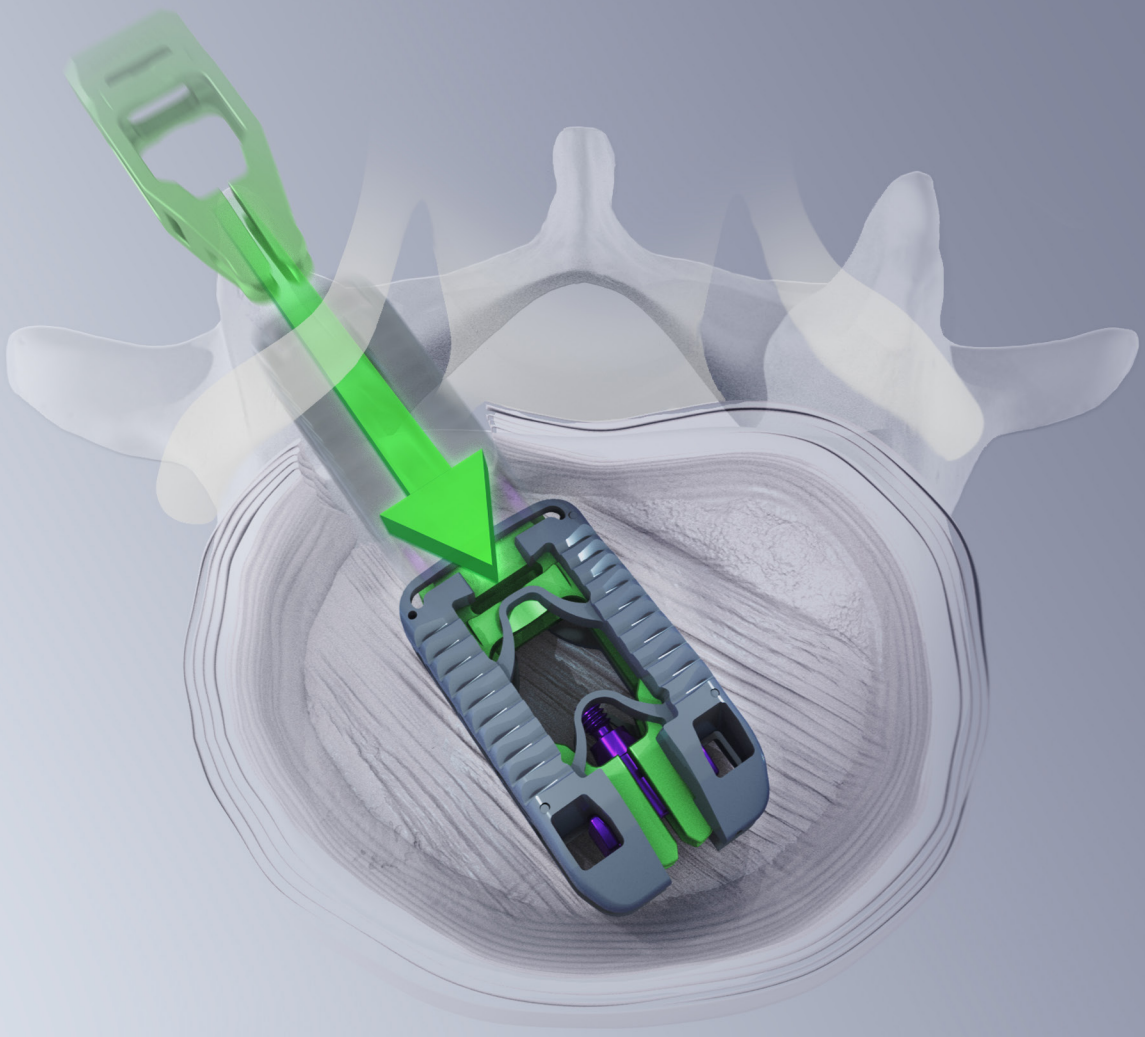
MINIMALLY INVASIVE SURGICAL TECHNIQUE MANUAL



TiHAWK

FlareHawk® Interbody Fusion System

Contents

FlareHawk Interbody Fusion System

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.

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

THE SHELL

FLAREHAWK9

The FlareHawk9 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, Tall, and Lordotic options.

TiHAWK

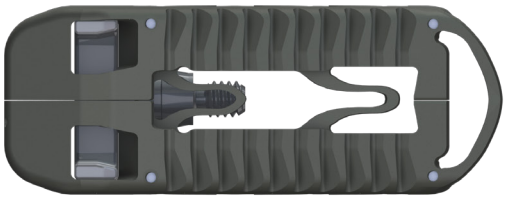
TiHawk Shells have an additional 0.5-micron thick layer of commercially pure titanium bonded to the surface of the PEEK. This thin layer is radiolucent and enables the TiHawk Shell to maintain the same properties as the FlareHawk Shell, but with a titanium surface.

THE SHIM

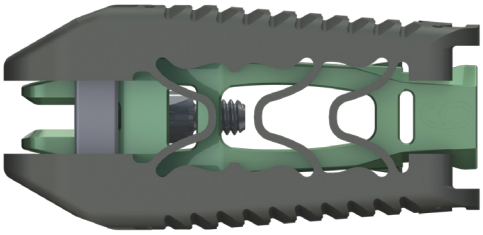
The **Shim** is manufactured from titanium alloy. It includes a split tip that locks with the Core when the Implant is deployed. All Shims are color-coded by size. Each Shim is marked with its lot number, its built-in lordosis, and the deployed height options that are possible when it is combined with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

▸ Fig. 1

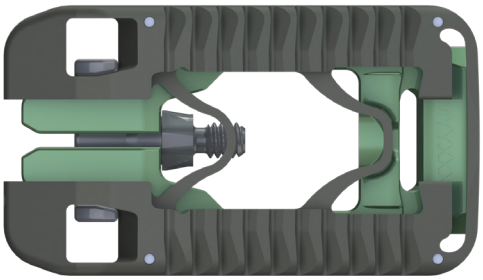
Lateral View Compressed



Axial View Compressed



Lateral View Expanded



Axial View Expanded

▸ Fig. 1

TiHAWK11™

TIHAWK11 SIZE OPTIONS

TiHawk11 provides the surgeon with a wide range of height and lordosis options in 23, 25, & 29mm lengths. All TiHawk11 Implants have an insertion profile of 7mm or 9mm high and 11mm wide. The "11" in TiHawk11 is named from the insertion width of 11mm. All TiHawk11 Implants insert at 11mm in width and expand to 17mm. The images below illustrate the insertion profiles and maximum expansion profiles of the TiHawk11 Implants. The chart to the right and the table below show the insertion profiles, height, and lordosis options for each Shell.

▶ Fig. 2-8

FINAL CONSTRUCT (H X W)	LORDOSIS 0°	6°	9°	15°
7 x 17mm	7 x 11mm			
8 x 17mm	7 x 11mm			
9 x 17mm	7 x 11mm			
10 x 17mm	7 x 11mm	7 x 11mm	9 x 11mm	
11 x 17mm	7 x 11mm	7 x 11mm	9 x 11mm	
12 x 17mm	9 x 11mm	7 x 11mm	9 x 11mm	9 x 11mm
13 x 17mm	9 x 11mm	9 x 11mm	9 x 11mm	9 x 11mm
14 x 17mm	9 x 11mm	9 x 11mm	9 x 11mm	9 x 11mm

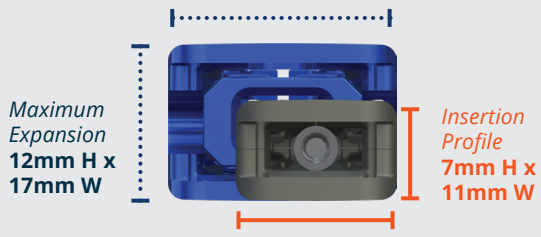
Insertion Profiles

▶ Fig. 2

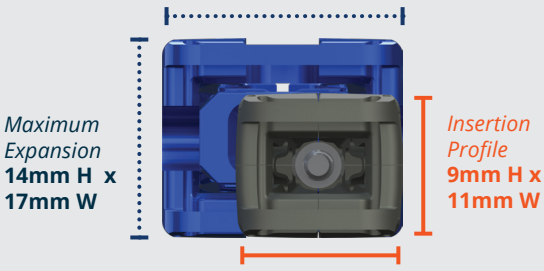
Shells (23, 25, & 29mm)	Insertion Profile	Width Expansion	0° Height Range	6° Height Range	9° Height Range	15° Height Range
Short Shell	7mm H x 11mm W	17mm	7 – 11mm	10 – 12mm	N/A	N/A
Tall Shell	9mm H x 11mm W	17mm	12 – 14mm	13 – 14mm	N/A	N/A
Lordotic Shell	9mm H x 11mm W	17mm	N/A	N/A	10 – 14mm	12 – 14mm

▶ Fig. 3

Short Shell



Tall & Lordotic Shell



▶ Fig. 4

TiHAWK11™

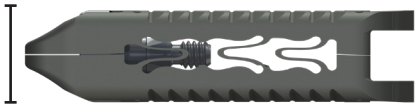
UNEXPANDED

▶ Fig. 5

Unexpanded Height

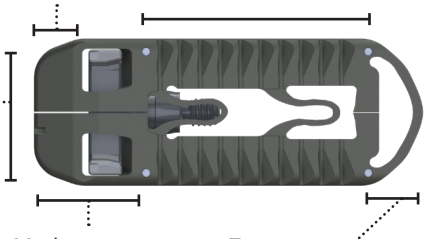
9mm
Lordotic &
Tall Shells

7mm
Short Shells



Nose to Core for
23mm Implant: **2mm**
25mm Implant: **4mm**
29mm Implant: **4mm**

Anterior to Posterior Markers
29mm Shells: **17mm**
23 and 25mm Shells: **13mm**



11mm
Unexpanded
Width

Nose to Anterior Markers
23mm Implant: **7mm**
25mm Implant: **9mm**
29mm Implant: **9mm**

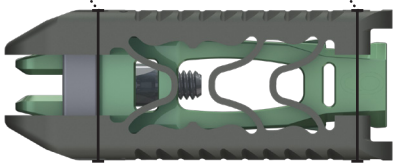
7mm
Posterior Markers to
Backstrap When
Unexpanded

EXPANDED

▶ Fig. 6

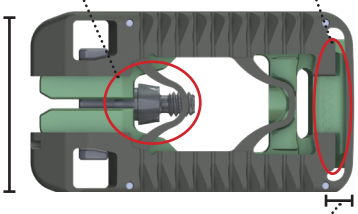
Anterior Height

Posterior Height



Anterior Lock

Posterior Lock



17mm
Expanded
Width

3mm
Posterior Markers to
Backstrap When Expanded

FLUOROSCOPIC VIEW

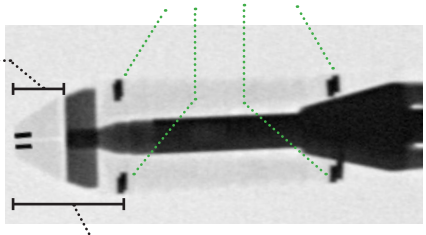
▶ Fig. 7

Tantalum Markers

2mm nose to
core for 23mm
implant

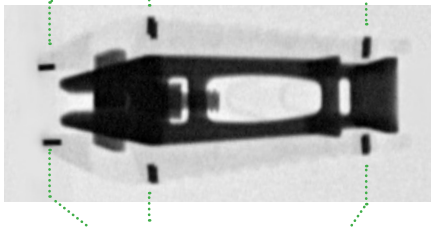
4mm nose to
core for 25 and
29mm implant

Nose marker
0.5mm recessed



Nose to Anterior Markers
23mm Implant: **7mm**
25mm Implant: **9mm**
29mm Implant: **9mm**

