Irix®-C

Cervical Integrated Fusion System

SURGICAL TECHNIQUE

IRIX®-C CERVICAL INTEGRATED FUSION SYSTEM SURGICAL TECHNIQUE

METHOD A: FREEHAND INSERTER TECHNIQUE

METHOD B: GUIDED INSERTER TECHNIQUE

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Patient Positioning and Surgical Exposure

- Position the patient in the supine position with the neck extended to maintain cervical lordosis (Figure 1).
- Perform a standard incision and tissue retraction to expose the affected levels, ensuring adequate exposure for the implant and associated instrumentation.
- Remove any osteophytes as needed.

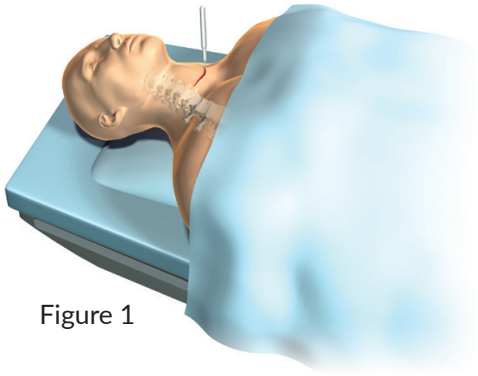


Figure 1

Step 1: Discectomy and Endplate Preparation

- Perform a discectomy using standard methods and remove the cartilaginous endplate.
- Rasps are available for removal of the endplate material (Figure 2).

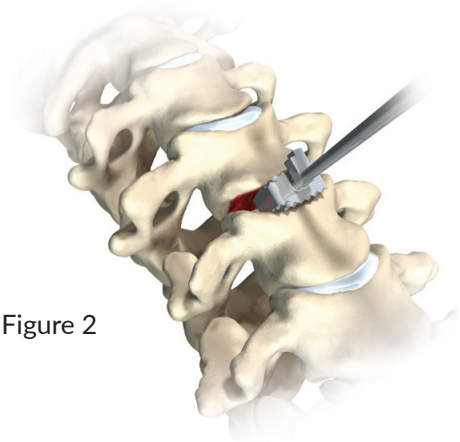


Figure 2

Step 2: Trialing

- Insert the trials into the disc space to determine the desired implant size. Trials have a 2mm stop designed to aid in positioning (Figure 3).

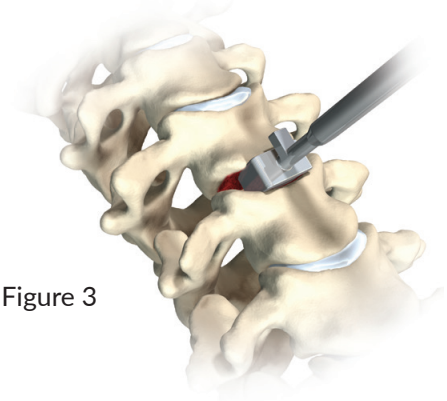


Figure 3

Freehand or Guided Inserter Techniques

There are two methods for inserting the implant and screws.

Method A: Freehand Technique (pages 3-5) uses an inserter that allows for freehand insertion of the screws.

Method B: Guided Inserter Technique (pages 6-8) uses a double-barreled drill guide to insert the implant into the intervertebral disc space, and to insert the screws.

METHOD A: FREEHAND INSERTER TECHNIQUE

Step A3: Freehand Inserter Assembly

- Unthread and slide the collar back to expose the distal tip of the inserter, then turn the knob to line up the laser marks at the tip (Figure 4).
- Load the Freehand Inserter Tip onto the tip of the inserter. Secure by sliding the collar forward and threading it tight (Figure 5a, 5b).
- Load the implant onto the inserter and secure by turning the knob clockwise (Figure 6a, 6b).

