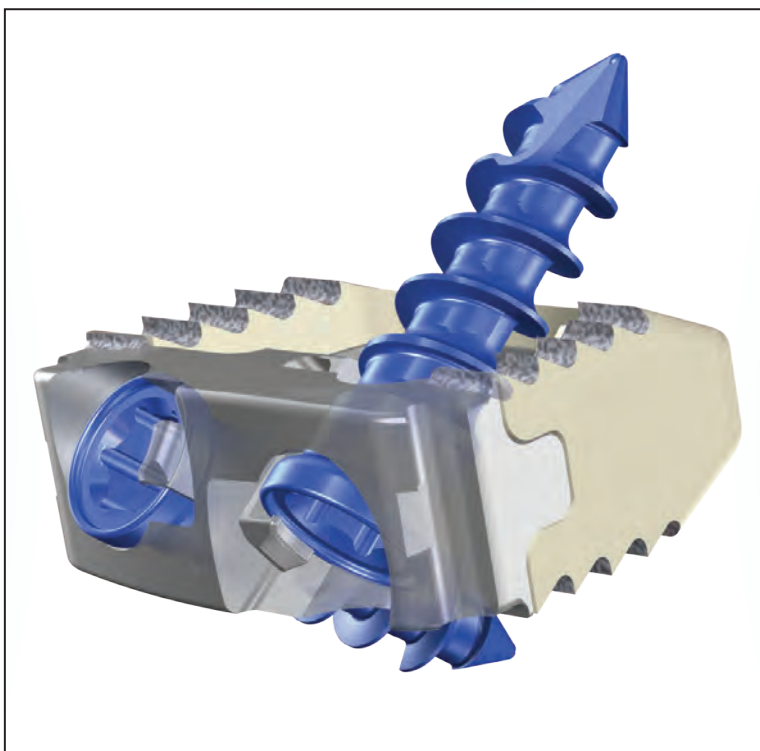




X-spineSM Surgical Technique



IRIX-CTM Cervical Integrated Fusion System

 X-spineSM
X-treme Innovations

Distribuidor exclusivo em Portugal: **yourspine** 



IRIX-CTM

Cervical Integrated Fusion System

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INSTRUCTIONS FOR USE

X-spine Systems, Inc. Irix-C™ Cervical Integrated Fusion System



IMPORTANT NOTE

The user acknowledges that he/she has read and agreed to the conditions in this insert, which are to be considered as contractual.

GENERAL INFORMATION

The Irix-C Cervical Integrated Fusion System is a stand-alone intervertebral fusion device used to restore biomechanical height and to act as an aid in fusion of the cervical spine in anterior discectomy procedures. The spacer is generally box-shaped with teeth on the superior and inferior surfaces of the device, and is manufactured either from titanium alloy (Ti6Al4V) in accordance with ASTM F136 and Invibio PEEK Optima LT1 in accordance with ASTM F2026, or from Ti6Al4V titanium alloy alone. The spacer may optionally have the teeth plasma coated with medical-grade titanium per ASTM F1580. The spacer is secured in location through the use of Ti6Al4V titanium alloy bone screws. The implants are provided in various sizes and lengths to adjust for variations in patient anatomy.

INDICATIONS FOR USE

The Irix-C Cervical Integrated Fusion System is a stand-alone cervical intervertebral fusion device intended for spinal fusion procedures at one level (C3 – T1 inclusive) in skeletally mature patients for treatment of degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Implants are to be implanted via an open, anterior approach and packed with autogenous bone graft. Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with a cervical intervertebral fusion device.

CONTRAINDICATIONS

Contraindications for the Irix-C Cervical Integrated Fusion 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 or manufacturers.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any other medical or surgical condition which would preclude the potential benefit of spinal implant 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.
12. Reuse or multiple uses.
13. Prior fusion at the level(s) to be treated.

WARNINGS AND PRECAUTIONS

As with any surgical system, the Irix-C Cervical Integrated Fusion System should only be used by experienced surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient

Knowledge of surgical techniques, proper 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 spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).

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 spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery. Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions, etc. which may have an impact on the performance of the system.

If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g. substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device. In some cases, progression of degenerative disease may be so advanced at the time of implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients should be instructed in detail about the limitations of the implants, including, but not



limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

Mixing Metal; some degree of corrosion occurs on all implanted metal alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, screws, etc. which come in contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing parameters, the components of Irix-C should not be used in conjunction with components from any other manufacturer's spinal system.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

As with all orthopedic and neurosurgical implants, none of the Irix-C Cervical Integrated Fusion System components should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The Irix-C Cervical Integrated Fusion System has not been evaluated for safety and compatibility in the MR environment. The Irix-C Cervical Integrated Fusion System has not been tested for heating or migration in the MR environment. The materials used in the manufacture of the Irix-C Cervical Integrated Fusion System have an established safety profile with respect to compatibility, heating and migration in the MR environment. However, it must be noted that there are several different manufacturers and generations of MRI systems available, and X-spine cannot make any claims regarding the safety of X-spine implants and devices with any specific MR system.

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 MANAGEMENT

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 MANAGEMENT

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.

INSTRUCTIONS FOR USE

For complete instructions regarding the proper use and application of all Irix-C implants and instruments, please refer to the Irix-C Surgical Technique Manual (available at no charge upon request).

POSTOPERATIVE MANAGEMENT

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. Rigid external orthosis/bracing should be utilized until fusion is confirmed clinically and radiographically.
4. If required, the device may be disassembled for 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.
5. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.



POTENTIAL COMPLICATIONS AND ADVERSE SIDE EFFECTS

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 of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants.
4. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
5. Infection.
6. Dural tears, persistent CSF leakage, meningitis.
7. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
8. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
9. Loss of bladder control or other types of urological system compromise.
10. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
11. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
12. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
13. Non-union (pseudarthrosis), delayed union, mal-union.
14. Cessation of any potential growth of the operated portion of the spine.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Death.

PACKAGING, LABELING, AND STORAGE

The implants are supplied clean and NON-STERILE. They must be sterilized (see below). The implants are delivered in packages. These must be intact at the time of receipt. All the legal information required for this type of implant is given on the label of each package. The implants may be delivered as a complete set: Implants and instruments are contained within specially designed trays or in boxes which can be sterilized directly. Use care in handling and storage of the implant components. Cutting, sharply bending, or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environments such as salt, air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if instruments or implants have been damaged during the storage processes.



X-treme Innovations

STERILIZATION

Irix-C Cervical Integrated Fusion System implants and all instruments are provided non-sterile and must be sterilized before use. All implants and instruments must be free of packaging material and bio-contaminants prior to sterilization. To achieve a sterility assurance level of not less than 10^{-6} , all non-sterile implants and instruments should be autoclave sterilized using the following validated cycle parameter:

Saturated steam method, pre-vacuum air removal, 270° F (132° C), 4-minute minimum exposure time, 30-minute minimum drying time, in a double–wrapped case configuration.

CLEANING OF INSTRUMENTS



Caution: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided. Cleaning must be performed by personnel trained in the general procedures involving contaminant removal. Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated system may be used in addition to the following manual cleaning procedure.

1. Thoroughly clean all instruments prior to use and as soon as possible after use (within a maximum of 2 hours post-operation) with intensive rinsing under cool tap water (<40°C) to remove gross soil. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent (Enzol® Enzymatic Detergent or equivalent) to delay drying.
2. No instruments within this system require disassembly as part of the cleaning process.
3. The following table describes the required steps for thoroughly cleaning the system instruments:

Step	Agent	Minimum Time (mm:ss)
	Instructions	
1. Initial Clean	Enzol Enzymatic Detergent Solution (or equivalent)	10:00
	Add one (1) ounce (30 mL) of Enzol to one (1) gallon (3.8 L) of tap water. Soak instruments immediately after use and flush detergent through all channels until evidence of organic material is removed. Soak for a minimum of ten (10) minutes. Use a soft bristle brush (Spectrum™ M-16 or equivalent) to gently remove visible debris. Pay close attention to threads, crevices, lumens and hard to reach areas. If organic material is dried-on, extend soak time and use two (2) ounces (60 mL) of Enzol per one (1) gallon (3.8 L) of warm tap water.	