Tantalum Markers



Tantalum Markers
Quantity: 10 per Shell
Length: 1.5mm
Diameter: 0.6mm

Implant Overview Continued

TiHAWK11™

Constructs	Insertion Profile (HxW)	Expanded Profile (HxW)	Shell	Shim	Expanded Profile (Anterior HxW)	23 and 25mm Posterior Height	Difference (A-P)	29mm Posterior Height	Difference (A-P)
7mm 0°	7x11mm	7x17mm	Short Shell	7 or 10, 0° Shim	7mm	7mm	0mm	7mm	0mm
8mm 0°	7x11mm	8x17mm	Short Shell	8 or 11, 0° Shim	8mm	8mm	0mm	8mm	0mm
9mm 0°	7x11mm	9x17mm	Short Shell	9 or 12, 0° Shim	9mm	9mm	0mm	9mm	0mm
10mm 0°	7x11mm	10x17mm	Short Shell	10 or 13, 0° Shim	10mm	10mm	0mm	10mm	0mm
11mm 0°	7x11mm	11x17mm	Short Shell	11 or 14, 0° Shim	11mm	11mm	0mm	11mm	0mm
12mm 0°	9x11mm	12x17mm	Tall Shell	9 or 12, 0° Shim	12mm	12mm	0mm	12mm	0mm
13mm 0°	9x11mm	13x17mm	Tall Shell	10 or 13, 0° Shim	13mm	13mm	0mm	13mm	0mm
14mm 0°	9x11mm	14x17mm	Tall Shell	11 or 14, 0° Shim	14mm	14mm	0mm	14mm	0mm
10mm 6°	7x11mm	10x17mm	Short Shell	10 or 12, 6° Shim	10mm	8mm	2mm	7.5mm	2.5mm
11mm 6°	7x11mm	11x17mm	Short Shell	11 or 13, 6° Shim	11mm	9mm	2mm	8.5mm	2.5mm
12mm 6°	7x11mm	12x17mm	Short Shell	12 or 14, 6° Shim	12mm	10mm	2mm	9.5mm	2.5mm
13mm 6°	9x11mm	13x17mm	Tall Shell	11 or 13, 6° Shim	13mm	11mm	2mm	10.5mm	2.5mm
14mm 6°	9x11mm	14x17mm	Tall Shell	12 or 14, 6° Shim	14mm	12mm	2mm	11.5mm	2.5mm
10mm 9°	9x11mm	10x17mm	Lordotic Shell	7 or 10, 0° Shim	10mm	7.5mm	2.5mm	7mm	3mm
11mm 9°	9x11mm	11x17mm	Lordotic Shell	8 or 11, 0° Shim	11mm	8.5mm	2.5mm	8mm	3mm
12mm 9°	9x11mm	12x17mm	Lordotic Shell	9 or 12, 0° Shim	12mm	9.5mm	2.5mm	9mm	3mm
13mm 9°	9x11mm	13x17mm	Lordotic Shell	10 or 13, 0° Shim	13mm	10.5mm	2.5mm	10mm	3mm
14mm 9°	9x11mm	14x17mm	Lordotic Shell	11 or 14, 0° Shim	14mm	11.5mm	2.5mm	11mm	3mm
12mm 15°	9x11mm	12x17mm	Lordotic Shell	10 or 12, 6° Shim	12mm	8.5mm	3.5mm	7.5mm	4.5mm
13mm 15°	9x11mm	13x17mm	Lordotic Shell	11 or 13, 6° Shim	13mm	9.5mm	3.5mm	8.5mm	4.5mm
14mm 15°	9x11mm	14x17mm	Lordotic Shell	12 or 14, 6° Shim	14mm	10.5mm	3.5mm	9.5mm	4.5mm

▶ Fig. 8

TIHAWK9 AND FLAREHAWK9 SIZE OPTIONS

TiHawk9 and FlareHawk9 provide the surgeon with a wide range of height and lordosis options in 25mm and 29mm lengths. All TiHawk9 Implants have an insertion profile of 7mm or 9mm high and 9mm wide. The "9" in TiHawk9 is named from the insertion width of 9mm. All TiHawk9 Implants insert at 9mm in width and expand to 14mm. The images below illustrate the insertion profiles and maximum expansion profiles of the TiHawk9 Implants. ▸ Fig. 9-14

NOTE: Both TiHawk9 and FlareHawk9 Shells are provided in the same sizes and are used in conjunction with the same Shims. TiHawk9 will be specifically named throughout this technique, but the the surgical steps apply to both FlareHawk9 and TiHawk9.

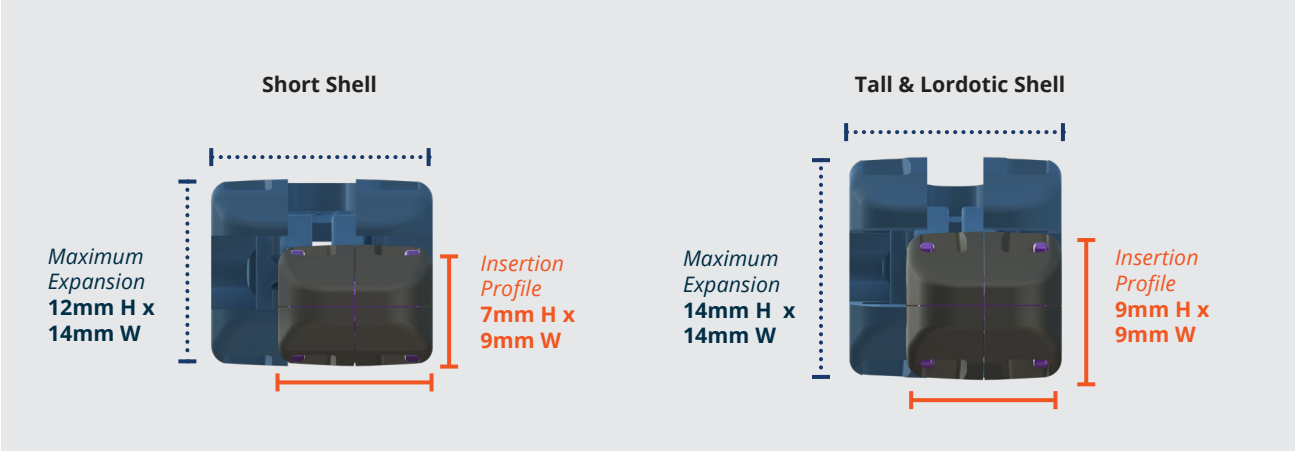
TiHAWK9™ FLAREHAWK9

FINAL CONSTRUCT (H X W)	LORDOSIS 0°	6°	9°	15°
8 x 14mm	7 x 9mm			
9 x 14mm	7 x 9mm			
10 x 14mm	7 x 9mm	7 x 9mm		
11 x 14mm	7 x 9mm	7 x 9mm	9 x 9mm	
12 x 14mm	9 x 9mm	7 x 9mm	9 x 9mm	9 x 9mm
13 x 14mm	9 x 9mm	9 x 9mm	9 x 9mm	9 x 9mm
14 x 14mm	9 x 9mm	9 x 9mm	9 x 9mm	9 x 9mm

Insertion Profiles ▸ Fig. 9

Shells (25 & 29mm)	Insertion Profile	Width Expansion	0° Height Range	6° Height Range	9° Height Range	15° Height Range
Short Shell	7mm H x 9mm W	14mm	8 – 11mm	10 – 12mm	N/A	N/A
Tall Shell	9mm H x 9mm W	14mm	12 – 14mm	13 – 14mm	N/A	N/A
Lordotic Shell	9mm H x 9mm W	14mm	N/A	N/A	11 – 14mm	12 – 14mm

▸ Fig. 10



▸ Fig. 11

TiHAWK9™ FLAREHAWK9

UNEXPANDED

▶ Fig. 12

LATERAL

Short Shells: 7mm

Lordotic & Tall Shells: 9mm

Implant teeth depth 0.75mm at lowest point.

AXIAL

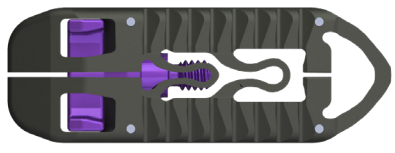
Nose to Anterior Markers: **9mm**

Anterior to Posterior Markers

25mm Shells: 13mm

29mm Shells: 17mm

9mm Unexpanded Width



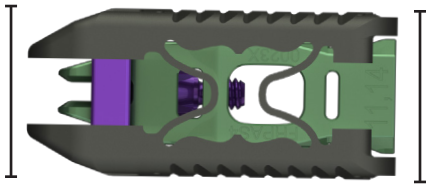
Nose to Core: **4mm**

Posterior Markers to Backstrap When Unexpanded: **6mm**

EXPANDED

▶ Fig. 13

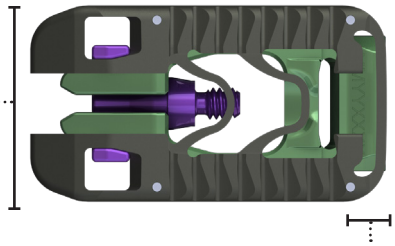
LATERAL



Anterior Height **Posterior Height**

AXIAL

14mm Expanded Width



Posterior Markers to Backstrap When Expanded: **3mm**

Implant Overview Continued

TiHAWK9™ FLAREHAWK9

Constructs	Insertion Profile (HxW)	Expanded Profile (HxW)	Shell	Shim	Expanded Profile (Anterior HxW)	25mm Posterior Heights	Difference (A-P)	29mm Posterior Height	Difference (A-P)
8mm 0°	7x9mm	8x14mm	Short Shell	8 or 11, 0° Shim	8mm	8mm	0mm	8mm	0mm
9mm 0°	7x9mm	9x14mm	Short Shell	9 or 12, 0° Shim	9mm	9mm	0mm	9mm	0mm
10mm 0°	7x9mm	10x14mm	Short Shell	10 or 13, 0° Shim	10mm	10mm	0mm	10mm	0mm
11mm 0°	7x9mm	11x14mm	Short Shell	11 or 14, 0° Shim	11mm	11mm	0mm	11mm	0mm
12mm 0°	9x9mm	12x14mm	Tall Shell	9 or 12, 0° Shim	12mm	12mm	0mm	12mm	0mm
13mm 0°	9x9mm	13x14mm	Tall Shell	10 or 13, 0° Shim	13mm	13mm	0mm	13mm	0mm
14mm 0°	9x9mm	14x14mm	Tall Shell	11 or 14, 0° Shim	14mm	14mm	0mm	14mm	0mm
10mm 6°	7x9mm	10x14mm	Short Shell	10 or 12, 6° Shim	10mm	8mm	2mm	7.5mm	2.5mm
11mm 6°	7x9mm	11x14mm	Short Shell	11 or 13, 6° Shim	11mm	9mm	2mm	8.5mm	2.5mm
12mm 6°	7x9mm	12x14mm	Short Shell	12 or 14, 6° Shim	12mm	10mm	2mm	9.5mm	2.5mm
13mm 6°	9x11mm	13x14mm	Tall Shell	11 or 13, 6° Shim	13mm	11mm	2mm	10.5mm	2.5mm
14mm 6°	9x9mm	14x14mm	Tall Shell	12 or 14, 6° Shim	14mm	12mm	2mm	11.5mm	2.5mm
11mm 9°	9x9mm	11x14mm	Lordotic Shell	8 or 11, 0° Shim	11mm	8.5mm	2.5mm	8mm	3mm
12mm 9°	9x9mm	12x14mm	Lordotic Shell	9 or 12, 0° Shim	12mm	9.5mm	2.5mm	9mm	3mm
13mm 9°	9x9mm	13x14mm	Lordotic Shell	10 or 13, 0° Shim	13mm	10.5mm	2.5mm	10mm	3mm
14mm 9°	9x9mm	14x14mm	Lordotic Shell	11 or 14, 0° Shim	14mm	11.5mm	2.5mm	11mm	3mm
12mm 15°	9x9mm	12x14mm	Lordotic Shell	10 or 12, 6° Shim	12mm	8.5mm	3.5mm	7.5mm	4.5mm
13mm 15°	9x9mm	13x14mm	Lordotic Shell	11 or 13, 6° Shim	13mm	9.5mm	3.5mm	8.5mm	4.5mm
14mm 15°	9x9mm	14x14mm	Lordotic Shell	12 or 14, 6° Shim	14mm	10.5mm	3.5mm	9.5mm	4.5mm

▸ Fig. 14

PATIENT POSITIONING

The patient is anesthetized and placed in an optimal position for the chosen surgical approach. The surgical region is sanitized, and an incision is made at the operative level(s) of the spine, continuing down to the target facet(s). Fluoroscopy or another imaging modality is used throughout the procedure for planning and to confirm proper Implant placement and locking.