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

Figure 4

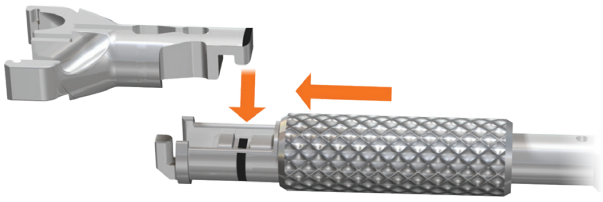


Figure 5a

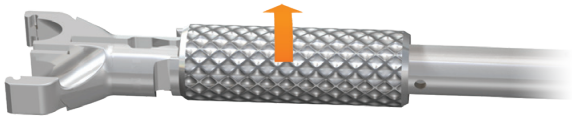


Figure 5b

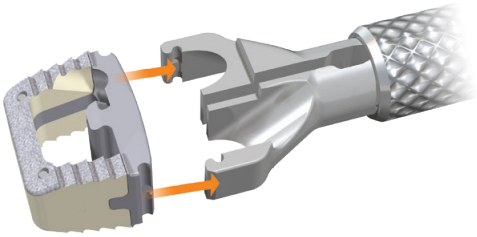
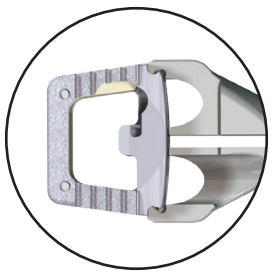


Figure 6a



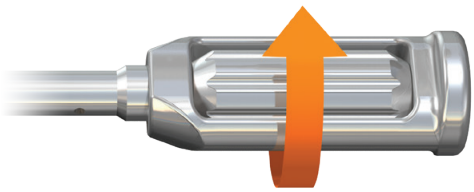


Figure 6b

Step A4: Freehand Implant Insertion

- Pack the implant with bone graft material. A packing block and graft packer are available to assist with packing the implant.
- Insert the implant into the intervertebral space (Figure 7).

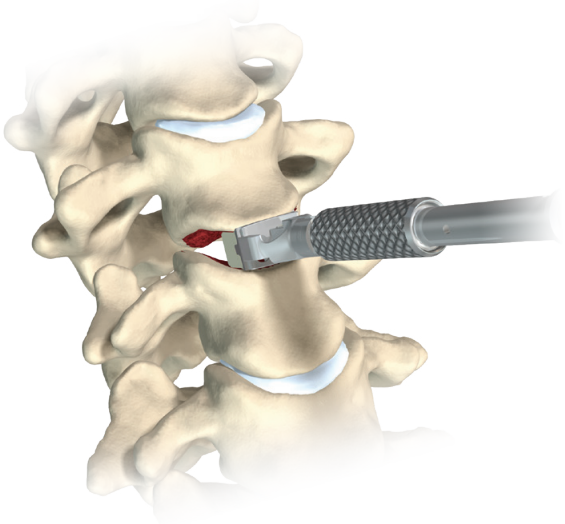


Figure 7

Step A5: Freehand Screw Hole Preparation

- Select either the Freehand Awl, or the Universal Joint Awl with the Universal Joint Awl Guide.
- Insert the tip of the Freehand Awl or the Universal Joint Awl Guide into the screw pocket on the implant, being sure to orient the flat surface on the tip with the locking arm of the implant.
- Align the awl to an angle of 38° cranial or caudal, and 0° medial.
- Prepare the screw hole by pushing the awl handle.

CAUTION – Angulating the awl greater than 3 degrees in any direction from the prescribed angle may result in driving a screw in a direction that prevents the locking arm from engaging and capturing the screw.

CAUTION – Take care that the implant does not migrate posteriorly when preparing the screw holes to avoid injury to neurologic elements.

