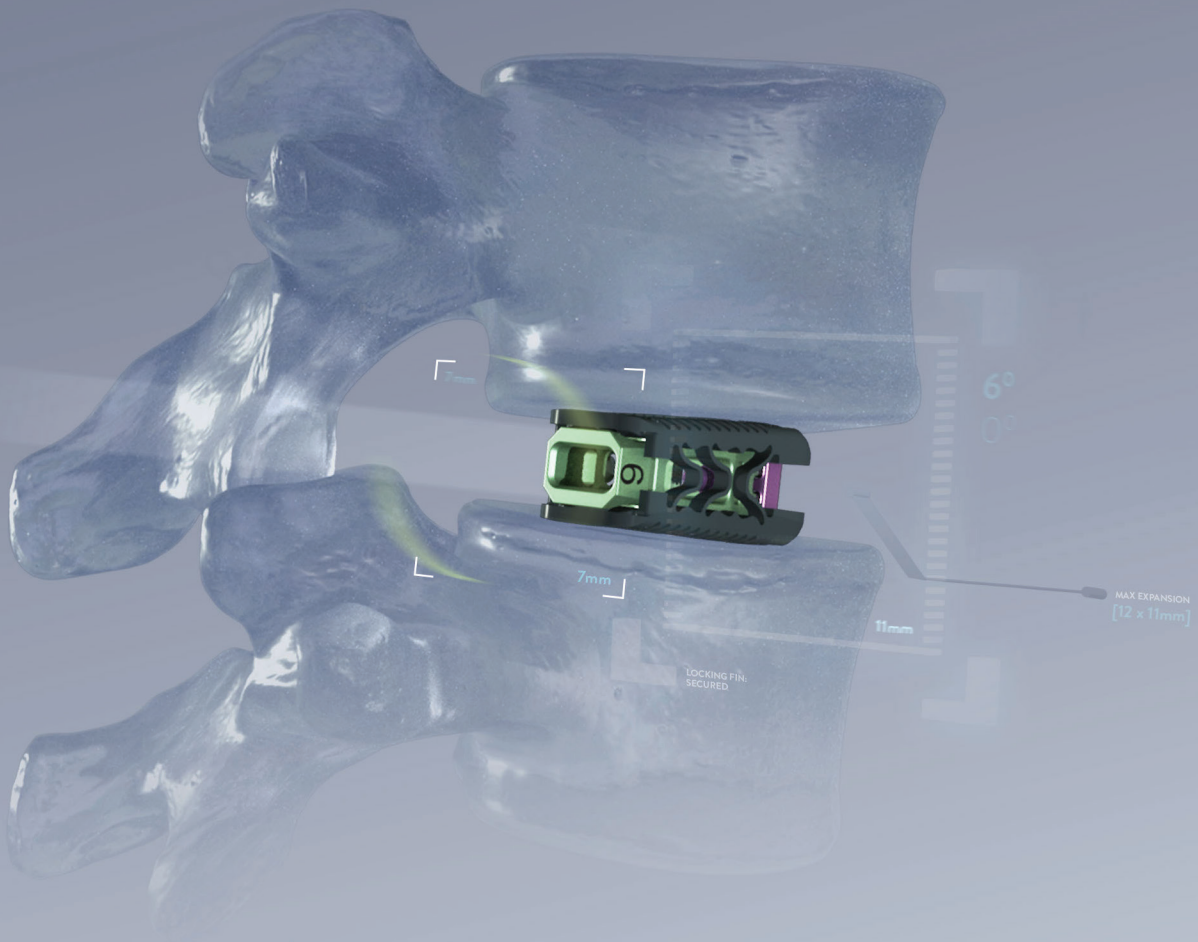
MINIMALLY INVASIVE SURGICAL TECHNIQUE MANUAL

Accelus



TiHAWK7™

FlareHawk® Lumbar Interbody Fusion System

Contents

System Overview & Intended Use

The core principles of successful fusion are widely recognized by spine surgeons: restoration of stability, minimization of neural and tissue disruption, and creation of an optimal fusion environment.

Accelus designed the FlareHawk7® Interbody Fusion System to respect each of these principles without compromise.

This surgical technique applies to both TiHawk7 and FlareHawk7 Shells although TiHawk7 is specifically called out within the surgical steps. TiHawk7 is included under the FlareHawk7 Interbody Fusion System.

FlareHawk7 permits concurrent expansion in height and width to restore disc height without sacrificing stability. It enters the disc space with a compact profile but maintains an open architecture when expanded that enables significant graft delivery.

With FlareHawk7, advantages formerly exclusive to either expandable or monolithic devices are united for the first time.

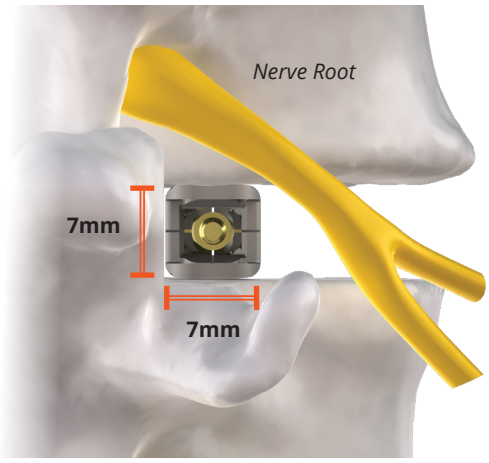
INDICATIONS FOR USE

The FlareHawk7 Interbody Fusion System is indicated for spinal intervertebral body fusion with autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone in skeletally mature individuals with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1, following discectomy.

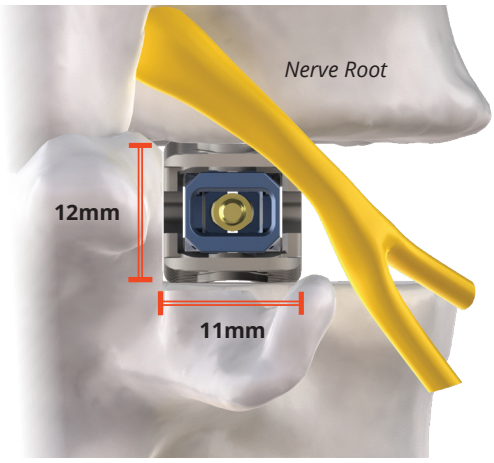
DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) months of non-operative treatment.

Additionally, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). FlareHawk system spacers are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

Insertion Profile



Expanded Profile



Each fully expanded FlareHawk7 and TiHawk7 device consists of two components: a Shim and a Shell. When the device is deployed, these components lock together to create one complete device. The dimensions of the final deployed device are determined by the dimensions of the selected Shim and Shell.

THE SHELL

FLAREHAWK7

The FlareHawk7 Shell is manufactured from a radiolucent polymer (PEEK). It contains an integrated titanium alloy Core that anchors the Inserter during Shim delivery and locks with the Shim when the Implant is deployed. There are ten tantalum markers embedded in the Shell, which enable radiographic verification of positioning and lock. Each Shell features a bulleted nose designed to facilitate ease of insertion, as well as directional teeth on its superior and inferior surfaces designed to resist expulsion by gripping the adjacent vertebral endplates. Shells are offered in Short and Tall options.

TiHAWK7™

TiHawk7 Shells have an additional 0.5-micron thick layer of commercially pure titanium bonded to the surface of the PEEK. This thin layer is radiolucent and enables the TiHawk7 Shell to maintain the same properties as the FlareHawk7 Shell, but with a titanium surface.

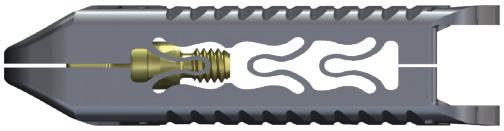
THE SHIM

The Shim is manufactured from titanium alloy. It includes a split tip that locks with the Core when the Implant is deployed. All Shims are color-coded by size. Each Shim is marked with its lot number, its built-in lordosis, and the deployed height options that are possible when it is combined with either a Short or Tall Shell.

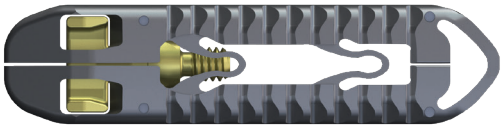
LOCKING MECHANISMS

There are two locking mechanisms that keep the Shim and Shell together after deployment.

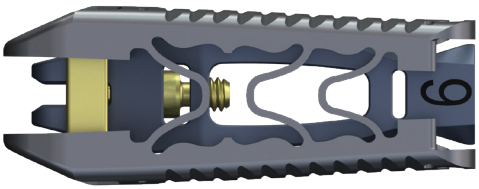
- **Anterior Lock**:
  The Shim mechanically locks to the Core.
- **Posterior Lock:**
  The Shim's Fins and the Shell's Posterior Locking Tabs create interference.



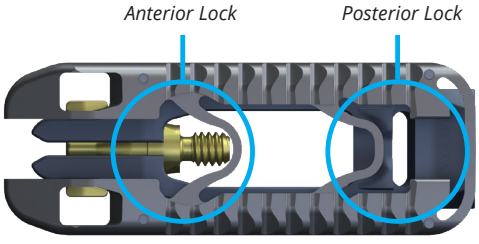
Lateral View Unexpanded



Axial View Unexpanded



Lateral View Expanded



Axial View Expanded

IMPLANT SIZE OPTIONS

The Implant size options are determined by the combination of the Shim and Shell. The Shell determines the insertion profile of the Implant, and its combination with the Shim determines final height and lordosis. The chart to the right and the table below show the insertion profiles, height, and lordosis options for each Shell. Both TiHawk7 and FlareHawk7 Shells are provided in the same sizes and are used in conjunction with the same Shims. TiHawk7 will be specifically named throughout this technique, but the the surgical steps apply to both FlareHawk7 and TiHawk7.

TiHawk7 provides the surgeon with a wide range of height and lordosis options in 26mm and 30mm lengths. All Implants have an insertion profile of 7mm or 9mm high and 7mm wide. The "7" in TiHawk7 corresponds to the insertion width of 7mm. All TiHawk7 Implants insert at 7mm in width and expand to 11mm. The images below illustrate the insertion profiles and maximum expansion profiles of the TiHawk7 Implants.

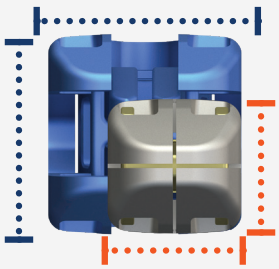
		LORDOSIS	
		0°	6°
FINAL CONSTRUCT (H X W)	8 x 11mm	7 x 7mm	
	9 x 11mm	7 x 7mm	
	10 x 11mm	7 x 7mm	7 x 7mm
	11 x 11mm	7 x 7mm	7 x 7mm
	12 x 11mm	9 x 7mm	7 x 7mm
	13 x 11mm	9 x 7mm	9 x 7mm
	14 x 11mm	9 x 7mm	9 x 7mm

Insertion Profiles

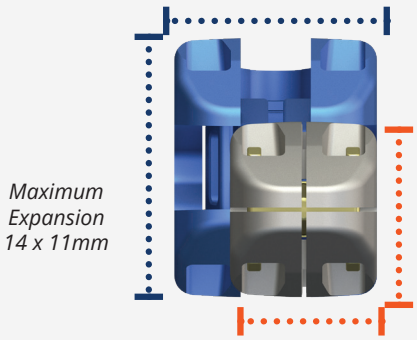
Shells (26 & 30mm)	Insertion Profile	Width Expansion	0° Height Range	6° Height Range
Short Shell	7mm H x 7mm W	11mm	8–11mm	10–12mm
Tall Shell	9mm H x 7mm W	11mm	12–14mm	13–14mm

NOTE: *Tall Shells can only be inserted through Tall Tubular Retractors and Tall Cannulas.*

Short Shell



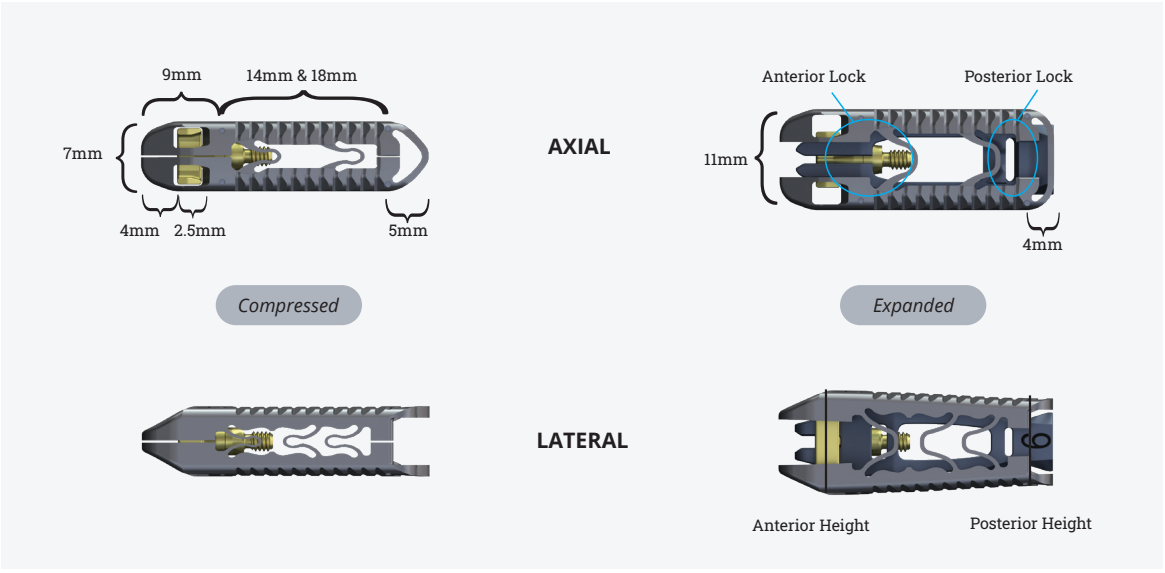
Tall Shell



Implant Overview Continued

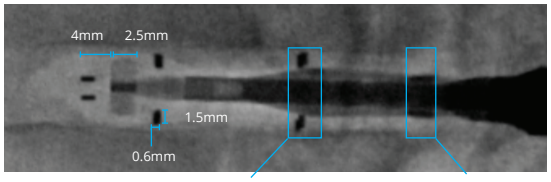
IMPLANT SPECS

CONSTRUCTS	ENTRY PROFILE (HxW)	SHELL	SHIM	EXPANDED PROFILE (ANTERIOR HxW)	POSTERIOR HEIGHT	DIFFERENCE (A-P)	POSTERIOR HEIGHT	DIFFERENCE (A-P)
					26MM IMPLANTS		30MM IMPLANTS	
8mm 0 Deg	7x7mm	Short Shell	8 or 11, 0 Deg Shim	8x11mm	8mm	0mm	8mm	0mm
9mm 0 Deg	7x7mm	Short Shell	9 or 12, 0 Deg Shim	9x11mm	9mm	0mm	9mm	0mm
10mm 0 Deg	7x7mm	Short Shell	10 or 13, 0 Deg Shim	10x11mm	10mm	0mm	10mm	0mm
11mm 0 Deg	7x7mm	Short Shell	11 or 14, 0 Deg Shim	11x11mm	11mm	0mm	11mm	0mm
12mm 0 Deg	9x7mm	Tall Shell	9 or 12, 0 Deg Shim	12x11mm	12mm	0mm	12mm	0mm
13mm 0 Deg	9x7mm	Tall Shell	10 or 13, 0 Deg Shim	13x11mm	13mm	0mm	13mm	0mm
14mm 0 Deg	9x7mm	Tall Shell	11 or 14, 0 Deg Shim	14x11mm	14mm	0mm	14mm	0mm
10mm 6 Deg	7x7mm	Short Shell	10 or 12, 6 Deg Shim	10x11mm	8mm	2mm	7.5mm	2.5mm
11mm 6 Deg	7x7mm	Short Shell	11 or 13, 6 Deg Shim	11x11mm	9mm	2mm	8.5mm	2.5mm
12mm 6 Deg	7x7mm	Short Shell	12 or 14, 6 Deg Shim	12x11mm	10mm	2mm	9.5mm	2.5mm
13mm 6 Deg	9x7mm	Tall Shell	11 or 13, 6 Deg Shim	13x11mm	11mm	2mm	10.5mm	2.5mm
14mm 6 Deg	9x7mm	Tall Shell	12 or 14, 6 Deg Shim	14x11mm	12mm	2mm	11.5mm	2.5mm



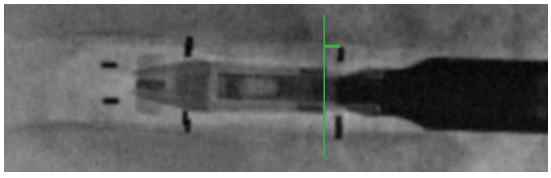
DIRECT LATERAL FLUOROSCOPIC VIEW

Compressed



Tantalum Markers (10 per Shell) Locking Fins

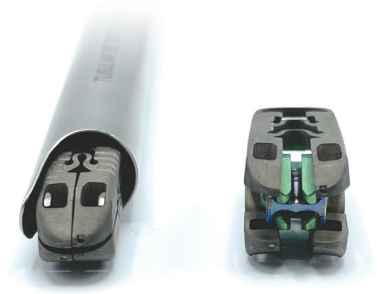
Expanded



Locking Fins anterior to the posterior Tantalum Markers = **Locked Implant**

ROUND TUBULAR RETRACTORS

The round Tubular Retractors in the TiHawk7 set are designed for an endoscopically assisted TLIF. The beveled tips of these retractors are designed to be rotated as needed to help protect the neural structures under direct visualization. These tubular retractors may be docked in the disc space or remain epidural based on surgeon preference and patient safety. Discectomy and Implant delivery may be performed through these Tubular Retractors.



Round Tubular Retractors

SQUARE CANNULAS

The square Cannulas are designed to be docked in the disc space after careful neuromonitoring and subsequent dilation. Discectomy and Implant delivery may be performed through these Cannulas.

Square Cannula

OPEN

Alternately, TiHawk7 can be utilized through any standard MIS retractor or in the Open setting to provide an Implant and Instruments designed to reduce the amount (or extent or degree) of neural retraction and number of neural passes.

Surgical Preparation

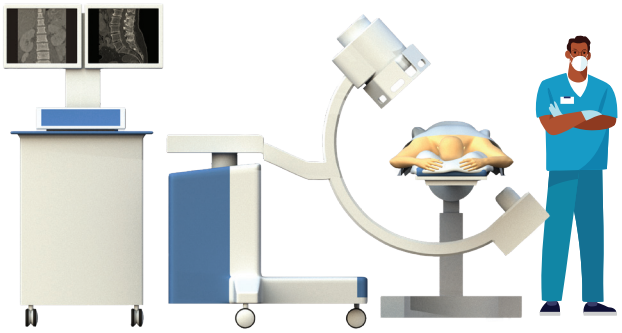
The patient is anesthetized and placed in an optimal position for the chosen surgical approach (TLIF (Transforaminal Lumbar Interbody Fusion), PLIF (Posterior Lumbar Interbody Fusion), or a minimally invasive TLIF through Kambin's Triangle. The surgical region is sanitized, and an incision is made at the operative level(s) of the spine based on the surgeon's chosen approach. Fluoroscopy and/or another imaging modality should be used throughout the procedure for planning and to confirm proper Implant placement and locking.

This surgical technique manual presents the steps suggested for a minimally invasive TLIF through Kambin's Triangle with the use of Tubular Retractors and Cannulas. The goal of this approach is to preserve normal anatomical structures as much as possible while providing safe access to the disc space. It is essential for a surgeon to have familiarity with the Kambin's Triangle approach and anatomy for utilization of these techniques, instrumentation and implants.

If the surgeon prefers Open TLIF or PLIF approach refer to the surgical steps in STM-00008, and ensure the surgeon's preferred retractor system is available so that access to the operative level(s) may be gained. Use appropriate instruments, such as osteotomes, rongeurs, and burrs, to partially or completely remove the facet and/or lamina to provide access to the disc. Expose the disc space using proper hemostatic technique. Use a nerve root retractor as required. Perform an annulotomy and remove disc material as needed, including cartilaginous endplates, using disc preparation instruments such as curettes, shavers, rasps, and/or other appropriate discectomy tools. Decompress neural anatomy as required.

Posterior stabilization should always be utilized at the appropriate level(s), before or after Implant placement, as preferred by the surgeon.

To confirm Implant alignment and lock out, the C-arm must be positioned on the opposite side of the TLIF being performed. This positioning will allow for a direct lateral image of the Implant or contralateral oblique image. See image to the right.