2. Rinse	Deionized water	3:00
	Thoroughly rinse each instrument with deionized water including all channels to remove detergent for a minimum of three (3) minutes.	
3. Inspection	Unaided eye	1:00
	Inspect each instrument for evidence of organic material. Particular attention should be taken to remove all debris from instruments with cannulations, holes, and features that may be shielded from brushing action. Subject instruments to ultrasonic cleaning if organic matter is present after the initial cleaning step.	
4. Ultrasonic Clean (if required)	Enzol Enzymatic Detergent Solution (or equivalent)	10:00
	Prepare a fresh solution by adding one (1) ounce (30 mL) of Enzol and one (1) gallon (3.8 L) of warm tap water to a sonication unit (Branson Bransonic® Ultrasonic Cleaner or equivalent). Fully immerse the instruments in the solution and sonicate for a minimum of ten (10) minutes.	
5. Ultrasonic Rinse	Deionized water	3:00
	Thoroughly rinse each instrument with deionized water including all holes and cannulations to remove detergent for a minimum of three (3) minutes.	
6. Inspection	Unaided eye	1:00
	Inspect each instrument for evidence of organic material. Repeat the ultrasonic clean and rinse steps if needed.	

4. Upon completion, visually inspect each instrument for contamination such as remaining soil and moisture or wetness. If soil remains, repeat the cleaning process. If wetness remains, use filtered pressurized air or lint-free wipes to dry.

INSPECTION

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your X-spine Systems representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your X-spine Systems representative for a replacement.



Manufacturer:

X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342 USA
Phone: (800) 903-0640
Fax: (937) 847-8410



Authorized Representative:

EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands
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Fax: +31.70.346.7299



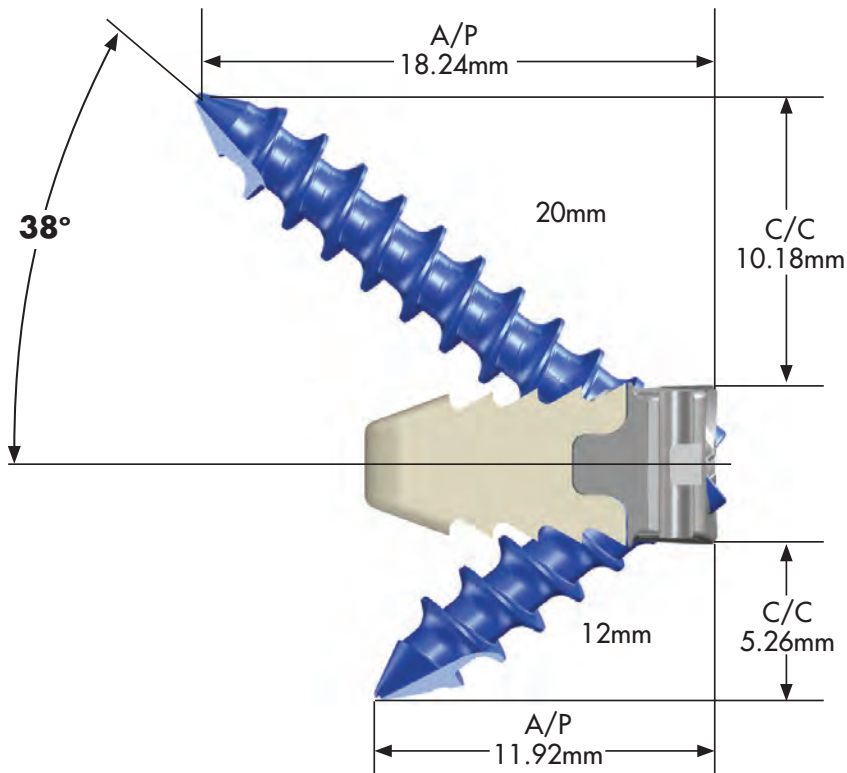
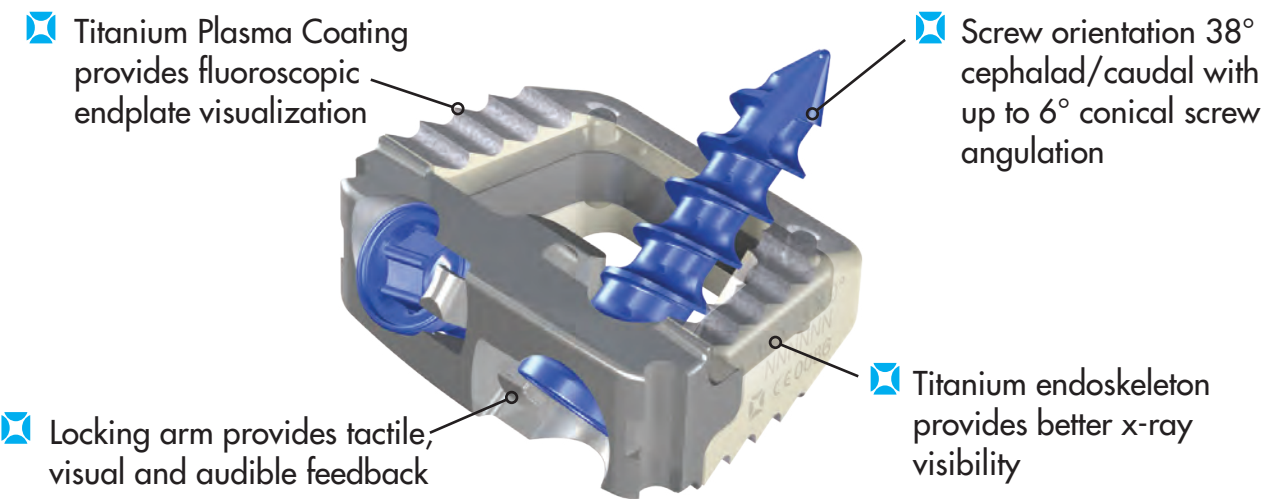
CAUTION: Federal Law (USA) restricts these devices to use by or on the order of a physician.

CE₀₀₈₆

REF Part Number
X066-2003 A



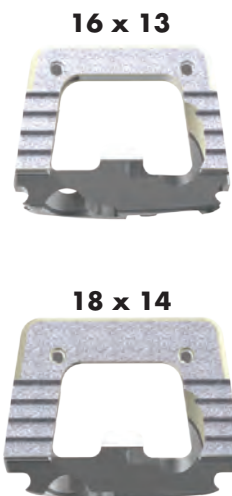
IRIX-C™ IMPLANTS



Screw Length	A/P Screw Depth	Cephalad/Caudad Screw Height
12mm	11.92mm	5.26mm
14mm	13.50mm	6.49mm
16mm	15.08mm	7.72mm
18mm	16.66mm	8.95mm
20mm	18.24mm	10.18mm
38° Screw Angulation Cephalad/Caudad		

Parallel Implants

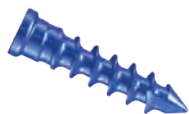
Item #	Description
X066-161305P-PC	Irix-C Implant, 16 X 13 X 0°, 5mm, PC
X066-161306P-PC	Irix-C Implant, 16 X 13 X 0°, 6mm, PC
X066-161307P-PC	Irix-C Implant, 16 X 13 X 0°, 7mm, PC
X066-161308P-PC	Irix-C Implant, 16 X 13 X 0°, 8mm, PC
X066-161309P-PC	Irix-C Implant, 16 X 13 X 0°, 9mm, PC
X066-161310P-PC	Irix-C Implant, 16 X 13 X 0°, 10mm, PC
X066-161311P-PC	Irix-C Implant, 16 X 13 X 0°, 11mm, PC
X066-161312P-PC	Irix-C Implant, 16 X 13 X 0°, 12mm, PC
X066-181405P-PC	Irix-C Implant, 18 X 14 X 0°, 5mm, PC
X066-181406P-PC	Irix-C Implant, 18 X 14 X 0°, 6mm, PC
X066-181407P-PC	Irix-C Implant, 18 X 14 X 0°, 7mm, PC
X066-181408P-PC	Irix-C Implant, 18 X 14 X 0°, 8mm, PC
X066-181409P-PC	Irix-C Implant, 18 X 14 X 0°, 9mm, PC
X066-181410P-PC	Irix-C Implant, 18 X 14 X 0°, 10mm, PC
X066-181411P-PC	Irix-C Implant, 18 X 14 X 0°, 11mm, PC
X066-181412P-PC	Irix-C Implant, 18 X 14 X 0°, 12mm, PC



