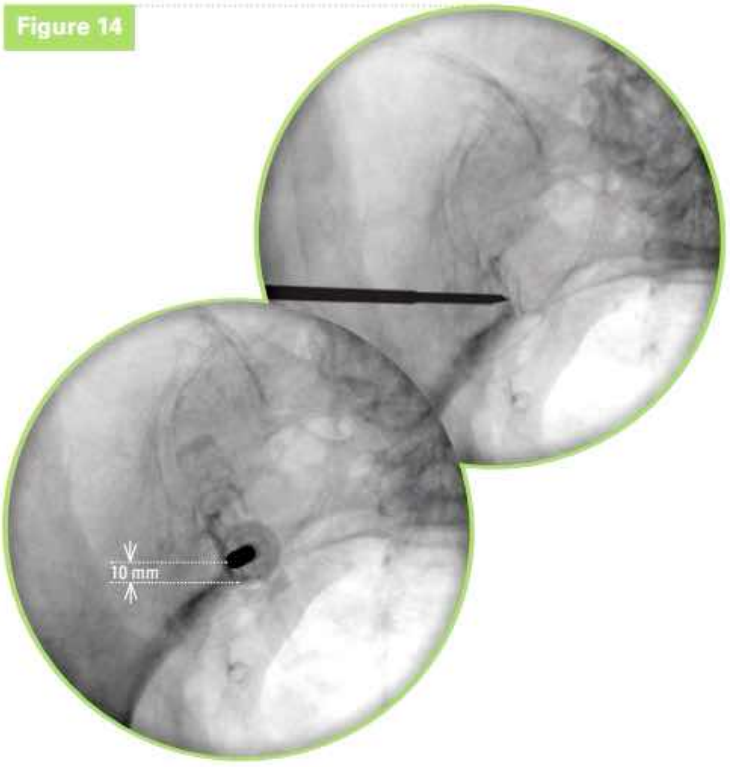


Place the Bone Access Needle through the skin incision.

- The Bone Access Needle should be docked in the inferior third of the joint and approximately 10 mm from the anterior pelvic brim.
- The Bone Access Needle should be angled such that it is aligned with the trajectory of the C-arm in the 'optimized' INTRA View.

Confirm that the Bone Access Needle is visualized as a dot **(Figure 14).**

**Figure 14**




### Lateral View

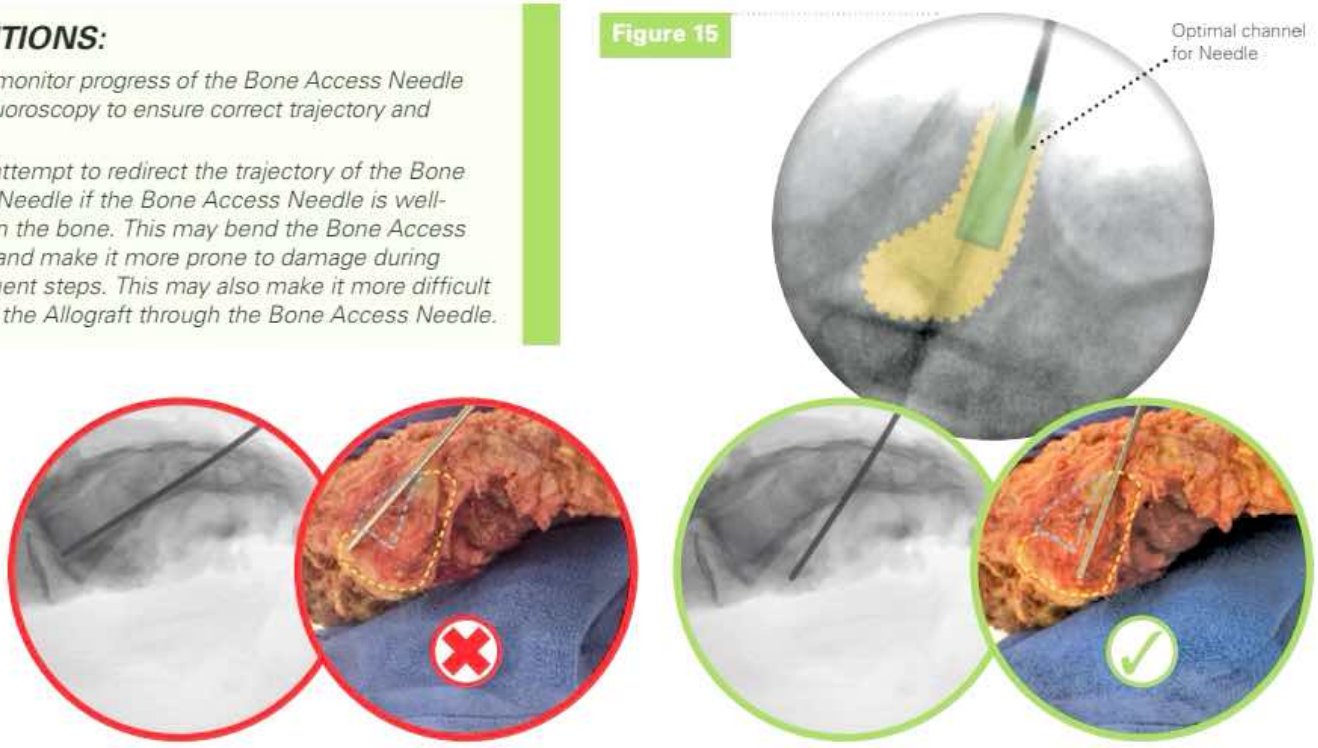
Adjust the trajectory of the Bone Access Needle to be parallel to the sciatic notch **(Figure 15).**

