

Irix[®]-A

Lumbar Integrated Fusion System



SURGICAL TECHNIQUE

IRIX®-A LUMBAR INTEGRATED FUSION SYSTEM SURGICAL TECHNIQUE

Patient Positioning and Exposure.	2
Endplate Preparation.	3
Implant Sizing.	3
Implant Preparation.	4
Implant Loading.	4
Implant Insertion.	6
Screw Hole Preparation and Screw Insertion	6
IMPLANT REMOVAL.	8
IRIX®-A INSTRUMENTS	10
IRIX®-A IMPLANTS	12

This document is intended exclusively for experts in the field, particularly physicians, and is not intended for laypersons.

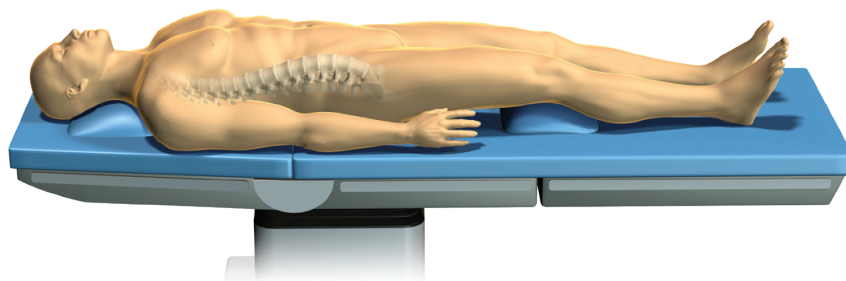
Information on the products and procedures contained in this document is general in nature and does not represent medical advice or recommendations. As with any technical guide, this information does not constitute any diagnostic or therapeutic statement with regard to a given medical case. An evaluation, examination, and advising of the patient are absolutely necessary for the physician to determine the specific requirements of the patient, and any appropriate adjustments needed, and the foregoing are not to be replaced by this document in whole or in part.

Information contained in this document was gathered and compiled by experts in the field and company employees to the best of their knowledge. Care was taken to ensure the information contained herein is accurate and understandable. The company does not assume any liability, however, for the accuracy and/or completeness of the quality of the information, and is not liable for any losses whatsoever of any kind or any nature that may be caused by the use and/or reliance of said information.

IRIX-A™ LUMBAR INTEGRATED FUSION SYSTEM SURGICAL TECHNIQUE

Step 1: Patient Positioning

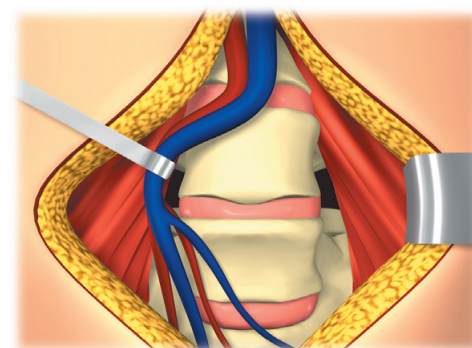
- The patient is placed in the supine position for a direct approach to the anterior lumbar spine at the midline for the vertebrae to be fused.



Step 2: Exposure and Distraction

- Use a straight metal instrument to confirm the appropriate operative level is located through the use of radiography. This will ensure direct access into the disc space.

Create an incision and retract using traditional methods for an anterior approach to allow for adequate exposure and visualization of the desired operative levels.



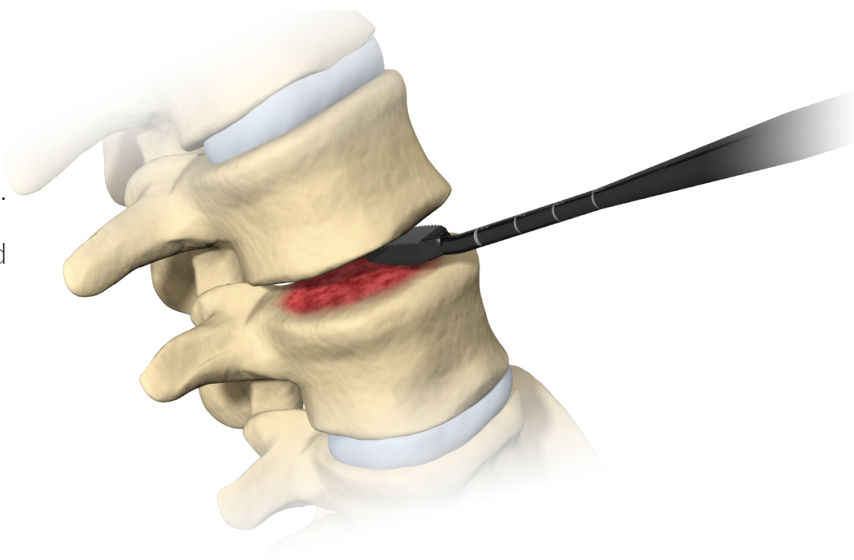
CAUTION – Anterior exposure of the lumbar spine is anatomically challenging, particularly above L4-5. The anterior approach and exposure should only be performed by an expert surgeon who is capable of urgently recognizing and repairing vascular and intra-abdominal complications. Complications of the anterior approach may also include sexual dysfunction, including retrograde ejaculation. Breach of iliac vessels during anterior spinal surgery, including unrecognized breach, has resulted in patient death. Reoperation and scarring of the prevertebral structures significantly increases complication risk.