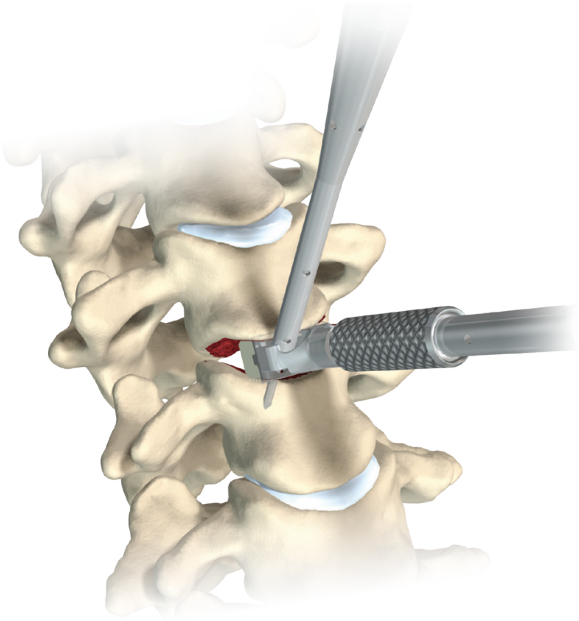


Figure 8

Step A6: Freehand Screw Insertion

- Load the appropriate length screw onto the Straight Screwdriver or the Freehand Screwdriver. A diagram of screw lengths is provided on page 13.
- Insert the screw into the prepared screw hole (Figure 9).

NOTE – Repeat steps A5 and A6 for the second screw.

CAUTION – Ensure the locking arm is securely covering the lip on the screw head. Failure to secure the head of the screw may result in early or late screw loosening.

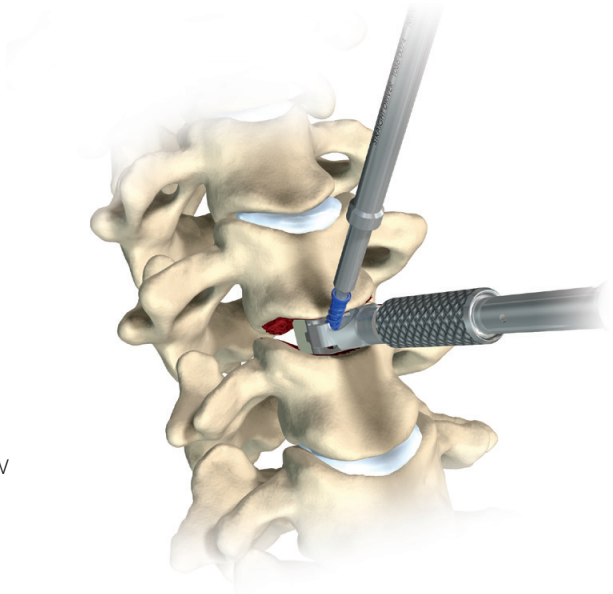


Figure 9

Step A7: Freehand Inserter Removal

- Remove the inserter by turning the knob counterclockwise until the implant is released (Figure 10).

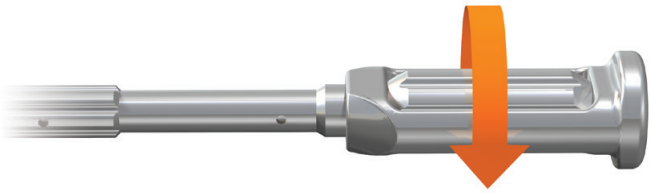


Figure 10

Step A8: : Confirm Implant Position

- Visually and radiographically confirm the position of the implant and the screws (Figure 11).
- Visually confirm that the locking arms are covering the lip of the screw heads.