▸ Fig. 15

A contralateral oblique image will need to be obtained for lock confirmation after the Implant has been deployed. Implant lock confirmation is detailed later in this document. In preparation for this image ensure that the C-arm is positioned on the opposite side of the TLIF or PLIF being performed. ▸ Fig. 16

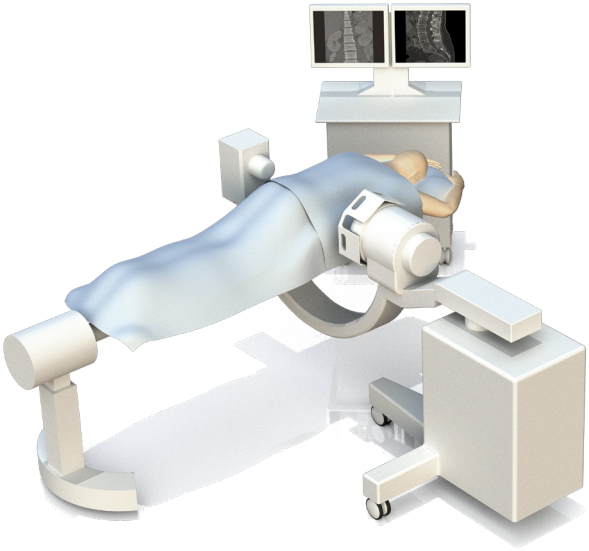
ACCESS

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 superior facet of the caudal vertebra and the inferior facet of the cephalad vertebra at the operative level(s) to create a unilateral, transforaminal space through which to access the disc.

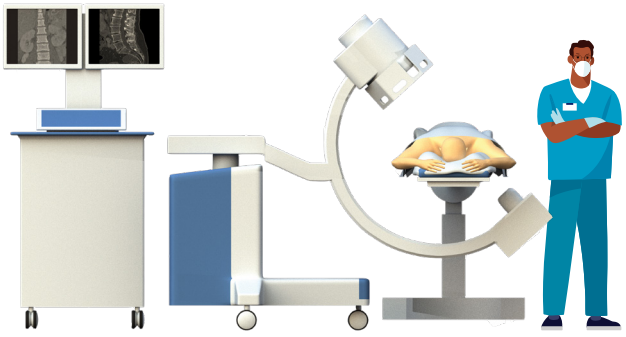
Expose the disc space using proper hemostatic technique. Use a nerve root retractor as required. Perform an annulotomy and remove disc material as needed, including cartilaginous endplates, using disc preparation instruments such as curettes, shavers, rasps, and/or other appropriate discectomy tools.

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.

Following decompression, continue to perform a sufficient discectomy at the operative level(s) if necessary.



▸ Fig. 15



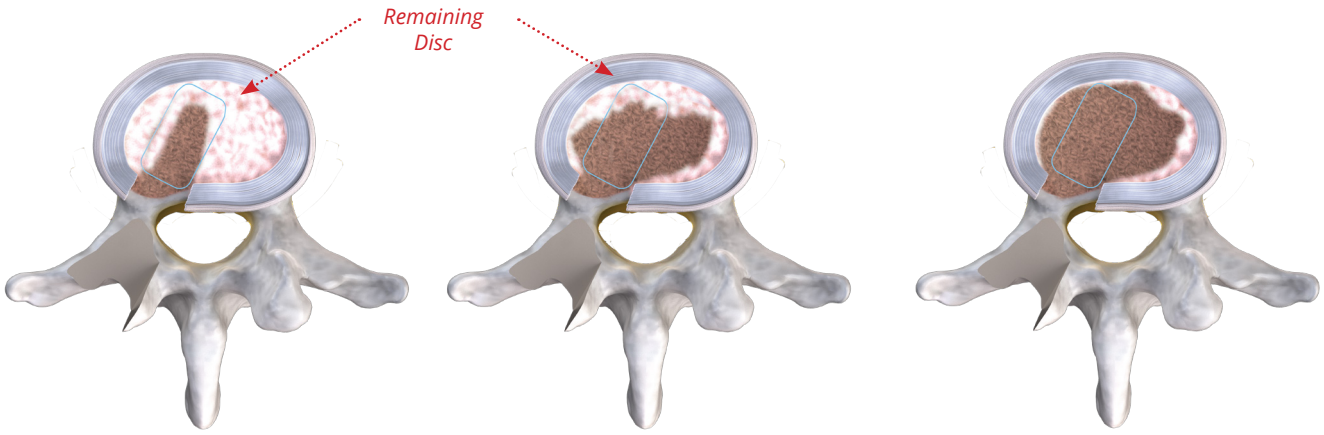
C-Arm positioned for lock confirmation

▸ Fig. 16

BIDIRECTIONAL DISC PREPARATION

The TiHawk Implant requires disc prep and distraction strategies that accommodate a bi-planar implant. The TiHawk Shell must have medial-lateral clearance to allow for for expansion to 17mm in width. A channel discectomy is inadequate to allow for the large footprint the TiHawk Implant provides. 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 17mm in width. ▸ Fig. 17

CAUTION: *Due to the width expansion capabilities of the TiHawk Implant, adequate discectomy of the affected disc is necessary to place and expand the TiHawk 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. If a PLIF is being performed, it is important to make sure enough space is available to expand both Implants.*



Inadequate Disc Prep

▸ Fig. 17a

Inadequate Disc Prep

▸ Fig. 17a

Adequate Disc Prep

▸ Fig. 17c

DISTRACTORS & SHAVERS

After the disc space is prepared for the Implant, sequential dilation with **Accelus Paddle Shaver(s)** and/or **Accelus Paddle Distractor(s)** should take place until a Shaver or Distractor is found to be self-retaining and snug in the tallest portion of the disc space. ▸ Fig. 18-19

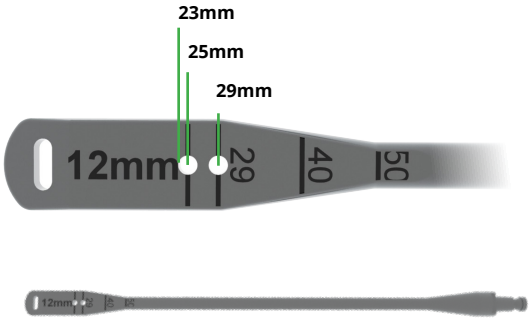
Begin by affixing the orange **Hudson T-Handle** to the desired Paddle Shaver or Paddle Distractor. While using the Paddle Shaver(s) or Paddle Distractor(s), confirm correct instrument placement and trajectory using fluoroscopy. The Shaver(s) have a through hole that can be seen fluoroscopically to help assess depth. 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.

It is strongly suggested in rigid spines that Distractors or Shavers are kept in place for adequate time to provide ligamentotaxis.

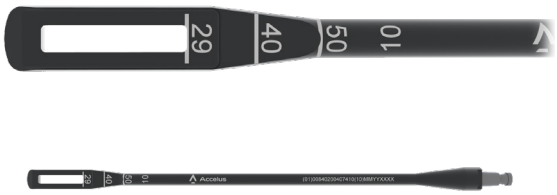
The disc space must always be distracted to at least the height of the desired Implant. There is no need to oversize the Implant and place the spine in a super physiological position. The Implant is deployed in an atraumatic fashion with a wide footprint designed to reduce settling.

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.*

NOTE: *Use of the Accelus Paddle Distractor or Paddle Shaver(s) is highly recommended. Failure to use these instruments may result in increased resistance when deploying the Implant which could result in failure to lock and/or Implant fracture.*



Distractor ▸ Fig. 18



Open Shaver ▸ Fig. 19

Disc Space Preparation

CMP-00698	7mm Shaver
CMP-00699	8mm Shaver
CMP-00700	9mm Shaver
CMP-00701	10mm Shaver
CMP-00702	11mm Shaver
CMP-00703	12mm Shaver
CMP-00704	13mm Shaver
CMP-00705	14mm Shaver

CMP-00688	7mm Paddle Distractor
CMP-00689	8mm Paddle Distractor
CMP-00690	9mm Paddle Distractor
CMP-00691	10mm Paddle Distractor
CMP-00692	11mm Paddle Distractor
CMP-00693	12mm Paddle Distractor
CMP-00694	13mm Paddle Distractor
CMP-00695	14mm Paddle Distractor

CMP-02456	7mm Shaver, Open
CMP-02457	8mm Shaver, Open
CMP-02458	9mm Shaver, Open
CMP-02459	10mm Shaver, Open
CMP-02460	11mm Shaver, Open
CMP-02461	12mm Shaver, Open
CMP-02462	13mm Shaver, Open
CMP-02463	14mm Shaver, Open

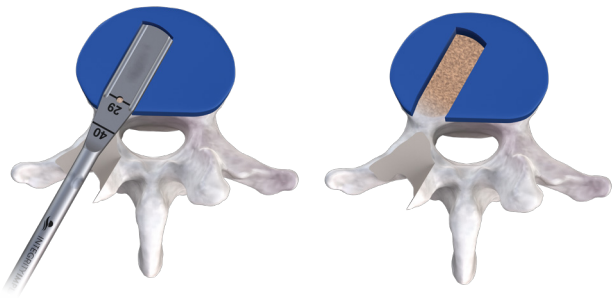
II-1-0328	Hudson T-Handle

Disc Space Preparation

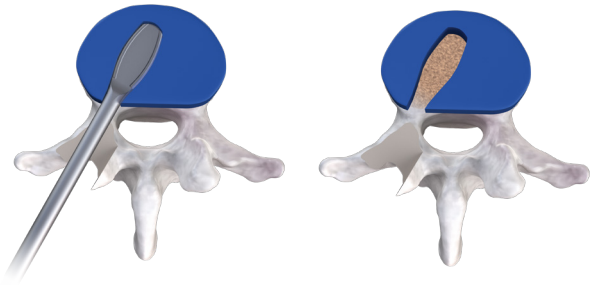
Accelus Paddle Shavers and Distractors were designed to account for a bidirectionally expanding Implant and should be the only shavers or distractors used in the procedure. Most commercially available shavers and distractors create a football shape when rotated in the disc space.

Accelus Shavers are designed to create a clearance in the space to allow room for the nose of the Implant to expand in width and height. Utilizing a football shaped shaver may not provide enough clearance for an Implant to expand bidirectionally.