Step 3: Discectomy and Endplate Preparation

- The vertebral disc should be excised using a standard technique.

The Rasp instrument should be used to carefully decorticate the endplate surfaces.

CAUTION – Care should be taken to avoid plunging disc prep instrumentation into surrounding neurological structures.



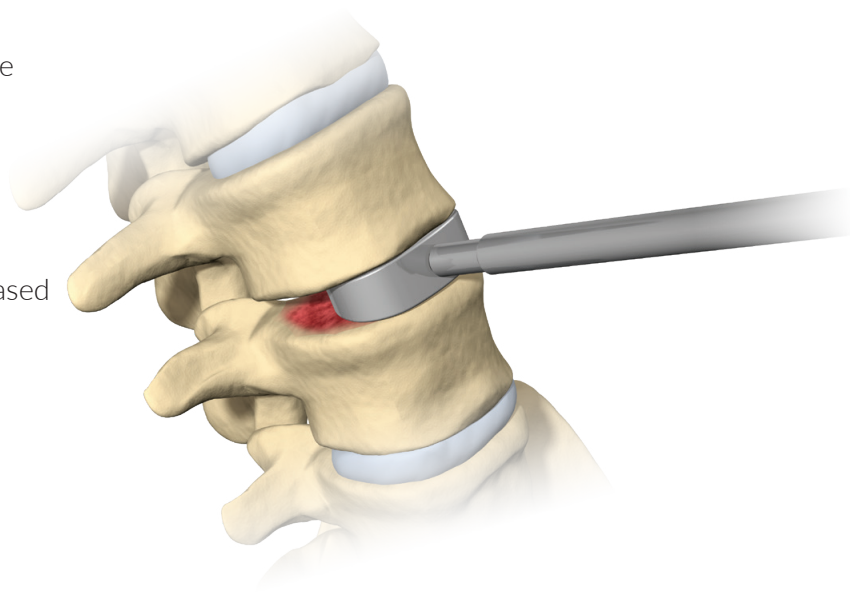
Step 4: Implant Sizing

- Use the Trial instruments to determine the footprint, height, and lordosis of the Implant to be used; a secure fit is desirable. Great care should be taken to maintain the anatomy and protect the neurological structure.

It is recommended that distraction be used during trialing to ensure secure implantation. Implants which are undersized carry an increased risk of pseudarthrosis and spacer expulsion.

NOTE – Trials are the same height as PEEK portion of the implant.

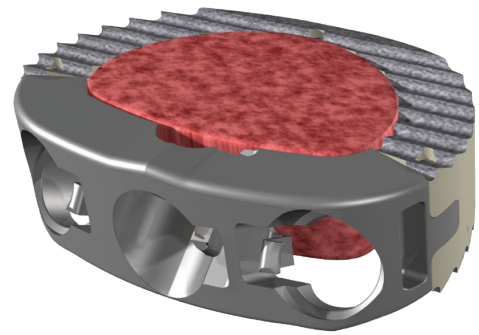
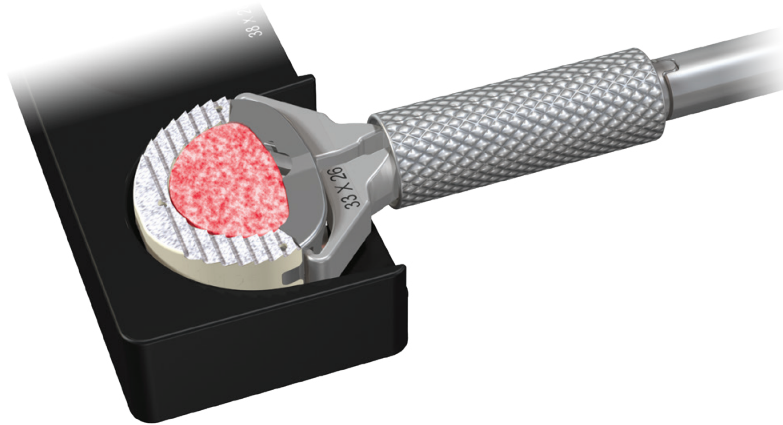
NOTE – The fork in the Mallet may be used to dislodge the Trial from the disc space by slapping it against the flange on the Trial.



Step 5: Implant Preparation

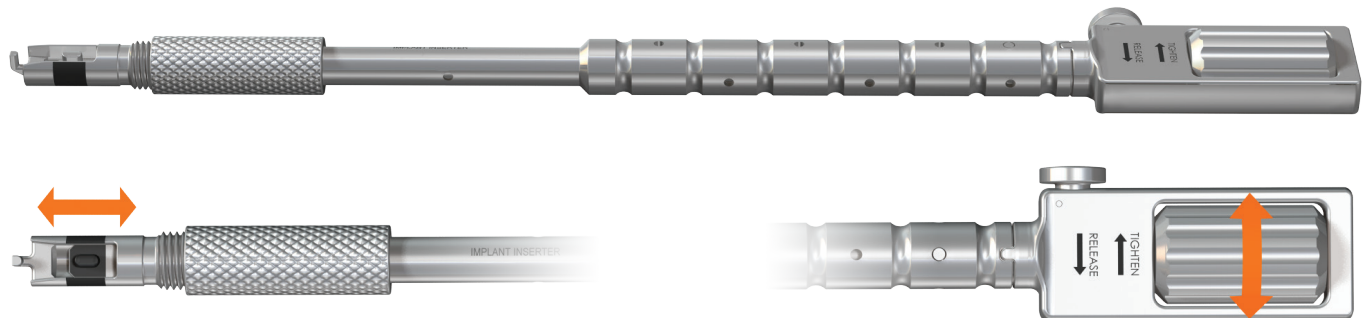
- The appropriate sized sterile implant should be selected and packed with bone graft material.