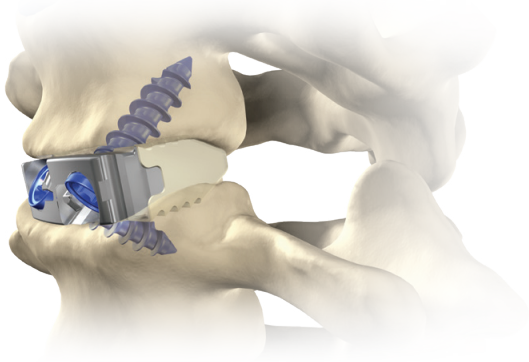


Figure 11

METHOD B: GUIDED INSERTER TECHNIQUE

Step B3: Guided Inserter Assembly

- Unthread and slide the collar back to expose the distal tip of the inserter, then turn the knob to line up the laser marks at the tip (Figure 12).
- Select the Guided Inserter Tip of the appropriate height, and load it onto the tip of the Inserter. Secure by sliding the collar forward and threading it tight (Figure 13a, 13b).
- Load the implant onto the inserter and secure by turning the knob clockwise (Figure 14a, 14b).

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

Figure 12

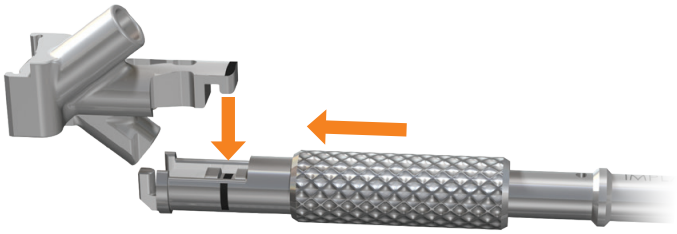


Figure 13a

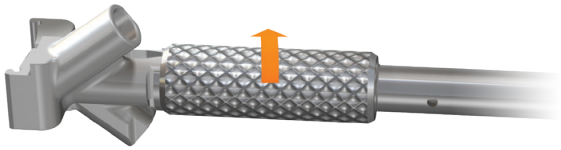


Figure 13b

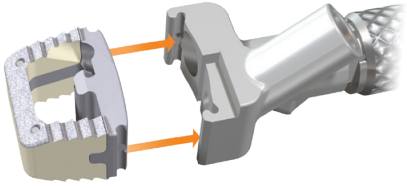
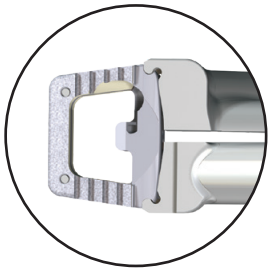


Figure 14a



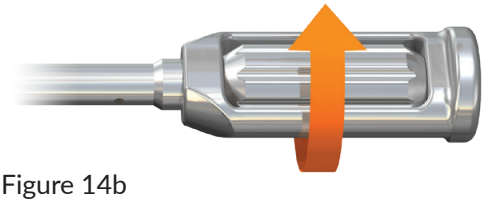


Figure 14b

Step B4: Guided Insertion

- Pack the implant with bone graft material. A packing block and graft packer are available to assist with packing the implant.
- Insert the implant into the intervertebral space (Figure 15).

CAUTION – Be sure to avoid recessing the implant too posteriorly to prevent injury to neurological elements.

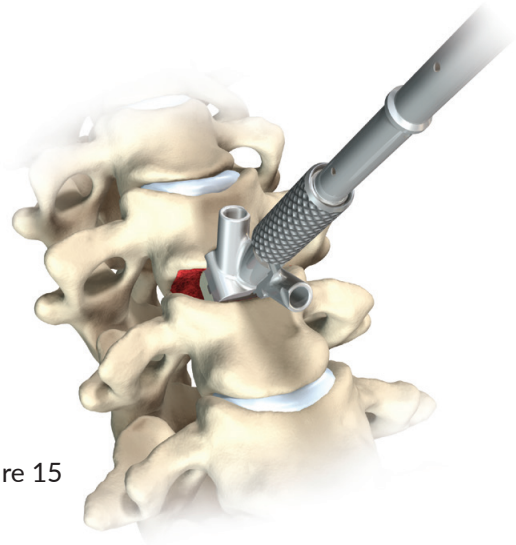


Figure 15

Step B5: Guided Screw Hole Preparation

- The screw hole may be prepared using an awl or drill. For the awl, select either the Straight Awl or the Fixed Angle Awl. For the drill, select either the Straight Drill or the Fixed Angle Drill of the appropriate length.
- Insert the awl or drill through the guide and into the bone (Figure 16).
- After the initial screw hole is prepared, the optional Straight Tap or Fixed Angle Tap may be inserted through the guide.