Advance the Bone Access Needle approximately 1 cm with gentle tapping with the Mallet. Hold the needle while malleting.

***PRECAUTIONS:***

- *Always monitor progress of the Bone Access Needle under fluoroscopy to ensure correct trajectory and depth.*
- *Do not attempt to redirect the trajectory of the Bone Access Needle if the Bone Access Needle is well-seated in the bone. This may bend the Bone Access Needle and make it more prone to damage during subsequent steps. This may also make it more difficult to place the Allograft through the Bone Access Needle.*

**Figure 15**



### INTRA View

Returning to the INTRA View, confirm the Bone Access Needle is still visualized as a dot and in the center of the C-arm image.

> ***NOTE:***
> *The C-arm may be obliqued in a 5° arc ipsilateral and contralateral once the Bone Access Needle is docked in the joint. The Bone Access Needle should stay positioned between the bony articular surfaces to indicate it is correctly placed in the joint.*

### Lateral View

Return to the Lateral view and confirm the Bone Access Needle trajectory **(Figures 16 and 17).**

- Identify where the iliac crest intersects the dorsal aspect of the sacrum **(A).**
- Identify where the sciatic notch intersects the ventral aspect of the sacrum **(B).**
- The line connecting these two points is the posterior aspect of the inferior limb of the joint and can be used to determine depth.
- Advance the needle until the cannula is 6-8 mm below the posterior aspect of the joint. Do not advance beyond the recommended depth.

> ***NOTE:***
> *The cannula width of the Bone Access Needle is 4.2 mm and can be used to determine appropriate depth of the Bone Access Needle. The final depth of the distal tip of the cannula should be approximately 6-8 mm or 1.5-2 cannula widths.*

> ***PRECAUTIONS:***
> ➤ *Do not advance beyond the recommended depth. The SI joint curves medial to lateral and the Allograft may diverge from the joint if placed too deep. Placing the Bone Access Needle too deep may result in difficulties removing the stylet from the cannula.*