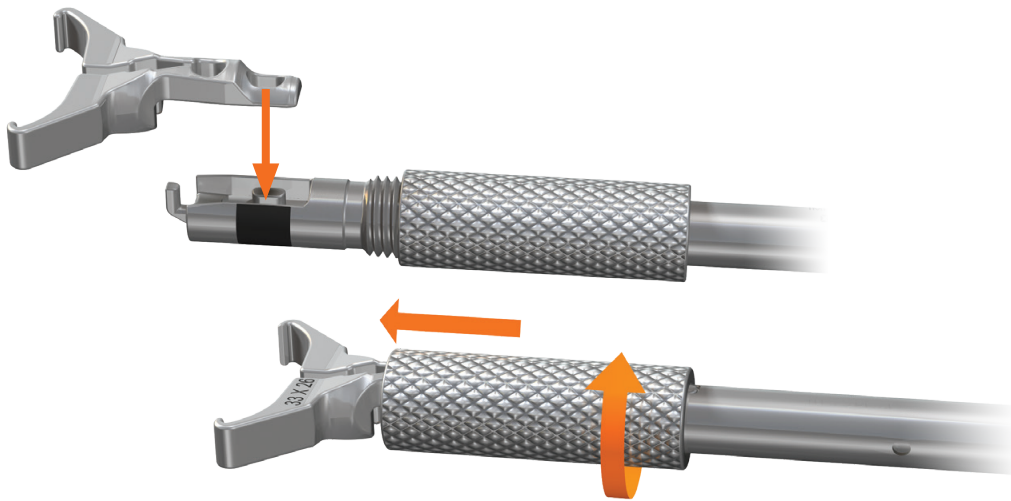
NOTE – There is a Graft Packing Block and Graft Tamp available for use. Additionally, the Graft Packing Block has been designed so it can be used when the implant is attached to the Inserter.



Step 6: Implant Loading

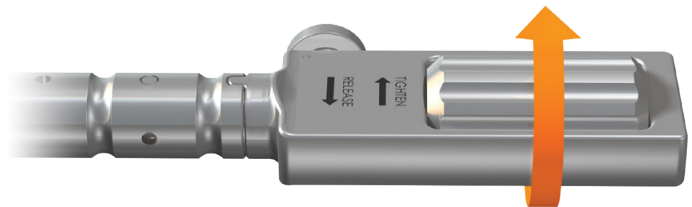
- Select the appropriate Inserter Tip for the determined implant footprint.
- Rotate the Inserter's locking nut clockwise and/or counter-clockwise to align the laser marked loading zone. Place the selected Inserter Tip onto the distal end of the instrument. Once fully seated, move the collar over the tip and rotate clockwise to tighten.



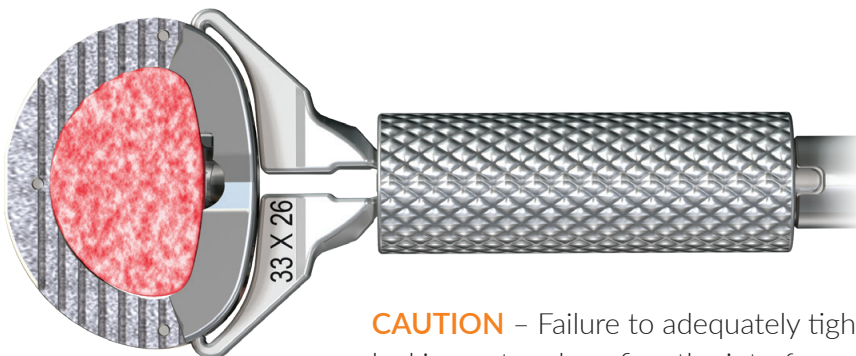
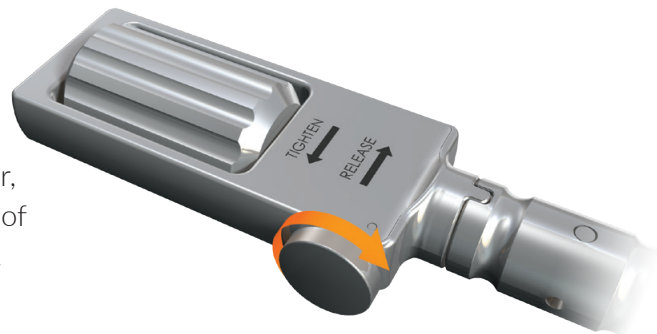


CAUTION – Failure to adequately tighten the threaded collar may result in loosening or release of the Inserter Tip and/or implant, resulting in injury.