CAUTION – Take care that the implant does not migrate posteriorly when preparing the screw holes to avoid injury to neurologic elements.

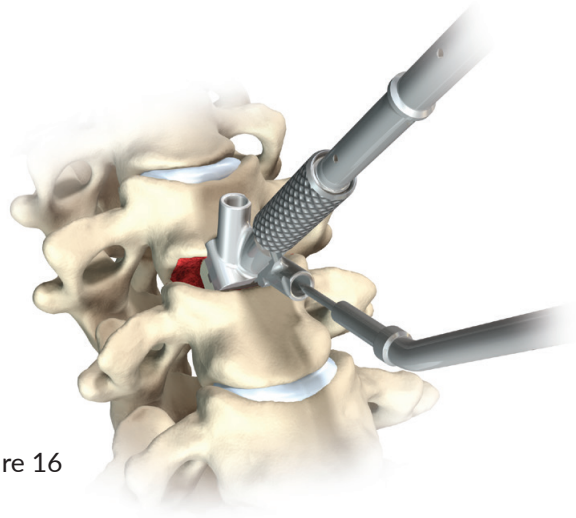


Figure 16

Fixed Angle Drill/Driver Assembly

- Insert the Fixed Angle Tip (drill, tap, or screwdriver) into the tip of the Fixed Angle Sleeve, and slide the Fixed Angle Shaft through the sleeve (Figure 17a).
- Secure the shaft by threading the collar into the sleeve (Figure 17b).
- Attach the optional Fixed Angle Side-Handle to the sleeve by sliding it over the end of the sleeve, and secure it by tightening the knob (Figure 18).

Figure 17a

Figure 17b

Figure 18

Step B6: Freehand Screw Insertion

- Load the appropriate length screw onto the Straight Screwdriver or the Fixed Angle Screwdriver. A diagram of screw lengths is provided on page 13.
- Insert the screw into the prepared screw hole (Figure 19).

NOTE – Repeat steps B5 and B6 for the second screw.

CAUTION – Ensure the locking arm is securely covering the lip on the screw head. Failure to secure the head of the screw may result in early or late screw loosening.

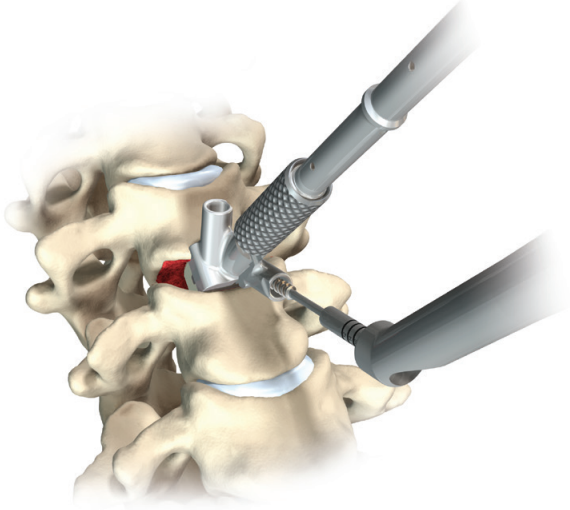


Figure 19

Step B7: Freehand Inserter Removal

- Remove the inserter by turning the knob counterclockwise until the implant is released (Figure 20).