**Figure 16**

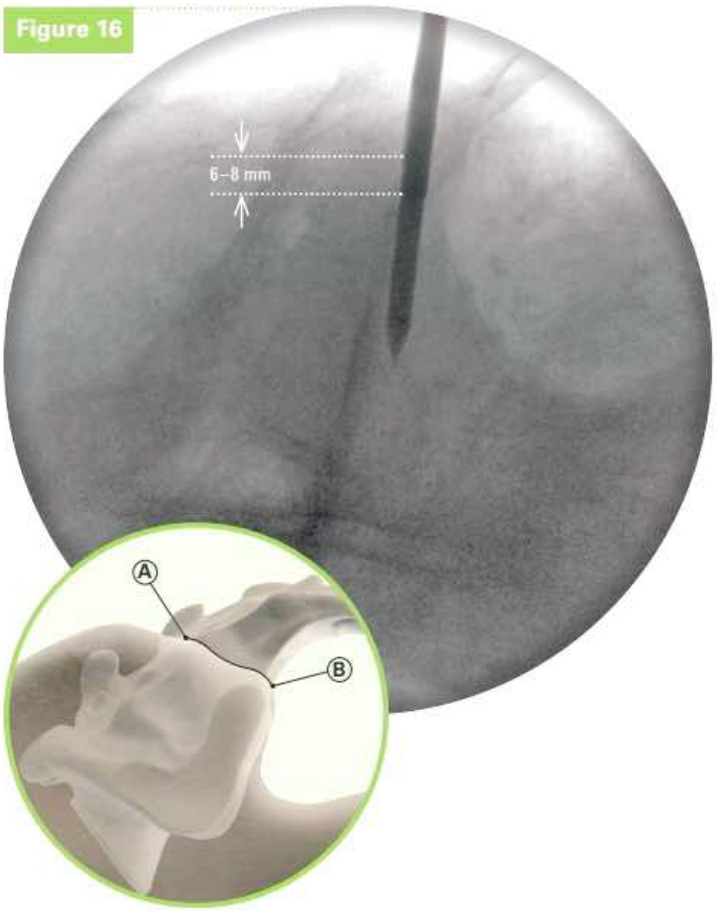



**Figure 17**

While holding the Bone Access Needle in place, disengage and remove the stylet by turning the stylet counterclockwise 90 degrees.

Use the Lever on the Assist to loosen the stylet from the bone before removing it from the cannula of the Bone Access Needle **(Figures 18).**

- Grasp the Assist near the lever end.
- Place a thumb on the knurling of the Assist near the Lever end.
- Grasp the Bone Access Needle with the other hand, placing a thumb on the green handle and two fingers around the cannula.
- Press down on the Assist while holding the Bone Access Needle to remove the stylet.

Figure 18

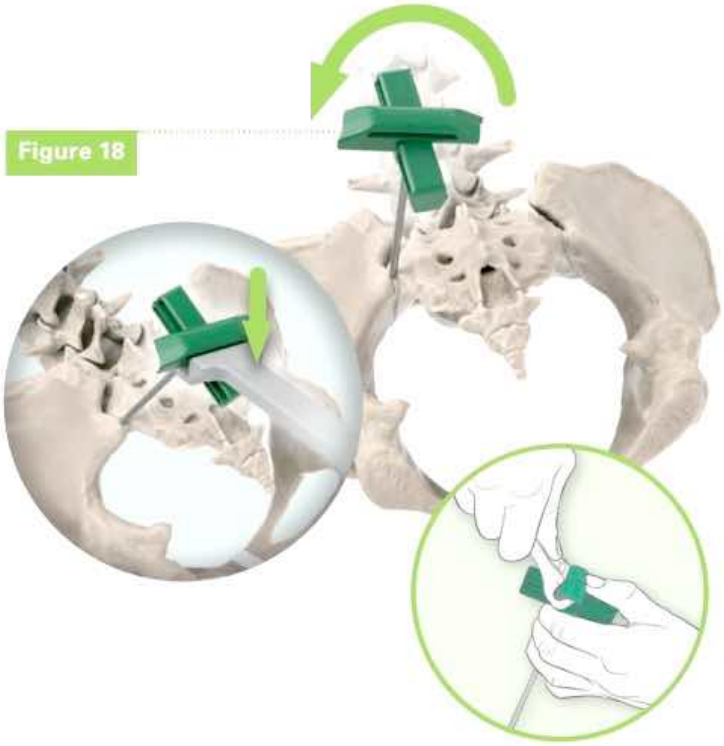
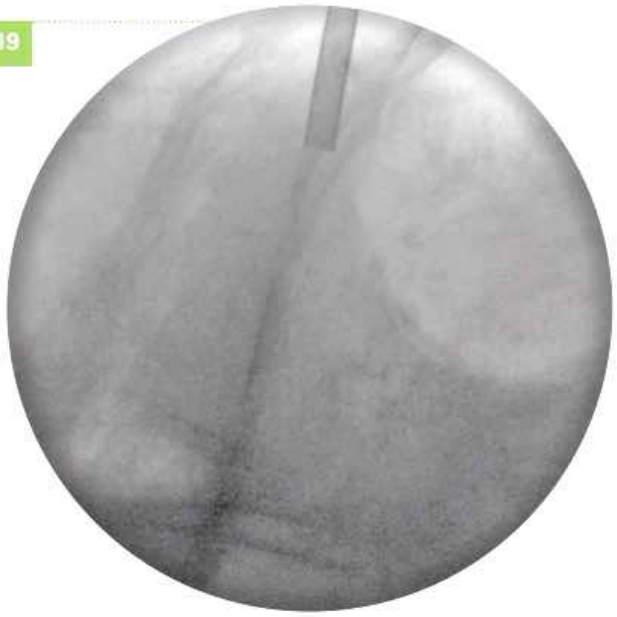