Lordotic Implants

Item #	Description
X066-161305L-PC	Irix-C Implant, 16 X 13 X 7°, 5mm, PC
X066-161306L-PC	Irix-C Implant, 16 X 13 X 7°, 6mm, PC
X066-161307L-PC	Irix-C Implant, 16 X 13 X 7°, 7mm, PC
X066-161308L-PC	Irix-C Implant, 16 X 13 X 7°, 8mm, PC
X066-161309L-PC	Irix-C Implant, 16 X 13 X 7°, 9mm, PC
X066-161310L-PC	Irix-C Implant, 16 X 13 X 7°, 10mm, PC
X066-161311L-PC	Irix-C Implant, 16 X 13 X 7°, 11mm, PC
X066-161312L-PC	Irix-C Implant, 16 X 13 X 7°, 12mm, PC
X066-181405L-PC	Irix-C Implant, 18 X 14 X 7°, 5mm, PC
X066-181406L-PC	Irix-C Implant, 18 X 14 X 7°, 6mm, PC
X066-181407L-PC	Irix-C Implant, 18 X 14 X 7°, 7mm, PC
X066-181408L-PC	Irix-C Implant, 18 X 14 X 7°, 8mm, PC
X066-181409L-PC	Irix-C Implant, 18 X 14 X 7°, 9mm, PC
X066-181410L-PC	Irix-C Implant, 18 X 14 X 7°, 10mm, PC
X066-181411L-PC	Irix-C Implant, 18 X 14 X 7°, 11mm, PC
X066-181412L-PC	Irix-C Implant, 18 X 14 X 7°, 12mm, PC

Self-Drilling Screws



Item #	Description
X066-3512SD	3.5 X 12mm, Self-Drilling Screw
X066-3514SD	3.5 X 14mm, Self-Drilling Screw
X066-3516SD	3.5 X 16mm, Self-Drilling Screw
X066-3518SD	3.5 X 18mm, Self-Drilling Screw
X066-3520SD	3.5 X 20mm, Self-Drilling Screw

Self-Tapping Screws



Item #	Description
X066-3512ST	3.5 X 12mm, Self-Tapping Screw
X066-3514ST	3.5 X 14mm, Self-Tapping Screw
X066-3516ST	3.5 X 16mm, Self-Tapping Screw
X066-3518ST	3.5 X 18mm, Self-Tapping Screw
X066-3520ST	3.5 X 20mm, Self-Tapping Screw

Self-Tapping Rescue Screws



Item #	Description
X066-3713	3.7 X 13mm, Self-Tapping Rescue Screw
X066-3715	3.7 X 15mm, Self-Tapping Rescue Screw
X066-3717	3.7 X 17mm, Self-Tapping Rescue Screw
X066-3719	3.7 X 19mm, Self-Tapping Rescue Screw
X066-3721	3.7 X 21mm, Self-Tapping Rescue Screw





IRIX-C™ Cervical Integrated Fusion System

Part One: Guided Surgical Technique

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 X-spine employees to the best of their knowledge. Care was taken to ensure the information contained herein is accurate and understandable. X-spine does not assume any liability, however, for the accuracy and/or completeness of the quality of the information, and X-spine 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.

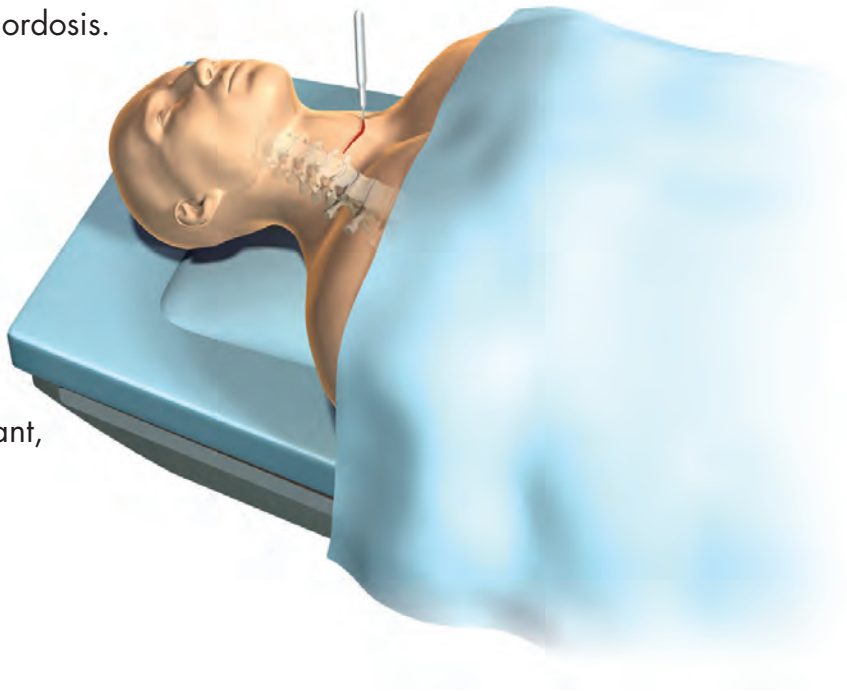
OR SETUP AND PREPARATION:

❑ Step 1: Patient Positioning

The patient is positioned on the operating table in the supine position. The patient should be positioned to maintain cervical lordosis.

❑ Step 2: Exposure

Create an incision and retract the prevertebral structures. Ensure that you have achieved adequate exposure for the Implant, associated instrumentation, and grafting procedure.



❑ **Step 3: Distraction**

Using standard methods distract the disc space.
Use caution to avoid over-distraction.

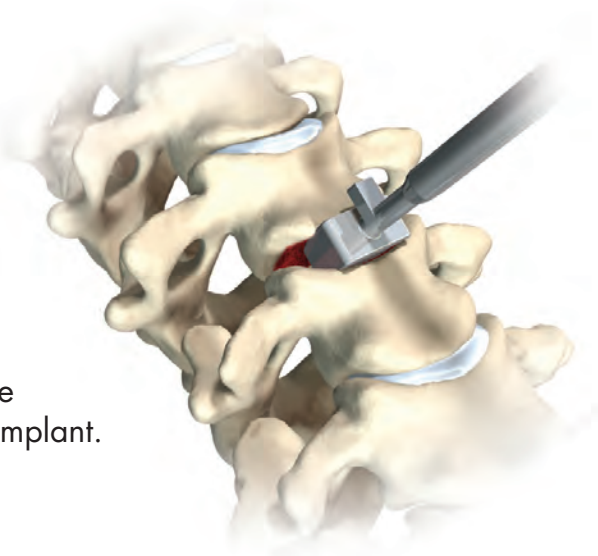
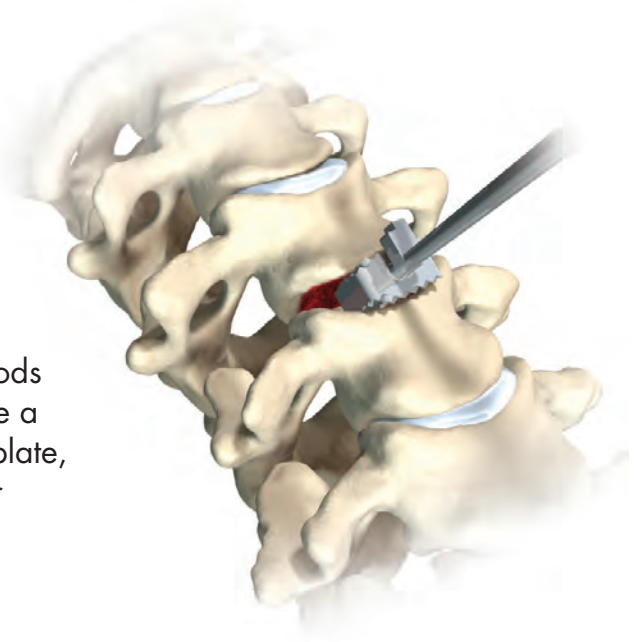
❑ **Step 4: Discectomy and Endplate Preparation**

Perform a discectomy using standard methods and remove the cartilaginous endplate. Use a rasp as necessary to expose the bony endplate, but be careful to avoid exposure of weaker cancellous bone.

❑ **Step 5: Implant Sizing**

Trials are provided to determine the appropriate implant size.

Tip: Removing any interfering anterior osteophytes in the surgical site can enhance the desired positioning of the trial and/or implant.



Step 6: Guided Inserter Assembly

- 1: Locate appropriate sized inserter tip.
- 2: Slide threaded collar back to expose distal inserter tip and laser marking.