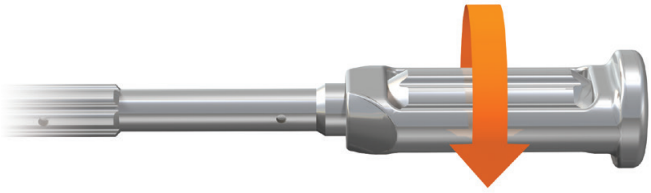


Figure 20

Step B8: : Confirm Implant Position

- Visually and radiographically confirm the position of the implant and the screws (Figure 21).
- Visually confirm that the locking arms are covering the lip of the screw heads.

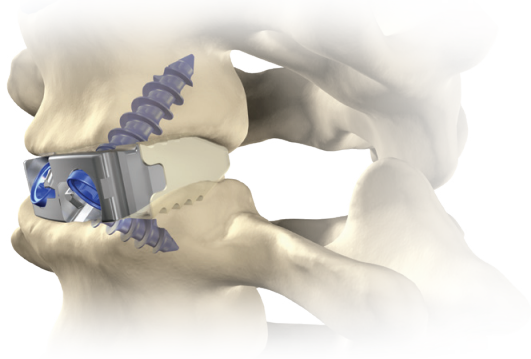


Figure 21

Implant Removal

Should it become necessary to remove the Irix®-C implant, perform the following steps.

- Insert the Screw Removal Tool into the screw head, being sure to orient the flat surface on the tip of the sleeve with the locking arm of the implant (Figure 22).
- Disengage the locking arm by rotating the sleeve of the removal tool (Figure 23).
- Unscrew the screw by turning the inner shaft of the removal tool.
- Repeat for the second screw.
- Attach the Freehand Inserter to the face of the implant. See page 3 for assembly instructions.
- Remove the implant from the intervertebral space. The handle of the Mallet may be used as a slap hammer if needed.

NOTE – If resistance is felt while attempting to rotate the removal tool sleeve, begin by advancing the screw slightly to clear the lip on the edge of the screw head.

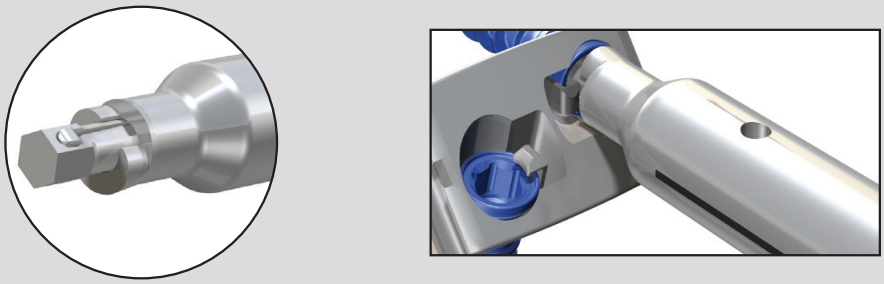


Figure 22

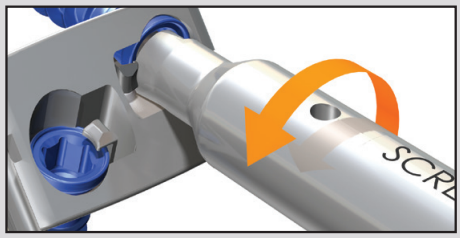
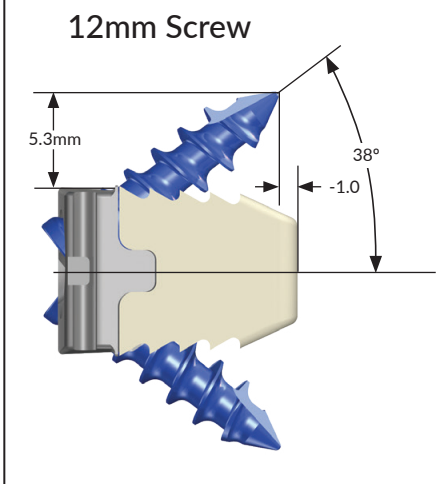