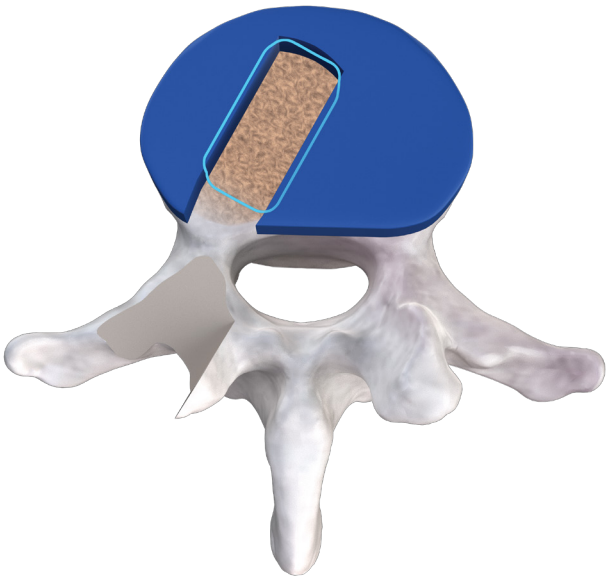
▶ Fig. 20-23



Accelus Shaver ▶ Fig. 20



"Football" Shaped Shaver ▶ Fig. 21



Clear Expansion ▶ Fig. 22

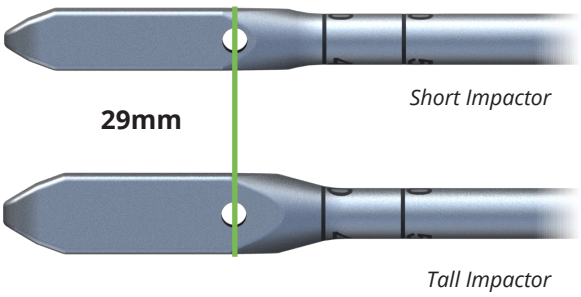
Impinged Expansion ▶ Fig. 23

SHORT AND TALL IMPACTORS

The **Short and Tall Impactors** have a through hole at 29mm and can be seen fluoroscopically to help assess depth within the disc space. ▸ Fig. 25

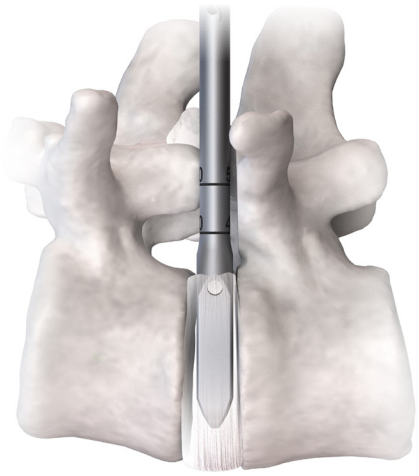
Affix an orange Hudson T-Handle to the selected Impactor, and insert the Impactor into the disc space with the hole running parallel to the end plates. The Short Impactor can be used for verification of an adequate working channel for insertion of a Short Shell. The Tall Impactor can be used for verification of an adequate working channel for insertion of a Tall Shell. ▸ Fig. 26

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



▸ Fig. 25

Axial View ▸ Fig. 24



Lateral View ▸ Fig. 26

CMP-00546 Short Impactor

CMP-00547 Tall Impactor

II-1-0328 Hudson T-Handle

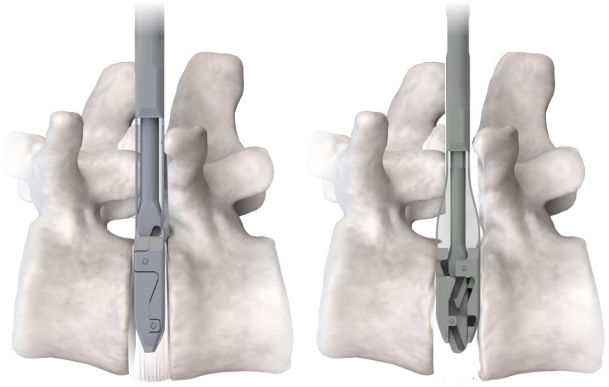
EXPANDABLE TRIAL

Expandable Trials are designed to provide incremental distraction of the disc space and trialing without passing the Paddle Distractors by the neural anatomy. The footprint of each Trial is similar to that of an unexpanded Implant. Begin with selecting either 0° or 9° Expandable Trial based on patient anatomy. Connect the axial handle to the proximal portion of the Expandable Trial. Insert the Expandable Trial into the disc space. Once the location has been confirmed via fluoroscopy, using only two fingers, rotate the axial handle clockwise until slight resistance is felt (approximately "finger tight"), and stop to verify size. Suggested Implant height will be displayed on the Height Indicator located on the handle portion of the instrument. ▸ Fig. 27-28

The 0° Trials provide an incremental distraction and trialing from 8mm to 14mm.

The 9° Trials provide an incremental distraction and trialing from 9mm to 14mm.

CAUTION: *Only expand Trial Instrument until resistance is encountered. Over-distraction could cause vertebral body damage and/or instrument damage.*

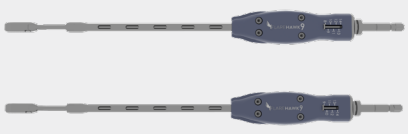


Lateral View - Closed *Lateral View - Expanded*

▸ Fig. 27

Height Indicator

▸ Fig. 28



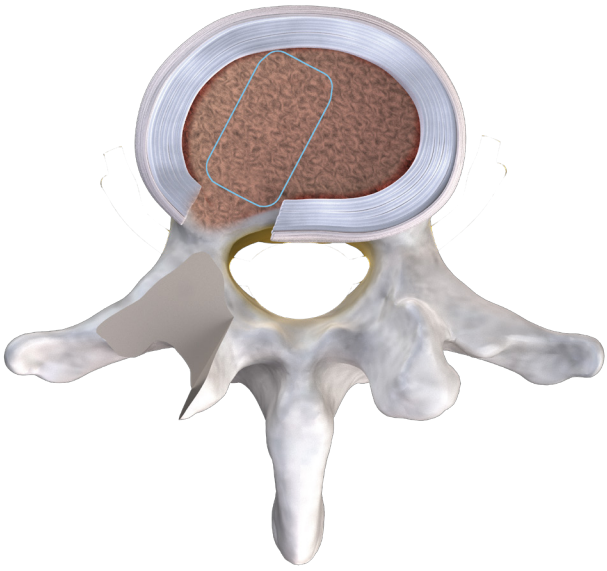
ASY-00143 Expandable Trial, 0 degree
ASY-00337 Expandable Trial, 9 degree

CMP-01024 Teardrop Handle

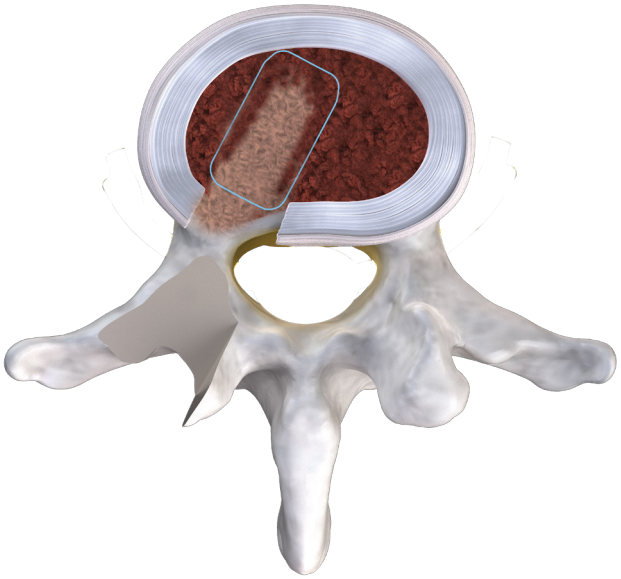
PRE-PACKING GRAFT

Graft placement is critical to obtaining fusion. Many surgeons may pre-pack graft in the disc space before inserting an Implant. TiHawk 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 out the lateral windows into the cleared-out disc space. Since TiHawk expands not only in height, but also in width, it is important to leave space for the TiHawk Implant to expand up to 17mm in width. ▸ Fig. 29-31

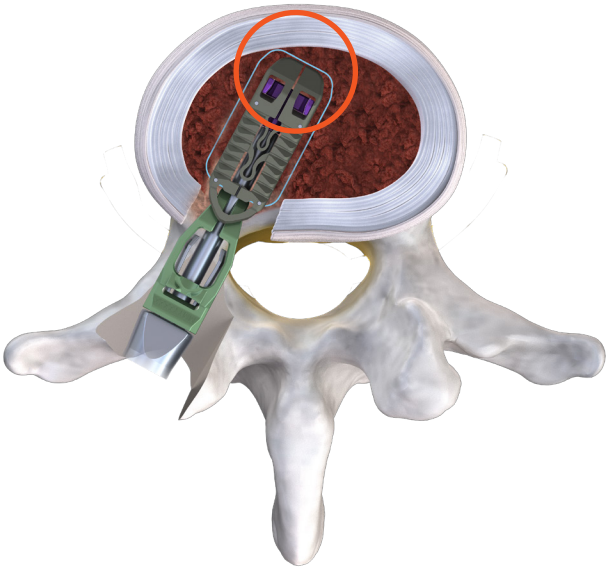
CAUTION: *It is highly advisable to not pre-pack graft. Pre-packed graft can impinge expansion of the Implant. This impingement can result in failure to lock and/or Implant fracture. If graft is placed prior to Implant insertion, it is recommended the surgeon utilize either an Impactor, Distractor, or Shaver to clear up to a 17mm wide pathway for the Implant.*



Optimal: No Pre-Packed Graft ▸ Fig. 29



Pre-Packed Graft ▸ Fig. 30



Impinged Expansion ▸ Fig. 31

TiHAWK9™ FLAREHAWK9

Nonsterile 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**. The specific selection of the Shim and Shell will achieve the desired height and lordosis upon deployment in the disc space. Unlike some adjustable height expanding interbodies, TiHawk9 reaches the desired height and lordosis upon lock out and can not 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 2 caddies, a 25mm Caddy and a 29mm 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 6 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 from an occupied space that shares the same color coding as the empty space.

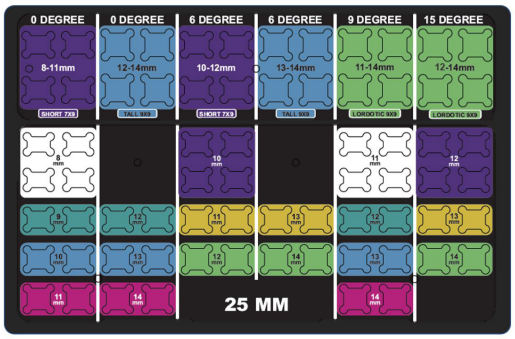
The illustration above shows the logic built into the Caddy layout. Each lane has a designated lordosis based off the Shim and Shell combination found below it. A 9° Implant is the combination of a 0° Shim and a 9° Lordotic Shell. Likewise, a 15° Implant is the combination of a 6° Shim and a 9° Lordotic Shell.

▸ Fig. 32-34

Construct Logic

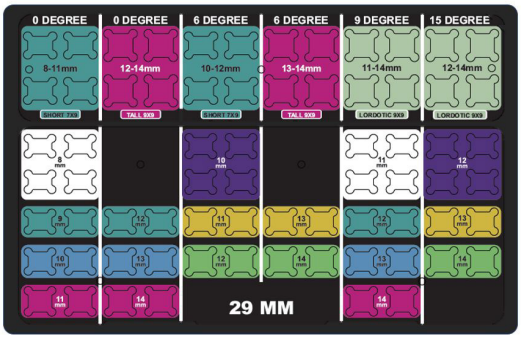
0° Shim + 0° Shell = 0° Construct
6° Shim + 0° Shell = 6° Construct
0° Shim + 9° Shell = 9° Construct
6° Shim + 9° Shell = 15° Construct

▸ Fig. 32



25mm Caddy

▸ Fig. 33



29mm Caddy

▸ Fig. 34

Example: **The surgeon requests a 25mm Length, 12mm Height, 6 Degree Implant.**

STEP 1

Choose the Implant Caddy that contains the desired Implant length, as indicated by its label plate. In this example the **25mm Caddy** is selected.