Figure 19



***NOTE:***

*Ensure the cannula and stylet remain colinear throughout the prying motion to reduce the internal friction between the Needle components.*

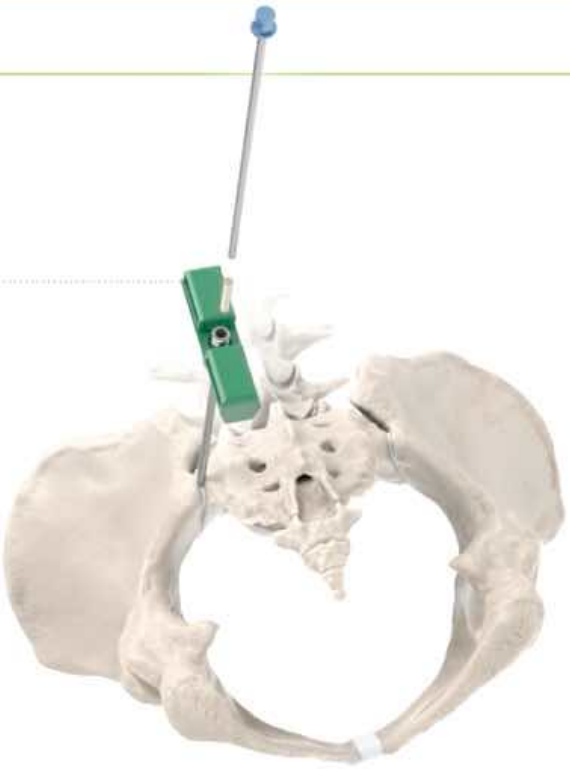
***PRECAUTIONS:***

- *When using the Assist to remove the stylet, monitor the position of the Bone Access Needle under fluoroscopy to ensure correct trajectory and depth.*
- *Do not attempt to redirect the trajectory of the Bone Access Needle if the Bone Access Needle is well-seated in the bone. This may bend the Bone Access Needle and make it more prone to damage during subsequent steps.*
- *Not using the Lever end of the Assist to loosen the stylet may result in unwanted needle advancement or changes to trajectory.*

Load the iFuse INTRA X Allograft into the proximal end of the Bone Access Needle cannula. The Allograft can be loaded in either direction **(Figure 20).**

- Place the Tamp into the Bone Access Needle.
- Use the Tamp to push the Allograft to depth.
- Hold the Bone Access Needle in place while advancing the Allograft with the Tamp to prevent needle advancement.
- Advance the Allograft by gently malleting the proximal end of the Tamp to the positive stop. **(Figure 21).**