- While holding the implant against the Inserter Tip, turn the Inserter's locking nut clockwise to engage the Inserter Tip with the instrument.



- Once the implant is secured to the Inserter, tighten the side thumb screw (on the side of the Inserter just below the tightening nut).



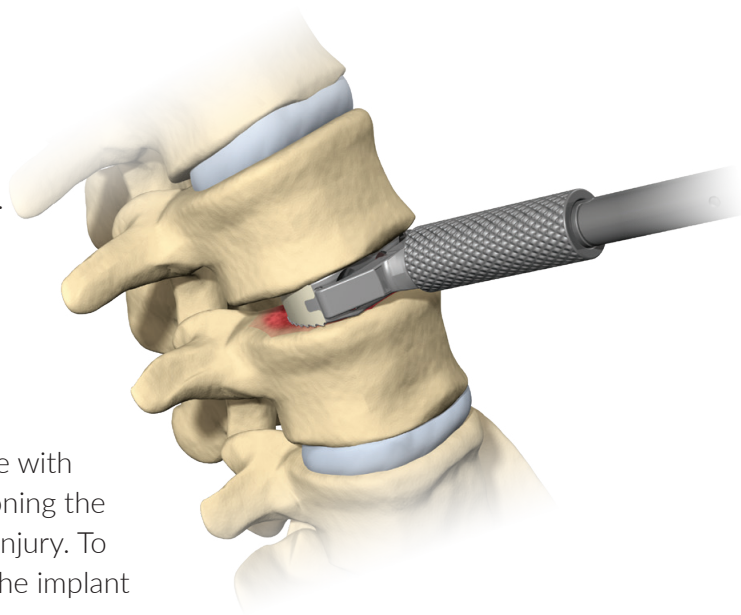
CAUTION – Failure to adequately tighten the Inserter's locking nut and confirm the interface may result in loosening or release of the implant, resulting in injury.

Step 7: Implant Insertion

- Under fluoroscopy, the implant should be gently impacted into the intervertebral space at the midline. The implant should be recessed into the disc space approximately 2mm. Radiographic imaging of the Integrated Titanium Ring and titanium plasma coated portions of the implant can be used to determine implant position.

CAUTION – The implant should be impacted in place with great care as over impaction of the implant or positioning the implant too far posteriorly can result in neurological injury. To avoid posterior displacement, take care in adjusting the implant or instrumentation.

Once the implant is positioned, disengage the inserter by first loosening the side thumbscrew and then turning the locking nut counter-clockwise. Remove the inserter from the body. Care should be taken to avoid neurological structures during inserter removal.

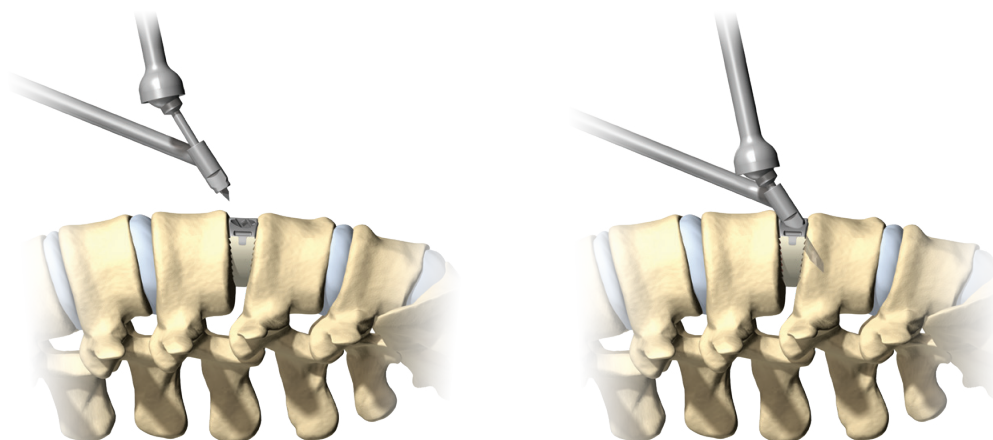
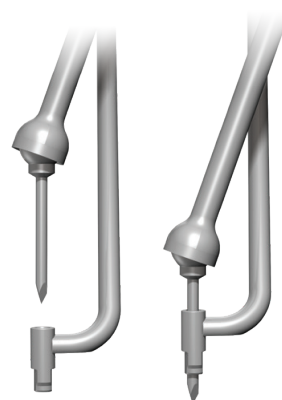


Step 8: Screw Hole Preparation and Screw Insertion

➤ Screw Hole Preparation

Place the Universal Awl into the Awl Guide Tube. Then place the Guide Tube into one of the screw holes in the Implant. Use the Universal Awl through the Guide Tube to break the cortex.