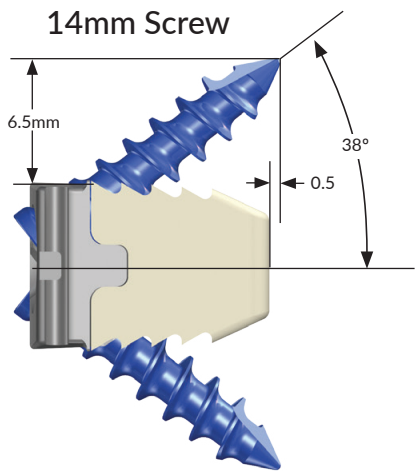
Figure 23

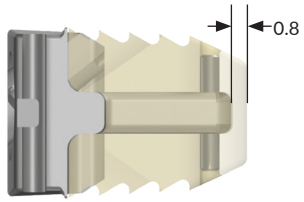
IRIX®-C SPECIFICATIONS

Screw Penetration **Marker Positions**

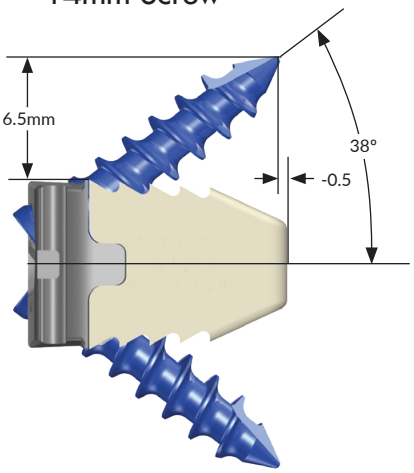
16 x 13

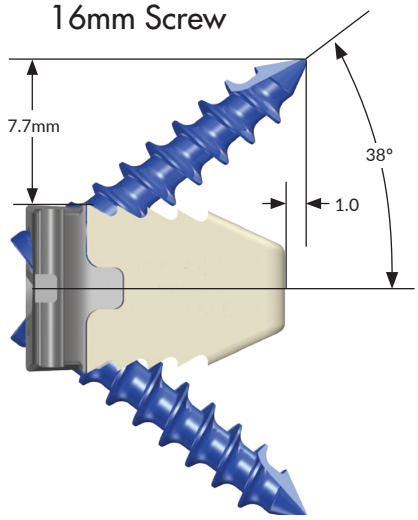


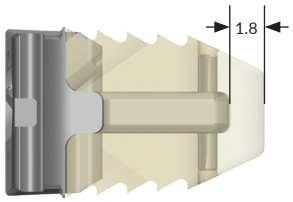




18 x 14







Graft Volume for 16 x 13 and 18 x 14 Implants

Height	0°	7°
5mm	0.36 cc	0.34 cc
6mm	0.42 cc	0.40 cc
7mm	0.48 cc	0.46 cc
8mm	0.54 cc	0.52 cc
9mm	0.60 cc	0.58 cc
10mm	0.66 cc	0.64 cc
11mm	0.72 cc	0.70 cc
12mm	0.78 cc	0.76 cc

IRIX®-C INSTRUMENTS

Trials

Height	0° 16 x 13	7° 16 x 13	7° 18 x 14
5/6mm	T066-0160	T066-0150	T066-0650
7/8mm	T066-0162	T066-0152	T066-0652
9/10mm	T066-0164	T066-0154	T066-0654
11/12mm	T066-0166	T066-0156	T066-0656