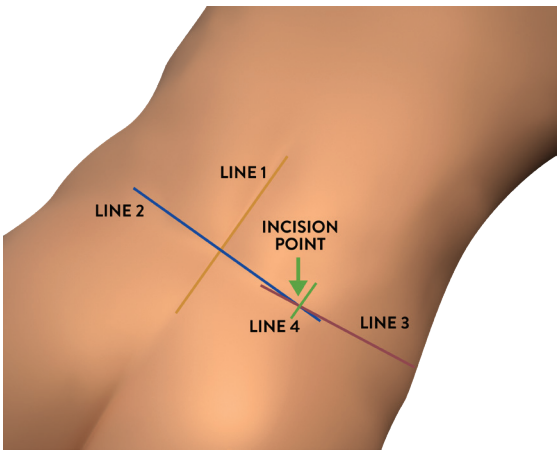
C-arm positioned for lock confirmation

Cannula Access With Neuromonitoring Probe

The laterality of the Implant approach must be determined. This should be on the opposite side of the fluoroscopy machine (e.g., if placing Implant from left, then fluoroscopy should be on right side of patient). The patient should be in a prone position on a Jackson table with abdomen free and hips well-padded. Drape out as wide as possible on the Implant insertion side in order to allow appropriate trajectory for the Implant.

If utilizing two C-arms, the C-arm machine taking lateral images needs to be positioned closest to the head. A lateral image is obtained perpendicular to operative level. The A/P fluoro machine is brought up at an angle from the feet upward obtaining an image parallel to endplates of the operative level. Once the images are obtained, lock machines in position.

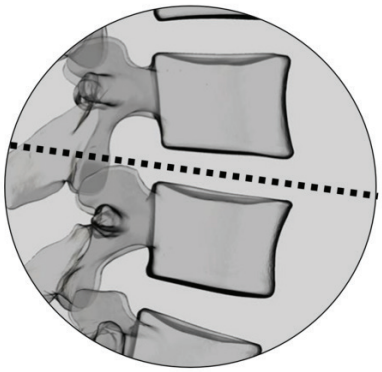
Alternately, if there is only one C-arm available, it will need to be moved between A/P and lateral positions to provide the appropriate images.



Yellow Line 1	**Midline**
Blue Line 2	**AP Line**
Purple Line 3	**Lateral Line**
Green Line 4	**Incision Point**

INCISION LOCATION

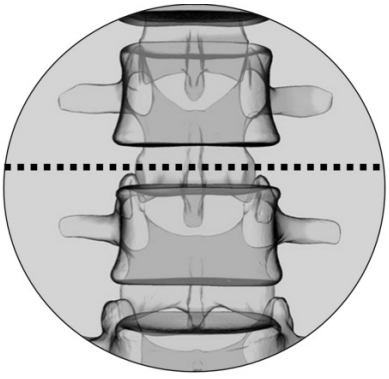
Based off the A/P image, draw a line parallel to the disc space of the intended operative level. Based off the lateral image, draw a line parallel to the disc space of intended operative level. The incision should be where the two lines cross. A horizontal incision should be made with a scalpel about 1 cm in size and an attempt to push through the fascia.



Lateral Image and Line to Draw

Typical incision range from midline: **6-8 cm**

Incision location will vary from patient to patient. These measurements are not meant to be prescriptive but rather an estimate of incision locations typically seen in this procedure.

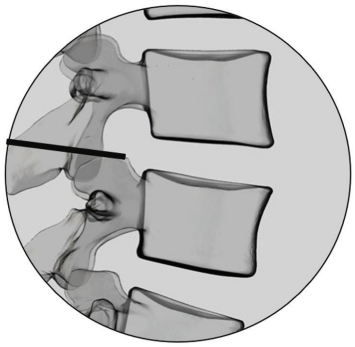


AP Image and Line to Draw

ACCESS: STARTING IN LATERAL TARGETING KAMBIN'S TRIANGLE

Start with C-Arm in Lateral Position

If using the Neuromonitoring Probe with Exchange Tube, stimulate the Probe to the surgeon's desired voltage/current within the manufacturer's suggested stimulation levels. Advance the Probe or needle to the Superior Articular Process (SAP) at the same angle determined by the intersecting lines. The surgeon should feel the instrument touch the SAP. Do not advance into the foramen without switching the C-Arm to the A/P position.

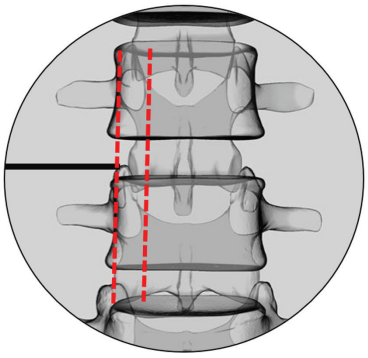


LATERAL
SAP and cephalad aspect of the pedicle

Change C-Arm to A/P Position

The tip of the instrument should be just lateral to the foramen touching the SAP.

If repositioning of the instrument is needed, ensure both and A/P and Lateral image confirm the proper location before moving forward.

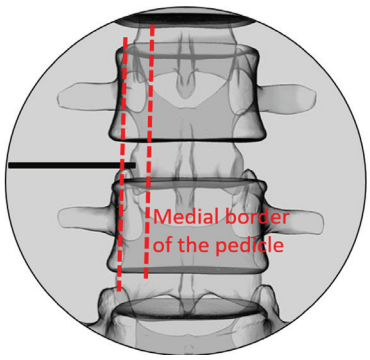


A/P:
Confirm location before advancing

Advance with Caution

Once the tip of the instrument is between the medial and lateral border of the pedicle in the foramen, switch the C-Arm into Lateral position.

Do not advance the instrument past the medial border of the pedicle.

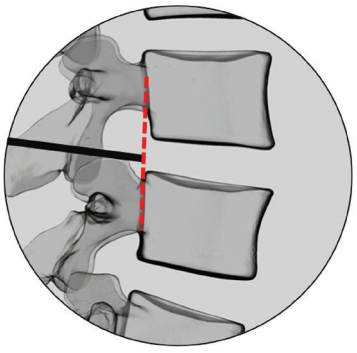


Target Zone A/P:
Between Medial and Lateral Border of the Pedicle

Change C-Arm to Lateral Position

With the C-Arm in Lateral position, ensure the tip of the instrument is in the inferior part of the foramen against the annulus in the Lateral view.

Transfer Sheath – If using the probe, the transfer sheath can be pushed down to the annulus if there is no depolarization of the nerve root at a minimum stimulation determined by the surgeon.



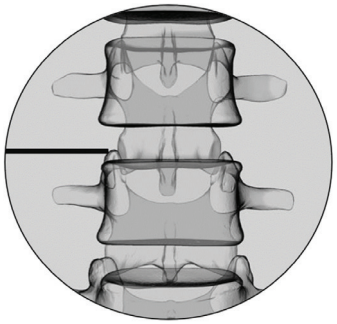
Target Zone Lateral:
Inferior part of the foramen against the annulus

CAUTION: *If a neuromonitoring response is found below the desired response level, then repositioning of the Neuromonitoring Probe and Probe Exchange Tube is necessary.*

ACCESS: STARTING IN A/P TARGETING KAMBIN'S TRIANGLE

Start with C-Arm in A/P Position

If using the Neuromonitoring Probe with Exchange Tube, stimulate the Probe to the surgeon's desired voltage/current within the manufacturer's suggested stimulation levels. Advance the Probe or needle to the Superior Articular Process (SAP) at the same angle determined by the intersecting lines. The surgeon should feel the instrument touch the SAP. Do not advance into the foramen without switching the C-Arm to the Lateral position.

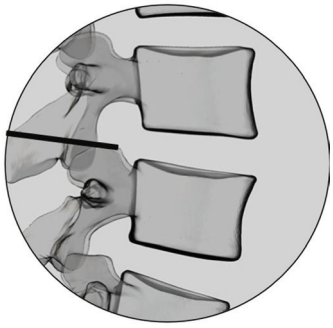


A/P :
SAP and cephalad aspect of the pedicle

Change C-Arm to Lateral Position

The tip of the instrument should be just lateral to the foramen touching the SAP.

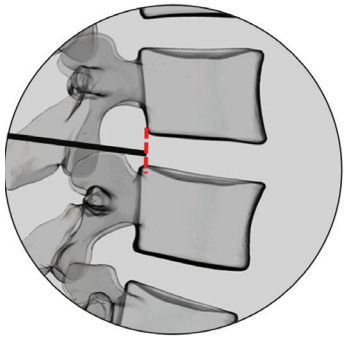
If repositioning of the instrument is needed, ensure both and A/P and Lateral image confirm the proper location before moving forward.



Lateral:
Confirm location before advancing

Advance with Caution

With the C-Arm in Lateral position, ensure the tip of the instrument is in the inferior part of the foramen against the annulus.



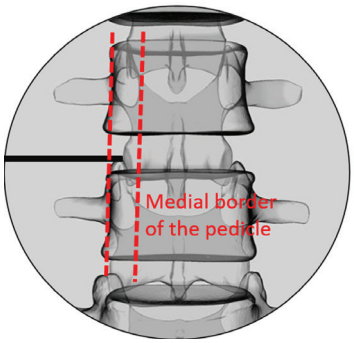
Target Zone Lateral:
Inferior part of the foramen against the annulus.

Change C-Arm to A/P Position

Ensure the tip of the instrument is between the medial and lateral border of the pedicle in the foramen.

Do not advance the past the medial border of the pedicle.

Transfer Sheath – If using the probe, the transfer sheath can be pushed down to the annulus if there is no depolarization of the nerve root at a minimum stimulation determined by the surgeon.



Target Zone A/P:
Between Medial and Lateral Border of the Pedicle

.

CAUTION: *If a neuromonitoring response is found below the desired response level, then repositioning of the Neuromonitoring Probe and Probe Exchange Tube is necessary.*

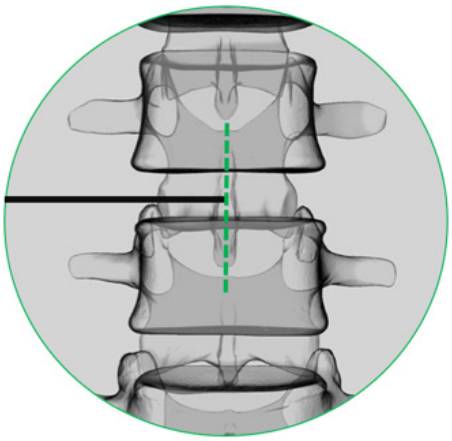
K-Wire Trajectory

Appropriate K-Wire Trajectory

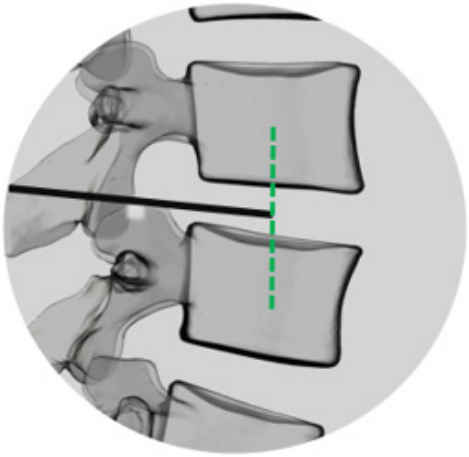
The Probe Exchange Tube is advanced into the annulus by gently rotating the tube away from the exiting nerve root while the Neuromonitoring Probe is removed. A 2.4mm K-Wire is placed through the Probe Exchange Tube and into the disc space. Remove the Probe Exchange Tube leaving the K-Wire in place.

Initial K-wire should be positioned about 50% across the disc space on A/P and 50% on Lateral to help ensure Implant placement across midline.

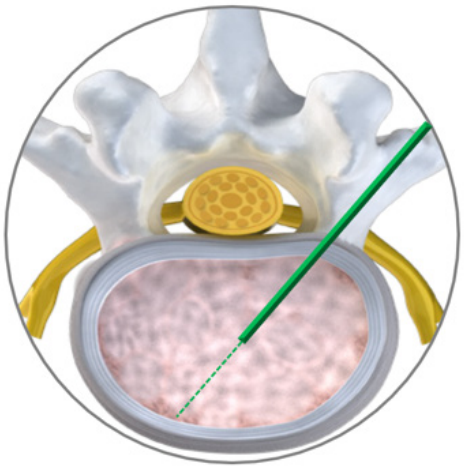
Alternately, if using a needle to target and then an endoscope prior to transitioning to the FlareHawk7 MIS System, similar trajectory images of the K-wire should be obtained before dilating to the FlareHawk7 Cannula or Tubular Retractor.



A/P **50%**



Lateral **50%**

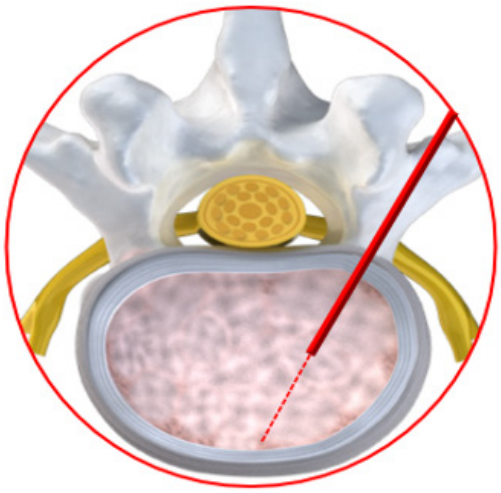


50/50 Axial View

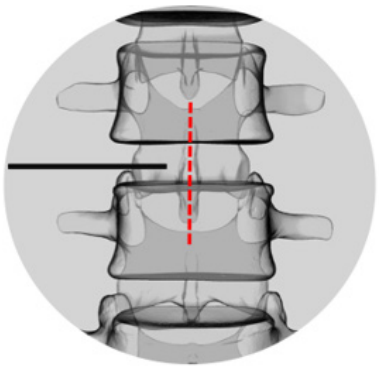
K-Wire Trajectory

If the trajectory is too steep:

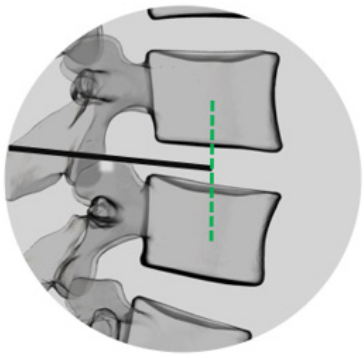
Withdraw the K-wire to the posterior edge of the disc space. Lower the hand to flatten the trajectory and re-advance the K-wire. Inspect in both A/P and Lateral.



Steep Trajectory



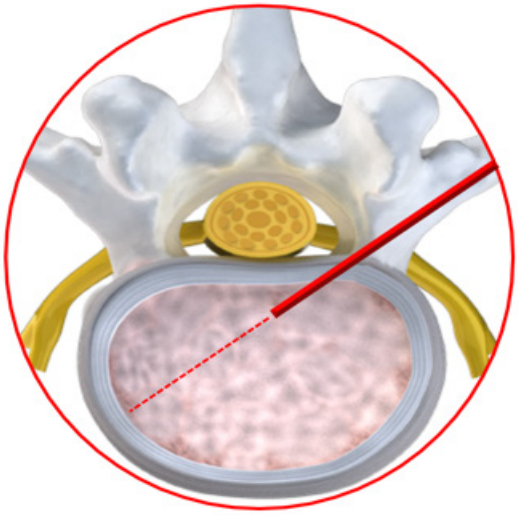
A/P: **<50%**



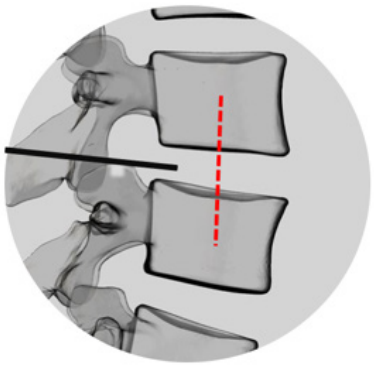
Lateral: **50%**

If the trajectory is too shallow:

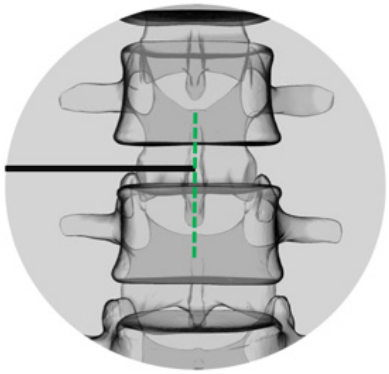
Withdraw the K-wire to the posterior edge of the disc space. Elevate the hand to steepen the trajectory and re-advance the K-wire. Inspect in both A/P and Lateral.



Shallow Trajectory



Lateral: **<50%**



A/P: **50%**

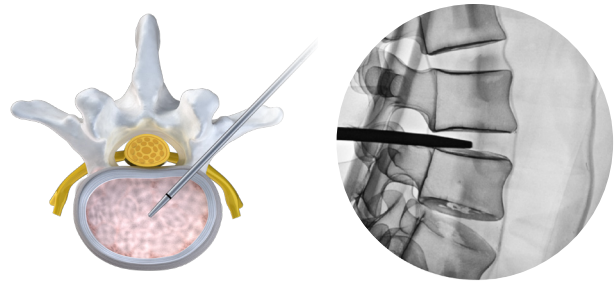
DILATION

Gently rotate and advance Dilator #1 over the K-Wire to the outer annulus. Use the Dilator Impactor to gently advance Dilator #1 over the K-Wire until the distal tip of Dilator #1 is at the center of the disc space. Confirm the correct placement of Dilator #1 using A/P and lateral fluoroscopy. Remove the K-Wire leaving Dilator #1 in place.

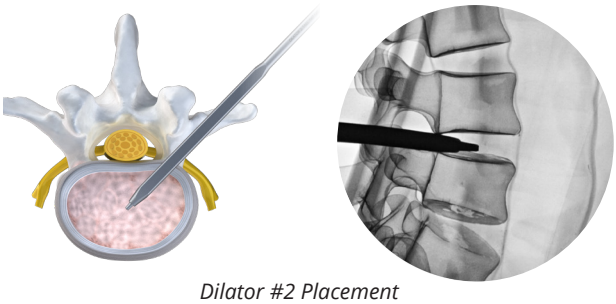
The black laser mark lines on Dilator #2 should be in the Medial-Lateral position. The Dilator Impactor may be utilized to impact the dilators into position. The smallest hole in the Dilator Impactor slides over the k-wire to impact Dilator #1. The larger hole slides over Dilator #1 to impact Dilator #2. The correct placement of Dilator #2 is confirmed using A/P and lateral fluoroscopy.

Pass the Cannula over Dilator #2 while ensuring the black laser mark lines on the Cannula are in the Medial-Lateral position aligning with Dilator #2. The Dilator Impactor may be used to advance the tip of the Cannula in to the disc space. Ensure the Cannula is at least 5mm in the disc space.

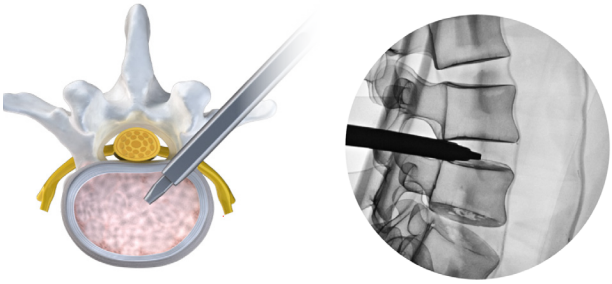
CAUTION: *Care should be taken not to advance the K-Wire anteriorly through the disc space.*



Dilator #1 Placement



Dilator #2 Placement



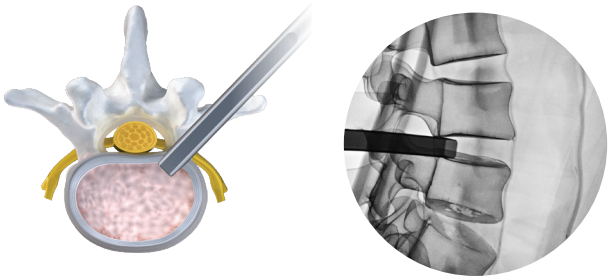
Cannula Placement

DILATION

Remove Dilators leaving the Cannula in place. The Dilator Handle may be utilized to help remove the Dilators.

The T-Handle and the black line on the body of the Cannula should be in-line with the endplates and disc space.

Black line on the body of the cannula is in-line with the disc space and endplates

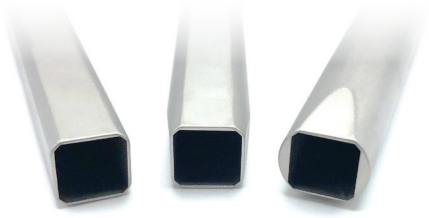


Removal of Dilators

THREE STYLES OF SHORT CANNULAS:

Short Cannula
Lengths: 140mm and 200mm
Inner Dimensions: 8x8mm
Outer Dimensions: See Right

Tall Cannula
Length: 200mm
Inner Dimension: 10x8mm
Outer Dimension: 11x9mm



Square
9x9mm (HxW)

Flat
9x9mm (HxW)

Round
9x11mm (HxW)

The round Tubular Retractors were designed for surgeons who already have accessed Kambin's Triangle in order to perform a direct decompression and /or discectomy. The following Tubular Retractor access steps assume the surgeon is already safely within Kambin's Triangle and can safely place the initial K-wire before dilating up to the Tubular Retractors.