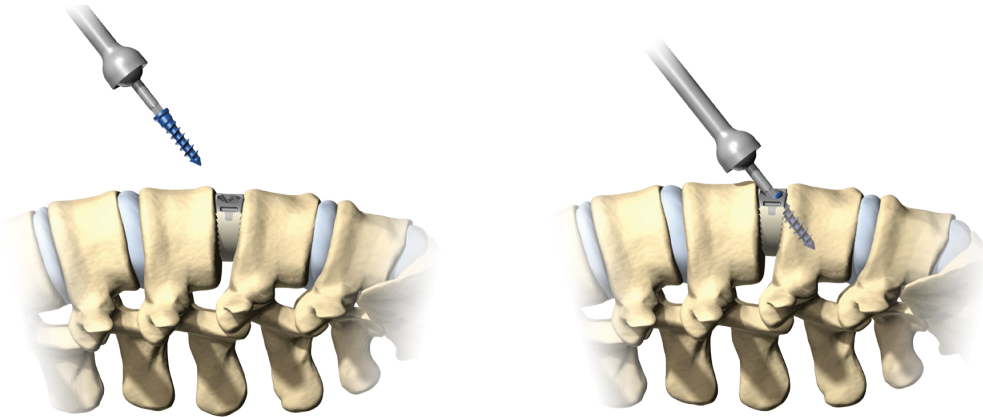
CAUTION – Use care to make sure the implant does not migrate posteriorly during screw preparation or placement. Posterior displacement of the implant can result in neurological injury. It is recommended to insert a screw in the first prepared hole before preparing another hole. Installing fewer than three screws will significantly reduce the implant fixation and increase the risk of implant failure.



➤ Screw Insertion

Place the desired length screw on the Screwdriver and insert the screw. Do not over tighten. A click may be heard as the screw passes the locking arm on the faceplate. This indicates the screw is near the final tightened position.

CAUTION – Over-angulation of the screw beyond 3 degrees in any direction may result in failure of the screw to engage the implant and/or locking arm.

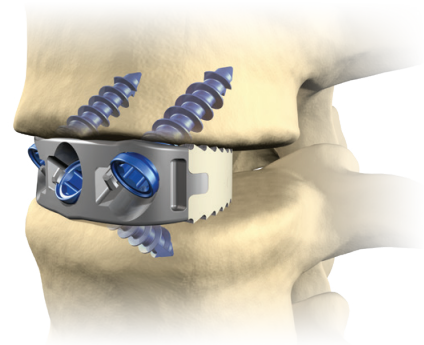
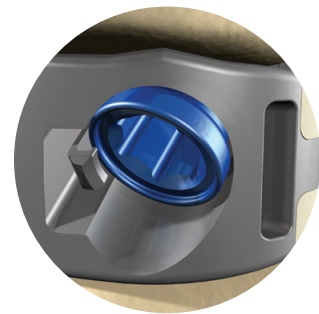


Visual confirmation of the locking arm over the screw and the screw's full seating in the faceplate should be performed.

CAUTION – Failure to confirm that the locking arm is in front of the screw may result in early or late screw loosening.

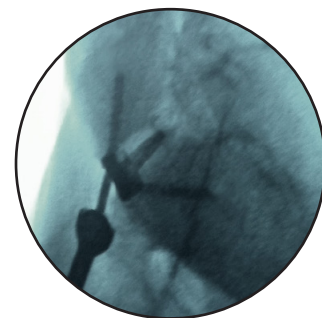
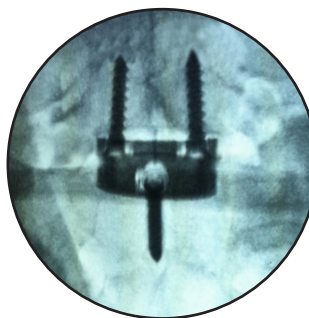
Screws should be placed immediately following screw hole preparation. Preparing multiple screw sites before inserting a screw is not recommended. Installing screws one at a time ensures minimal implant movement during screw insertion.

Install the remaining two screws following the aforementioned steps. It is recommended inserting two screws into the superior vertebral body, then one screw into the inferior vertebral body. The Irix-A Lumbar Integrated Fusion System requires three screws to be installed.



Step 9: Final Imaging

➤ Final radiographic imaging of the implant and screws should be performed to confirm placement.

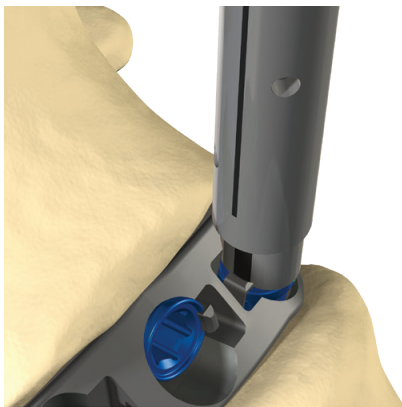


****SYSTEM REMOVAL OR REVISION:**

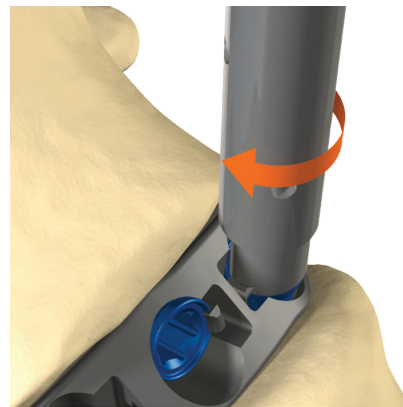
- Should it become necessary to remove or revise the Irix-A™ Lumbar Integrated Fusion System implants, the following steps should be followed:

Step 1: Screw Removal

- After the screw has been properly inserted, the screw may then be removed from its position using the Screw Removal Instrument. The removal instrument has an outer sleeve with an oval distal tip that, when properly aligned with the locking arm using the laser marking, can be rotated 180° to push the locking arm over and out of the screw path. This will allow the surgeon to back the screw out past the retaining hook by rotating the inner hex shaft counter-clockwise.