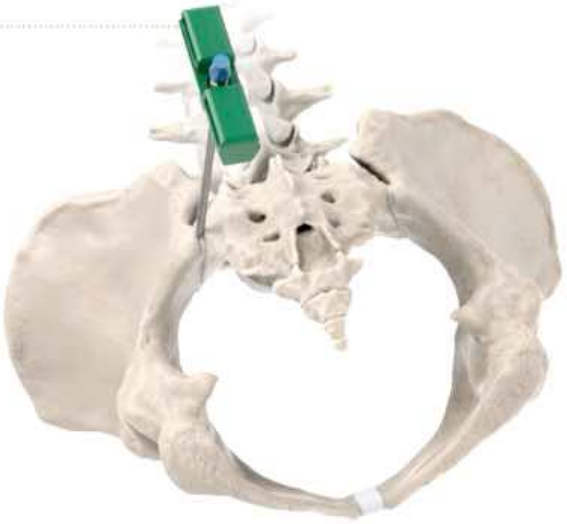
Figure 20



***NOTE:***

*Consider saving the Lateral View image with the Tamp fully inserted. This may serve as a reference for placement of the second Allograft.*

Figure 21



***PRECAUTIONS:***

- *Confirm that the Bone Access Needle is fully seated before inserting the Tamp and Allograft.*
- *Ensure the Bone Access Needle and Tamp remain colinear during advancement of the Tamp and Allograft.*
- *Forceful impaction of the Tamp may advance the Bone Access Needle and Allograft deeper than desired. Do not continue malleting once you've hit the positive stop. Always monitor the progress of the instruments and Allograft under fluoroscopy.*

### First Impant Positioning

- The proximal end of the Allograft should be 6-8 mm below the posterior aspect of the joint. This is well short of the iliac cortical densities (ala line) **(Figure 22).**

Figure 22

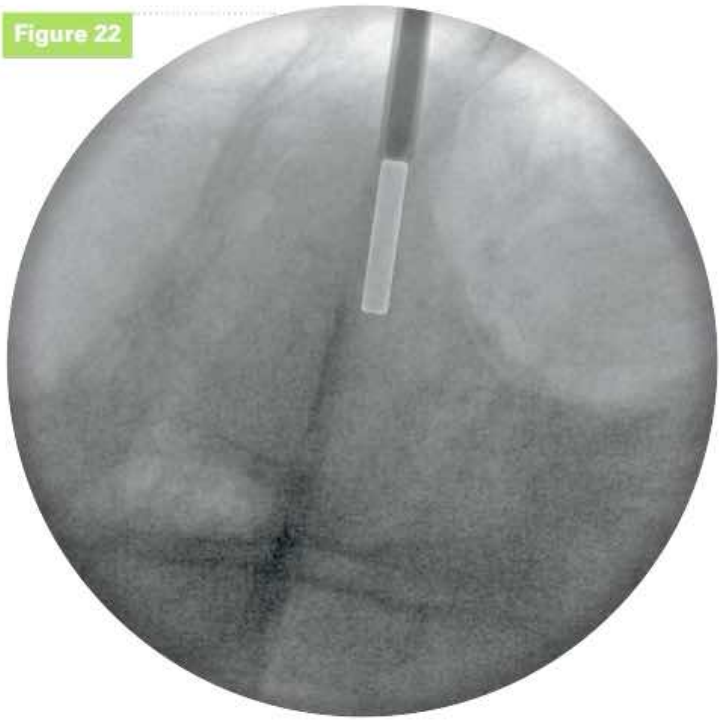
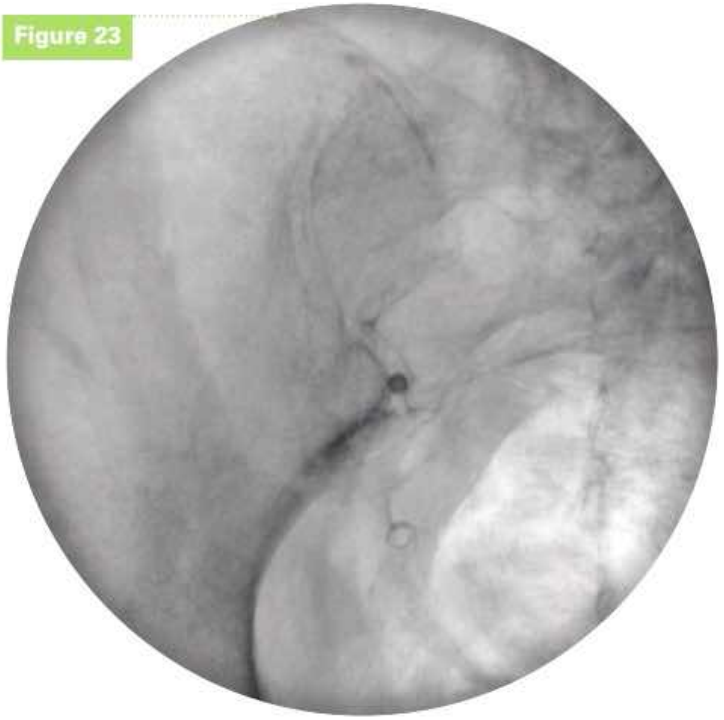