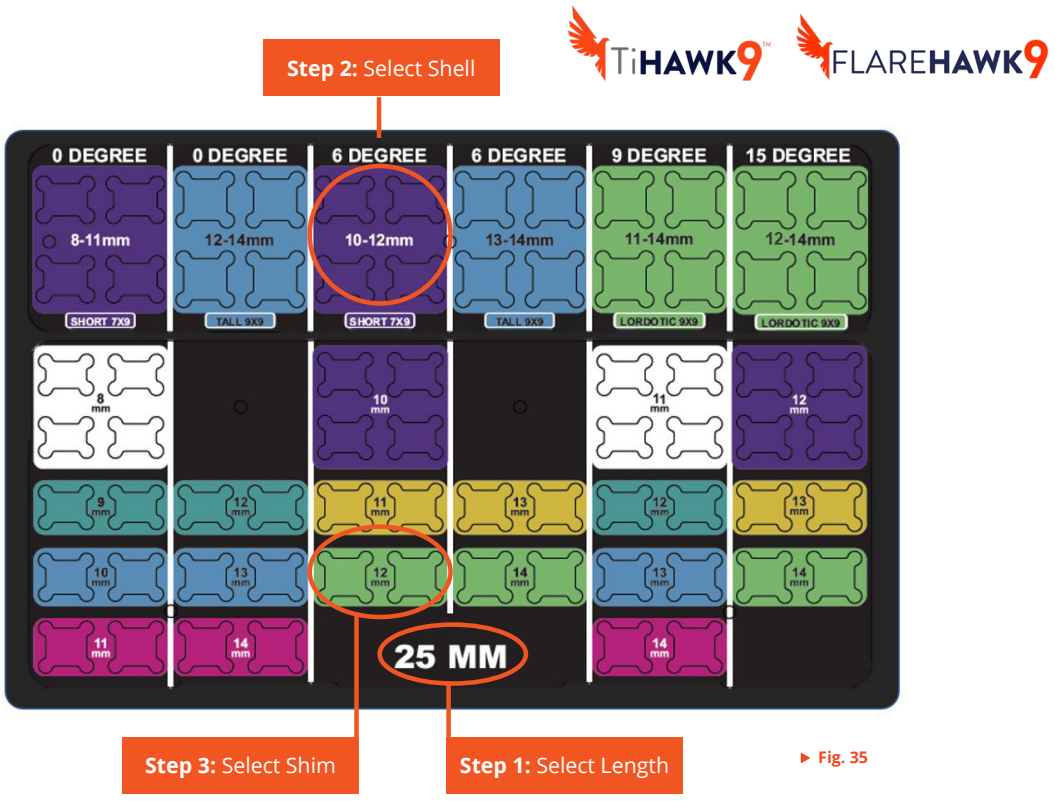
STEP 2

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 purple **Short Shell** is selected since it is found in the purple 10-12mm section within the corresponding 6 DEGREE column. The color of the Shell can be seen by looking at the Core.

STEP 3

Select the green **12mm Shim** found directly below the selected Shell.

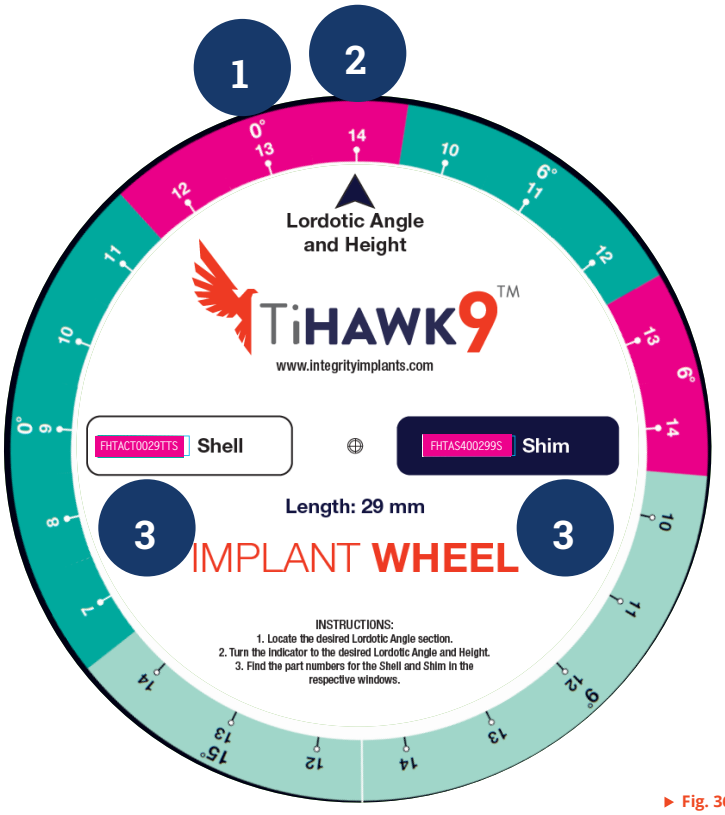
▸ Fig. 35



▸ Fig. 35

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.

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



▶ Fig. 36

TiHawk9 Sterile Packaged Implants have a circular color coded sticker

▶ Fig. 37

TiHawk9 Sterile Pack Implant Selection

Implant Part Number Selection:

Demonstration of the selection of a 29mm, 0°, 14mm height TiHawk9 Implant.

To begin, ensure you have selected the appropriate length Implant side of wheel then:

STEP 1

Locate the desired Lordotic Angle section.

STEP 2

Turn the indicator to the desired Lordotic Angle and Height.

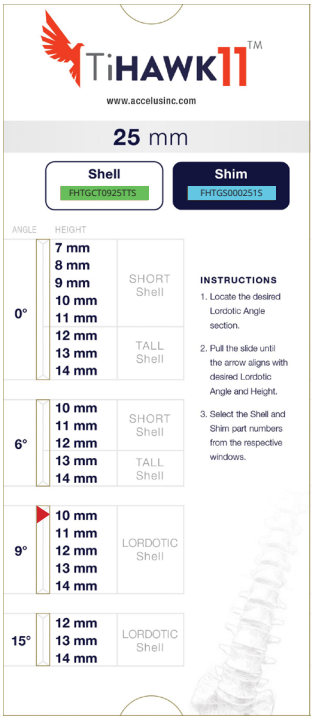
STEP 3

Find the part numbers for the Shell and Shim in the respective windows.

STEP 4

Select the Implants with the coloring and part numbers as displayed in the windows from the carrying case.

▶ Fig. 36



▶ Fig. 38

TiHawk11 Sterile Packaged Implants have a square color coded sticker

▶ Fig. 39

TiHawk11 Sterile Pack Implant Selection

Implant Part Number Selection:

Demonstration of the selection of a 25mm, 9°, 10mm height TiHawk11 Implant.

STEP 1

Open the TiHawk11 Implant Selection Guide to the page that corresponds to the appropriate Implant length desired.

STEP 2

Locate the desired Lordotic Angle section.

STEP 3

Pull the slide until the arrow aligns with the desired Lordotic Angle and Height.

STEP 4

Select the Shell and Shim part numbers from the respective windows.

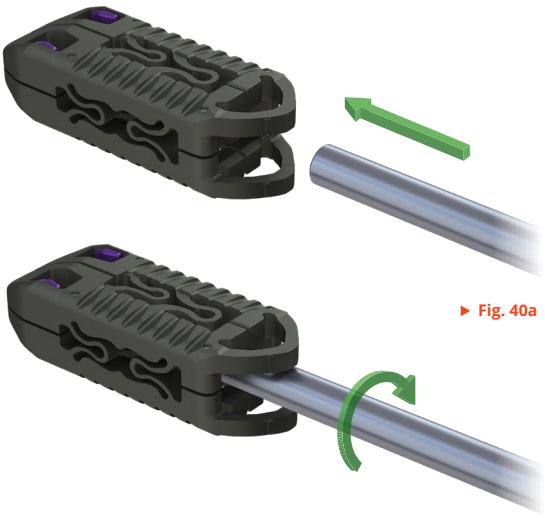
▶ Fig. 38

Inserter Loading

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

STEP 1

Attach the **Guide Pin** to desired Shell. To do this, screw the female thread on the Guide Pin clockwise onto the male thread inside the Shell until it is completely tightened, and a hard stop is felt. ▶ Fig. 40



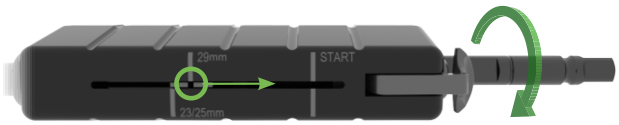
▶ Fig. 40a

▶ Fig. 40b

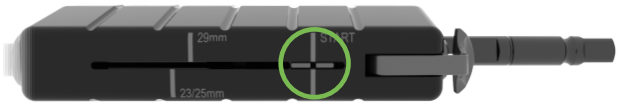
STEP 2

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 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.

▶ Fig. 41



▶ Fig. 41a



▶ Fig. 41b

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

NOTE: *Guide Pins are single-use only.*

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

FHTAGP27A Guide Pin, 27mm

ASY-00316 Insertion Instrument

STEP 3

Affix the desired Shim to the prongs at the tip of the Inserter. ▸ Fig. 43a

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.

▸ Fig. 43b-c

STEP 5

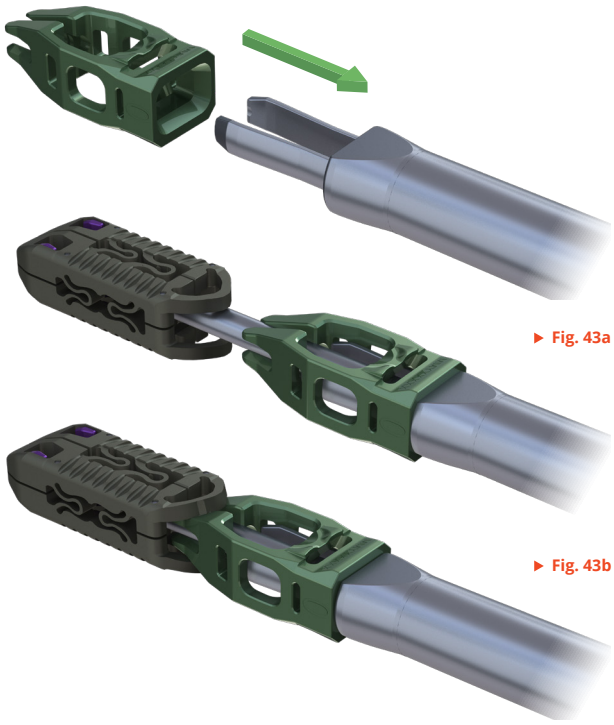
Tug firmly on the Shell to confirm it is locked into place. If it isn't, repeat Step 2 and 4.

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. ▸ Fig. 43d

STEP 7

Advance the Shim slightly into the Shell. The **backstrap** may slightly flare up from the nose of the Shim. This will help remove the toggle of the Shell in relation to the Shim, limit Shell rotation during insertion, and ensure the Shim and Shell remain properly aligned. See illustrations to the right. ▸ Fig. 44

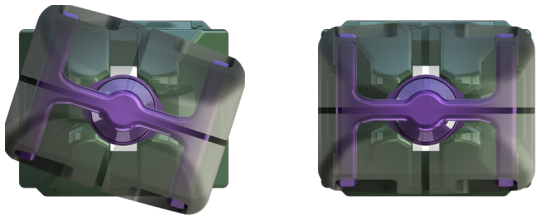


▸ Fig. 43a

▸ Fig. 43b

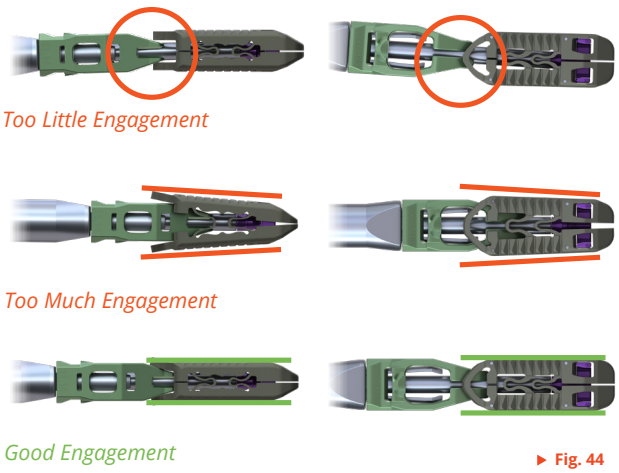
Audible click is heard when Guide Pin is locked into the Inserter.

▸ Fig. 43c



Rotation Misaligned *Correct Alignment*

▸ Fig. 43d



Too Little Engagement

Too Much Engagement

Good Engagement

▸ Fig. 44

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

STEP 1

If desired, the surgeon may pre-pack the disc space with autograft and/or allograft. If this is done, the surgeon must ensure sufficient space remains to allow for expansion of the TiHawk device.