Alignment of Removal Instrument and Retaining Hook



Removal Instrument rotated to move the Retaining Hook

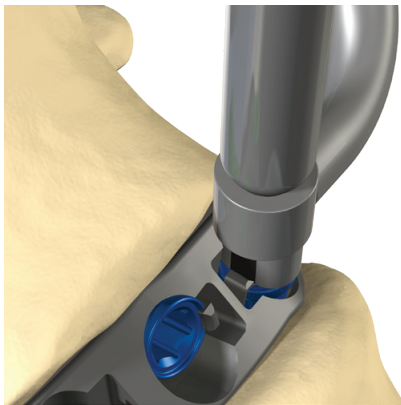
****NOTE** – if resistance is felt while trying to rotate the outer sleeve or during the initial counter-clockwise turning of the inner sleeve, the screw may need to be advanced prior to removal. Advance the screw by rotating the inner hex shaft $\frac{1}{4}$ - $\frac{1}{2}$ turns clockwise to ensure that the screw head is seated beyond the lip of the locking arm prior to screw removal.

Step 2: Implant Removal

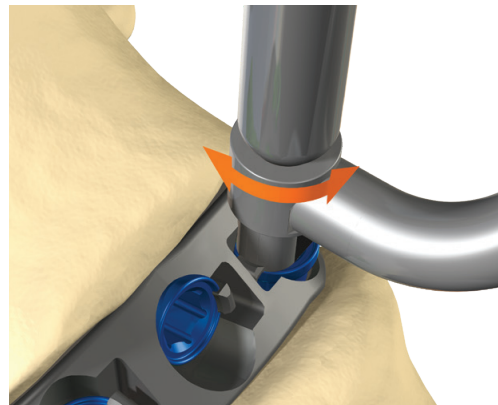
- After the screws have been removed, the Implant may be removed by re-engaging the implant with the appropriate Inserter Tip loaded onto the Implant Inserter and following (Step 6) – Implant Loading. The forked end of the Mallet may be used as a slap hammer to help persuade the implant to back out of the intervertebral disc space.

Step 1: Alternate – Screw Removal

- After the screw has been properly inserted, the screw may then be removed from its position using the Angled Screw Removal Sleeve (red handle) and the Universal Joint Screwdriver or Straight Screwdriver. The Angled Screw Removal Sleeve has an oval distal tip that, when properly aligned with the locking arm, can be rotated 90° to push the locking arm over and out of the screw path. This will allow the surgeon to back the screw out past the retaining hook by turning the screwdriver counter-clockwise.



Alignment of Angled Screw Removal Sleeve and Retaining Hook

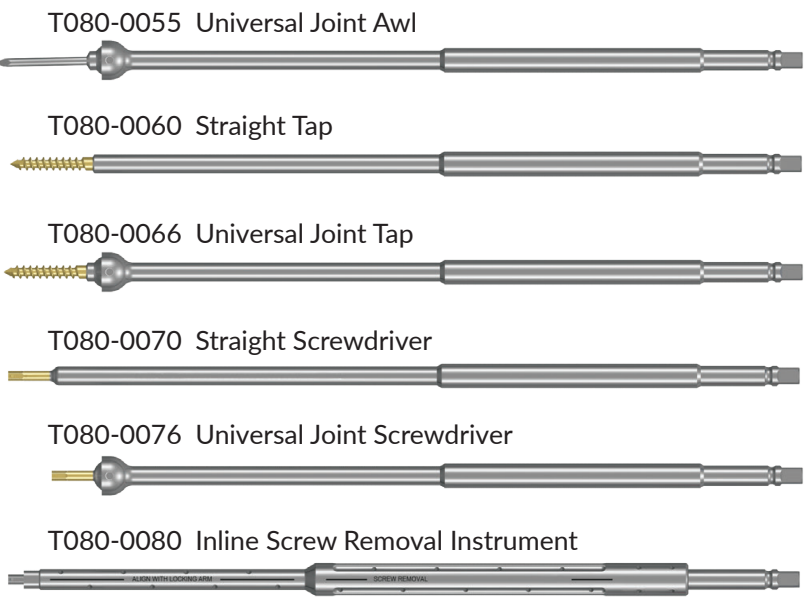


Angled Screw Removal Sleeve rotated to move the Retaining Hook

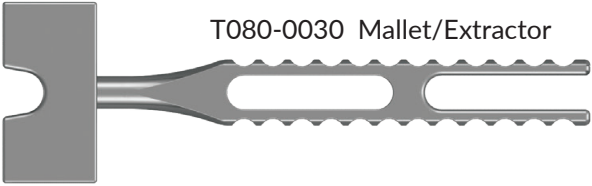
****NOTE** – If resistance is felt while trying to rotate the Angled Screw Removal Sleeve or during the initial counter-clockwise turning of the screwdriver, the screw may need to be better seated prior to removal. Advance the screw by rotating the screwdriver $\frac{1}{4}$ - $\frac{1}{2}$ turns clockwise to ensure that the screw head is seated beyond the lip of the locking arm prior to screw removal.