REDIRECT THE TRAJECTORY

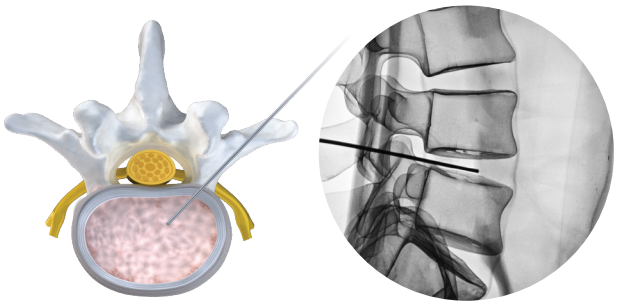
After direct decompression is performed utilizing the surgeon's selected endoscope, redirect the endoscopic working channel to a more lateral trajectory. The K-Wire is then placed through the working channel or endoscope under direct visualization and into the disc space lateral to the dura and medial to the exiting root. Lateral and medial fluoroscopic images are taken to ensure adequate trajectory and depth. Once in position, the working endoscopic channel can be removed.

DILATION

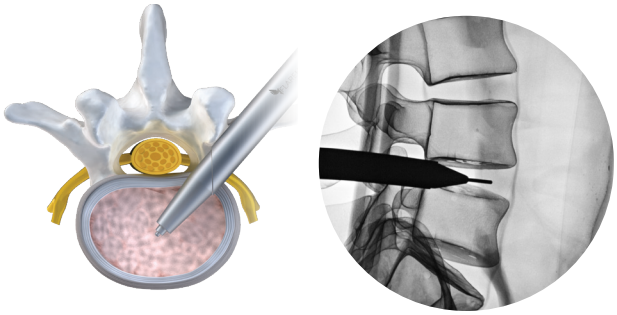
Dilator #1 is placed over the K-Wire into the disc space. Use fluroscopy to confirm that the K-Wire does not advance anteriorly. The tapered tip of the Dilator is designed to provide distraction of the disc space if needed. Confirm placement using fluoroscopy. Once safely in the disc space, Dilator #2 may be placed over Dilator #1 using fluoroscopy.

Once the Second Dilator is in position, place the selected Tubular Retractor over the Dilator with the open bevel facing the exiting nerve root. The bevel may partially enter the disc space or remain epidural based upon surgeon discretion. The K-Wire may be removed after the Tubular Retractor is placed.

CAUTION: *Care should be taken not to advance the K-Wire anteriorly through the disc space.*



K-Wire Placement



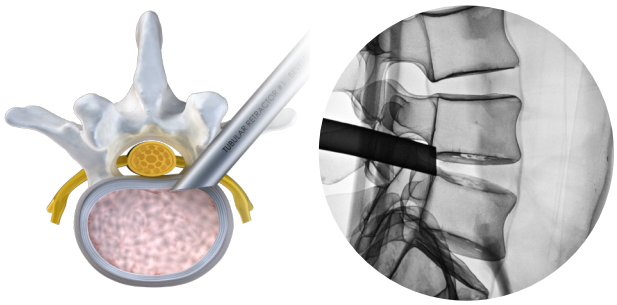
Dilator and Tubular Retractor Placement

Tubular Rectractor Access (Continued)

Once the location of the exiting nerve root and traversing nerve root have been identified, the Tubular Retractor is turned clockwise if on the right side of the patient or counterclockwise if on the left side of the patient to provide protection to the exiting and traversing roots. Visualize the traversing root, then advance and rotate the Tubular Retractor to elevate and protect the traversing root and exiting nerve root.

Once the Tubular Retractor is positioned to safely protect the exiting and traversing nerve roots and firmly secured in the disc space, the discectomy may be performed.

CAUTION: *Care should be taken not to advance the K-Wire anteriorly through the disc space.*



Tubular Retractor protecting exiting and traversing nerve roots

FOUR STYLES OF TUBULAR RETRACTORS:

Short Tubular Retractors
Lengths: 140mm and 170mm
Inner Dimensions: 10mm
Outer Dimensions: 11mm

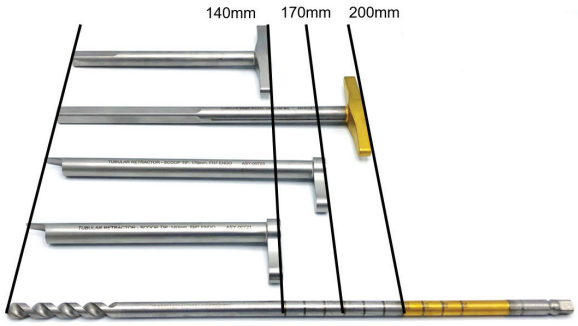
Tall Tubular Retractor
Length: 140mm
Inner Dimension: 11.5mm
Outer Dimension: 12.5mm

DISC PREPARATION

Most disc prep instruments have depth markings every 10mm that correspond to the two lengths of the 140mm round Tubular Retractors and 200mm square Cannulas. A 170mm Tubular Retractor is available through special order.

Take fluoroscopic images to ensure safe usage and that the Cannula or Tubular Retractor stays in place protecting the exiting and traversing roots during the discectomy. The surgeon should also hold the Cannula or Tubular Retractor at all times to ensure it stays in a safe position.

CAUTION: *Care should be taken when performing the discectomy with the provided Instruments so as to not damage the endplates.*



Markings: 140mm — 10mm increments up to 50mm
200mm — 10mm increments up to 30mm

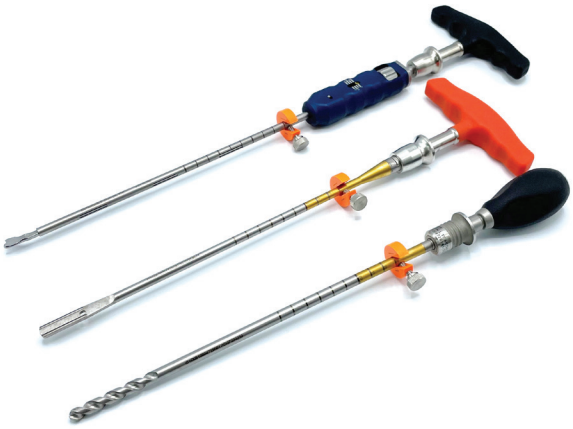
DEPTH STOP

Adjustable Depth Stops are available by special request only and can be affixed to the shaft of the Disc Drills, Shavers, and Expandable Shaver to help control the depth of the instruments within the Cannula or Tubular Retractor.

Using fluoroscopy, advance the instrument through the Cannula or Tubular Retractor until the instrument tip reaches the desired position. Confirm instrument position using the AP and lateral view. To secure the depth stop to the instrument shaft, ensure the thumb screw is backed off. Maintaining the instrument position, slide the stop onto the shaft until it is flush with the Cannula or Tubular Retractor handle. Tighten the thumb screw until the depth stop is secure and parallel to the Cannula or Tubular Retractor face. It is important to make sure the depth stop is tight on the shaft and not skewed.

The depth stop will now limit the instrument from advancing further into the disc space. Excessive force should never be used when utilizing the depth stop as the depth stop could unintentionally move.

CAUTION: *Depth markings on the instruments do not replace the need for fluoroscopy for safe usage of the instruments.*



Disc Space Preparation (Continued)

COMPATIBILITY

Part Number	Description	Round Tubular Retractors	Square Cannulas
ASY-00145	Disc Drill, 6.5mm, TiH7	●	●
ASY-00491	Disc Drill, 7.5mm, TiH7	●	●
ASY-00147	Pituitary, Straight 3mm, TiH7	●	●
ASY-00149	Articulating Curette, TiH7	●	●
ASY-00256	Expandable Shaver, TiH7	●	●
ASY-00564	Small Ring Curette, TiH7	●	●
ASY-00584	Medium Ring Curette, TiH7	●	●
ASY-00571	Large Ring Curette, TiH7	●	●
CMP-01345	7mm Shaver, TiH7	●	●
CMP-01346	8mm Shaver, TiH7	●	
CMP-01347	9mm Shaver, TiH7	●	
ASY-00113	0° Expandable Trial, TiH7	●	

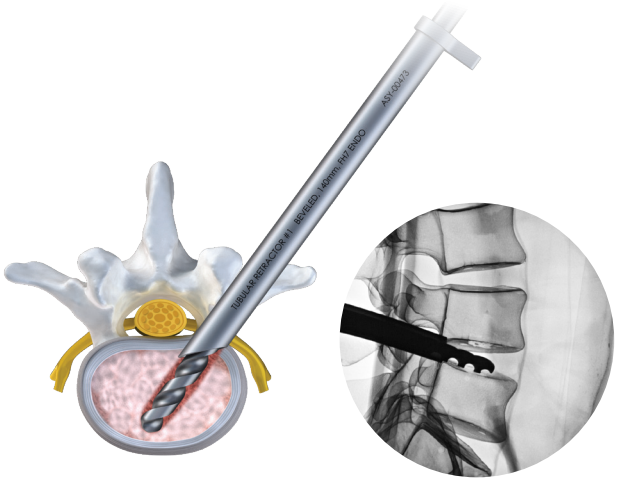
CAUTION: *Not all instruments fit through the desired Cannula or Tubular Retractor*

DISC DRILL & PITUITARY

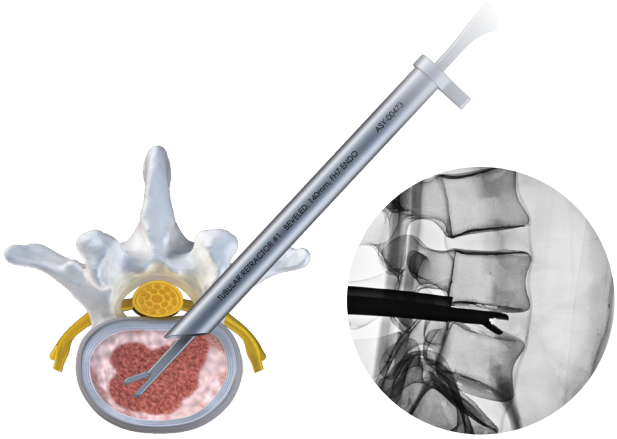
The surgeon may initiate the discectomy by using the Disc Drill to remove disc and create the pathway for the other discectomy instruments. Affix the Black T-Handle to the Disc Drill. Insert the Disc Drill through the Cannula or Tubular Retractor and advance it down the Cannula or Tubular Retractor using fluoroscopic imaging until the tip contacts the annulus. The Disc Drill should be advanced as far anteriorly and laterally as possible within the anatomic boundaries of the disc. Continually rotate the Disc Drill clockwise to remove disc material. Caution should be exercised when utilizing the Disc Drill since it will advance forward because it is rotated clockwise. Use fluoroscopy to ensure safe depth in the disc space. This step may be repeated as necessary to remove additional disc material and prepare the endplates. The Pituitary is utilized to remove any disc fragments. Fluoroscopy should be used to ensure safe usage of the Pituitary.

TIP: *The depth of the Disc Drill should be noted as this will be useful for helping to determine the length of the Implant.*

CAUTION: *Caution should be exercised when utilizing the Disc Drill because it will advance forward as it is rotated clockwise.*



Disc Drill removing disc material



Pituitary removing disc material

EXPANDABLE SHAVER

Before assembling the the shaver blade into the Expandable Shaver, rotate the expansion dial counter-clockwise until the height gauge reads 7.

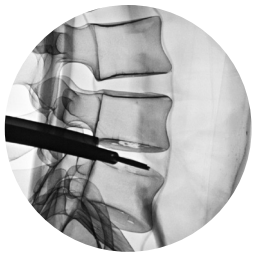
TIP: *When the Expandable Disc Shaver blade is in solid contact with the endplates, this represents the height of the disc space being prepared.*

Line up the laser-marked lines on the Shaver Blade and Shaft to ensure that the Shaver Blade Hook is in the correct position.

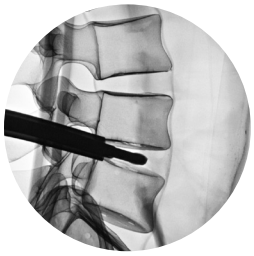
Depress the blade release button while inserting the shaver blade into the shaft of the Expandable Shaver with the hook side facing away from the blade release button. A hard stop should be felt when the blade has been fully seated. Release the button and gently tug on the shaver blade to ensure it is locked into the Expandable Shaver.

Next, affix the Black T-Handle to the Expandable Shaver with the handle in line with the flats of the handle and the shaver blade. With the Expandable Disc Shaver in the fully collapsed position, insert the Expandable Disc Shaver through the Cannula or tubular retractor into the pathway created by the Disc Drill. Be sure not to depress the blade release button while using the Expandable Shaver. Expand the blade in 1mm increments and rotate clockwise at each 1mm incremental expansion. The clockwise rotation and distal-to-proximal movement will help prepare the endplates and loosen additional disc material. Retract the Shaver blades back to their original position before attempting to remove the Shaver from the disc space. If the Shaver blade is not fully retracted, the Shaver may not be able to be removed and/or may cause damage to the Shaver or Tubular Retractor. It may also pull the Cannula or Tubular Retractor out of its safe position.

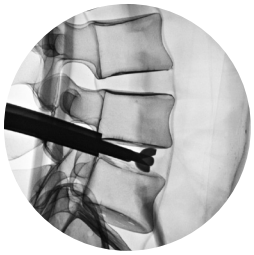
CAUTION: *Do not rotate the shaver blade counter-clockwise. Rotating the shaver blade counter-clockwise may bend or break the shaver blade.*



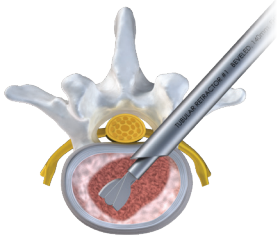
Insertion of shaver



Blade vertical in collapsed position



Blade vertical and expanded



Shaver in Expanded Position

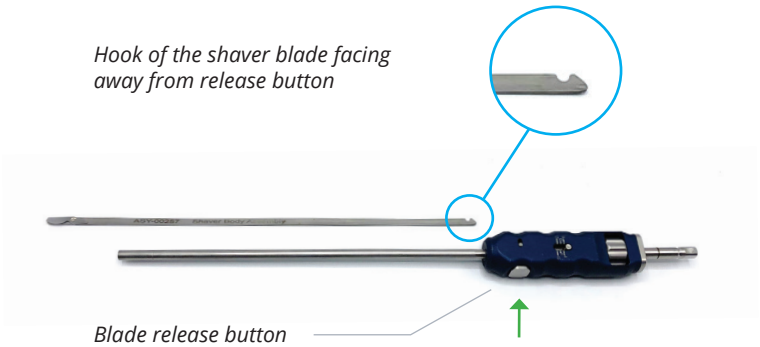
CAUTION: *Care should be taken when expanding the blade and rotating the Expandable Disc Shaver to not damage the endplates, especially in patients with poor bone quality.*

CAUTION: *Care should be taken not to advance the Expandable Shaver too far anteriorly through the disc space. Use Fluoroscopy to monitor location with the disc space.*

EXPANDABLE SHAVER

The shaver blade should be removed and disposed of after each surgery. The shaver blade should never be left inside the Expandable Shaver shaft during the sterilization cycle. To remove the shaver blade, depress the blade release button and gently pull the shaver blade out of the shaft of the Expandable Shaver.

TIP: *Line up the laser-marked lines on the Shaver Blade and Shaft to ensure that the Shaver Blade Hook is in the correct position.*

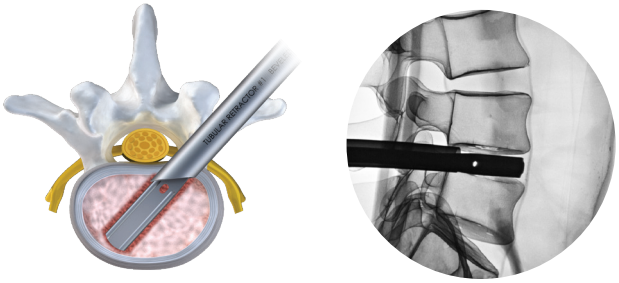


Blade assembled and locked into the Expandable Shaver

SHAVERS

There are three static Shavers: 7mm, 8mm, and 9mm. Affix the orange Hudson T-Handle to utilize the Shaver.

Depth can be assessed using the fluoroscopic through-hole as a guide. The front of the hole is 26mm from the tip and the back is 30mm from the tip. Shavers are designed to create a rectangular clearance in the space to allow room for the nose of the Implant to expand in width and height.



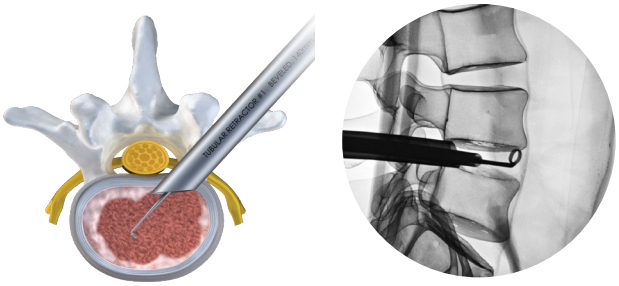
Static Shaver

MIS RING CURETTES

There are three styles of Curettes available in the system. These may be utilized through the Tubular Retractor for disc preparation. Use fluoroscopy to ensure safe usage of the Curettes.

The black Mini-AO Handle must be affixed to the shaft of the Curettes before use. Laser markings on the handle and shaft of the Curette are provided to help align the connection point. If the surgeon chooses to utilize the Curettes with an endoscope (or smaller working channel), the Curette shaft must first be fed up through the working channel and the handle attached on the back end.

Laser markings are provided on the working end of the Curette at 10mm increments to help show depth when being utilized under direct visualization.



MIS Ring Curette

Large MIS Ring Curette assembled with Mini-AO Handle

Three Styles of MS Ring Curettes

Small ring (LxW): 5 x 3.5mm
Medium Ring (LxW): 6 x 5mm
Large Ring (LxW): 7 x 7mm

Small

Medium

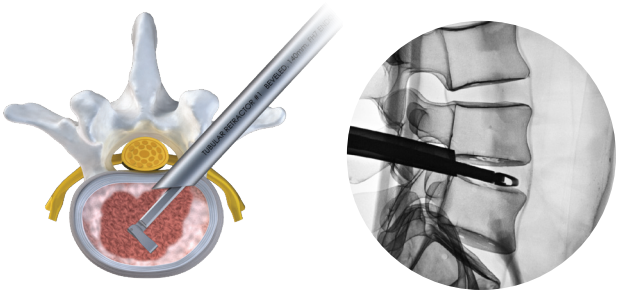
Large

ARTICULATING CURETTE

The discectomy may be further expanded by using the Articulating Curette to remove disc from both the cephalad and caudal endplates. The Curette articulates up when the handle is squeezed. Squeeze the handle to cut disc material and articular cartilage from the endplates. This process may be repeated multiple times until the desired amount of disc material is removed. Rotate the instrument 180º and repeat the process.

Repeat the steps for using the Articulating Curette in both directions at different depths. This will help ensure that adequate disc material is removed and endplate preparation is completed in the proximal and distal portions of the disc space.

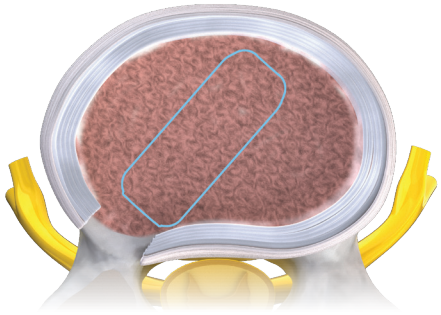
CAUTION: *Care should be taken to not damage the endplates when using the Articulating Curette. Cutting should be performed with the sides of the blade and not the tip.*



Articulating Curette

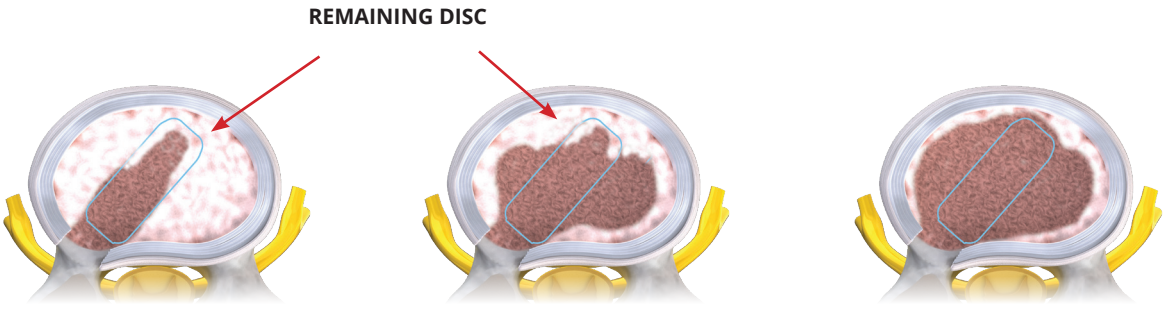
BIDIRECTIONAL DISC PREPARATION

The TiHawk7 Implant requires disc prep and distraction strategies that accommodate a bi-planar expandable Implant. The TiHawk7 Shell must have medial-lateral clearance to allow for expansion from 7 to 11mm in width, especially where the distal tip of the Implant will be placed. A channel discectomy is inadequate to accommodate the large footprint of the TiHawk7 Implant. Leaving disc material in the path of expansion can prohibit deployment which could result in failure to lock and/or Implant fracture. When possible, a four-quadrant discectomy is encouraged to allow for width expansion and to take advantage of the flow-through of graft during post-packing. However, it is essential to remove at least enough disc material for the Implant to expand to 11mm in width.