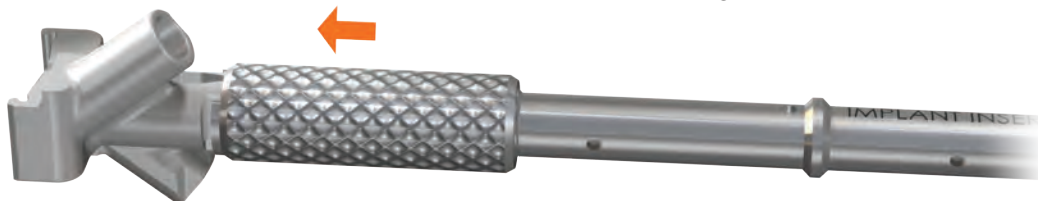
- 3: Rotate the proximal knob to align inner shaft laser mark with outer shaft before you load the tip.



- 4: Once laser marks are aligned, place the appropriate inserter tip.



- 5: Slide threaded collar forward, rotate clockwise to tighten.

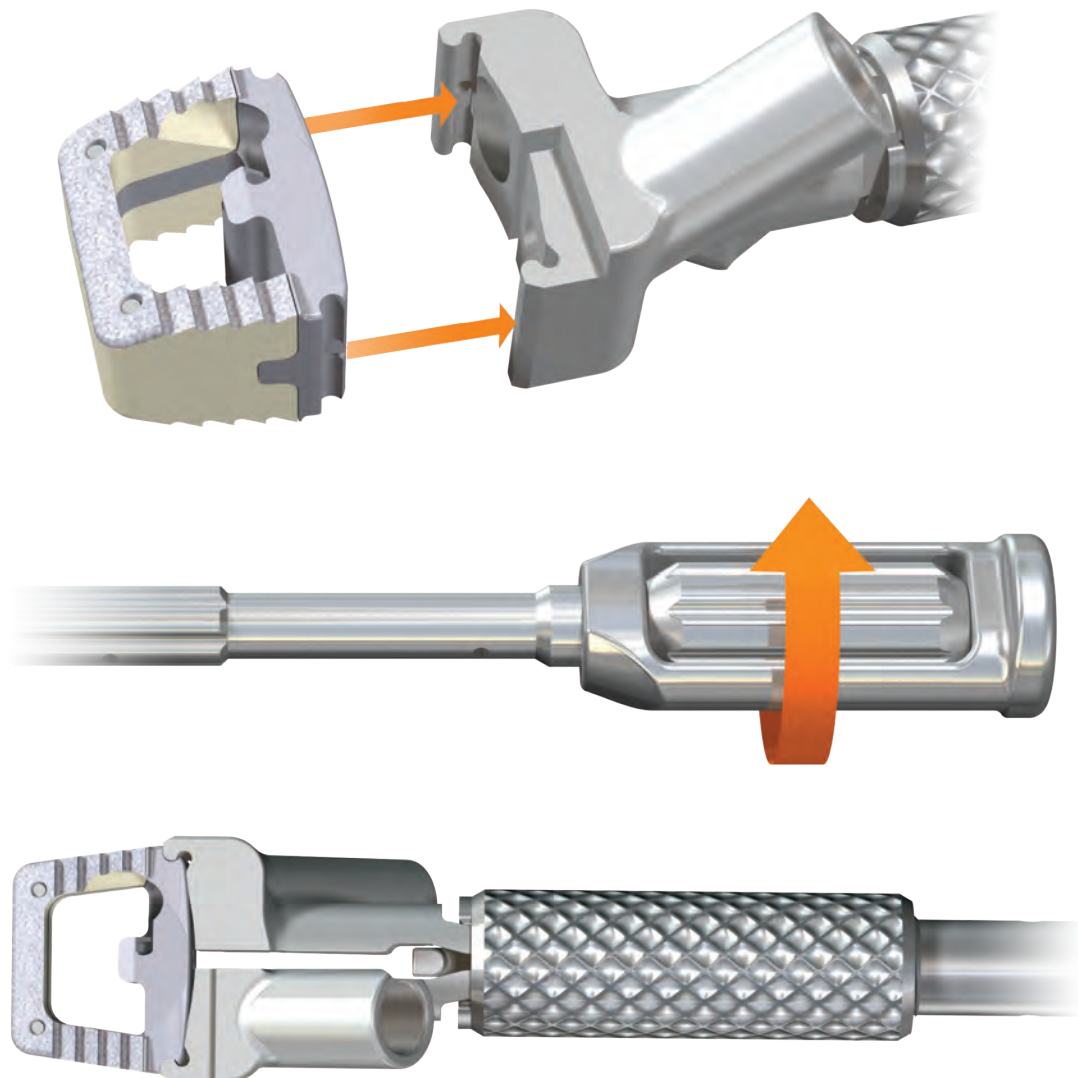


CAUTION – Failure to adequately tighten the threaded collar may result in loosening or release of the Inserter tip and/or Implant, resulting in injury.

Step 7: Implant Loading

Load the implant into the modular tip of the inserter by aligning the grooves on the sides of the implant faceplate with the grooves on the modular tip. Turn the proximal knob clockwise to close the inserter and lock onto implant. Visually inspect the inserter-implant interface to ensure that there is no gapping or debris between the inserter jaws and the implant. Manually confirm that there is no motion between the inserter and the implant.

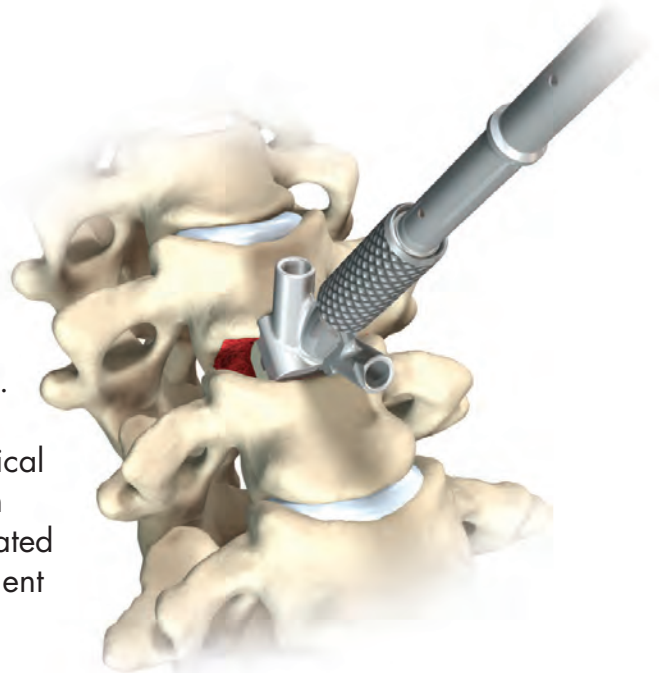
CAUTION – Failure to adequately tighten the proximal knob and confirm the interface may result in loosening or release of the implant, resulting in injury.



❑ Step 8: Insertion

Pack the implant with bone graft material. Insert the implant into the intervertebral space. A mallet is provided for light tapping if needed. The implant should be placed 1-2mm posterior to the anterior longitudinal ligament.

CAUTION – The implant should be impacted in place with great care and two-handed control. Over impaction of the implant or positioning the implant too far posteriorly can result in neurological injury. Particular caution must be observed when adjusting the implant or manipulating the associated instrumentation to avoid any posterior displacement of the implant.

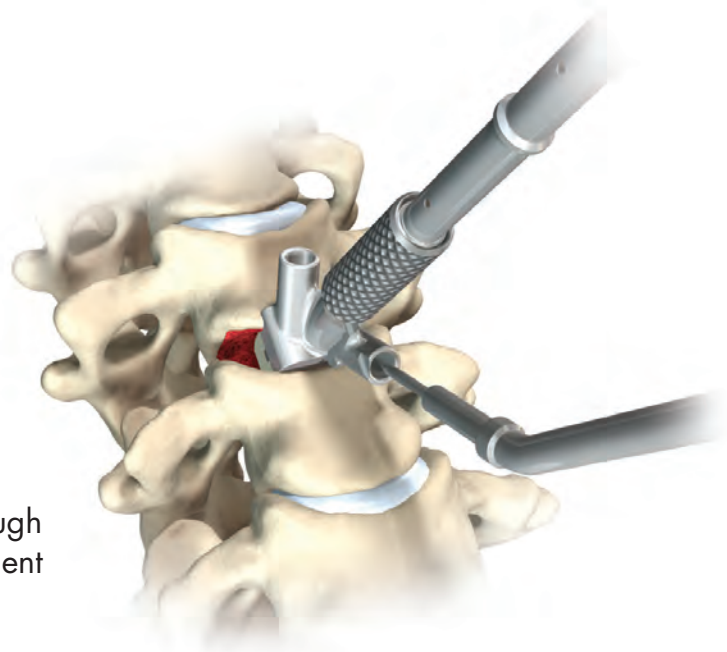


❑ Step 9: Screw Hole Preparation - Awl

Use the awl to prepare the hole. A straight and fixed angle awl are offered. Push down on the awl handle to push out the awl tip. Use the inserter to guide the awl into the appropriate position.