Step 2: Alternate – Implant Removal

- After the screws have been removed, the Implant may be removed by re-engaging the implant with the appropriate Inserter Tip loaded onto the Implant Inserter and following (Step 6) – Implant Loading. The forked end of the Mallet may be used as a slap hammer to help persuade the implant to back out of the intervertebral disc space.



T080-0020 Graft Packer



T080-0030 Mallet/Extractor

T080-0025 Graft Packing Block



T080-0085 Angled Screw Removal Sleeve



T080-0047 Awl Guide



Implant Inserter Tips

Item #	Description
T080-3326	(33 x 26mm)
T080-3828	(38 x 28mm)
T080-4230	(42 x 30mm)

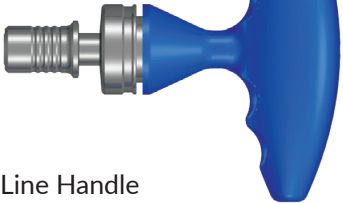


T080-0056 Self-Centering Awl



T080-0042 Implant Inserter

N60000472 Ratcheting T-Handle



N60000473 In-Line Handle



IRIX®-A INSTRUMENTS

T080-0100-1 12mm Osteotome



T080-0100-2(20mm), T080-0100-3(25mm) Elevator



T080-0100-12(4mm), T080-0100-13(6mm)
Straight Up Angle Cup Curette



T080-0100-14 6mm Left Angle Cup Curette



T080-0100-15 6mm Right Angle Cup Curette



T080-0100-16 4mm Ring Curette,
T080-0100-17 8mm Ring Curette



T080-0100-18 4mm x11mm Teardrop Curette



T080-0100-19 20mm X 8mm Box Curette



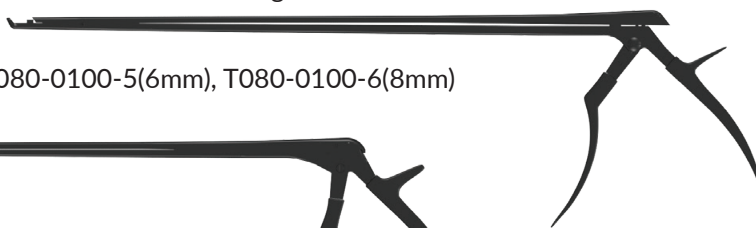
T080-0100-20 8mm Up Angled Double Sided Rasp



T080-0100-8 Scalpel Handle



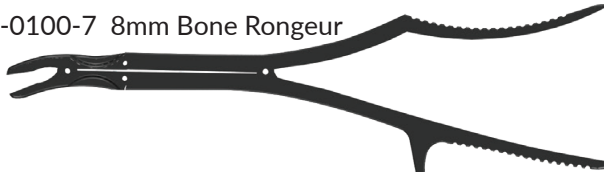
T080-0100-9(4mm), T080-0100-10(6mm), T080-0100-11(8mm)
Anterior Kerrison Rongeur



T080-0100-4(4mm), T080-0100-5(6mm), T080-0100-6(8mm)
Pituitary Rongeur



T080-0100-7 8mm Bone Rongeur



IRIX®-A INSTRUMENTS

Trials



33 x 26mm

8° Lordotic

T080-332611-08TR(11mm) to -332619-08TR(19mm)

12° Lordotic

T080-332611-12TR(11mm) to -332619-12TR(19mm)

38 x 28mm

8° Lordotic

T080-382811-08TR(11mm) to -382819-08TR(19mm)

12° Lordotic

T080-382811-12TR(11mm) to -382819-12TR(19mm)

42 x 30mm

8° Lordotic

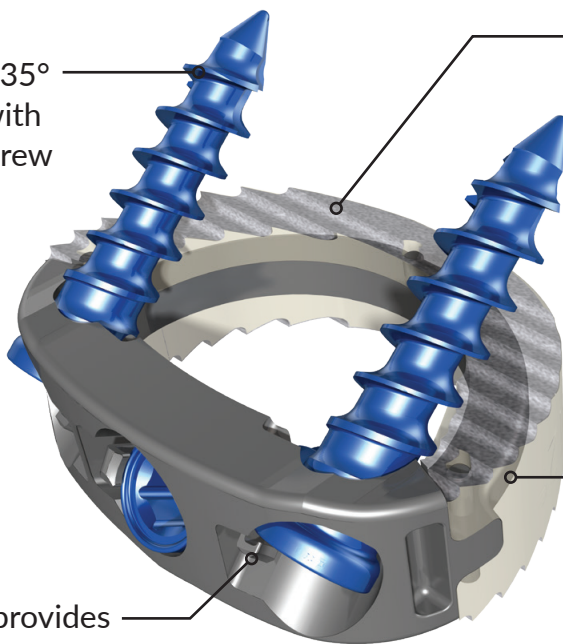
T080-423011-08TR(11mm) to -423019-08TR(19mm)

12° Lordotic

T080-423011-12TR(11mm) to -423019-12TR(19mm)