STEP 2

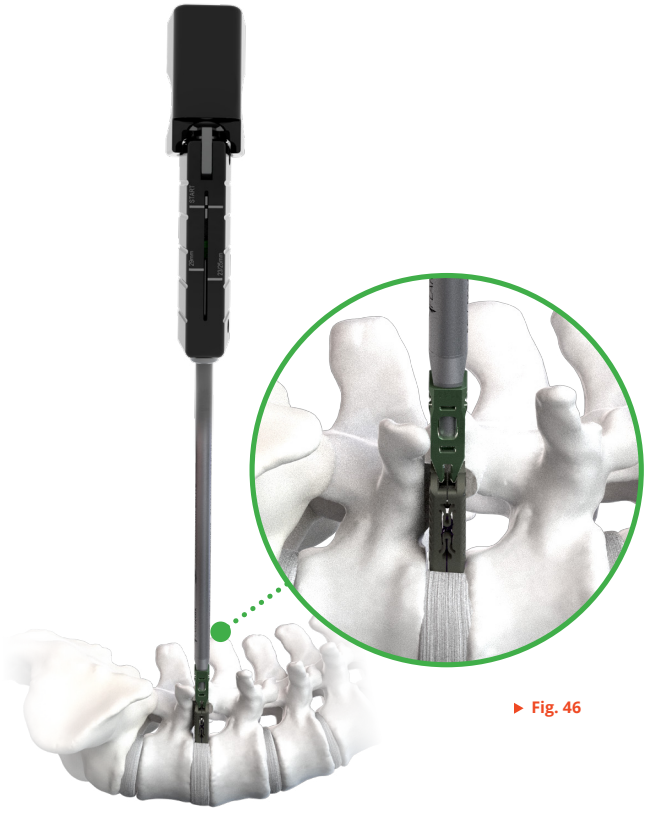
Slide the **Impact Cap** over the Inserter's drive shaft until it clicks into place. ▸ Fig. 45

STEP 3

Position the Inserter at the desired trajectory relative to the disc space. 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. ▸ Fig. 46

NOTE: *Pre-packing graft without ensuring proper clearance for the Implant to deploy in width may cause increased resistance when deploying the Implant.*

▸ Fig. 45



▸ Fig. 46

ASY-00316 Insertion Instrument

II-1-0045 Impact Cap

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 2mm or 4mm in front of the titanium Core when viewing the images. 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.

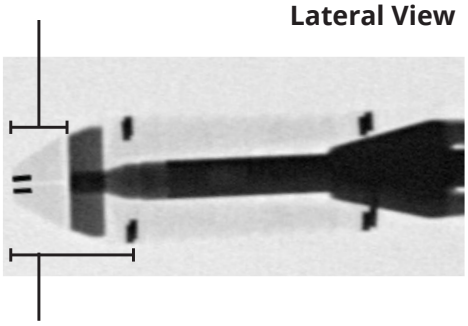
▶ Fig. 47-49

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.*

NOTE: *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 in the desired trajectory.*

2mm:
23mm shells
4mm:
25mm and
29mm shells

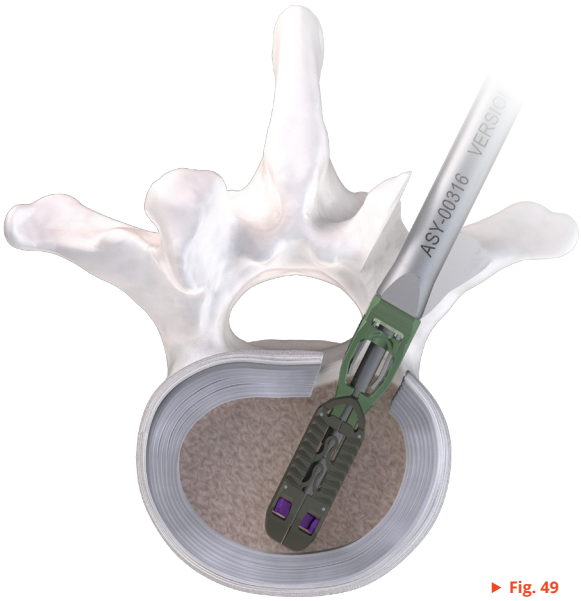
Lateral View



7mm:
23mm shells
9mm:
25 and 29mm shells

▶ Fig. 47

▶ Fig. 48



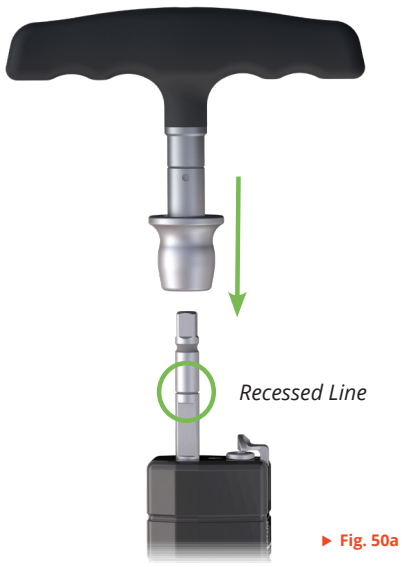
▶ Fig. 49

STEP 5

Select the **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. ▸ Fig. 50

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



▸ Fig. 50a

▸ Fig. 50b

ASY-00316 Insertion Instrument

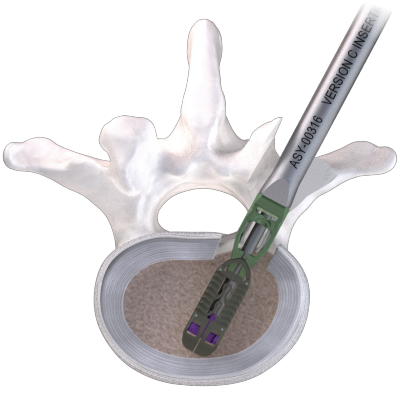
II-1-0372 Fixed T-handle

STEP 6

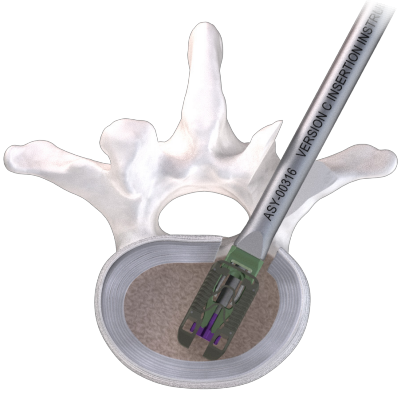
To **expand the Implant**, advance the Shim into the Shell by rotating the T-Handle clockwise until the audible locking click is heard. Once the audible click is heard, the surgeon should use two fingers to rotate the handle gradually until resistance to turning is felt. Confirm Implant placement and trajectory via fluoroscopy during expansion. Once the Shim is locked into the Shell, the Fixed T-Handle should not be rotated further and the lock should be confirmed via fluoroscopy as shown on the next page. The Inserter has 23/25mm and 29mm 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. 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 as this may prevent the Shim from locking into the Shell. ▶ Fig. 51-52

CAUTION: *Once the Shim is locked into the Shell and resistance to turning further is encountered, the Fixed 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 such as Guide Pin and core disassociation.*

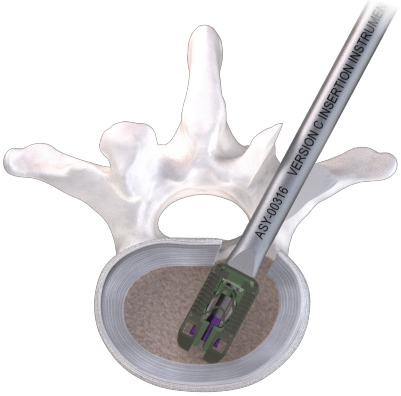
▶ Fig. 51



Not Deployed ▶ Fig. 52a



Partially Deployed ▶ Fig. 52b



Fully Deployed ▶ Fig. 52c

Lock Gauge

After the Inserter has been removed, the **25mm or 29mm Lock Gauge** can be utilized as additional lock confirmation. The 25mm Lock Gauge functions for both 25 and 23mm length Implants. This instrument does not replace fluoroscopic visualization as the primary form of lock confirmation.

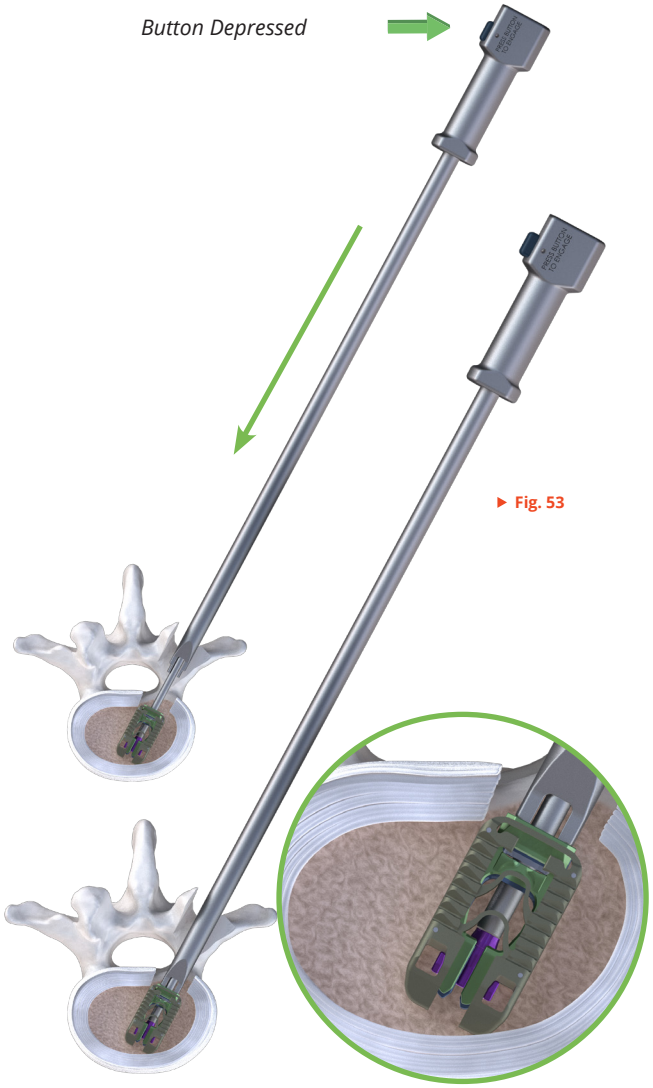
Confirm the Guide Pin is fully threaded to the core by turning the Guide Pin clockwise. If it is fully seated no turning will occur. If it does turn, continue turning until a stop is felt. The Guide Pin Wrench can be utilized to ensure the Guide Pin is threaded to the Core.

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 Guide Pin in the guide pin hole in the back of the handle.

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

▸ Fig. 53-54



▸ Fig. 53

Fully seated ▸ Fig. 54

ASY-00308 FH9 29mm Lock Gauge
ASY-00417 FH9 25mm Lock Gauge

FHTAGP27A Guide Pin, 27mm

Lock Gauge

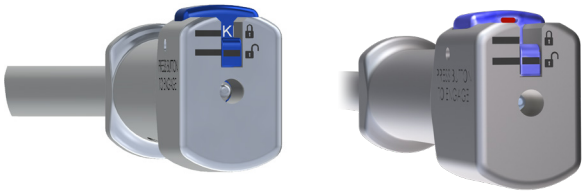
Once fully seated, release the button on the Lock Gauge. If the Implant is locked, the laser mark on the button should align with the locked symbol. Depending on which version of the Lock Gauge is in the set, green marks should appear on button when it is locked, or the word "LOCKED" will be visible 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 lock 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 placed. ▸ Fig. 55-56

NEWER VERSION

Implant Locked ▸ Fig. 55



NEWER VERSION

Implant Unlocked ▸ Fig. 56

Lock Gauge

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.

Use fluoroscopy to confirm the Shim is locked and fully engaged with the Shell. To do this, obtain a lateral image of the Implant. This can also be described to the radiologic technologist as a contralateral oblique image. With a standard C-arm, position the flat face of the image intensifier parallel to the Inserter or Guide Pin. The resulting beam from the image intensifier will be perpendicular to the Inserter or Guide Pin. This will approximate the correct angle for a lateral image of the Implant (contralateral oblique view).