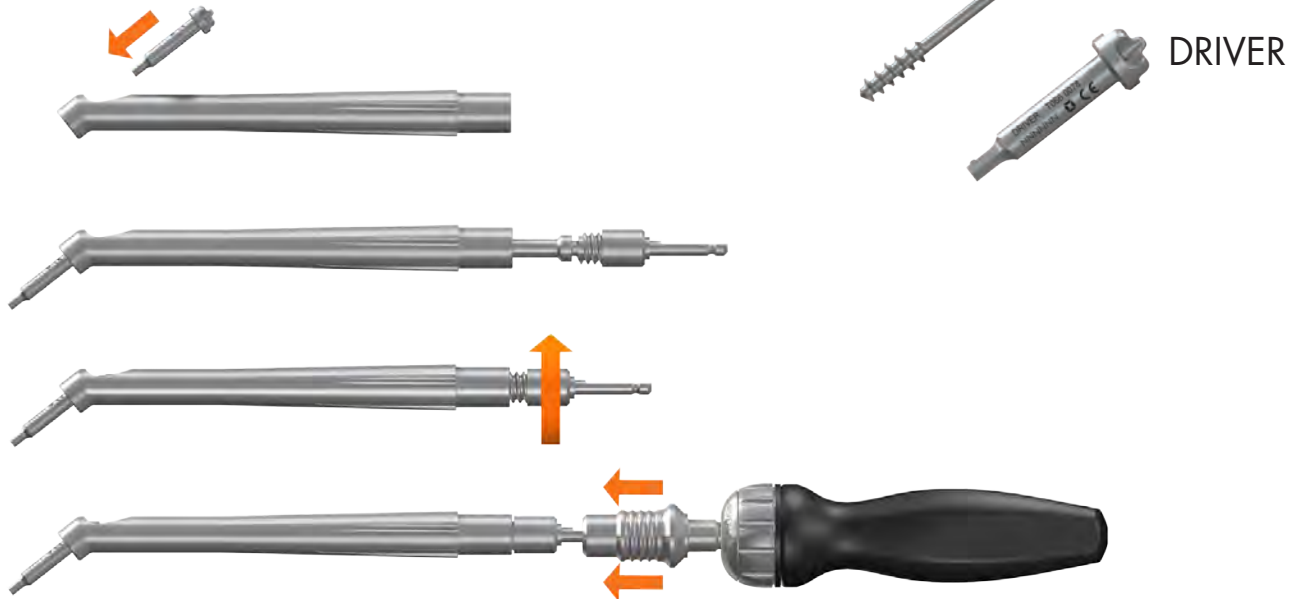
Note: Align the flat on the distal tip of the awl with the locking arm on the implant.

CAUTION – While placing the bone awl through the inserter or implant, ensure that such placement does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.



❑ Step 10: Fixed Angle Driver

Attach the appropriate length screw to the self-retaining screwdriver. A straight and fixed-angle driver are offered. Use the inserter to guide the screwdriver into the appropriate position. Repeat steps for second screw.



❑ Step 11: Optional Guide Handle

A guide handle is included in the case for use if desired. With the quick connect handle removed, slide the rings of the guide handle down over the fixed-angle driver assembly. Rotate guide handle to the desired direction and tighten the knob.

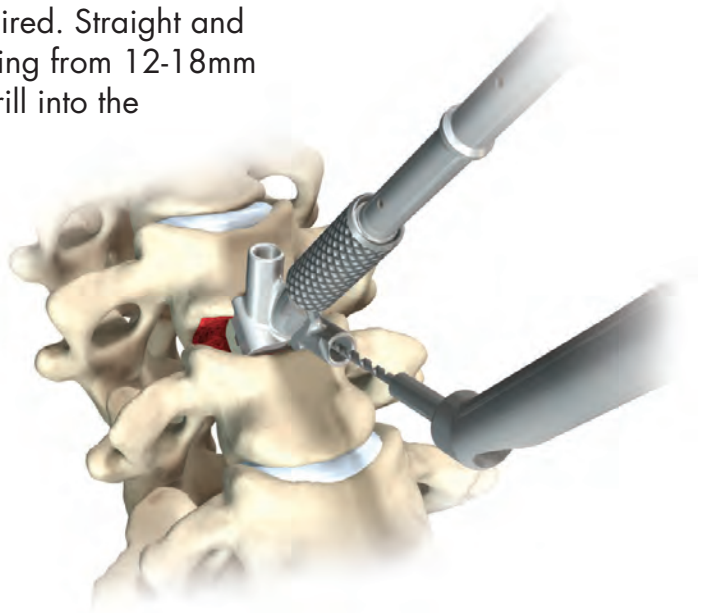
Note: Place guide handle onto fixed angle driver prior to ratcheting handle.



❑ Step 12: Screw Hole Preparation - Drill

The hole may be prepared using a drill if desired. Straight and fixed-angle drills are provided. Drill tips ranging from 12-18mm are available. Use the inserter to guide the drill into the appropriate position.

CAUTION – While placing the drill through the inserter or implant, ensure that such placement does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.

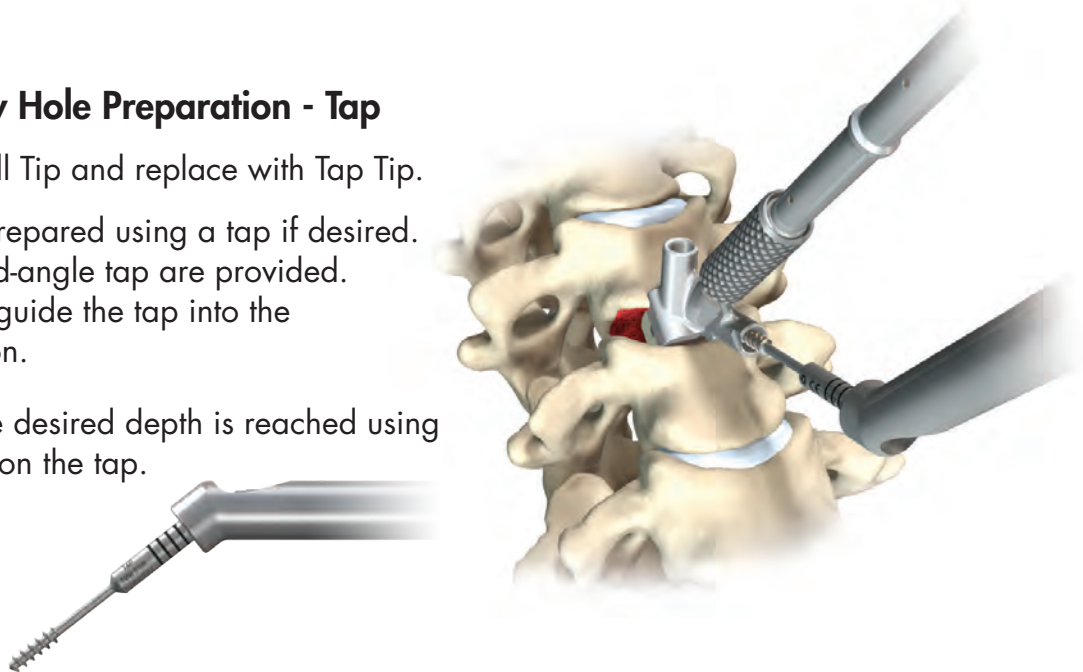


❑ Step 13: Screw Hole Preparation - Tap

Note: Remove Drill Tip and replace with Tap Tip.

The hole may be prepared using a tap if desired. A straight and fixed-angle tap are provided. Use the inserter to guide the tap into the appropriate position.

Note: Tap until the desired depth is reached using the laser markings on the tap.