Optimal Disc Prep

CAUTION: *Due to the width expansion capabilities of the TiHawk7 Implant, adequate discectomy of the affected disc is necessary to place and expand the TiHawk7 Implant. Failure to perform a sufficient discectomy may limit the Implant's ability to deploy properly which could result in failure to lock and/or Implant fracture.*



Inadequate Disc Prep

Inadequate Disc Prep

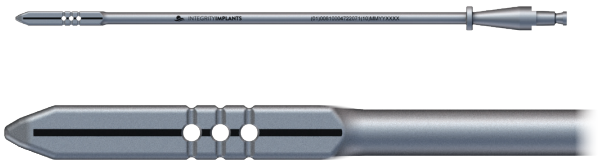
Adequate Disc Prep

Obturator Impactor

The Short Obturator Impactor and Tall Obturator Impactors have through-holes at 26, 30, and 34mm and can be seen fluoroscopically to help assess depth within the disc space.

Affix an orange Hudson T-Handle to the selected Impactor, and insert the Impactor into the disc space with the holes parallel to the endplates. The Obturator Impactor can be used for verification of an adequate working channel for insertion of an implant.

The Impactor can be utilized to determine if additional distraction or prep work may be required for Implant entry into the disc space. While using the selected Impactor, confirm correct instrument placement and trajectory using fluoroscopy.



Short Obturator Impactor

WIRE BRUSHES

Wire Brushes are available to help assist in clearing out remaining disc material. These brushes may be attached to a power drill. Always use fluoroscopy to safely utilize the brushes within the disc space. If a slight bend is needed in the brush, the Wire Brush Crimp Tool may be used to crimp the shaft of the brush near the bristles. Brushes are sterile packaged and intended to be single use/disposable.

Wire Brush Sizes (Diameter):
6.5mm Wire Brush 7.5mm Wire Brush 9.5mm Wire Brush

CAUTION: *Use x-ray to ensure the Wire Brush is not advanced anterior.*

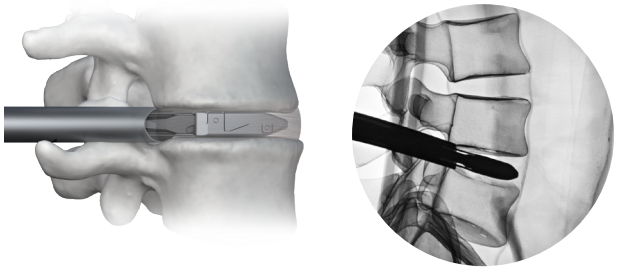
CAUTION: *Always hold the Tubular Retractor or Cannula in position to be sure the Wire Brush does not dislodge it when being removed from the disc space.*

EXPANDABLE TRIAL

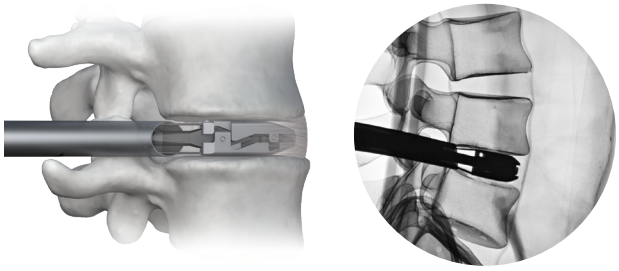
Connect the Tear Drop Handle to the proximal portion of the Expandable Trial. Insert the Expandable Trial through the Tubular Retractor and into the disc space. The footprint of the tip is 30mm in length. In order to distract through the Tubular Retractor, ensure at least 35mm of clearance past the tip of the Tube in the disc space.

Once the location has been confirmed via fluoroscopy, rotate the Tear Drop Handle clockwise until slight resistance is felt (approximately "finger tight") and stop to confirm size. Do not exceed 12mm in expansion on the Expandable Trial when using it within a Tubular Retractor.

Use Static Shavers, an Expandable Trial, or an alternate method preferred by the surgeon to distract the intervertebral space until the desired disc height is established. The disc space must always be distracted to at least the height of the selected Implant. There is no need to oversize the Implant and place the spine in a supraphysiological position. Compare the operative disc space(s) to healthy adjacent level discs seen in preoperative radiographic images to assist in determining appropriate implant height and lordosis.



Collapsed Position



Expanded Position

CAUTION: *Only open the Expandable Trial instrument until resistance is encountered. Overdistraction could cause vertebral body damage.*

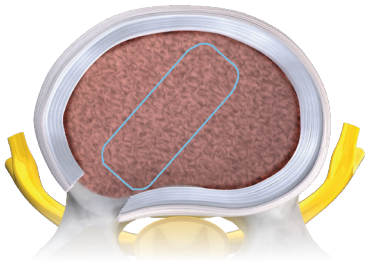
CAUTION: *It is advisable that the surgeon not deliberately select an Implant that is oversized relative to the disc space. If an Implant height larger than appropriate for the disc space is used, increased resistance may be encountered when expanding and locking the Implant which could result in failure to lock and/or Implant fracture.*

TIP: *The tallest Implant that can be deployed through the Short Tubular Retractors is 12mm. Do not distract past 12mm with the Expandable Trial in the Short Tubular Retractor.*

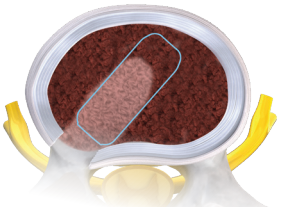
DO NOT PRE-PACK GRAFT

Graft placement is critical to obtaining fusion. Many surgeons may be accustomed to pre-packing graft. TiHawk7 is designed to be post-packed. Large axial and lateral windows in the Implant allow for the flow of graft from endplate to endplate and also through the lateral windows into the cleared-out disc space. Since TiHawk7 expands both in height and in width, it is important to leave space around the TiHawk7 Implant to expand from 7mm to 11mm in width.

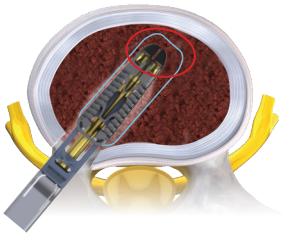
CAUTION: *It is highly advisable to not pre-pack graft. Pre-packed graft can impinge expansion of the Implant. This impingement can result in failure to lock and/or implant fracture. If graft is placed prior to Implant insertion, it is recommended the surgeon utilize either an Impactor, Distractor, or Shaver to clear an 11mm-wide pathway for the Implant.*



Optimal: No Pre-Packed Graft



Pre-Packed Graft

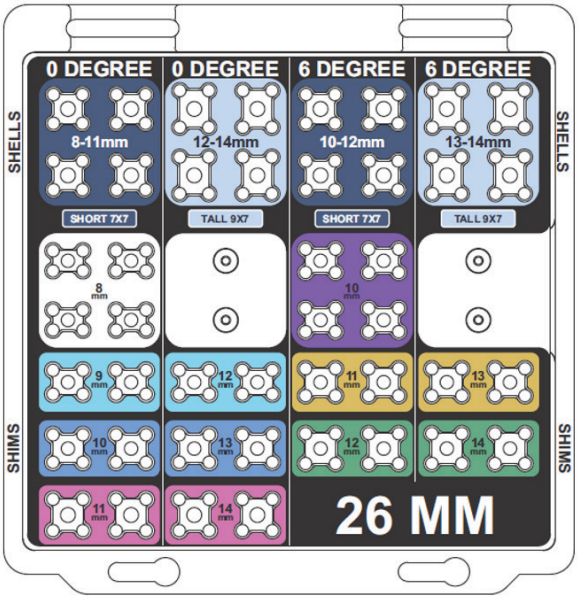


Impinged Expansion

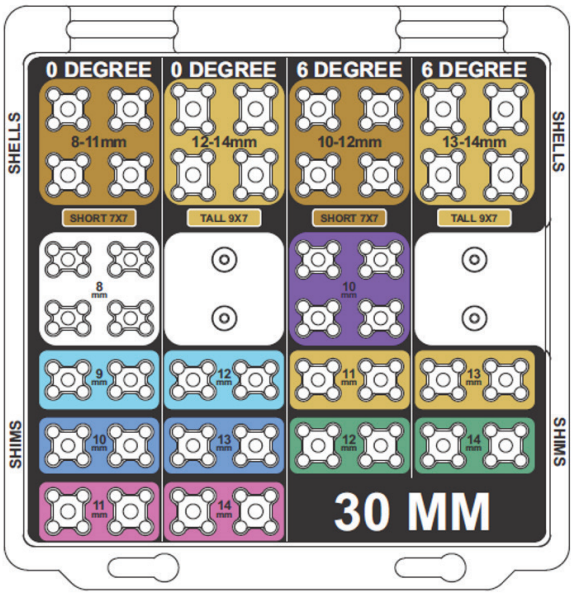
Implant Selection

Once the surgeon determines the desired Implant length, height, and lordosis for the disc space, the appropriate Shim and Shell combination is selected from the Implant Caddy. Tall Shells can only be delivered through the Tall Tubular Retractor and Tall Cannula. The specific selection of the Shim and Shell will achieve the desired height and lordosis upon deployment in the disc space. A deployed TiHawk7 reaches the desired height and lordosis upon lock-out and cannot be stopped short or increased to greater heights than what was selected. If the surgeon desires a different height or lordosis, another Shim and Shell combination must be selected.

The Implant Caddy is designed to guide the scrub tech in selecting the appropriate Implant. There are two caddies, a 26mm Caddy and a 30mm Caddy. Implants from different caddies should never be combined. All Shims and Shells of the same color within the Caddy are the same. Each Caddy has four columns or "lanes" designated by degrees of lordosis and height range. The scrub tech should stay within the same lane when selecting the Shell and Shim. All Shims and Shells are color coded, so if there are Implants missing from a needed section, simply select the same color Shim or Shell to the direct left or right of the color coded empty space.



26mm Caddy



30mm Caddy

EXAMPLE: The surgeon requests a 30mm Length, 12mm Height, 6° Lordosis Implant.

STEP 1

Choose the Implant Caddy that contains the desired Implant length, as indicated by its label plate. In this example, the **30mm Caddy** is selected.

STEP 2

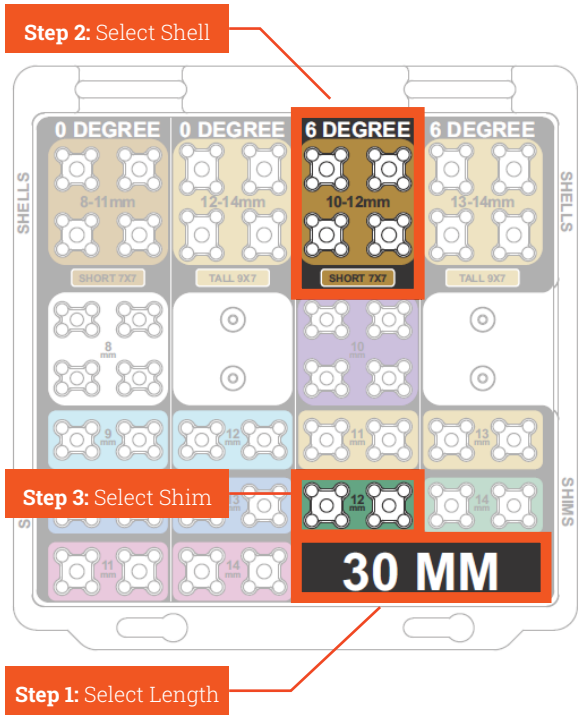
Go to the columns labeled 6 DEGREE and select the Shell located in the section where the height range is listed. In this example, the bronze **Short Shell** is selected since it is found in the bronze 10-12mm section within the corresponding 6 DEGREE column. The color of the

STEP 3

Shell can be seen by looking at the Core. Select the green **12mm Shim** found directly below the selected Shell.

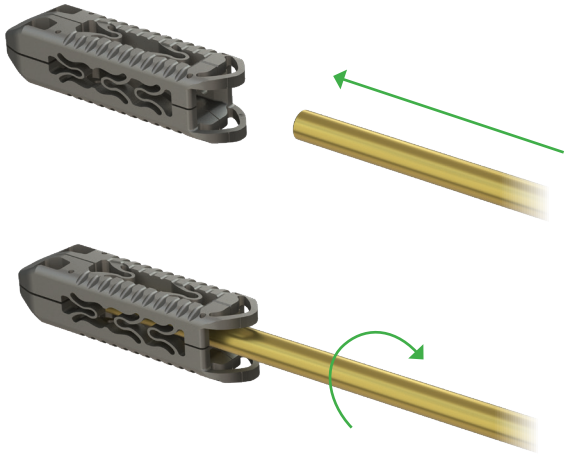
The combination of the 12mm Shim and the Shell found within the 6 DEGREE column will make a 12mm, 6 Degree Implant once fully expanded in the disc space.

TIP: *Staying within the selected lane will ensure the right Implant combination is chosen.*



Inserter Loading

Once the desired Shell and Shim have been selected, perform the following steps:

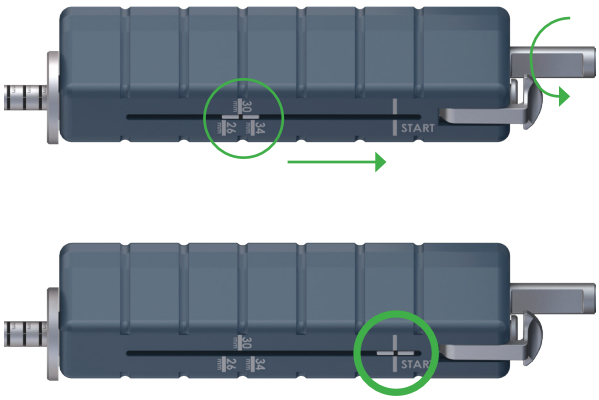


STEP 1

With the Shell still in the Caddy, attach the gold TiHawk7 Guide Pin to the desired Shell. To do this, screw the female thread on the Guide Pin clockwise onto the male thread on the core within the Shell until it is completely tightened and a hard stop is felt.

STEP 2

Before loading the Shim or Shell onto the Inserter, rotate the drive shaft of the Inserter counterclockwise until the indicator tab (indicated by the green circle in the images to the right) is fully bottomed out at the back end of the Inserter in the "Start" position. This will ensure the Guide Pin is properly engaged with the Inserter.



The Inserter has 26mm, 30mm, and 34mm laser markings along the travel of the indicator. When the indicator reaches or has traveled past the designated marking of the selected Implant length during deployment, the Implant should become locked. This indicator does not replace fluoroscopic visualization for lock confirmation.

TIP: *The Inserter must be properly maintained and serviced to ensure optimal performance. Surgical instrument lubricant should be regularly applied to its internal mechanisms.*

TIP: *Guide Pins are single-use only and are not to be re-used. TiHawk7 Guide Pins are colored gold and are not interchangeable with FlareHawk9. Similarly, the FlareHawk7 Inserter is blue and is not interchangeable with FlareHawk9.*

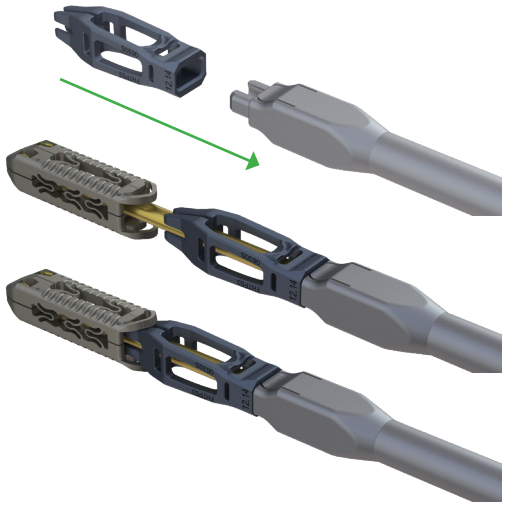
TIP: *Over-tightening the Guide Pin onto the Core can cause the Core to rotate out of place within the Shell. If this occurs, another Shell must be selected.*

STEP 3

With the Shim still in the Caddy, affix the desired Shim to the prongs at the tip of the Inserter and remove the Shim from the Caddy.

STEP 4

Insert the proximal end of the Guide Pin through the cannulated nose of the Shim into the Inserter's central lumen until a **noticeable "click" is heard**. This click confirms the Guide Pin is locked within the Inserter.



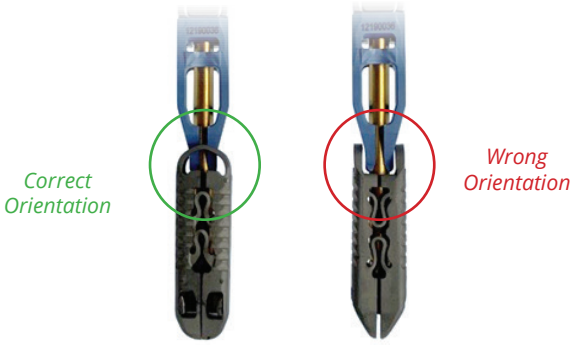
Audible "click" is heard when Guide Pin is locked into the Inserter.

STEP 5

Tug firmly on the Shell to confirm it is locked into the Inserter. If it is not, repeat Step 2 and 4.

STEP 6

Ensure the orientation of the Shell relative to the Shim is correct. In the correct orientation, the Shell's backstraps will point toward the split in the Shim and the flat section of the Inserter's tip, as shown to the right.

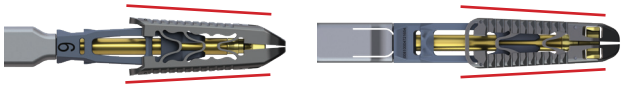


Backstrap points to the split in the Shim

STEP 7

It is important to note that the Shim cannot be advanced as far into the Shell if it is going to be inserted through a Cannula or Tubular Retractor. Advance the Shim to the back of the Shell. If the Shell's backstraps flare, the Implant will likely not fit into the Cannulas or Tubular Retractors. See illustrations to the right. If an extra Tubular Retractor or Cannula is available on the back table, confirm that the Shim and Shell will fit through the Tubular Retractor before adding the Impact Cap and handing to the surgeon.

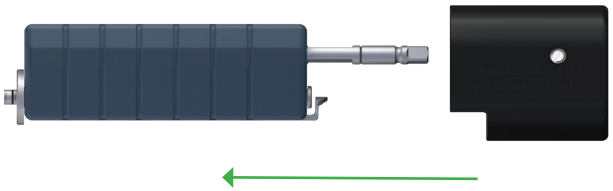
Good engagement for use in cannula or tubular retractor



Too much engagement

Implant Insertion & Deployment

Prior to impaction of the Shim and Shell into the disc space, perform the following steps:



STEP 1

If pre-packing graft, the surgeon must ensure there is sufficient space to allow for the expansion of the Implant to 11mm wide.

STEP 2

Slide the Impaction Cap over the Inserter's drive shaft until it clicks into place.

STEP 3

Verify that the Inserter and Implant are properly aligned, with the Shell's teeth facing the endplates and the body of the Inserter parallel to the endplates. Place the Implant and Inserter down the Cannula or Tubular Retractor.

TIP: *Pre-packing graft without ensuring proper clearance for the Implant to deploy to 11mm wide may cause increased resistance when deploying the Implant.*

STEP 4

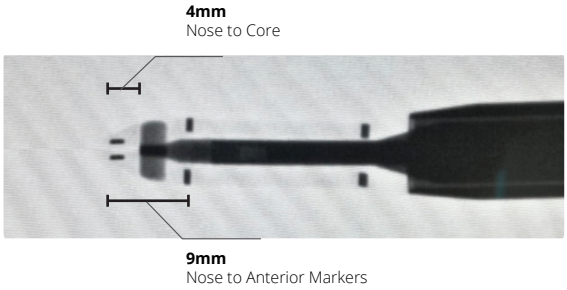
Advance the Shell into the disc space utilizing the palm of the hand to impact on the back of the Impact Cap. Use fluoroscopic guidance to assist with placement and keep in mind the PEEK nose of the Implant is 4mm in front of the titanium Core when viewing the images. There are two tantalum markers in the nose of the Shell that allow for anterior visualization of the implant. If the Shell begins to rotate relative to the Shim, instead of trying to control the Shell with the Inserter, orientate the Inserter and Shim to follow the Shell into the disc space. This will help the Shim and Shell stay in proper orientation for deployment.