Figure 23



***PRECAUTIONS:***

➤ *Always monitor the progress of the Allograft under fluoroscopy.*

### Second Implant Positioning

- The second Allograft should be placed at the junction of the middle third and dorsal third of the joint and parallel to the first Allograft **(Figure 24).**
- Reassemble the Bone Access Needle by inserting the stylet back into the cannula.
- In the INTRA View, reposition the Bone Access Needle to access the junction of the middle third and dorsal third of the joint. This should be minimum 5 mm of distance center-to-center between the first and second Allograft.
- Ensure the Bone Access Needle is a dot in the INTRA View when placing the second Allograft. This will ensure the Allografts are parallel.
- Follow the technique previously described for placing the second Allograft **(Figure 25).**

***NOTE:***

*The saved Lateral view image with the Tamp fully inserted can be used as a reference.*

***PRECAUTIONS:***

- *Always monitor the progress of the instruments and Allograft under fluoroscopy.*

Figure 24

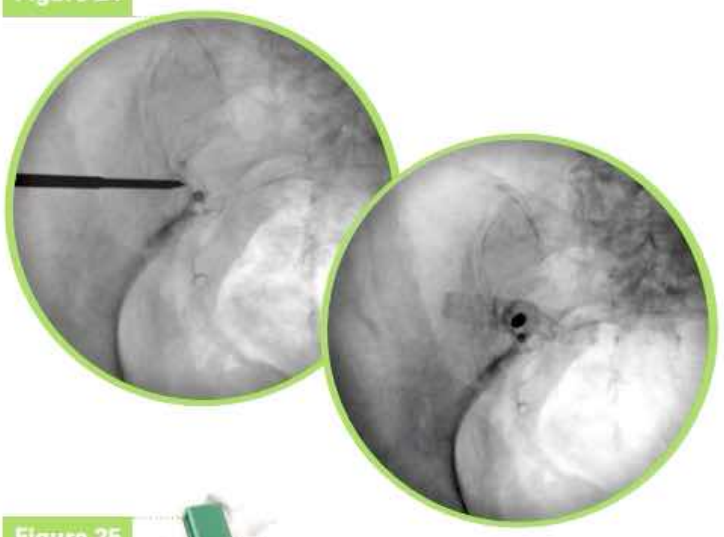


Figure 25

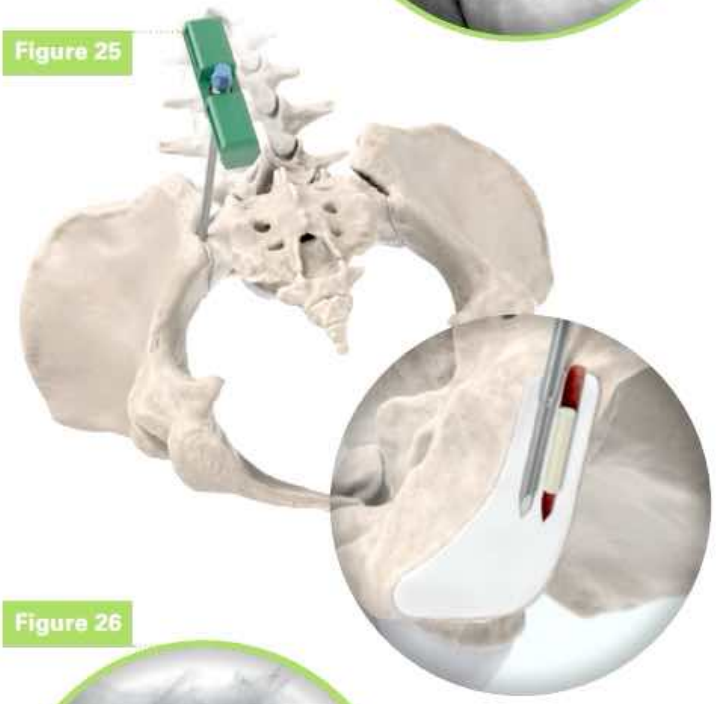
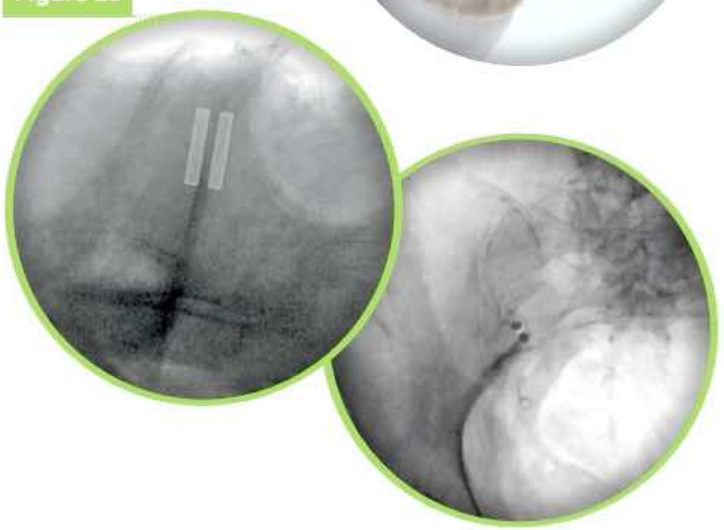


Figure 26



### Closure

- Obtain final Lateral and INTRA Views.
- Proceed with the standard wound closure. Most incisions can be closed with a single nylon suture.
- Local anesthetic may be injected at the procedure site after closure.

Figure 27