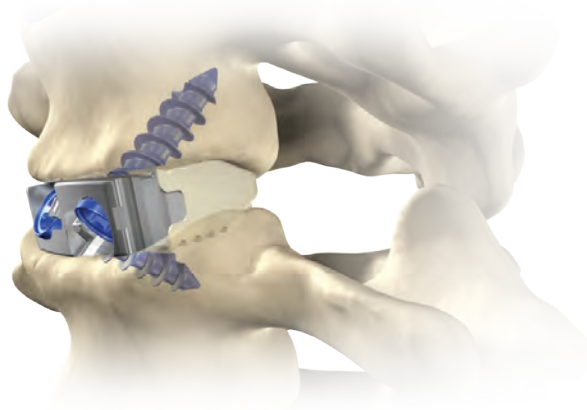
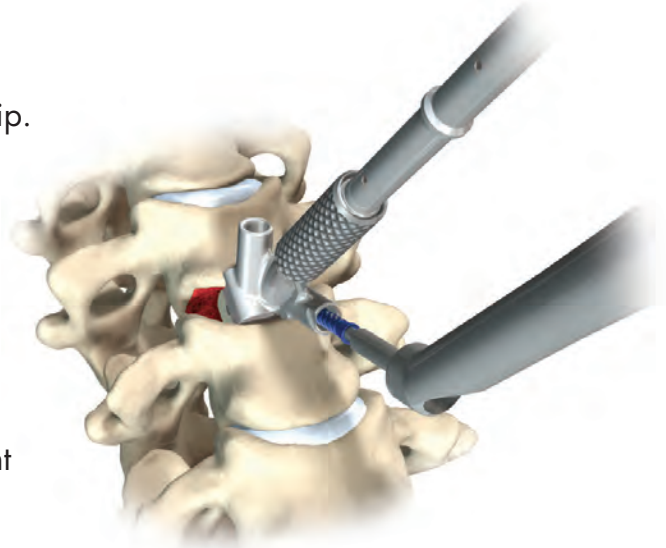
CAUTION – While placing the tap through the inserter or implant, ensure that such placement does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.

❑ Step 14: Screw Insertion

Note: Remove Tap Tip and replace with Driver Tip.

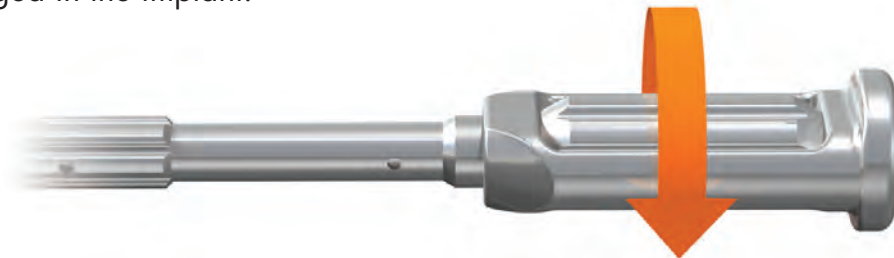
Attach the appropriate length screw to the self-retaining screwdriver. A straight and fixed-angle driver are offered. Use the inserter to guide the screwdriver into the appropriate position. Repeat steps for second screw.

CAUTION – While placing the screws through the inserter or implant, ensure that such placement does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.



❑ Step 15: Inserter Removal

Once the screws are fully seated, to remove the implant inserter, turn the knob on the proximal end of the inserter counter-clockwise to release it from the implant. Visually confirm that the locking tabs are in front of the screws, and the screws are fully engaged in the implant.



CAUTION – Failure to confirm that the locking tabs are in front of the screws may result in early or late screw loosening.



IRIX-C™ Cervical Integrated Fusion System

Part 2: Freehand Surgical Technique

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 X-spine employees to the best of their knowledge. Care was taken to ensure the information contained herein is accurate and understandable. X-spine does not assume any liability, however, for the accuracy and/or completeness of the quality of the information, and X-spine 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.

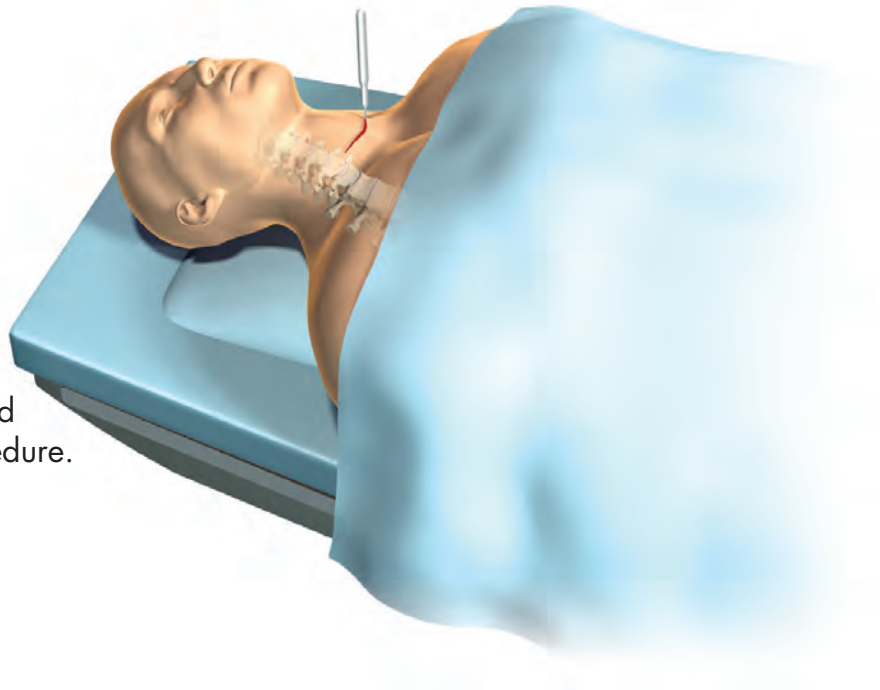
OR SETUP AND PREPARATION:

❑ Step 1: Patient Positioning

The patient is positioned on the operating table in the supine position. The patient should be positioned to maintain cervical lordosis.

❑ Step 2: Exposure

Create an incision and retract the prevertebral structures. Ensure that you have achieved adequate exposure for the Implant, associated instrumentation, and grafting procedure.



❑ **Step 3: Distraction**

Using standard methods, distract the disc space.
Use caution to avoid over-distraction.

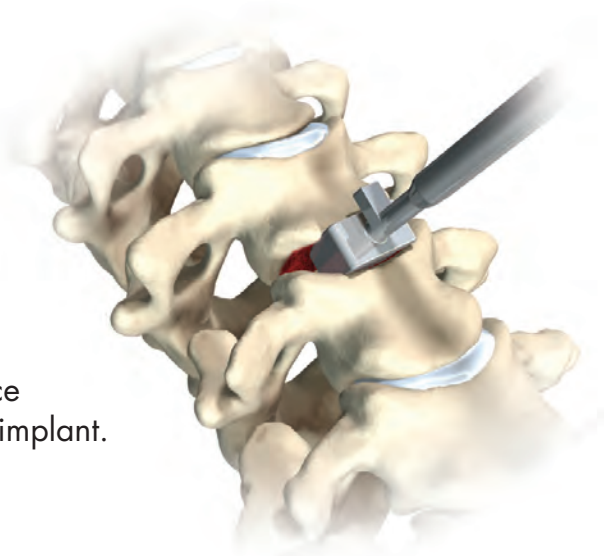
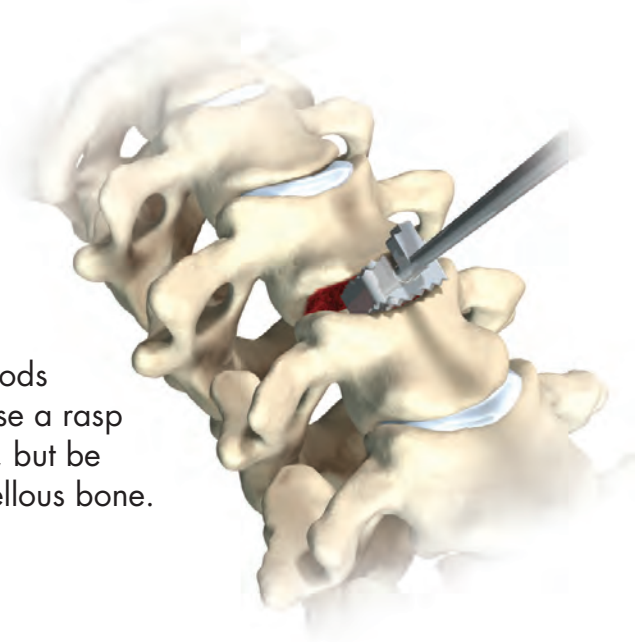
❑ **Step 4: Discectomy and Endplate Preparation**

Perform a discectomy using standard methods and remove the cartilaginous endplate. Use a rasp as necessary to expose the bony endplate, but be careful to avoid exposure of weaker cancellous bone.