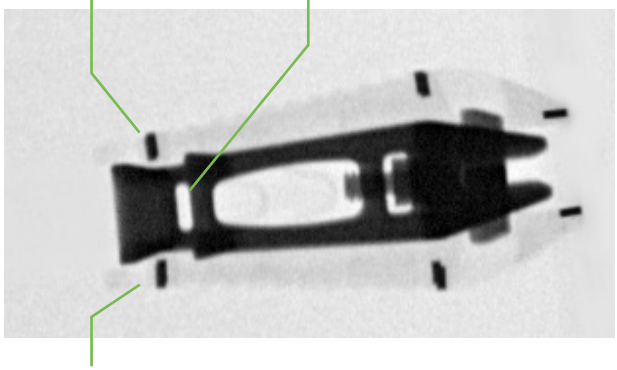
When the Implant is locked, the **posterior tantalum markers** will appear posterior to the **Lock Confirmation Window**. Removal of the Guide Pin and/or Inserter (as described in the following pages) prior to lock verification may be necessary to allow visualization of the Lock Confirmation Window.

▸ Fig. 57-58

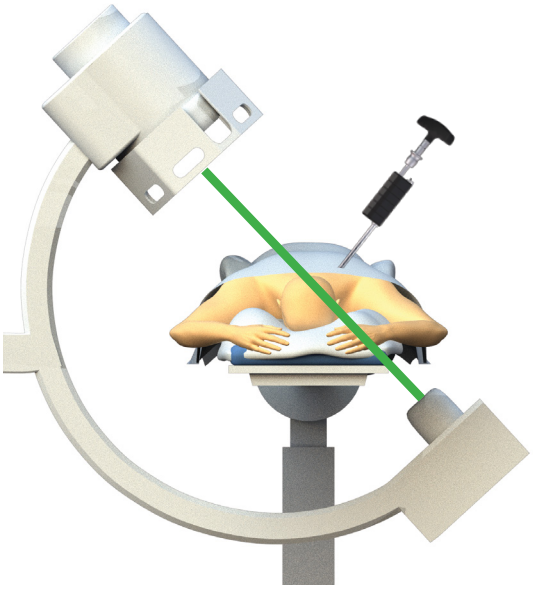
CAUTION: *An unlocked Implant or Implant without a Shim should never be left in a patient.*

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

NOTE: *In order to obtain a direct lateral image of the Implant during a TLIF, the C-arm must be placed opposite to the side on which the surgeon is performing the surgery.*



▸ Fig. 57

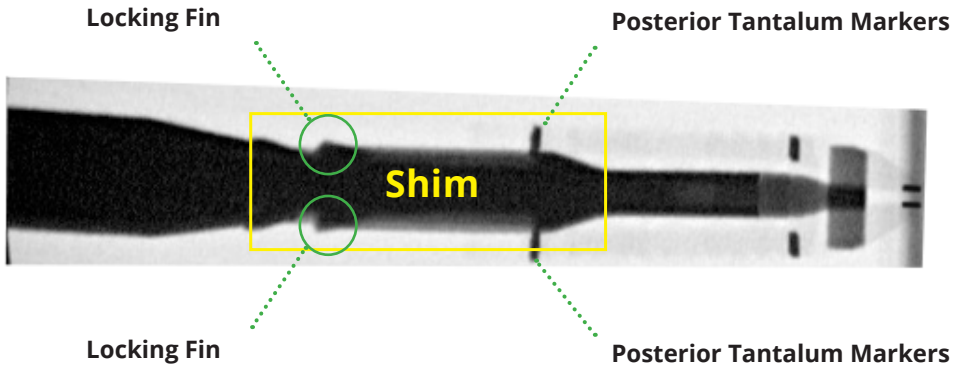


▸ Fig. 58

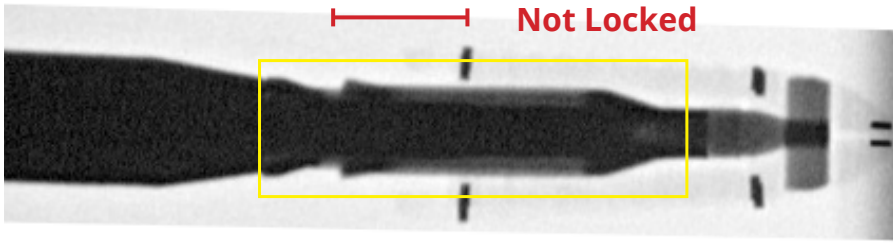
Lock Verification

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.**

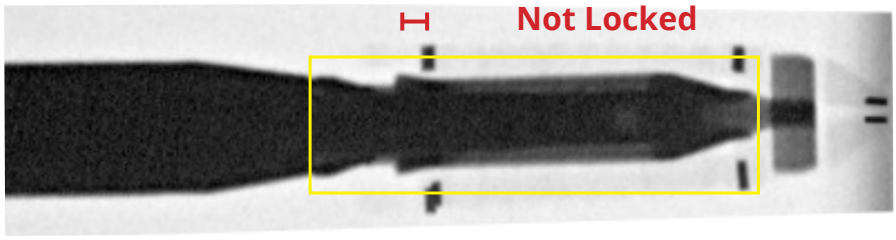
▶ Fig. 59-62



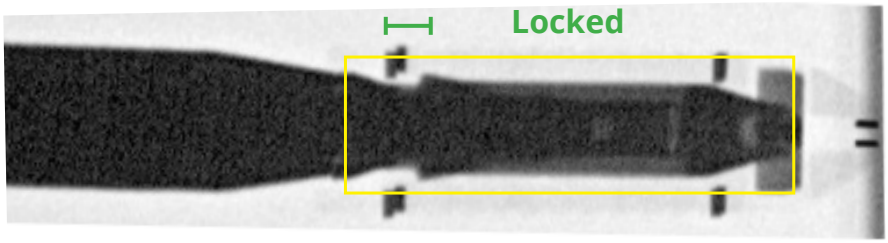
▶ Fig. 59



▶ Fig. 60



▶ Fig. 61

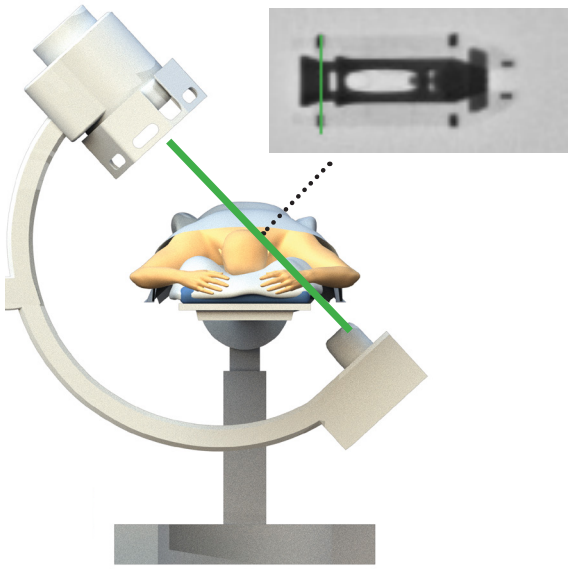


▶ Fig. 62

Locking Fins Anterior to the Posterior Tantalum Markers.

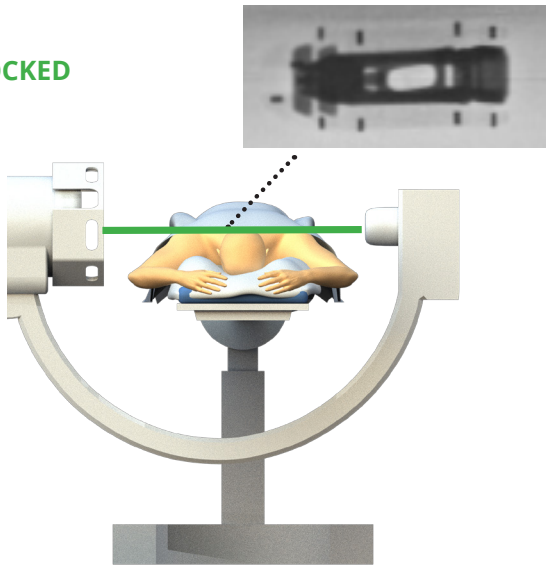
Lock Verification

The images below 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. ▸ Fig. 63-64

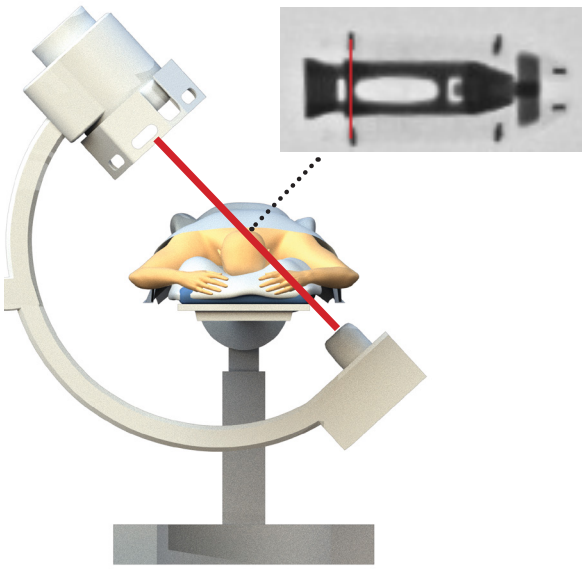


Contralateral Oblique ▸ Fig. 63a

LOCKED

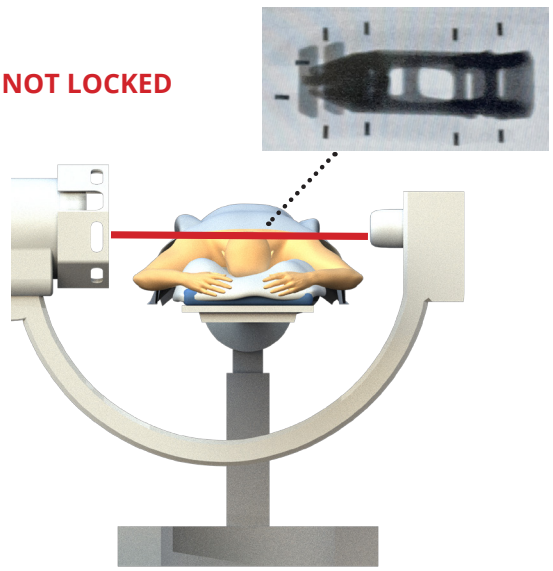


Lateral ▸ Fig. 63b



Contralateral Oblique ▸ Fig. 64a

NOT LOCKED



Lateral ▸ Fig. 64b

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 and disc space, leaving the Guide Pin attached to the expanded Implant.

▶ Fig. 65-66

▶ Fig. 65

Depress Guide Pin release button to remove Inserter

▶ Fig. 66

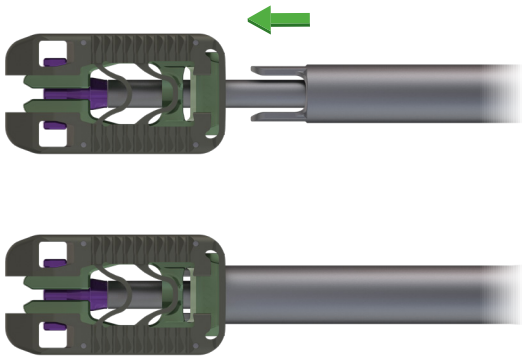
Bone Funnel Preparation

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.