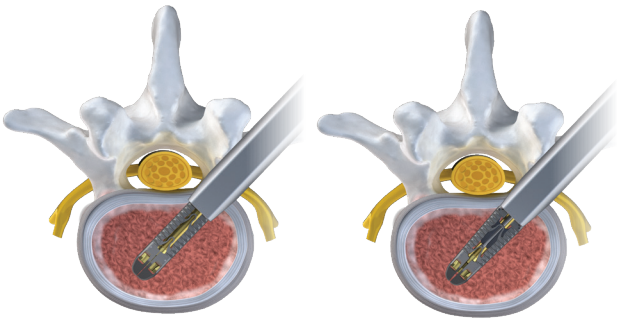
Prior to deployment, be sure the Shell's backstraps have fully cleared the tip of the Tubular Retractor or Cannula. The backstraps extend 5mm posteriorly to the posterior tantalum markers. Failure to do so may result in a non-deployment.

CAUTION: *Impaction with a mallet may be required to fully advance the Shell into the disc space. Once the Shell is fully impacted, do not attempt to manipulate its position, as this may damage the Shell's interface with the Guide Pin.*

TIP: *During insertion and deployment, the surgeon should be mindful of the Inserter's orientation relative to the orientation of the Implant. Maintaining a consistent orientation between the Implant and the Inserter will help guide the Implant along the desired trajectory.*

LATERAL VIEW

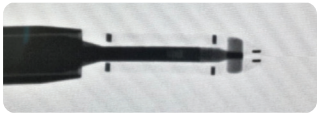


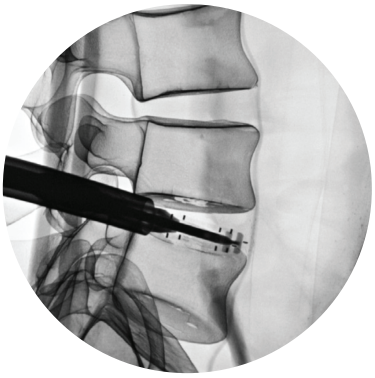


Backstrap Not Cleared

Backstrap Not Cleared

Backstrap Cleared



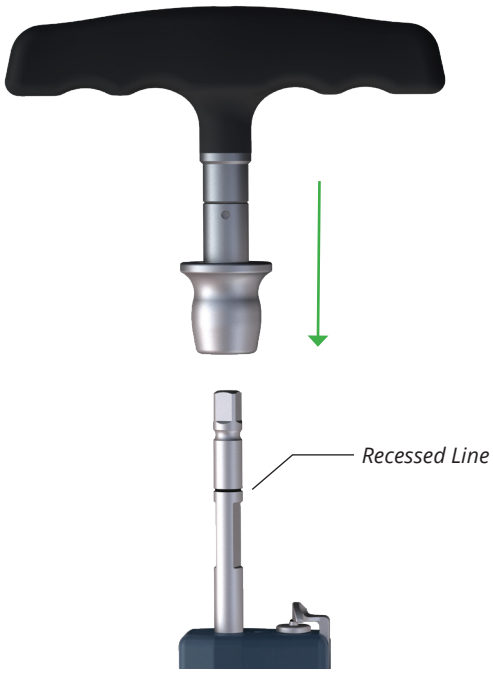


STEP 5

After confirming the appropriate Implant position based on A/P and lateral fluoroscopic images, the T-Handle may be attached. Select the black T-Handle and attach it to the Inserter's drive shaft. Rotate the handle counterclockwise and press down until it is fully engaged (as indicated by alignment with the recessed line on the drive shaft). An audible click alone may not indicate correct T-Handle engagement.

Always ensure the T-Handle is fully engaged with the Inserter before attempting to deploy the Implant. When the T-Handle is correctly seated, the recessed line on the Inserter's drive shaft will line up with the distal end of the T-Handle.

CAUTION: *Do not impact on the Fixed T-Handle, as this may damage the instrument. If mallet use is necessary, always affix the Impaction Cap to the Inserter.*

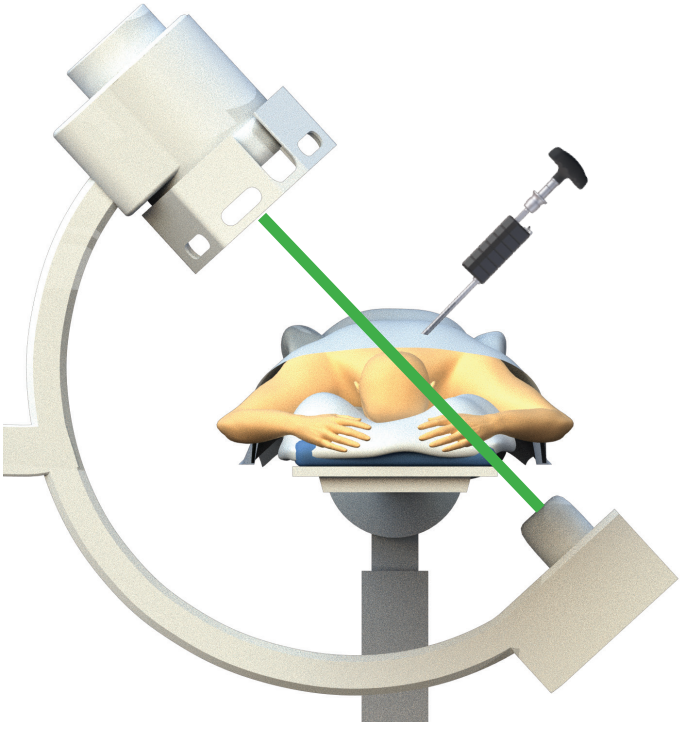


STEP 6

Once the T-Handle is engaged, place the C-arm in the contralateral oblique position for deployment and locking confirmation. With a standard C-arm, position the flat face of the image intensifier parallel to the Inserter (see image below). This will approximate the correct angle for a lateral image of the Implant. If further alignment is needed, the C-arm can be rotated to align with the flats of the Inserter.

Setting up the C-arm in the contralateral oblique orientation will allow the surgeon to view the orientation of the Shim relative to the Shell during deployment as well as confirm the Implant is locked when fully deployed.

TIP: *In order to obtain a direct lateral image, the C-arm must be placed on the opposite side from which the surgeon is performing the surgery.*

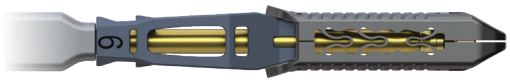


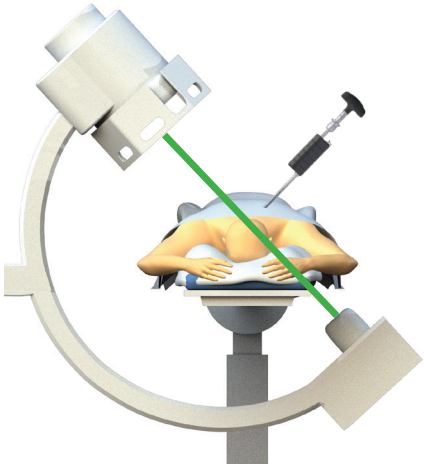
STEP 6 (CONT.)

The Shim's locking fins should be dark and distinct compared to the rest of the Shim. The Shell's eight tantalum markers should be relatively aligned with one another so it appears as though there are four markers. Maintaining this orientation during deployment will help ensure a proper deployment and allow for lock confirmation via fluoroscopy. If the Shim and Shell do not appear to be aligned as in the images to the right, remove the Inserter and Implant and confirm correct orientation of the Shim to the Shell before repositioning the Implant.

It may not be possible to see the Shim features through the Square Cannulas. The Square Cannulas are designed to help maintain Shim and Shell alignment as they are inserted. If the chosen Cannula has a flat surface on the cephalad and caudal sides, the Cannula should appear symmetrical and concise when the Shell's markers are aligned.

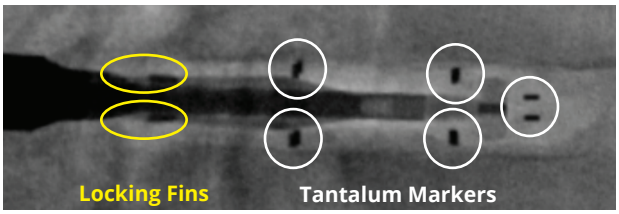
Proper Shim/Shell orientation



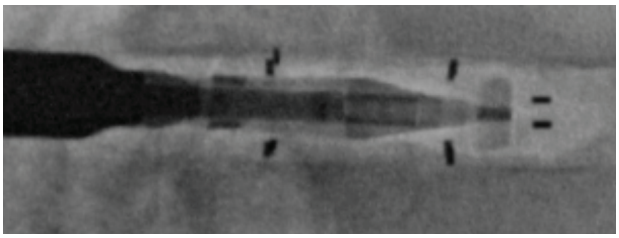


When the C-arm is not in the contralateral oblique position (image to right), the fins on the Shim and the markers in the Shell are not aligned. This makes it difficult to verify the Shim and Shell are aligned properly to ensure deployment will occur.

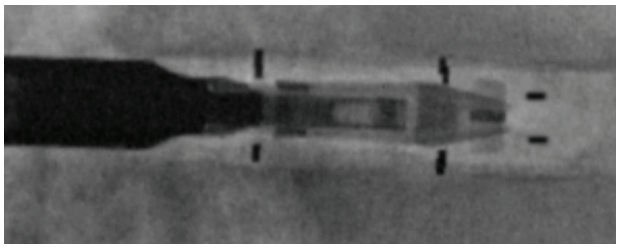
Initial Insertion, Beginning of Deployment



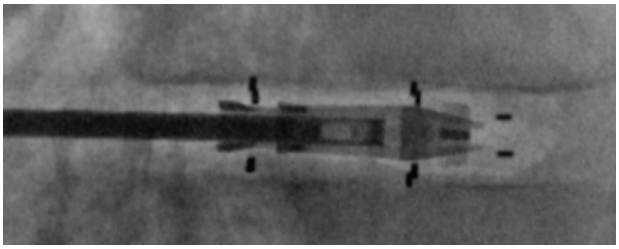
50% Deployment



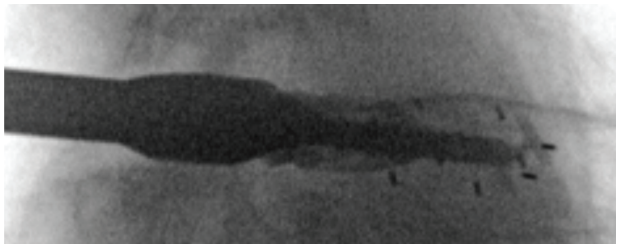
100% Deployment and Locked



Locked with Guide Pin, Inserter Removed

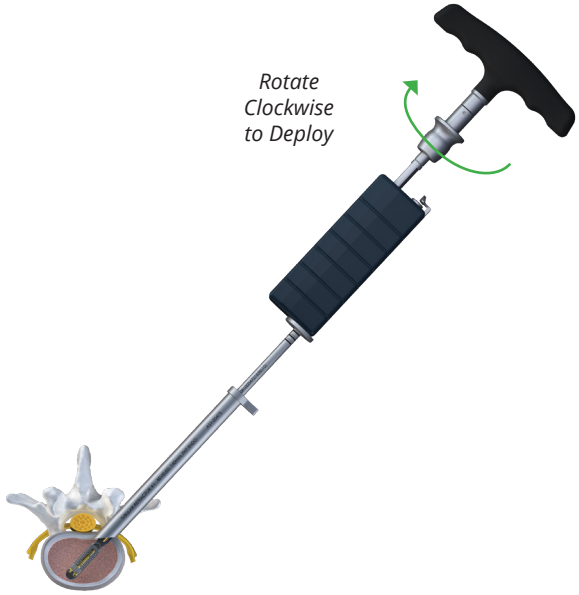


Initial Insertion, C-arm in True Lateral to Spine



STEP 7

To expand the Implant, advance the Shim into the Shell by rotating the T-Handle clockwise until the audible locking click is heard. Once the audible click is heard, the surgeon should use two fingers to rotate the T-Handle gradually until resistance to turning is felt. Confirm Implant placement and trajectory via fluoroscopy during expansion. Once the Shim is locked into the Shell, the T-Handle should not be rotated further and the lock should be confirmed via fluoroscopy as shown on the next page. Alternately, if no audible click is heard and heavy resistance is felt, check the indicator on the side of the Inserter. The indicator should be at or just past the selected length Implant marking if the Implant is locked out. However, the indicator does not replace the need for fluoroscopic visualization of the lock. Failure to limit the advancement of the Inserter in this manner may result in damage to the instrument or Implant. The surgeon should be mindful of the Inserter's orientation while deploying the Implant to avoid unintentionally rotating the Shim relative to the Shell.



Not Deployed *Partially Deployed* *Fully Deployed*

CAUTION: *Once the Shim is locked into the Shell and resistance to turning further is encountered, the T-Handle should not be rotated further. Failure to limit the advancement of the Inserter in this manner may result in damage to the Instrument or Implant, including Guide Pin and Core disassociation.*

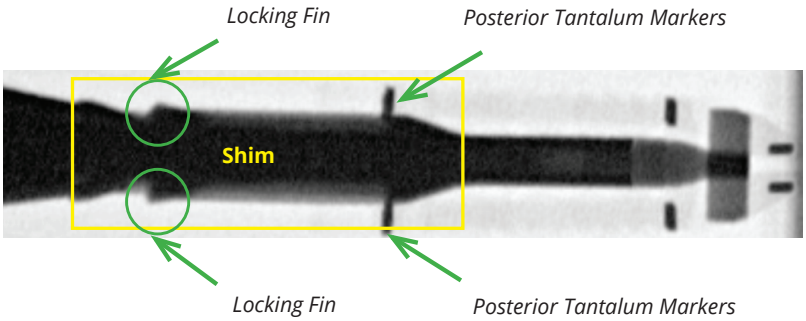
CAUTION: *Attempting to reposition the Implant following deployment is not recommended.*

CAUTION: *An unlocked Implant or Implant without a Shim should never be left in a patient.*

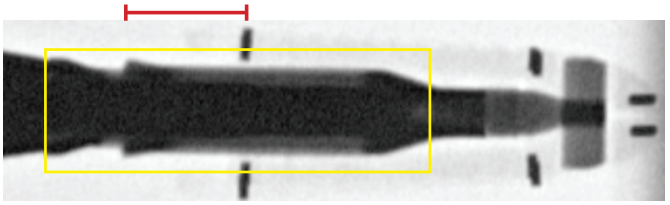
Lock Verification

As the Shim is inserted into the Shell, a tactile and audible click may be heard when the lock engages. This indicates that the Implant is fully deployed. Nevertheless, lock engagement should always be confirmed using fluoroscopy.

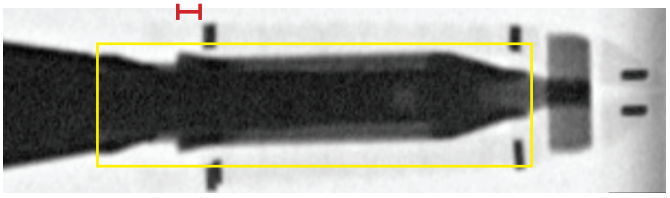
The series of images below show the progression of the Shim advancing into the Shell during deployment under fluoroscopic view. In the images below, the Lock Confirmation Window is blocked by the Inserter tip and Guide Pin. It is important to pay attention to where the Locking Fins are in relation to the Posterior Tantalum Markers. When the Implant is fully deployed and locked, the Locking Fins will be anterior to the Posterior Tantalum Markers.



Not Locked

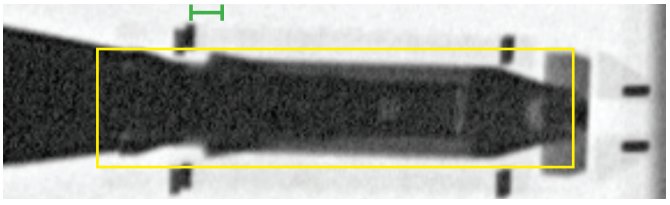


Not Locked



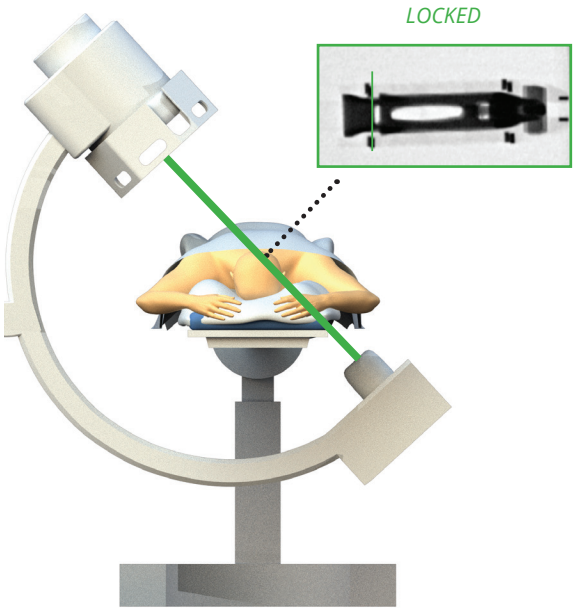
Locked

Locking fins anterior to the posterior tantalum markers.

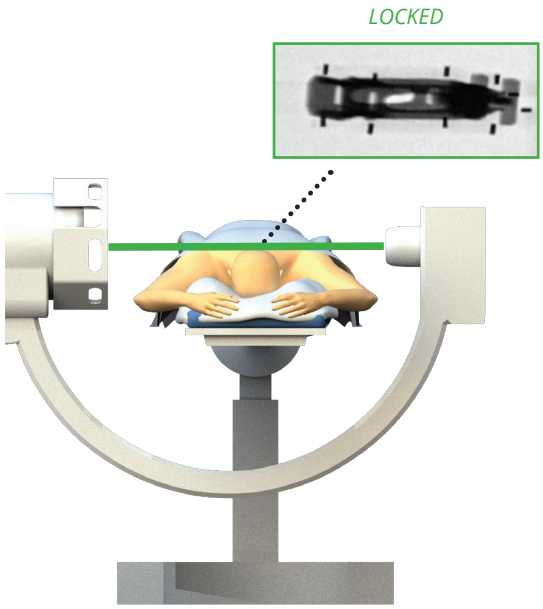


Lock Verification (Continued)

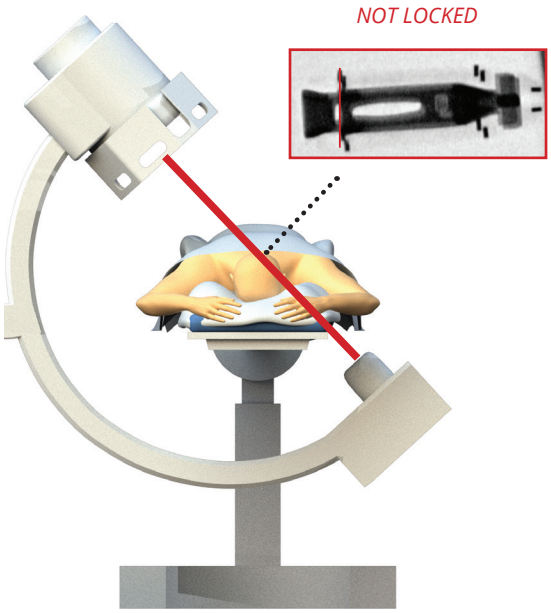
The images below show a deployed Implant after the Inserter and Guide Pin have been removed. A Lock Confirmation Window can be seen at the posterior portion of the Shim. When fluroscopically assessing the lock in this view, note that the posterior tantalum markers are posterior to the Lock Confirmation Window. These images illustrate the importance of taking a contralateral oblique fluoroscopic image of the Implant to confirm it is locked. As seen in the lateral image, it is not always possible to visually confirm the Implant is locked until a contralateral oblique image of the Implant is taken.