❑ **Step 5: Implant Sizing**

Trials are provided to determine the appropriate implant size.

Tip: Removing any interfering anterior osteophytes in the surgical site can enhance the desired positioning of the trial and/or implant.



Step 6: Freehand Inserter Assembly

1: Locate the freehand inserter tip.

2: Slide threaded collar back to expose distal inserter tip and laser marking.



3: Rotate the proximal knob to align inner shaft laser mark with outer shaft before you load the tip.



4: Once laser marks are aligned, place the freehand inserter tip.



5: Slide threaded collar forward, rotate clockwise to tighten.

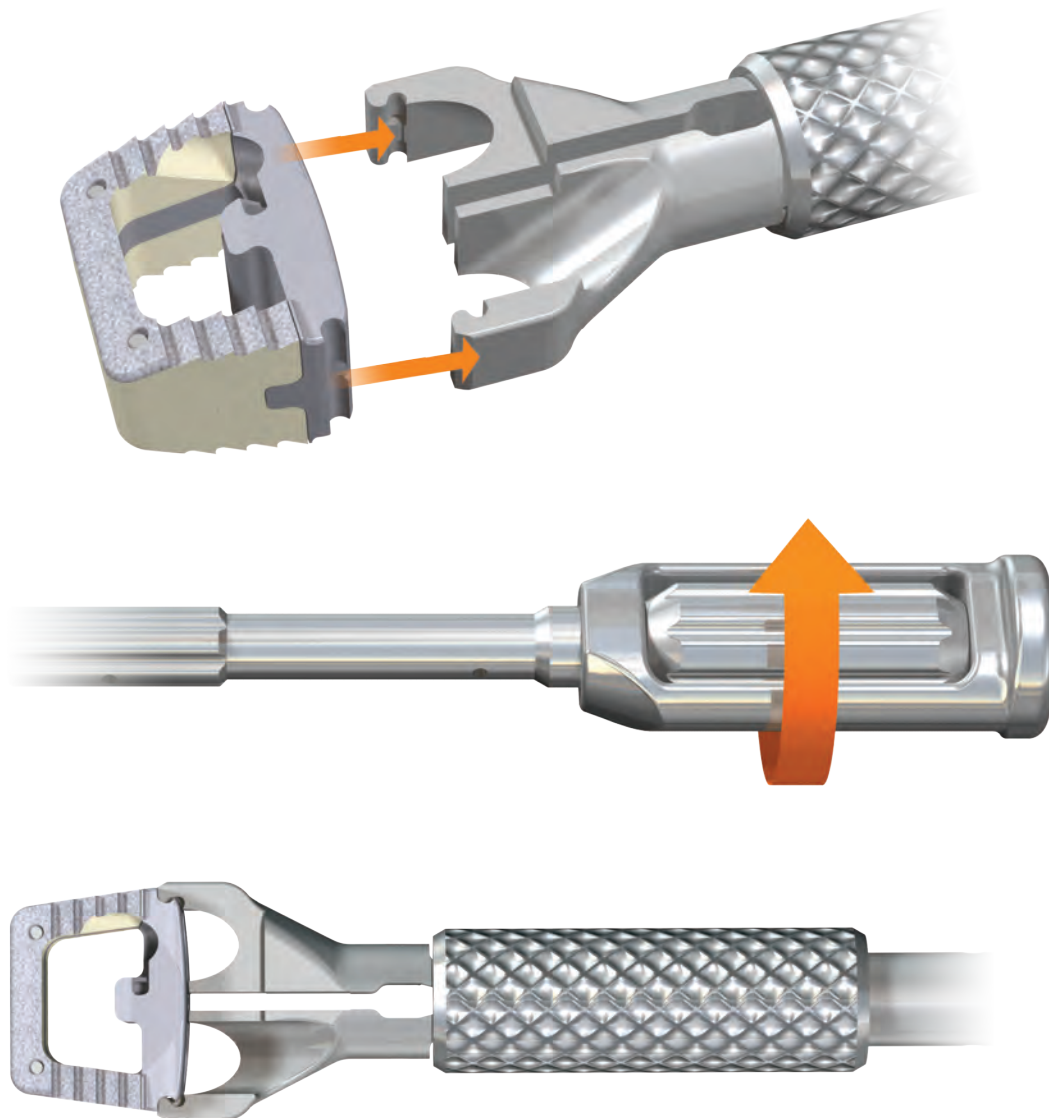


CAUTION – Failure to adequately tighten the threaded collar may result in loosening or release of the Inserter tip and/or Implant, resulting in injury.

Step 7: Implant Loading

Load the implant into the modular tip of the inserter by aligning the grooves on the sides of the implant faceplate with the grooves on the modular tip. Turn the proximal knob clockwise to close the inserter and lock onto implant. Visually inspect the inserter-implant interface to ensure that there is no gapping or debris between the inserter jaws and the implant. Manually confirm that there is no motion between the inserter and the implant.

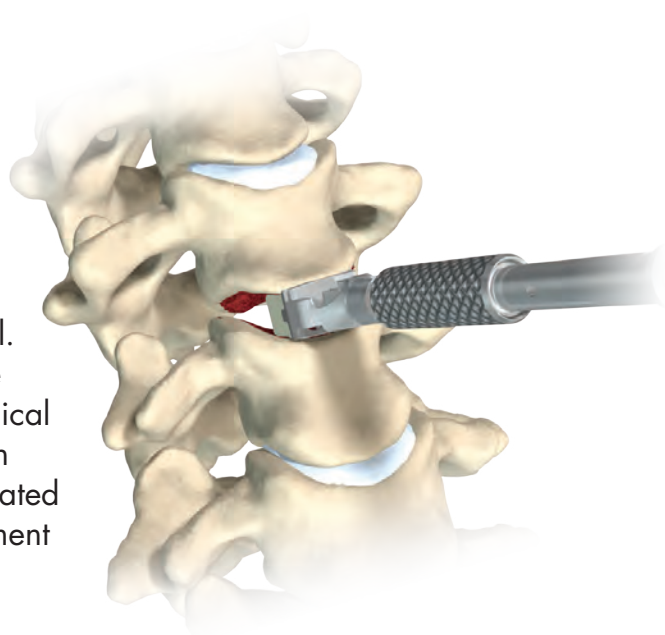
CAUTION – Failure to adequately tighten the proximal knob and confirm the interface may result in loosening or release of the implant, resulting in injury.



❑ Step 8: Insertion

Pack the implant with bone graft material.
Insert the implant into the intervertebral space.
A mallet is provided for light tapping if needed.
The implant should be placed 1-2mm posterior to the anterior longitudinal ligament.

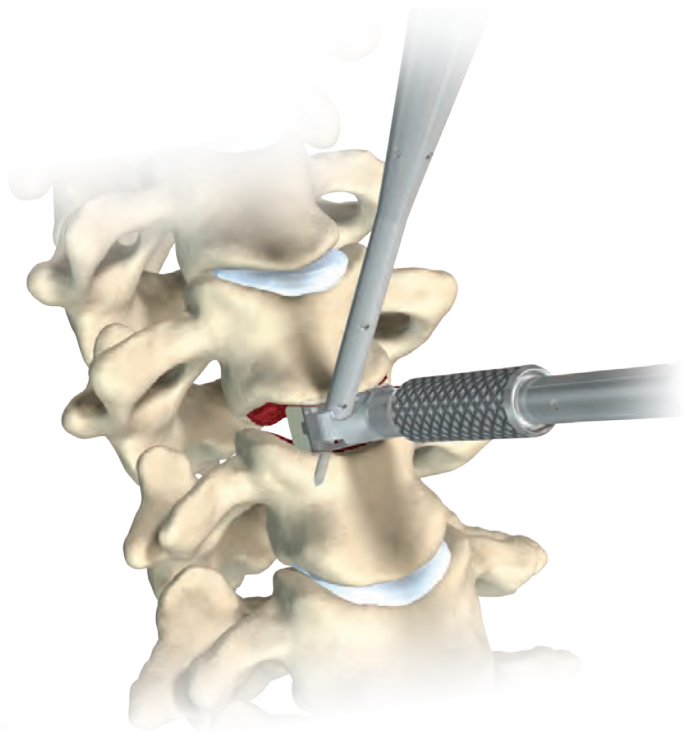
CAUTION – The implant should be impacted in place with great care and two-handed control. Over impaction of the implant or positioning the implant too far posteriorly can result in neurological injury. Particular caution must be observed when adjusting the implant or manipulating the associated instrumentation to avoid any posterior displacement of the implant.