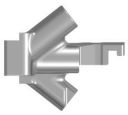
Rasps

Height	0° 16 x 13
5mm	T066-0160
7mm	T066-0162
9mm	T066-0164
11mm	T066-0166

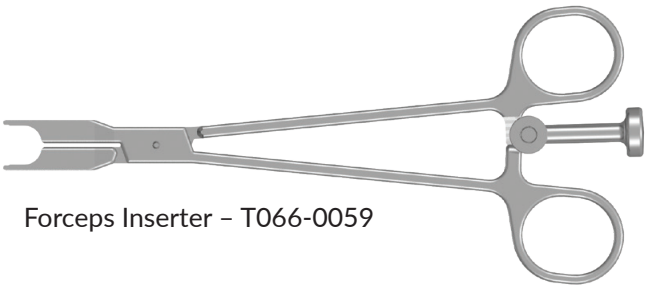
Inserter Handle – T066-0040

Guided Inserter Tips

Height	0° 16 x 13
5mm	T066-0050
6mm	T066-0051
7mm	T066-0052
8mm	T066-0053
9mm	T066-0054
10mm	T066-0055
11mm	T066-0056
12mm	T066-0057



Freehand Inserter Tip – T066-0060



Forceps Inserter – T066-0059

Tamp – T066-0190

Graft Packing Block – T066-0230

Graft Packer – T066-0225

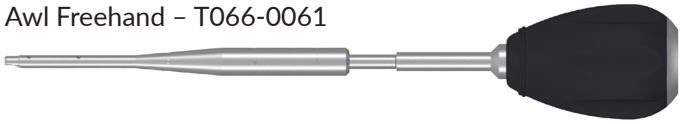
Mallet – T066-0195

IRIX®-C INSTRUMENTS

Awl Straight – T066-0200

Awl Fixed Angle – T066-0200

Awl Freehand – T066-0061



Awl Universal Joint – T066-0300

Awl Guide Universal Joint – T066-0310

Drills Straight

Length	Drill
12mm	T066-0090
14mm	T066-0091
16mm	T066-0092
18mm	T066-0093

Tap Straight– T066-0110

Screwdriver Straight– T066-0074

Screwdriver Freehand – T066-0320

Fixed Angle Sleeve – T066-0063

Fixed Angle Driver Shaft – T066-0068

Fixed Angle Side-Handle – T066-0098

Fixed Angle Drill Tips

Length	Drill
12mm	T066-0085
14mm	T066-0086
16mm	T066-0087
18mm	T066-0088

Fixed Angle Tap Tip – T066-0105

Fixed Angle Screwdriver Tip – T066-0105

Handle AO – X067-0560

Screw Removal Tool – T066-0213

IRIX®-C IMPLANTS

16 x 13

18 x 14

Interbody Spacers

Height	16 x 13 0°	16 x 13 7°	18 x 14 0°	18 x 14 7°
5mm	X066-161305P-PC	X066-161305L-PC	X066-181405P-PC	X066-181405L-PC
6mm	X066-161306P-PC	X066-161306L-PC	X066-181406P-PC	X066-181406L-PC
7mm	X066-161307P-PC	X066-161307L-PC	X066-181407P-PC	X066-181407L-PC
8mm	X066-161308P-PC	X066-161308L-PC	X066-181408P-PC	X066-181408L-PC
9mm	X066-161309P-PC	X066-161309L-PC	X066-181409P-PC	X066-181409L-PC
10mm	X066-161310P-PC	X066-161310L-PC	X066-181410P-PC	X066-181410L-PC
11mm	X066-161311P-PC	X066-161311L-PC	X066-181411P-PC	X066-181411L-PC
12mm	X066-161312P-PC	X066-161312L-PC	X066-181412P-PC	X066-181412L-PC

Standard Screws

Length	Self-Drilling 3.5mm	Self-Tapping 3.5mm
12mm	X066-3512SD	X066-3512ST
14mm	X066-3514SD	X066-3514ST
16mm	X066-3516SD	X066-3516ST
18mm	X066-3518SD	X066-3518ST
20mm	X066-3520SD	X066-3520ST

Rescue Screws

Length	Self-Tapping 3.7mm
13mm	X066-3713ST
15mm	X066-3715ST
17mm	X066-3717ST
19mm	X066-3719ST
21mm	X066-3721ST

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.

FM-C-MRK-69 Rev D 10/21

XTANT MEDICAL

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