IRIX®-A IMPLANTS

Screw orientation 35°
cephalad/caudal with
up to 6° conical screw
angulation

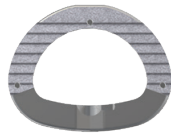


Titanium Plasma Coated (PC)
PEEK provides fluoroscopic
endplate visualization

Integrated Titanium Ring
provides better x-ray
visibility

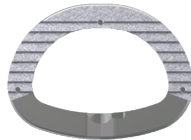
Locking arm provides
tactile, visual and
audible feedback

Irix-A™
33mm x 26mm Implants



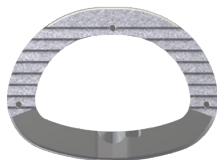
Item #	Description
X080-332611-08PC-STR	33 X 26 X 8°, 11mm, PC (Sterile)
X080-332613-08PC-STR	33 X 26 X 8°, 13mm, PC (Sterile)
X080-332615-08PC-STR	33 X 26 X 8°, 15mm, PC (Sterile)
X080-332617-08PC-STR	33 X 26 X 8°, 17mm, PC (Sterile)
X080-332619-08PC-STR	33 X 26 X 8°, 19mm, PC (Sterile)
X080-332611-12PC-STR	33 X 26 X 12°, 11mm, PC (Sterile)
X080-332613-12PC-STR	33 X 26 X 12°, 13mm, PC (Sterile)
X080-332615-12PC-STR	33 X 26 X 12°, 15mm, PC (Sterile)
X080-332617-12PC-STR	33 X 26 X 12°, 17mm, PC (Sterile)
X080-332619-12PC-STR	33 X 26 X 12°, 19mm, PC (Sterile)

Irix-A™
38mm x 28mm Implants

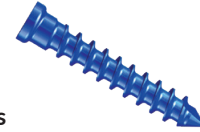


Item #	Description
X080-382811-08PC-STR	38 X 28 X 8°, 11mm, PC (Sterile)
X080-382813-08PC-STR	38 X 28 X 8°, 13mm, PC (Sterile)
X080-382815-08PC-STR	38 X 28 X 8°, 15mm, PC (Sterile)
X080-382817-08PC-STR	38 X 28 X 8°, 17mm, PC (Sterile)
X080-382819-08PC-STR	38 X 28 X 8°, 19mm, PC (Sterile)
X080-382811-12PC-STR	38 X 28 X 12°, 11mm, PC (Sterile)
X080-382813-12PC-STR	38 X 28 X 12°, 13mm, PC (Sterile)
X080-382815-12PC-STR	38 X 28 X 12°, 15mm, PC (Sterile)
X080-382817-12PC-STR	38 X 28 X 12°, 17mm, PC (Sterile)
X080-382819-12PC-STR	38 X 28 X 12°, 19mm, PC (Sterile)

Irix-A™
42mm x 30mm Implants



Item #	Description
X080-423011-08PC-STR	42 X 30 X 8°, 11mm, PC (Sterile)
X080-423013-08PC-STR	42 X 30 X 8°, 13mm, PC (Sterile)
X080-423015-08PC-STR	42 X 30 X 8°, 15mm, PC (Sterile)
X080-423017-08PC-STR	42 X 30 X 8°, 17mm, PC (Sterile)
X080-423019-08PC-STR	42 X 30 X 8°, 19mm, PC (Sterile)
X080-423011-12PC-STR	42 X 30 X 12°, 11mm, PC (Sterile)
X080-423013-12PC-STR	42 X 30 X 12°, 13mm, PC (Sterile)
X080-423015-12PC-STR	42 X 30 X 12°, 15mm, PC (Sterile)
X080-423017-12PC-STR	42 X 30 X 12°, 17mm, PC (Sterile)
X080-423019-12PC-STR	42 X 30 X 12°, 19mm, PC (Sterile)



Self-Drilling Screws

Item #	Description
X080-5525SD	5.5 X 25mm, Self-Drilling Screw
X080-5530SD	5.5 X 30mm, Self-Drilling Screw
X080-5535SD	5.5 X 35mm, Self-Drilling Screw
X080-5540SD	5.5 X 40mm, Self-Drilling Screw



Self-Tapping Screws

Item #	Description
X080-5525ST	5.5 X 25mm, Self-Tapping Screw
X080-5530ST	5.5 X 30mm, Self-Tapping Screw
X080-5535ST	5.5 X 35mm, Self-Tapping Screw
X080-5540ST	5.5 X 40mm, Self-Tapping Screw



Self-Tapping Rescue Screws

Item #	Description
X080-6025	6.0 X 25mm, Self-Tapping Rescue Screw
X080-6030	6.0 X 30mm, Self-Tapping Rescue Screw
X080-6035	6.0 X 35mm, Self-Tapping Rescue Screw
X080-6040	6.0 X 40mm, Self-Tapping Rescue Screw



☎ 888-886-9354
✉ cs@xtantmedical.com
🌐 xtantmedical.com

INDICATIONS: See Package Insert for a more complete listing of indications, contraindications, warnings, precautions, and other important information.

LIMITED WARRANTY and DISCLAIMER: Xtant Medical products have a limited warranty against defects and workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information. CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

Irix®-A is a product and trademark of Xtant Medical

© Xtant Medical. All Rights Reserved.

FM-C-MRK-67 Rev E 11/21