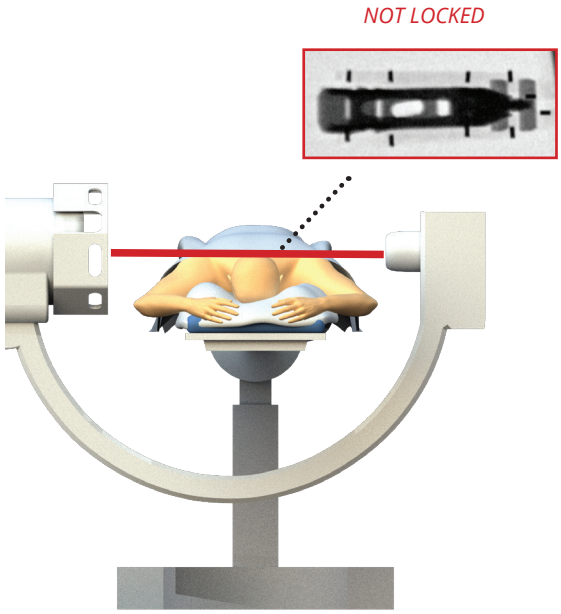


Contralateral Oblique



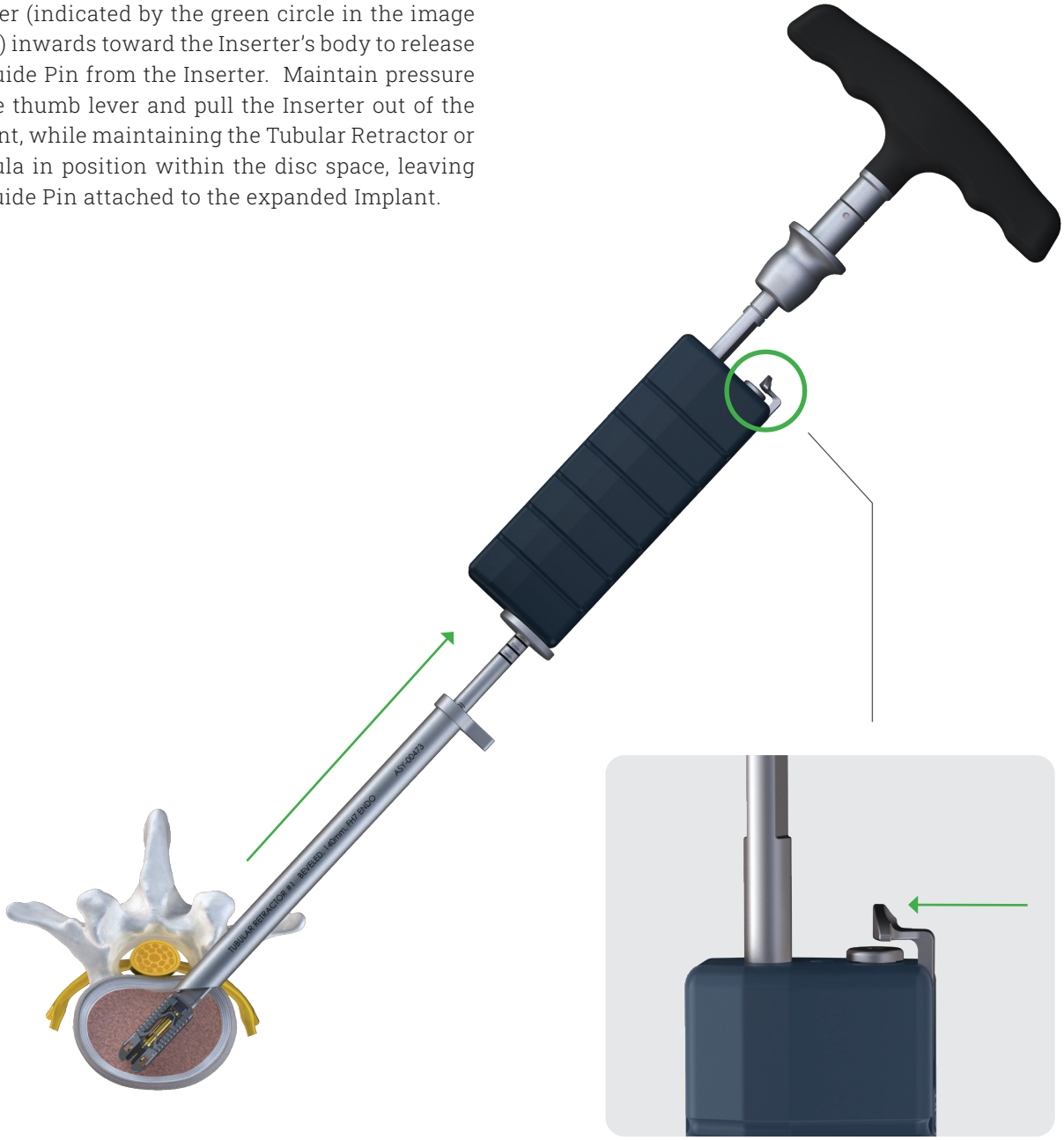
Lateral





Inserter Removal

After Implant lock confirmation, rotate the T-Handle counterclockwise one full turn to release the tension on the Guide Pin. Disconnect the Inserter from the Guide Pin by pushing the thumb lever on the Inserter (indicated by the green circle in the image below) inwards toward the Inserter's body to release the Guide Pin from the Inserter. Maintain pressure on the thumb lever and pull the Inserter out of the Implant, while maintaining the Tubular Retractor or Cannula in position within the disc space, leaving the Guide Pin attached to the expanded Implant.



Depress Guide Pin release button to remove Inserter

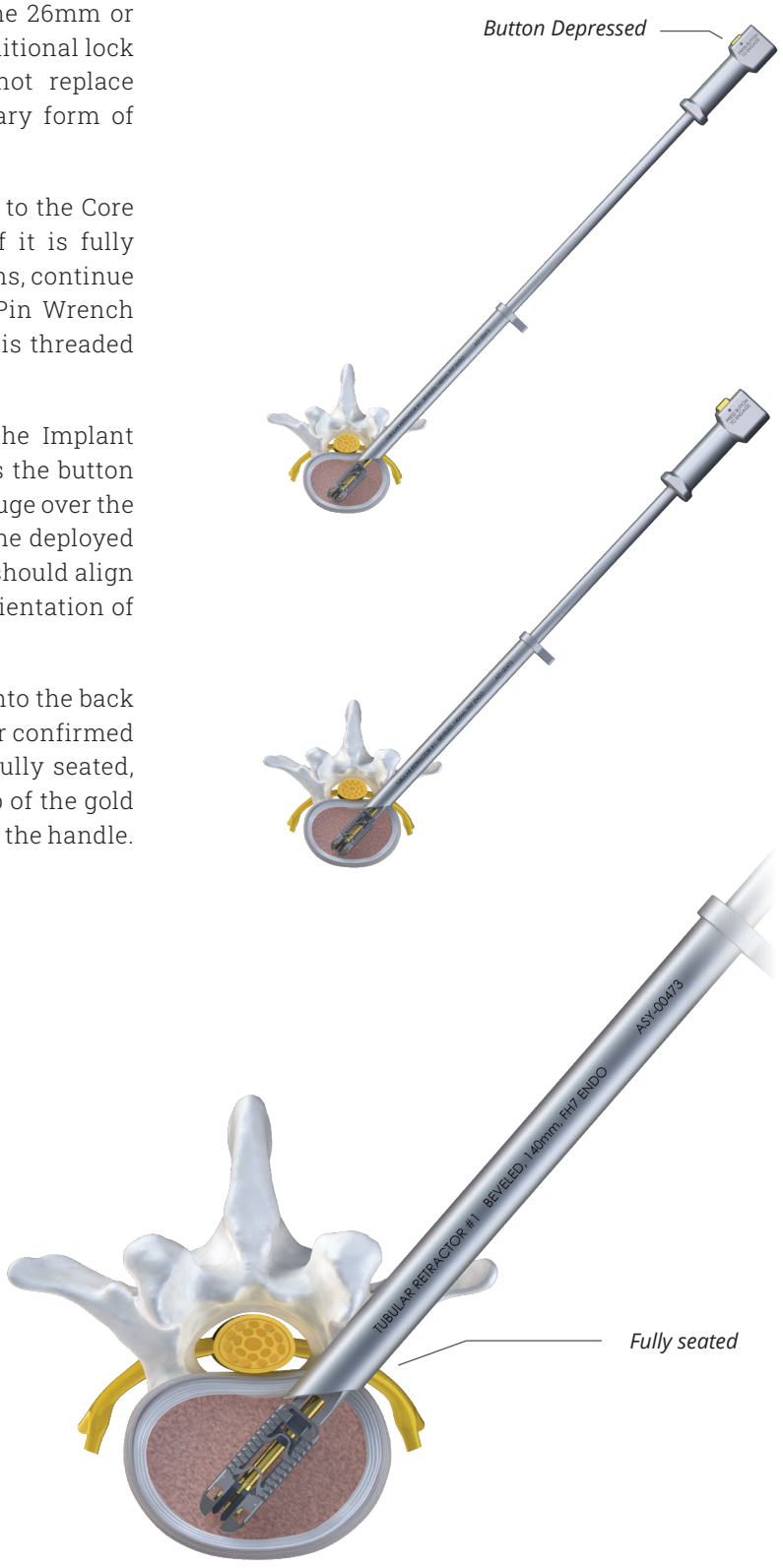
Lock Gauge

After the Inserter has been removed, the 26mm or 30mm Lock Gauge can be utilized as additional lock confirmation. This instrument does not replace fluoroscopic visualization as the primary form of lock confirmation.

Confirm the Guide Pin is fully threaded to the Core by turning the Guide Pin clockwise. If it is fully seated no turning will occur, but, if it turns, continue turning until a stop is felt. The Guide Pin Wrench can be utilized to ensure the Guide Pin is threaded to the Core.

Select the Lock Gauge that matches the Implant length that was deployed. Fully depress the button on the proximal end while sliding the gauge over the Guide Pin into the back of the Shim of the deployed Implant. The flats of the tip and handle should align with the flats of the endplate and the orientation of the deployed Implant.

The Lock Gauge should be fully seated into the back of the Shim. This may be seen visually or confirmed fluoroscopically. If the Lock Gauge is fully seated, the surgeon should be able to see the tip of the gold Guide Pin through the hole in the back of the handle.



Lock Gauge (Continued)

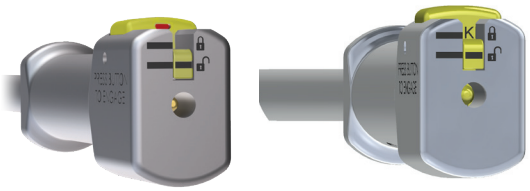
If the surgeon cannot see the tip of the Guide Pin in the hole, the Lock Gauge is not fully seated.

Once fully seated, release the button on the Lock Gauge. If the Implant is locked, the laser mark on the button should align with the lock symbol. Depending on which version of the Lock Gauge is in the set, green marks should appear on button when it is locked, or the word "LOCKED" will be visible on the button when it is locked. If the Implant is not locked, the laser mark on the button should align with the unlocked symbol.

Once locking is confirmed, fully depress the button and slide the Lock Gauge off the Guide Pin.

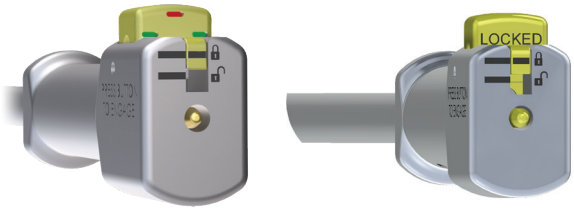
If the Implant is not locked, remove the Lock Gauge by fully depressing the button and sliding the Lock Gauge off the Guide Pin. Re-attach the Inserter to the Implant and Guide Pin to finish the deployment. If the Implant still does not lock, utilize the removal tools to remove the Implant. After removal another Implant can be selected.

TIP: *Starting at Step 2, follow the instructions on page 28 to re-attach the Inserter to the Guide Pin.*



NEWER VERSION

Implant Unlocked



NEWER VERSION

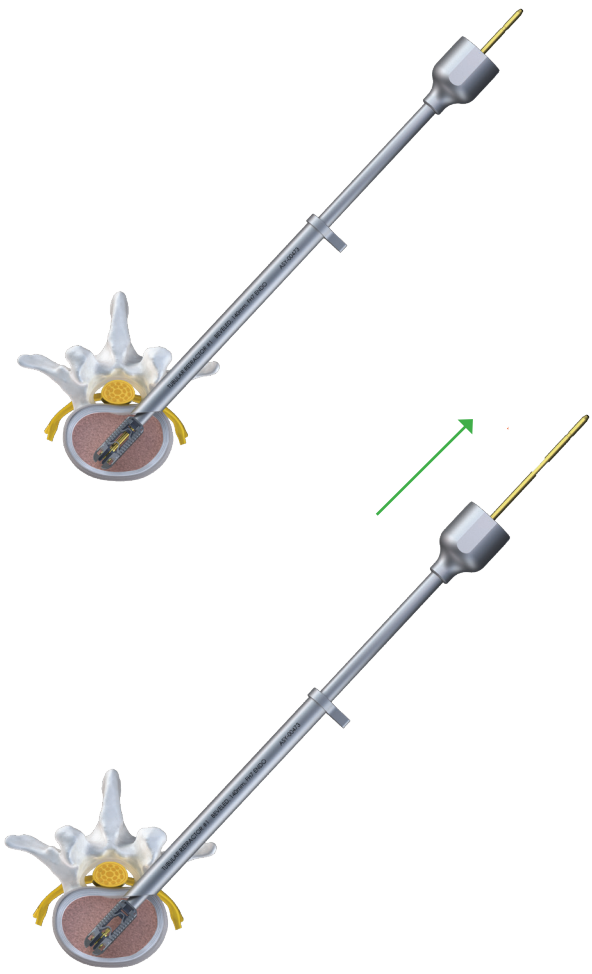
Implant Locked

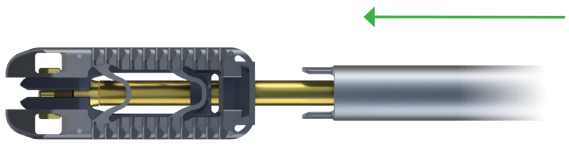
Bone Funnel Preparation

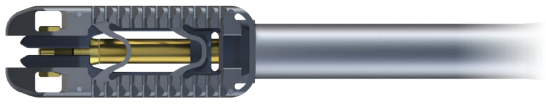
To place the Bone Funnel, slide it over the Guide Pin until the tip of the Bone Funnel engages with the posterior window of the Shim. Ensure that the two prongs at the Bone Funnel's tip are correctly seated in the posterior aperture of the Implant. Keep the Bone Funnel engaged throughout the graft delivery process by maintaining consistent downward pressure.

Unscrew and remove the Guide Pin by rotating it counterclockwise. This may be done using the Guide Pin Wrench or by hand. Once the Guide Pin has been removed, fill the Bone Funnel with autograft and/or allograft. To reduce the chance of clogging, ensure the bone graft is adequately morselized. All particles should be 3mm in size or smaller.

Alternately, the Bone Funnel may be preloaded and placed freehand if the Guide Pin is removed beforehand. Please note that Bone Funnel should be loaded as close to the time of usage as possible to avoid solidification or drying of the bone graft within it.







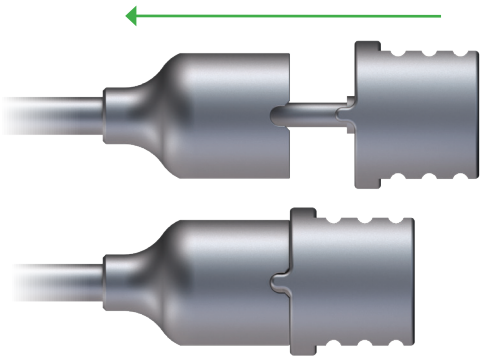
Bone Graft Delivery

Using the Bone Tamp, push the bone graft through the Bone Funnel into the deployed TiHawk7 Implant while maintaining consistent downward pressure on the Bone Funnel. Continue to advance the Tamp until all graft in the Bone Funnel is delivered. If the Tamp will not advance, discontinue impaction and remove the Tamp. It is not recommended to use a mallet on the Tamp.

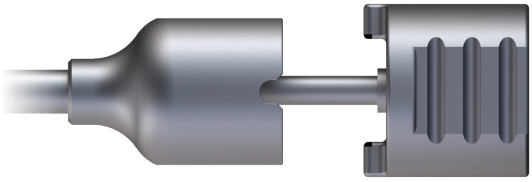
Repeat the Bone Funnel Preparation and Bone Graft Delivery steps as many times as needed, until the Implant is sufficiently packed with allograft and/or autograft.

Ensure all graft material is safely within the disc space before removing the Cannula or Tubular Retractor.

CAUTION: *If the Bone Tamp will not advance through the Bone Funnel, do not attempt to impact it with a mallet, as this may damage or advance the Implant.*



Correct Alignment



Incorrect Alignment

GRAFT DELIVERY PROCESS *Images for illustration purposes only.*

Bone Graft Delivery With Repeaters

The Repeater Bone Funnel system consists of three components: Bone Funnel, Bone Funnel Crucible, and Bone Tamp.

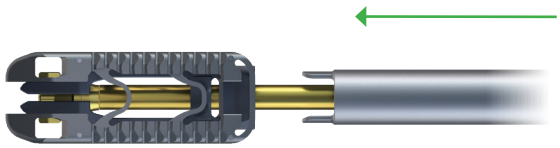
STEP 1

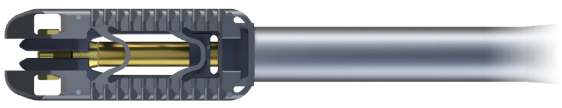
On the back table, load the desired number of Crucibles with bone graft, just as you would with a standard Bone Funnel. Each Crucible holds approximately 2cc of bone graft. Ensure the allograft and/or autograft is appropriately morselized (all particles should be less than 3mm in size) to reduce the chance of clogging. Please note that the Crucibles should be pre-loaded as close to the time of usage as practicable to avoid binding or drying of the bone graft inside the Crucible.

STEP 2

Dock the tip of the Bone Funnel in situ into the graft window of the deployed Implant. Ensure that the two prongs at the Bone Funnel's tip are correctly seated in the posterior aperture of the Implant.

If desired, the Bone Funnel can be passed over the Guide Pin while the Guide Pin is still attached to the deployed Implant. If this is done, the Guide Pin must be removed before the Crucible is used. Alternatively, the Bone Funnel can be placed freehand following removal of the Guide Pin.



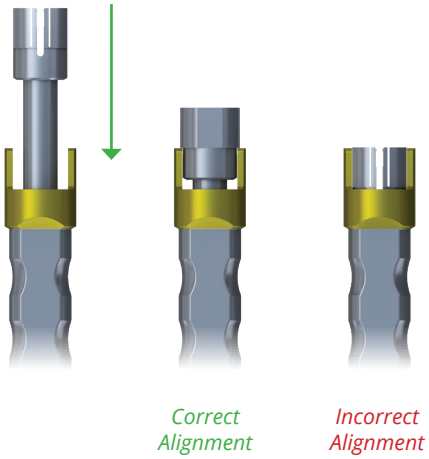


STEP 3

Insert one pre-loaded Crucible into the top section of the Bone Funnel. Ensure that the Crucible is properly seated in the Funnel. When properly placed, the Crucible will be completely flush with the top of the Funnel.

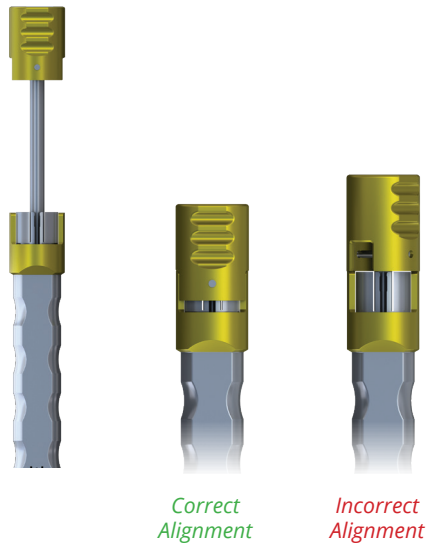
STEP 4

Using the Bone Tamp, push the bone graft in the Repeater through the Funnel and into the deployed Implant. Continue to advance the Tamp until it clicks into the top of the Repeater. To do this, the Tamp and Repeater must be properly aligned.



STEP 5

Once the Tamp is completely advanced and the Repeater is empty, remove the Tamp from the Funnel. The Tamp will automatically retain and remove the Repeater. Once the Tamp is completely removed, detach the empty Repeater from the Tamp.

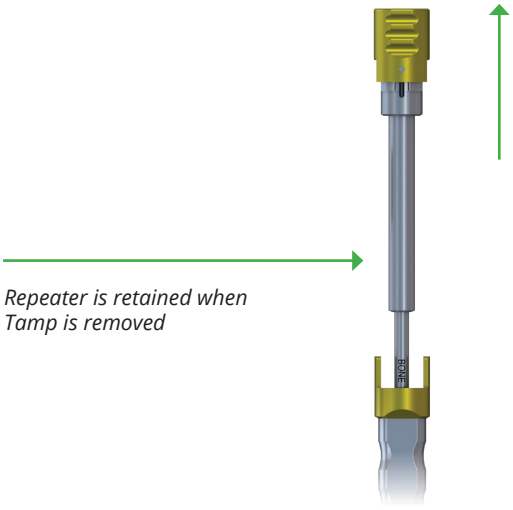


STEP 6

Repeat steps 3 through 5 as many times as needed until the Implant is sufficiently packed with bone graft. Empty Repeaters may be reloaded and used as needed. Once allograft and/or autograft delivery is complete, remove the Bone Funnel and Bone Tamp.