❑ Step 9: Screw Hole Preparation - Awl

Use the freehand awl to prepare the hole.
Push down on the awl handle to push out the awl tip.

Note: Align the flat on the distal tip of the awl with the locking arm on the implant.

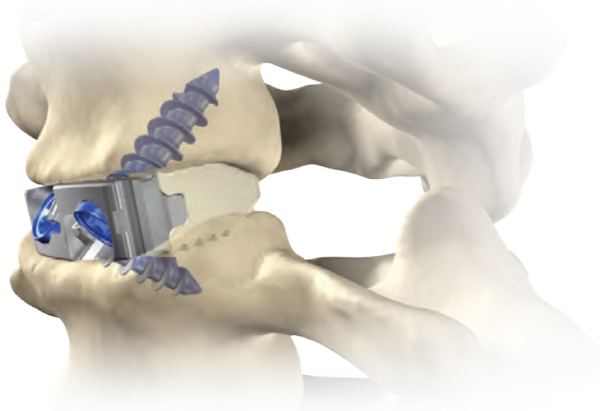
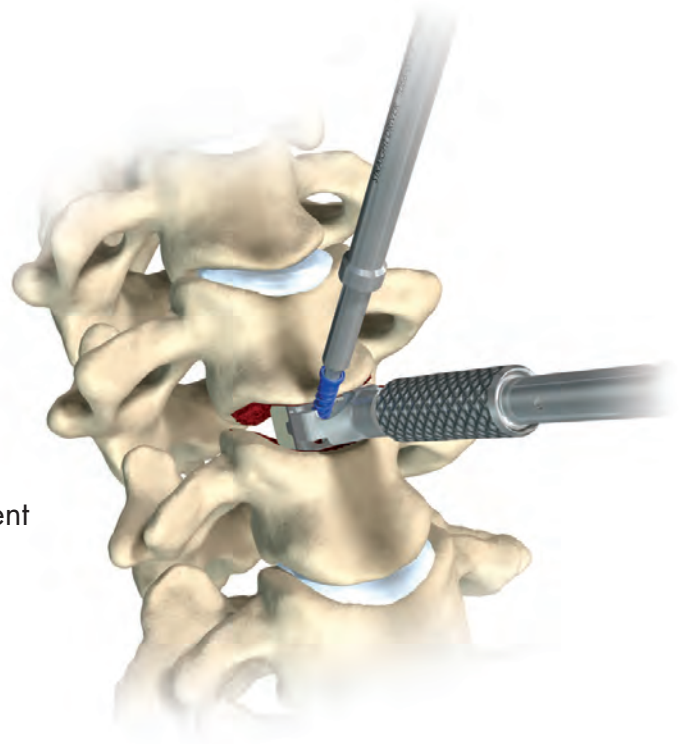


CAUTION – While placing the bone awl through the inserter or implant, ensure that such placement does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.

❑ Step 10: Screw Insertion

Attach the appropriate length screw to the self-retaining screwdriver. A straight and fixed-angle driver are offered. Use the screwdriver to place the screw into the appropriate position. Repeat steps for second screw.

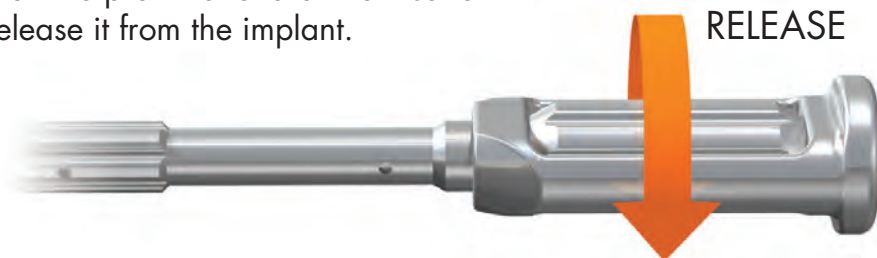
CAUTION – While placing the screws through the inserter or implant, ensure that such placement does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.



CAUTION – Angulating the screws greater than 3 degrees in any one direction may prevent the screw from engaging the locking mechanism properly. Failure to confirm that the locking tabs are in front of the screws may result in early or late screw loosening.

❑ Step 11: Inserter Removal

Once the screws are fully seated, to remove the implant inserter, turn the knob on the proximal end of the inserter counter-clockwise to release it from the implant.



**System Removal or Revision:

Should it become necessary to remove or revise the Irix-C™ implants, the following steps should be followed:

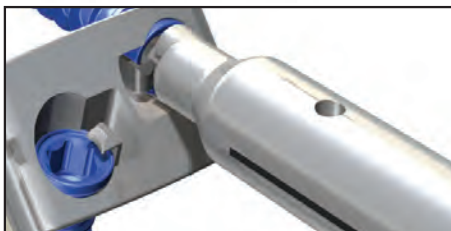
- **Attach inserter with freehand tip**

Before the screw(s) are removed, attach the freehand inserter to the implant using the standard technique. Ensure that the inserter is fully engaged to the implant. It may be necessary to remove osteophyte or scar tissue to fully access the inserter engagement slots on the implant.

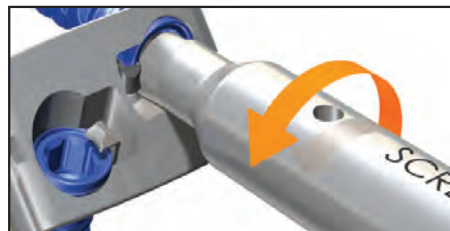
CAUTION – While attaching the inserter to an implanted implant, ensure that such attachment does not result in posterior displacement of the implant. Posterior displacement of the implant can result in neurological injury.

- **Screw Removal**

The screw may then be removed from its position using the screw removal tool. The removal tool has an outer sleeve with an eccentric distal tip that, when properly aligned with the retaining tab using the laser marking, can be rotated 180° to push the retaining tab over and out of the screw path. This will allow the surgeon to back the screw out past the retaining mechanism by rotating the inner hex shaft counter clockwise.



Outer sleeve cut out on distal tip aligned with the retaining mechanism



Outer sleeve rotated 180°, moving the retaining mechanism over and allowing the screw to pass

****Note:** if resistance is felt while trying to rotate the outer sleeve or during the initial counterclockwise turning of the inner sleeve, the screw may need to be advanced prior to removal. Advance the screw by rotating the inner hex shaft 1/4 - 1/2 turns clockwise to ensure that the screw head is seated beyond the lip of the retaining mechanism prior to screw removal.

- **Implant Removal**

The forked end of the mallet may be used as a slap hammer to be used on the inserter body to back the implant out of the intervertebral space.



IRIX-C™ INSTRUMENTS



T066-0050 (5mm) thru
T066-0057 (12mm)
Guided Modular Inserter Tips



T066-0060 Freehand Inserter Tip



T066-0040 Modular Inserter Handle

T066-0063 Fixed Angle Driver Sleeve



T066-0068 Fixed Angle Driver Shaft



T066-0085 (12mm) thru T066-0088 (18mm)
Fixed Angle Drill Tip



T066-0105 Fixed Angle Tap Tip



T066-0078 Fixed Angle Driver Tip

T066-0230
Graft Packing Block



T066-0098 Guide Handle



T066-0090 (12mm) thru T066-0093 (18mm) Straight Drill



T066-0110 Straight Tap



T066-0074 Straight Driver



X067-0560 Non-Ratcheting Handle



X067-0500 Ratcheting Handle



T066-0061
Freehand Awl



T066-0200 Straight Awl



T066-0205 Fixed Angle Awl



T066-0190 Tamp



T066-0195 Mallet



T066-0213 Screw Removal Tool



T066-0225 Graft Packer



Trials



16 x 13

- Lordotic T066-0150 (5mm) to -0156 (12mm)
- Parallel T066-0160 (5mm) to -0166 (12mm)

18 x 14

- Lordotic T066-0650 (5mm) to -0656 (12mm)

Rasps



16 x 13

- Parallel T066-0690 to 0696 (5,7,9,11mm)



WARNING: In the USA, this product has labeling limitations.
See package insert for complete information.

CAUTION: Federal Law (USA) restricts this device to sale
by or on the order of a physician.

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Products Patented and Patents Pending

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