### SI Joint Fusion Post-Op Care

- Some patients may be able to progress rapidly to full weightbearing. Other patients may require a period of protected weight-bearing due to associated health conditions such as age, osteoporosis, altered bone health, impaired balance and/or gait, or other musculoskeletal conditions.
- Most physicians and therapists recommend a heel toe gait with normal foot progression.


| No. | Instrument Set | Part No. |
|---|---|---|
| ❶ | 8 Gauge Bone Access Needle | 501979 |
| ❷ | Tamp | 501979 |
| ❸ | Assist | 501986 |
| ❹ | Mallet | 501984 |

***NOTE:***

*The 8 Gauge Bone Access Needle and Tamp are packaged together and share the same part number.*

## NOTES

**Indications**
The iFuse INTRA X™ Instruments are indicated for placement of the iFuse INTRA X Allograft. The iFuse INTRA X Allograft is indicated for homologous use.

Healthcare professionals should refer to 503004 iFuse INTRA X Allograft *Instructions For Use*, and 503005 iFuse INTRA X Instruments *Instructions For Use*, for contraindications, warnings and precautions at *www.si-bone.com/label*.

There are potential risks associated with the iFuse INTRA X Allograft Implant System. It may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit *www.si-bone.com/risks*.

Complaints and adverse events relating to use of the procedure and/or device should be reported to SI-BONE, Inc. Toll Free: *(855) 511-1545* or E-mail *qara@si-bone.com*



℞ ONLY

SI-BONE® | **iFuse** INTRA X™
Allograft Implant System

US | Providers | 303013-US Rev. B
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