Ensure all graft material is safely within the disc space before removing the Cannula or Tubular Retractor.

The Cannula Plunger or the Short Obturator may be used to push any remaining graft within the Cannula into the disc space.



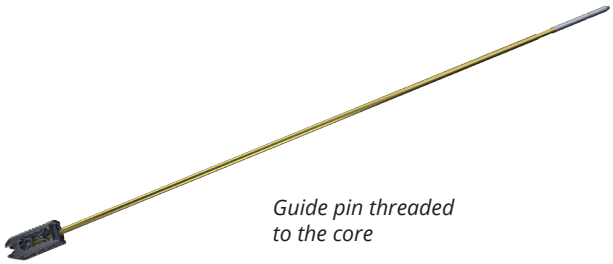
TIPS: *The Repeater, Bone Funnel, and Bone Tamp are not disposable. The TiHawk7 and Bone Tamp are not interchangeable with FlareHawk9 or TiHawk9.*

STEP 1

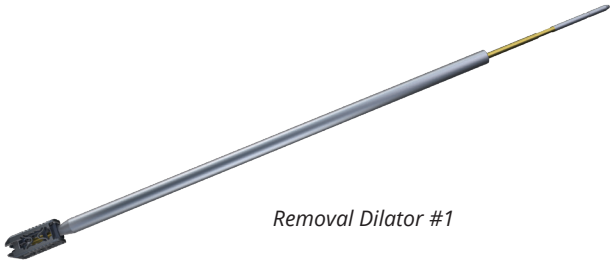
Ensure Guide Pin is threaded onto the Core or inside the deployed Implant.

Slide Removal Dilator #1 over the Guide Pin until it bottoms out at the back of the Implant. Use fluoroscopy to confirm placement. Remove the Cannula or Tubular Retractor from the surgical field. Slide Removal Dilator #2 over Dilator #1 until the Dilator has reached the back of the Implant and confirm with fluoroscopy.

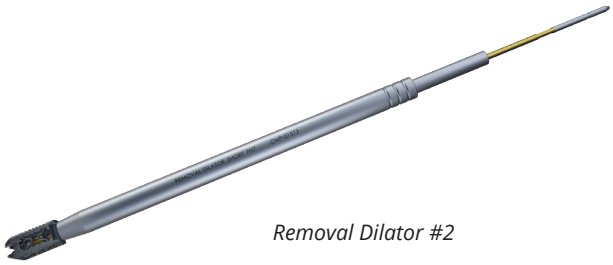
Slide the Removal Tube with the prongs and handle inline with the disc space over Dilator #2. The prongs of the Tube should enter the disc space medial and lateral to the cage. If needed, use a mallet to gently advance the Removal Tube around the cage so prongs are around the sides of the Shell. Confirm placement with fluoroscopy. Once in position, remove the Guide Pin from the Implant and remove Dilators #1 and #2.



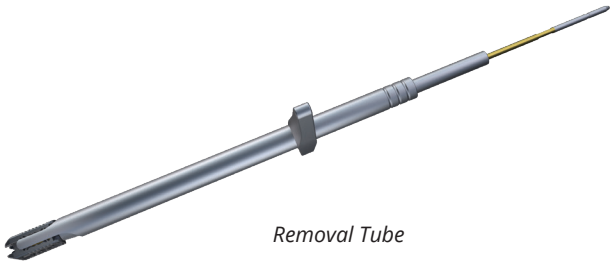
Guide pin threaded to the core



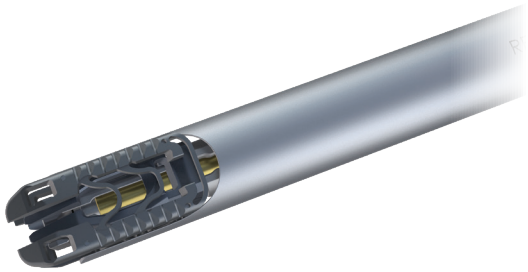
Removal Dilator #1



Removal Dilator #2



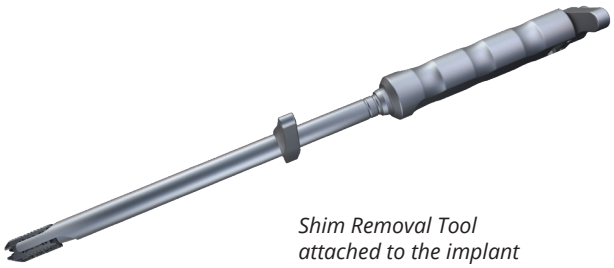
Removal Tube



Axial view of removal tube prongs surrounding the implant

STEP 2

To use the Shim Removal Tool, rotate the proximal knob on the Shim Removal Tool counterclockwise until the lock indicator on its shaft is in the "LOCKED" position. Orient the flats of the instrument handle parallel with the disc space and insert the instrument tip into the back of the Shim until its tip is completely within the Implant and a stop is felt. Using fluoroscopy, confirm that the tip of the instrument is completely seated within the Implant. There will be a small gap between the back of a 26mm Shim and the base of the Shim Removal Tool shaft. The base of the Shim Removal Tool shaft will be flush against the back of 30mm Shim when properly engaged.



Shim Removal Tool attached to the implant

Shim Unlocked Position

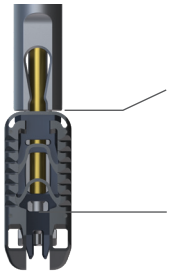
Shim Locked Position

STEP 3

While maintaining downward pressure on the Shim Removal Tool, rotate its proximal knob clockwise until the lock indicator on the shaft reaches the "UNLOCKED" position. This will disengage the Shim's Anterior Lock.

STEP 4

While maintaining downward pressure on the Removal Tube, carefully pull upward on the Shim Removal Tool to remove the Shim from the Shell. Monitor the Implant fluoroscopically to verify the position of the Shim and Shell during removal. Alternately, the Slap Hammer may be affixed to the Shim Removal Tool and used to assist with Shim removal. This may help overcome the Posterior Lock.



There will be a small gap between the back of a 26mm Implant and the base of the Shim Removal Tool shaft.

Stop is felt when instrument abuts the core.

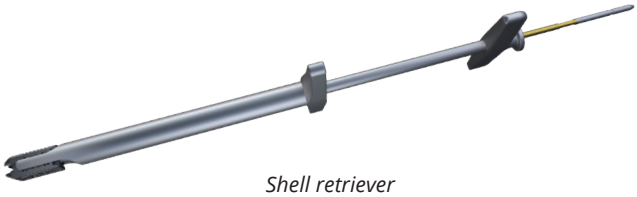
CAUTION: *Never re-use a Shim, Shell, or Guide Pin.*

TIPS: *The interface between the Shim Removal Tool and Slap Hammer should be grasped firmly during use to ensure a consistent connection between the two instruments is maintained.*

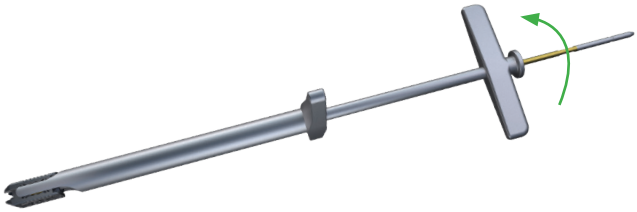
TIPS: *Removal of the Shim from the Implant assembly for any reason requires removal of the Shell and replacement with a new Shell.*

STEP 5

Once the Shim is removed, reattach the Guide Pin to the Shell and slide the Shell Retriever over the Guide Pin into the Shell. If it is not possible to reconnect the Guide Pin, insert the Shell Retriever into the Shell until a hard stop is felt. The flats of the Shell Retriever tip should be parallel with the flats of the Shell and endplates. The Shell Retriever should be inserted as deep into the Shell as possible without advancing the Shell out of the Removal Tube prongs. Confirm with fluoroscopy. Rotate the Shell Retriever 90º to grab the flexors of the Shell.



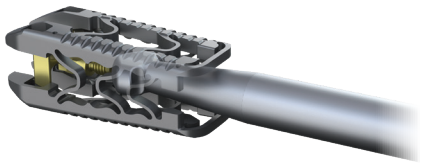
Shell retriever inserted into shell



Shell retriever turned 90 degrees to grab the flexors of the implant

STEP 6

If possible, pull the Shell farther into the Removal Tube by pulling up on the Shell Retriever and Guide Pin while maintaining light downward pressure on the Removal Tube. Confirm with fluoroscopy that the Shell is corralled within the Removal Tube. Maintaining alignment between the Removal Tube and the Shell Retriever, simultaneously pull the instruments out of the disc space. If desired, the Slap Hammer may be used. Monitor the Shell's progress visually to verify that removal is effective.



Shell retriever fully seated in shell

Rotate instrument 90º to grab flexors

NON-STERILE IMPLANTS

Part Numbers	Description
FHTPCS0026C	Shell, Short 26mm, FlareHawk7
FHTPCT0026C	Shell, Tall 26mm, FlareHawk7
FHTPCS0026TT	Shell, Short 26mm, TiHawk7
FHTPCT0026TT	Shell, Tall 26mm, TiHawk7
FHTPS20026S	Shim, 8mm or 11mm x 26mm, 0 Degree, FlareHawk7
FHTPS30026S	Shim, 9mm or 12mm x 26mm, 0 Degree, FlareHawk7
FHTPS40026S	Shim, 10mm or 13mm x 26mm, 0 Degree, FlareHawk7
FHTPS50026S	Shim, 11mm or 14mm x 26mm, 0 Degree, FlareHawk7
FHTPS10626S	Shim, 10mm or 12mm x 26mm, 6 Degree, FlareHawk7
FHTPS20626S	Shim, 11mm or 13mm x 26mm, 6 Degree, FlareHawk7
FHTPS30626S	Shim, 12mm or 14mm x 26mm, 6 Degree, FlareHawk7
FHTPCS0030C	Shell, Short 30mm, FlareHawk7
FHTPCT0030C	Shell, Tall 30mm, FlareHawk7
FHTPCS0030TT	Shell, Short 30mm, TiH7
FHTPCT0030TT	Shell, Tall 30mm, TiH7
FHTPS20030S	Shim, 8mm or 11mm x 30mm, 0 Degree, FlareHawk7
FHTPS30030S	Shim, 9mm or 12mm x 30mm, 0 Degree, FlareHawk7
FHTPS40030S	Shim, 10mm or 13mm x 30mm, 0 Degree, FlareHawk7
FHTPS50030S	Shim, 11mm or 14mm x 30mm, 0 Degree, FlareHawk7
FHTPS10630S	Shim, 10mm or 12mm x 30mm, 6 Degree, FlareHawk7
FHTPS20630S	Shim, 11mm or 13mm x 30mm, 6 Degree, FlareHawk7
FHTPS30630S	Shim, 12mm or 14mm x 30mm, 6 Degree, FlareHawk7

STERILE IMPLANTS

Part Numbers	Description
FHTPS200267S	Shim, 8mm or 11mm x 26mm, 0 Degree, FH7 Sterile
FHTPS300267S	Shim, 9mm or 12mm x 26mm, 0 Degree, FH7 Sterile
FHTPS400267S	Shim, 10mm or 13mm x 26mm, 0 Degree, FH7 Sterile
FHTPS500267S	Shim, 11mm or 14mm x 26mm, 0 Degree, FH7 Sterile
FHTPS106267S	Shim, 10mm or 12mm x 26mm, 6 Degree, FH7 Sterile
FHTPS206267S	Shim, 11mm or 13mm x 26mm, 6 Degree, FH7 Sterile
FHTPS306267S	Shim, 12mm or 14mm x 26mm, 6 Degree, FH7 Sterile
FHTPCS0026TTS	Shell, Short 26mm, TH7 Sterile
FHTPCT0026TTS	Shell, Tall 26mm, TH7 Sterile
FHTPS200307S	Shim, 8mm or 11mm x 30mm, 0 Degree, FH7 Sterile
FHTPS300307S	Shim, 9mm or 12mm x 30mm, 0 Degree, FH7 Sterile
FHTPS400307S	Shim, 10mm or 13mm x 30mm, 0 Degree, FH7 Sterile
FHTPS500307S	Shim, 11mm or 14mm x 30mm, 0 Degree, FH7 Sterile
FHTPS106307S	Shim, 10mm or 12mm x 30mm, 6 Degree, FH7 Sterile
FHTPS206307S	Shim, 11mm or 13mm x 30mm, 6 Degree, FH7 Sterile
FHTPS306307S	Shim, 12mm or 14mm x 30mm, 6 Degree, FH7 Sterile
FHTPCS0030TTS	Shell, Short 30mm, TH7 Sterile
FHTPCT0030TTS	Shell, Tall 30mm, TH7 Sterile

DISPOSABLES

Part Numbers	Description
FHTPGP1A	Guide Pin, FH7
FHTPKW1	K-Wire, Blunt Tip, FH7 MIS
FTHPKW2	K Wire, Trocar Tip, FH7 MIS
ASY-00257	Expandable Shaver, Blade, FH7
NP003-1	Monopolar Neuromonitoring Probe with Exchange Tube, 210mm
FHTPWB1	Wire Brush, 6.5mm, FlareHawk7, Sterile, 2-Pack
FHTPWB3	Wire Brush, 7.5mm, FlareHawk7, Sterile, 2-Pack
FHTPWB4	Wire Brush, 9.5mm, FlareHawk7, Sterile, 2-Pack
FHTPWB4	Wire Brush, 9.5mm, FlareHawk7, Sterile, 2-Pack

INSTRUMENTS

Part Numbers	Description
CMP-01431	Dilator Impactor, FH7 ENDO
ASY-00473	Tubular Retractor #1 - Beveled, 140mm, FH7 ENDO
ASY-00474	Tubular Retractor #2 - Beaked, 140mm, FH7 ENDO
ASY-00476	Tubular Retractor #3 - Beveled, 140mm, FH7 ENDO
ASY-00501	Tubular Retractor #1 - Beveled, 170mm, FH7 ENDO [Special Order Only]
ASY-00502	Tubular Retractor #2 - Beaked, 170mm, FH7 ENDO [Special Order Only]
ASY-00503	Tubular Retractor #3 - Beveled, 170mm, FH7 ENDO [Special Order Only]
CMP-01345	7mm Shaver, FH7 ENDO
CMP-01346	8mm Shaver, FH7 ENDO
CMP-01347	9mm Shaver, FH7 ENDO
ASY-00564	Small Ring Curette, FH7 ENDO
ASY-00584	Medium Ring Curette, FH7 ENDO
ASY-00571	Large Ring Curette, FH7 ENDO
ASY-00569	Inline Handle, Mini AO, FH7
ASY-00113	0° Expandable Trial, FH7
CMP-00480	Dilator Impactor, FH7 MIS
CMP-01449	Dilator Remover, FH7 MIS
ASY-00481	Dilator Handle, FH7 MIS
CMP-01336	1 Step Dilator, Short, FH7 MIS
CMP-00422	Dilator 1, FH7 MIS
CMP-00423	Dilator 2, Short, FH7 MIS
ASY-00116	Cannula #1 - Short, Square, 200mm, FH7 MIS
ASY-00138	Cannula #2 - Short, Round, 200mm, FH7 MIS
ASY-00483	Cannula #3 - Short, Flat, 200mm, FH7 MIS
CMP-00484	Suction Tube, FH7 MIS
ASY-00768	Tubular Retractor, Tall – Scoop Tip, 140mm, FH7 ENDO
CMP-01983	Tall Dilator, FH7 Endo
CMP-01984	Dilator 2, FH7 Endo
ASY-00764	Cannula #3- Short, Flat, 140mm, FH7 MIS
CMP-02003	6mm Distractor, FH7
CMP-02035	Cannula Plunger, Short, 200mm, FH7
ASY-00721	Tubular Retractor - Scoop Tip, 140mm, FH7 ENDO
ASY-00723	Tubular Retractor - Scoop Tip, 170mm, FH7 ENDO
CMP-01984	Dilator 2, FH7 ENDO
CMP-00424	Dilator 2, Tall, FlareHawk 7 MIS
ASY-00482	Cannula #3 - Tall, Flat, 200mm MIS

Catalog (Continued)

CASES, TRAYS, AND CADDIES

Part Numbers	Description
ASY-00579	Implant Delivery/Access Case, FH7
ASY-00580	Implant Insertion Tray, FH7
ASY-00367	FH7 26mm Caddy
ASY-00368	FH7 30mm Caddy
ASY-00581	ENDO Access Tray, FH7
ASY-00582	MIS Access Tray, FH7
ASY-00480	MIS Instrument Case, FH7
ASY-00521	MIS Disc Prep Tray, FH7
ASY-00522	General Instrument Tray, FH7
ASY-00523	Ancillary Instrument Tray, FH7
ASY-00653	Expandable Trial Insert Tray, FH7
ASY-00823	Universal Access Tray, FH7

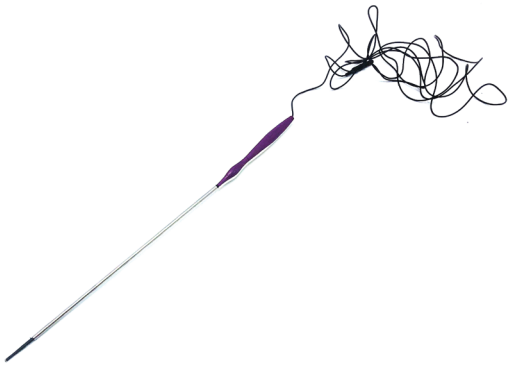
STANDARD INSTRUMENTS

Part Numbers	Description
ASY-00120	Insertion Instrument, FH7
II-1-0015	Guide Pin Wrench
II-1-0045	Impact Cap
II-1-0372	Backup Fixed T-Handle
II-1-0328	Fixed Hudson T-Handle
ASY-00145	Disc Drill, 6.5mm, FH7
ASY-00491	Disc Drill, 7.5mm, FH7
ASY-00147	Pituitary, Straight 3mm, FH7
ASY-00149	Articulating Curette, FH7
ASY-00256	Expandable Shaver, FH7
CMP-01024	Small Tear Drop Handle
ASY-00153	Obturator Impactor, Short, FH7
ASY-00418	26mm Lock Gauge, FH7
ASY-00422	30mm Lock Gauge, FH7
ASY-00133	Repeater Bone Funnel, FH7
ASY-00132	Repeater Bone Funnel Tamp, FH7
II-1-0434	Bone Funnel Crucible
ASY-00122	Bone Funnel, FH7
ASY-00121	Bone Funnel Tamp, FH7
II-1-0005	Slap Hammer
ASY-00409	Shim Removal Tool, FH7
ASY-00255	Shell Retriever, FH7
CMP-01512	Removal Dilator 1, FH7
CMP-01513	Removal Dilator 2, Short, FH7
CMP-01515	Removal Tube, Short, FH7
ASY-00479	Wire Brush Crimp Tool

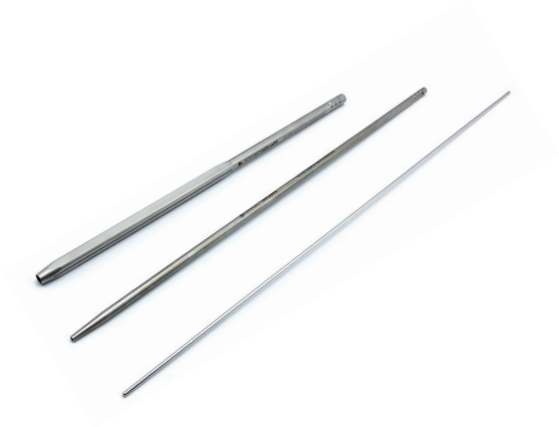
LABELING

Part Numbers	Description
1-IFU-0150	Instructions for Use

Instrument Catalog



NP003-1	Monopolar Neuromonitoring Probe with Exchange Tube, 210mm



FHTPKW1	K-Wire, Blunt Tip, FH7 MIS
CMP-00422	Dilator 1, FlareHawk7 MIS
CMP-00423	Dilator 2, Short, FlareHawk7 MIS

ASY-00116	Cannula #1 - Short, Square, 200mm, FH7 MIS
ASY-00138	Cannula #2 - Short, Round, 200mm, FH7 MIS
ASY-00483	Cannula #3 - Short, Flat, 200mm, FH7 MIS
ASY-00764	Cannula #3 - Short, Flat, 140mm, FH7 MIS

ASY-00473	Tubular Retractor #1 - Beveled, 140mm, FH7 ENDO
ASY-00474	Tubular Retractor #2 - Beaked, 140mm, FH7 ENDO
ASY-00476	Tubular Retractor #3 - Beveled, 140mm, FH7 ENDO
ASY-00721	Tubular Retractor - Scoop Tip, 140mm, FH7 ENDO

Instrument Catalog

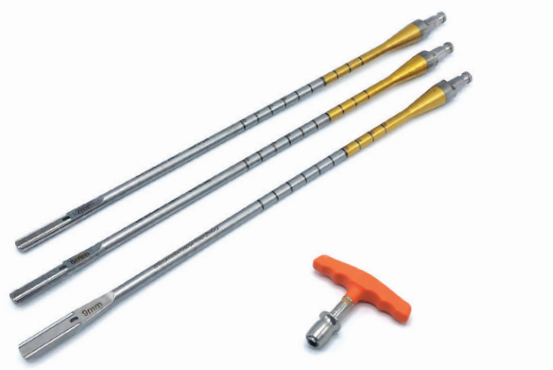
ASY-00147	Pituitary, Straight 3mm, FH7

CMP-01431	Dilator Impactor, FH7 ENDO

II-1-0328	Fixed Hudson T-Handle

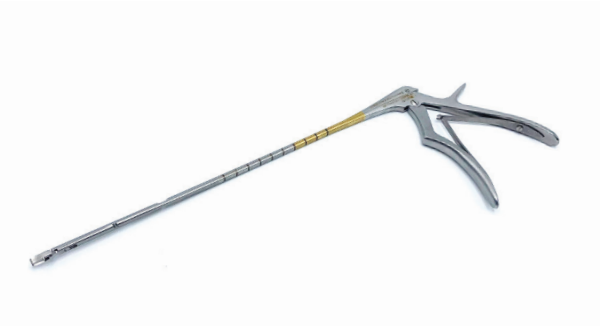
II-1-0372	Fixed T-Handle

ASY-00491	Disc Drill, 7.5mm, FH7
ASY-00145	Disc Drill, 6.5mm, FH7



CMP-01345	7mm Shaver, FH7 ENDO
CMP-01346	8mm Shaver, FH7 ENDO
CMP-01347	9mm Shaver, FH7 ENDO

Instrument Catalog



ASY-00149	Articulating Curette, FH7

ASY-00256	Expandable Shaver, FH7

ASY-00564	Small Ring Curette, FH7 ENDO
ASY-00584	Medium Ring Curette, FH7 ENDO
ASY-00571	Large Ring Curette, FH7 ENDO
ASY-00569	Inline Handle, Mini AO, FH7

ASY-00153	Obturator Impactor, Short, FH7
ASY-00154	Obturator Impactor, Tall, FH7

CMP-01024	Small Tear Drop Handle
ASY-00113	0° Expandable Trial, FH7

II-1-0045	Impact Cap

Instrument Catalog

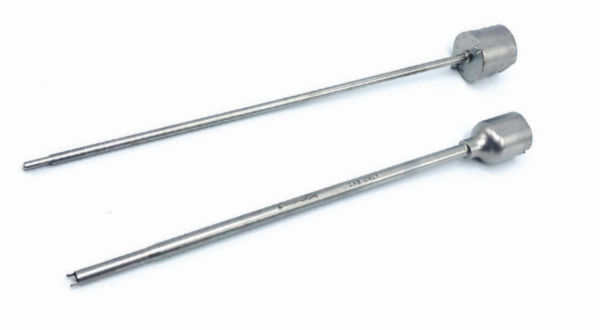
ASY-00120	Insertion Instrument, FH7

CMP-00414	Guide Pin, FH7

II-1-0015	Guide Pin Wrench

ASY-00418	26mm Lock Gauge, FH7
ASY-00422	30mm Lock Gauge, FH7

ASY-00132	Repeater Bone Funnel Tamp, FH7
ASY-00133	Repeater Bone Funnel, FH7
II-1-0434	Bone Funnel Crucible



ASY-00121	Bone Funnel Tamp, FH7
ASY-00122	Bone Funnel, FH7

Instrument Catalog

ASY-00409	Shim Removal Tool, FH7

ASY-00255	Shell Retriever, FH7

II-1-0005	Slap Hammer

CMP-01024	Small Tear Drop Handle

CMP-01512	Removal Dilator 1, FH7
CMP-01513	Removal Dilator 2, Short, FH7
CMP-01515	Removal Tube, Short, FH7

CMP-00480	Dilator Impactor, FH7 MIS

Instrument Catalog

ASY-00768	Tubular Retractor, Tall – Scoop Tip, 140mm, FH7 ENDO
CMP-01983	Tall Dilator, FH7 Endo

CMP-02003	6mm Distractor, FH7

ASY-00479	Wire Brush Crimp Tool

CMP-00422	Dilator 1, FlareHawk7 MIS
CMP-01984	Dilator 2, FH7 ENDO

ASY-00481	Dilator Handle, FH7 MIS

CCMP-02035	Cannula Plunger

ASY-00903	Depth Stop

FLAREHAWK INTERBODY FUSION SYSTEM

Please carefully read and understand this document in its entirety before using the FlareHawk® Interbody Fusion System. The components of the device are designed to be used in combination and function as a single unit. Failure to properly follow instructions may lead to patient injury and may result in improper functioning of the device.

Product Description

The Integrity Implants FlareHawk Interbody Fusion System is an expandable lumbar intervertebral body fusion device intended for use in the lumbosacral spine from L2 to S1 and is intended for intervertebral lumbar fusion. The FlareHawk implant consists of a Shell and a Shim component that are offered in a range of sizes to accommodate variation in patient anatomy. The Shell component is a rectangular frame with struts on all four sides that allow for insertion into the intervertebral body space in a non-expanded form, and subsequent expansion following the insertion of the Shim component. The Shim component has a tapered front end that inserts into and expands the Shell component to the desired vertical and horizontal dimensions. When fully inserted, the Shim locks within the Shell to provide structural stability for interbody fusion. An integrated "Core" in the Shell serves to anchor the delivery instrument during Shim insertion. Protrusions on the superior and inferior surfaces of the implant grip the adjacent vertebral endplates to resist expulsion. The FlareHawk implant is to be filled with autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone. Once implanted, the FlareHawk implant is designed to restore intervertebral disc height, provide anterior column support and maintain structural stability of the motion segment to facilitate intervertebral body fusion.

The FlareHawk Interbody Fusion System is a family of lumbar interbody fusion devices that includes FlareHawk9, FlareHawk7, FlareHawk11, TiHawk9, TiHawk7, and TiHawk11 devices.

The Integrity Implants FlareHawk Shells are manufactured from polyetheretherketone (PEEK) per ASTM F2026 and have integrated tantalum radiographic markers per ASTM F560. Additionally, the TiHawk9, TiHawk7, and TiHawk11 Shells are coated with a thin non-porous layer of Grade 2 commercially pure titanium that meets the chemical composition requirements of ASTM F67.

The FlareHawk Shim and Core are made from Titanium alloy per ASTM F136.

The Integrity Implants FlareHawk Interbody Fusion System includes sets of manual surgical instruments for delivery of the device.

Indications for Use/Intended Use

The FlareHawk Interbody Fusion System is indicated for spinal intervertebral body fusion with autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone in skeletally mature individuals with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1, following discectomy. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) months of non-operative treatment. Additionally, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). FlareHawk system spacers are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

Contraindications

Use of the FlareHawk system is contraindicated in patients with the following conditions:

- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials.
- Any case not needing fusion.
- Any case not described in the indications.
- Any patient unwilling to cooperate with postoperative instructions.

- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade I.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Active systemic infection.
- Infection localized to the site of the proposed implantation or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Prior fusion at the level(s) to be treated.
- Severe osteoporosis, which may prevent adequate fixation.
- Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
- Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
- Any condition not described in the indications for use.
- Active local or systemic infection.
- Allergy to any device materials, including Polyetheretherketone, Tantalum, Titanium Alloy, or Commercially Pure Titanium.
- Irreversible bleeding disorder or coagulopathy.

Warnings

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- device component fracture
- device or device component migration
- device subsidence
- loss of fixation
- non-union
- fracture of the vertebrae
- neurological injury, and
- vascular or visceral injury

The FlareHawk Interbody Fusion System should only be used by physicians with experience and training in spine surgery.

Interbody fusion devices for the treatment of degenerative conditions are designed to be full load bearing and withstand the loads associated with long-term use which could result from the presence of non-union or delayed union.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Precautions

- Read all instructions carefully prior to use. Failure to do so may result in possible patient injury.
- FlareHawk devices are provided either sterile or non-sterile. All devices provided non-sterile must be cleaned and sterilized by the user prior to use. All devices provided within sterilization trays are provided non-sterile. Refer to the product label for the sterility status of Individually packaged implants and instruments. Do not use devices labeled as sterile if the package is opened or damaged.
- A thorough understanding of the principles and techniques involved in spinal surgery procedures is essential to avoid possible injury to the patient. Only experienced spinal surgeons should perform the implantation of intervertebral fusion devices, having specific training in the use of this system, as this is a technically demanding procedure presenting a risk of serious injury to the patient.

- Preoperative planning and patient anatomy should be considered when selecting implant size.
- Surgical implants must never be reused. An explanted implant must never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns, which could lead to breakage.
- Adequately instruct the patient. Mental or physical impairment, which compromises or prevents a patient's ability to comply with necessary limitations or precautions, may place that patient at a particular risk during postoperative rehabilitation.
- FlareHawk implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating or migration in the MR environment.
- Postoperative care is important. The patient should be instructed of the limitations of physical activity such as lifting, twisting, or other excessive motions to reduce risk of excessive load bearing on the implant, and that failure to do so may compromise the implant integrity or delay the healing process. The surgeon should instruct the patient on the time frame required prior to returning to full physical activity.

Cleaning, Decontamination and Sterilization

Purpose

Unless supplied sterile, all devices should be cleaned and sterilized before use. This section provides recommended instructions for the cleaning and sterilization of non-sterile FlareHawk implants and accessory surgical instruments. This document is intended to assist health care personnel in the safe handling practices and effective reprocessing of these implants and instruments.

Scope

This instruction provides information on the care, cleaning, disinfection, maintenance and sterilization of single-use implants and reusable instruments and is applicable to the FlareHawk single-use implants and reusable accessory instruments that are supplied non-sterile but are intended to be used in a sterile state. FlareHawk implants and instruments are cleaned using either manual or a combination of a manual and automated process.

- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent generation of aerosols and splashing which may spread contaminants. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.
- Dry soiled surgical instruments are more difficult to clean. Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids, bone and tissue debris, saline,

Precautions (Cleaning/Sterilization)

- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent generation of aerosols and splashing which may spread contaminants. Cleaning agents must be completely rinsed from device surfaces to prevent accumulation of detergent residue.
- Dry soiled surgical instruments are more difficult to clean. Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids, bone and tissue debris, saline, or disinfectants to dry on used instruments.
- Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used. Instruments must not be placed or soaked in Ringers Solution.

Point of Use

- Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.

Note: Soaking in proteolytic enzyme solutions or other pre-cleaning solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (specifically including instruments with handles containing internal mechanisms including Integrity Implants FlareHawk Expandable Trials and Inserter Instruments (with cleaning slots), and more generally cannulated and tubular designs, etc.). These enzymatic solutions as well as enzymatic foam sprays break down protein matter and prevent blood and protein based materials from drying on instruments. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed.

- For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.
- Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

Preparation Before Cleaning

- Where applicable assemblies of multiple devices and instruments should be disassembled for appropriate cleaning.
- Care should be exercised to avoid losing small screws and components.
- For instruments with turnable knobs and handles, prepare the instrument for cleaning by turning the knob or handle clockwise until stop is reached before cleaning and then repeat the cleaning procedure with the knob turned counterclockwise until stop is reached.

Note: For certain instruments, a handle may need to be temporarily attached to the instrument in order to turn the handle in both directions as instructed above.

Note: For instruments where a knob or handle position creates an opening between, leave the instrument in an open position.

Preparation of Cleaning Agents

- Neutral pH enzymatic and cleaning agents with low foaming surfactants are recommended.
- Alkaline agents with pH ≤ 12 may be used in countries where required by law or local ordinance. Alkaline agents should be followed with a neutralizer and/or thorough rinsing.
- Only agents with proven efficacy (FDA cleared, VAH listed, or CE mark) should be used.
- Agents used during the validation of these processing instructions are: Steris®, Prolystica™ 2X Enzymatic Pre Soak and Cleaner, Prolystica™ Ultra Concentrate Neutral Detergent.
- All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.
- Dry powdered cleaning agents should be completely dissolved prior to use to avoid staining or corrosion of instruments and to ensure correct concentration.
- Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).
- Considerations for alumium care:
  - DO NOT USE abrasive cleaners, metal brushes or abrasive cleaning pads. Use of abrasive products can cause permanent damage to aluminum surfaces.
  - Cleaning wipes with pH range of 6.5 to 8.0 that do not contain chlorides will not harm aluminum surfaces.
  - Use detergent in a water solution where the detergent and water have a pH range of 6.5 to 8.0 to avoid causing damage to aluminum surfaces. Check pH level of water and detergent solution throughout the process, reduce to a pH of 6.5 to 8.0, if needed.
  - The use of utility water may result in the water having a high alkaline level which could be harmful to aluminum surfaces.
  - DO NOT USE solvents such as acetone or benzene, which may be found in chemical drying rinses.

Table 1: Cleaning/Disinfection Options

Method	Description
Manual	Enzymatic soak and scrub followed by sonication
Combination Manual/ Automated	Enzymatic soak and scrub followed by automated washer/ disinfector cycle

- The manual method is effective for all devices and may be used when an automated option is not available.

Note: Manual cleaning may require onsite validation by the healthcare facility and appropriate procedures/ documentation should be in place to avoid human factor variability.

- The combination manual/automated method is preferred and can be used for all devices.

Manual Cleaning/Disinfection Instructions

- Completely submerge implants (within implant caddies) and instruments in an enzyme or alkaline (pH ≤12) solution and allow to soak for 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
- Use a soft-bristled, nylon brush to gently scrub instrument devices until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
- Remove the devices from the cleaning solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes, slots and other difficult-to-reach areas.
- Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50 kHz.
- Rinse devices in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
- Repeat the sonication and rinse steps above.
- Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.
- For instruments where a knob or handle position creates an opening between components, leave the instrument in an open position for cleaning.

Note: If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis.

Combination Manual/Automated Cleaning and Disinfection Instructions

- Completely submerge the implants (within caddies) or instruments in an enzyme or alkaline (pH ≤12) solution and allow to soak for 10 minutes.
- Use a soft nylon-bristled brush to gently scrub instrument devices until all visible soil has been removed. Particular attention must be given to crevices, lumens, slots, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush (i.e. pipe cleaner).

Note: Use of a sonicator at 45-50 KHz will aid in thorough cleaning of devices. Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

- Remove devices from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes and other difficult-to-reach areas.
- Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/ disinfector cleaning cycle. The following minimum parameters are essential for thorough cleaning and disinfection..

Table 2: Typical U.S. Automated Washer/ Disinfector Cycle for Surgical Devices

Step	Description
1	2 minute prewash with cold tap water
2	20 second enzyme spray with hot tap water
3	1 minute enzyme soak
4	15 second cold tap water rinse (X2)
5	2 minutes detergent wash with hot tap water (64-66 C/146-150 F)
6	15 second hot tap water rinse
7	10 second purified water rinse with optional lubricant (64-66 C/146-150 F)
8	7 to 30 minute hot air dry (116 C/240 F)

Inspection, Maintenance, Testing and Lubrication

- Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning/disinfection process.
- Visually inspect for cleanliness, and damage (including but not limited to, corrosion (rusting, pitting), discoloration, excessive scratches, flaking, crack and excessive wear).

Note: If damage or wear is noted that may compromise the function of the device, contact your representative for a replacement.

- Check the action of moving parts (e.g. hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
- Hinged, rotating, or articulating instruments should be lubricated with a water soluble product (e.g. Instrument Milk or equivalent lubricant) intended for surgical instruments that must be sterilized. Some water-based instrument lubricants contain bacteriostatic agents which are beneficial. To remain effective, the expiration date specified by the manufacturer should be adhered to for both stock and use-dilution concentrations.

Note: Mineral oil or silicone lubricants should not be used because they 1) coat microorganisms; 2) prevent direct contact of the surface with steam; and 3) are difficult to remove.

Note: These lubrication instructions are not applicable to air-powered or electrical instruments. These devices have different requirements and should be lubricated according to the manufacturer's instructions.

- Check instruments with long slender features (particularly rotating instruments) for distortion.
- Where instruments form part of a larger assembly, check that the devices assemble readily with mating components. Dissembled devices should be reassembled prior to sterilization unless otherwise noted.

Sterile Packaging

Individual devices

- Single devices should be packaged in a medical grade sterilization pouch or wrap which conforms to the recommended specifications for steam sterilization provided in the table below. Ensure that the pouch or wrap is large enough to contain the device without stressing the seals or tearing the pouch or wrap.
- Double-wrap the instruments for sterilization and handling with an FDA-cleared wrap using the envelope technique per ANSI/AAMI ST79.

Note: If sterilization wraps are used they must be free of detergent residues. Reusable wraps are not recommended.

Trays and cases with defined, preconfigured layouts

- Areas designated for specific devices shall contain only devices specifically intended for these areas.
- Optional Integrity Implants devices should not be added to a preconfigured tray, caddie or case unless a dedicated universal space or compartment has been included in the design and the guidelines described below for trays and cases without defined layouts or universal spaces can be applied.
- Only devices manufactured and/or distributed by Integrity Implants should be included in Integrity Implants trays and caddies. These validated reprocessing instructions are not applicable to Integrity Implants trays and caddies that include devices that are not manufactured and/or distributed by Integrity Implants.
- Double-wrap the trays for sterilization and handling with an FDA-cleared wrap using the envelope technique per ANSI/AAMI ST79 or package into an FDA-cleared rigid sterilization container in accordance with the instructions in the next section.

Rigid Sterilization Container Use Instructions and Considerations

In order to ensure proper sterilization of Integrity Implants' devices and populated trays/caddies when using a rigid sterilization container, the following must be taken into consideration:

- Only FDA-cleared rigid sterilization containers must be used.
- Only rigid sterilization containers approved for pre-vacuum steam sterilization must be used.
- The rigid sterilization container must have a minimum vent to volume ratio of 0.00061 mm2/mm3. For any questions related to the vent to volume ratio, please contact the container manufacturer.
- Follow the sterilization container manufacturer's instructions for inserting and replacing filters in the sterilization container.
- Clean, inspect and prepare the rigid sterilization container according to the manufacturer's instructions.
- Refer to sterilization container manufacturer's IFU for limits on sterile product storage time and storage requirements following sterilization.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

Sterilization Instructions

- See Table 3 for recommended minimum sterilization parameters that have been validated by Integrity Implants to provide a 10^{-6} sterility assurance level (SAL).

- The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the devices after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.
- Moist heat/steam sterilization is the preferred and recommended method for Integrity Implants device sets.
- Sterilizer manufacturer recommendations should always be followed. When sterilizing multiple sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.
- Devices should be properly prepared and packaged in trays, caddies and/or cases that will allow steam to penetrate and make direct contract with all surfaces.
- Ethylene oxide or gas plasma sterilization methods should not be used unless package inserts for the applicable product specifically provide instructions for sterilization using these methods.
- Gravity displacement sterilization cycles are not recommended because cycle times are too long to be practical.
- For instruments where a knob or handle position creates an opening between components, leave the instrument in an open position for sterilization.

Table 3: Recommended Pre-Vacuum Steam Sterilization Parameters[1]

Temperature	Exposure Time	Minimum Dry Time[2]	Minimum Cool Down Time[3]
132°C/270°F	4 minutes	45 minutes	15 minutes

[1] This cycle is not to be used for the inactivation of prions.

[2] Drying times vary according to load size and should be increased for larger loads.

[3] Outside of chamber on a wire rack

Note: The Sterilizer Manufacturer's instructions for operation and load configuration should be followed explicitly.

- Gravity displacement sterilization cycles are not recommended because cycle times are too long to be practical.

Storage Instructions

- Sterile, packaged devices and sets should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.
- Sterile device packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

Note: Maintenance of sterile package integrity is generally event related. If a sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the instrument set must be cleaned, repackaged and sterilized.

Note: If there is any evidence that the lid seal or filters on a sterilization container have been opened or compromised, the sterile filters must be replaced and the set resterilized.

Note: A surgical technique manual is available by contacting Integrity Implants.

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Symbols Glossary

Label symbols - ISO 15223-1

Symbol	Definition
REF	Reference number (Catalogue number)
LOT	Batch code (Lot number)
SN	Serial number
	Consult instructions for use
	Do not re-use / Single Use Only (Single Patient, Single-Use)
	Manufacturer
NON STERILE	Non-sterile
	Date of manufacture
STERILE R	Sterilized using irradiation
	Do not used if package is damaged
	Use-by-date

Label symbols - Other

Symbol	Definition
Rx Only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
IP	Intellectual Property: The labeled item or components within are protected under intellectual property according to US, state and federal law as well as foreign law. Detailed intellectual property information can be found at the website address.

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

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