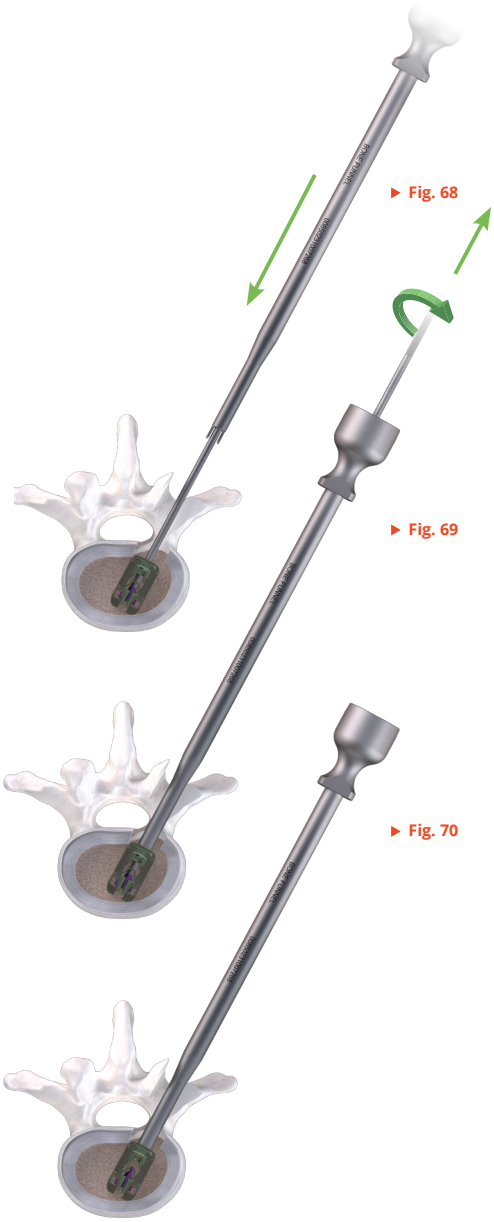
Unscrew and remove the Guide Pin by rotating it counterclockwise. This may be done using the Guide Pin Wrench or the surgeon's fingers. Once the Guide Pin has been removed, fill the Bone Funnel with autograft and/or allograft. To reduce the chance of clogging, ensure the bone graft is adequately morselized (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.

▶ Fig. 67-70



▶ Fig. 67



▶ Fig. 68

▶ Fig. 69

▶ Fig. 70

II-1-0038 Bone Funnel Assy

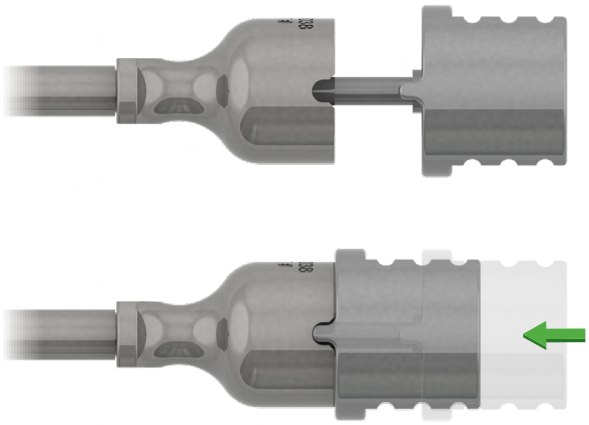
II-1-0042 Bone Tamp

Bone Graft Delivery

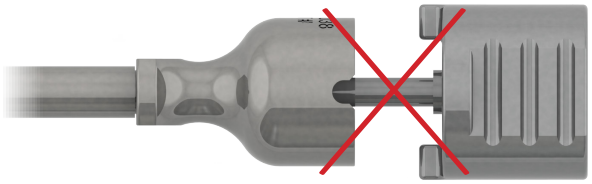
Using the **Bone Tamp**, push the bone graft through the Bone Funnel into the deployed TiHawk Implant, while maintaining consistent downward pressure on the Bone Funnel. Continue to advance the Tamp until all graft in the Bone Funnel is delivered. If the Tamp will not advance, discontinue impaction and 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. ▸ Fig. 71

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 the Implant.*



Correct Alignment ▸ Fig. 71a



Incorrect Alignment ▸ Fig. 71b

GRAFT DELIVERY PROCESS

▸ Fig. 72

Bone Graft Delivery With Repeaters

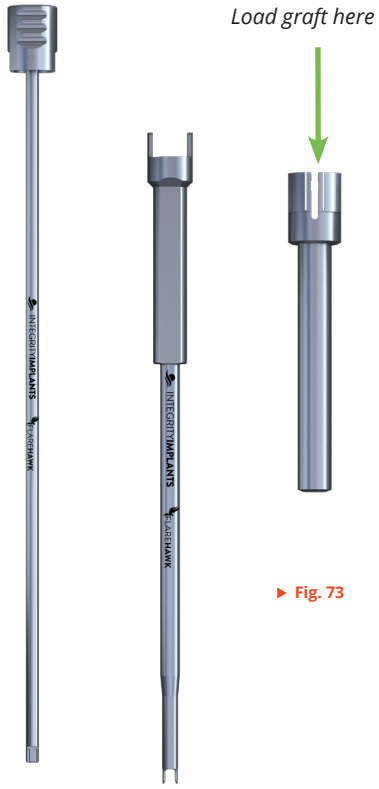
The **Repeater Bone Funnel system** consists of three components: Bone Funnel (II-1-0431), Bone Funnel Crucible (II-1-0434), and Bone Tamp (II-1-0435).

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 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.

Repeat the Bone Funnel preparation and graft delivery steps as many times as needed, until the Implant is sufficiently packed with allograft and/or autograft.

▶ Fig. 73



▶ Fig. 73

II-1-0435 Bone Tamp

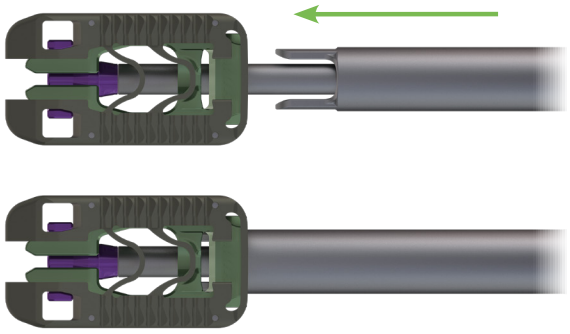
II-1-0434 Crucible (Repeater)

II-1-0431 Bone Funnel

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.

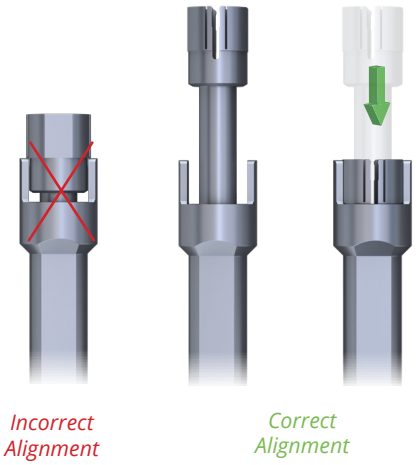
If desired, the Bone Funnel can be passed over the Guide Pin while the Guide Pin is still attached to the deployed Implant. If this is done, the Guide Pin must be removed before the Crucible is used. Alternatively, the Bone Funnel can be placed freehand following removal of the Guide Pin. ▸ Fig. 74



▸ Fig. 74

STEP 3

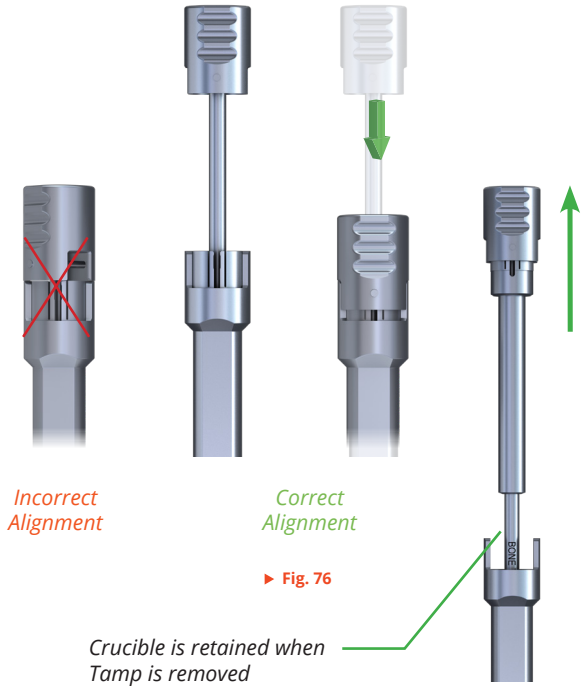
Insert one pre-loaded Crucible into the top section of the Bone Funnel. Ensure that the Crucible is properly seated in the Funnel. When properly placed, the Crucible will be completely flush with the top of the Funnel. ▸ Fig. 75



▸ Fig. 75

STEP 4

Using the Bone Tamp, push the bone graft in the Crucible through the Funnel and into the deployed Implant. Continue to advance the Tamp until it clicks into the top of the Crucible. To do this, the Tamp and Crucible must be properly aligned. ▸ Fig. 76



▸ Fig. 76

▸ Fig. 77

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 Crucible. Once the Tamp is completely removed, detach the empty Crucible from the Tamp. ▸ Fig. 76-77

STEP 6

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

NOTE: *The Crucible, Bone Funnel, and Bone Tamp are not disposable.*

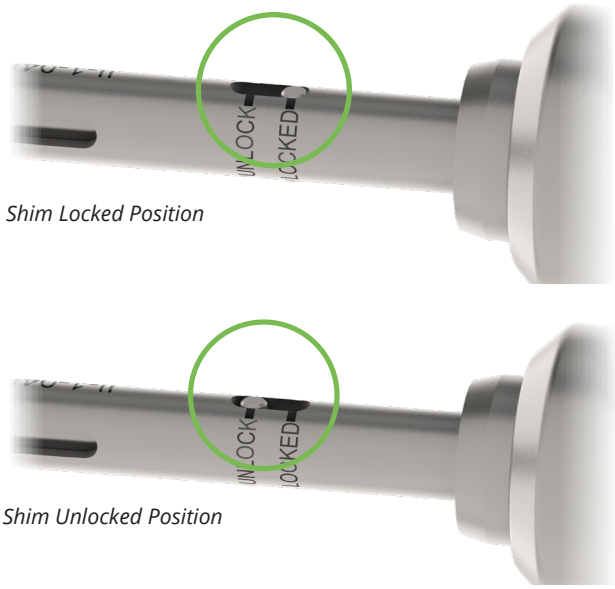
STEP 1

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. Insert the instrument 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. The Shim Removal Tool will be flush with the back of 29mm Shims, while the 23/25mm Shims will have a small gap between the Shim and Shim Removal Tool as shown in the image below. ▸ Fig. 78-79

STEP 2

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

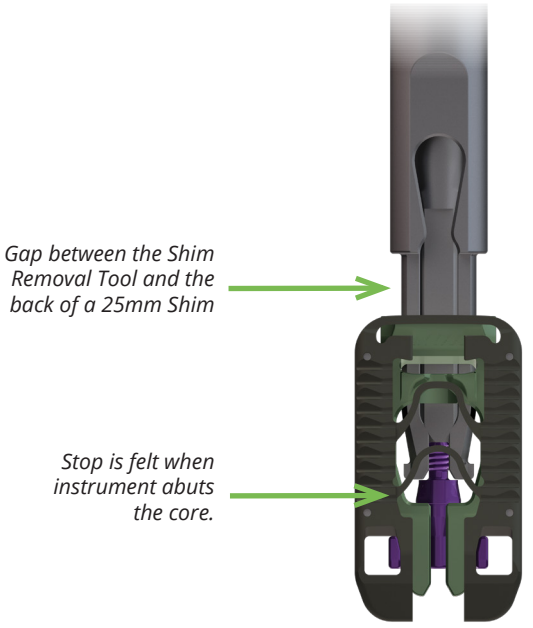
▸ Fig. 80



Shim Locked Position

Shim Unlocked Position

▸ Fig. 78



▸ Fig. 79

▸ Fig. 80

STEP 3

Carefully pull upward to remove the Shim from the Shell. Monitor the Implant visually and/or 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 should overcome the Posterior Lock.

▸ Fig. 81

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

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

NOTE: *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.*

▸ Fig. 81

II-1-0005 Slap Hammer

II-1-0458 Split Shim Removal Tool

STEP 4

Once the Shim is removed, 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. Rotate the instrument ninety degrees to grab the flexors of the Shell. ▸ Fig. 82

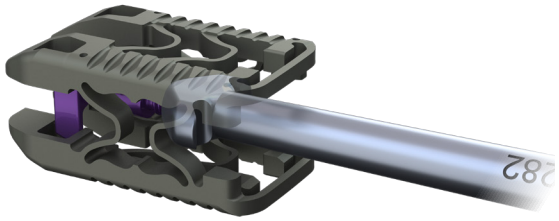
STEP 5

Pull the Shell out of the disc space using the Shell Retriever. If desired, the Slap Hammer may be used. Monitor the Shell's progress visually to verify that removal is effective.

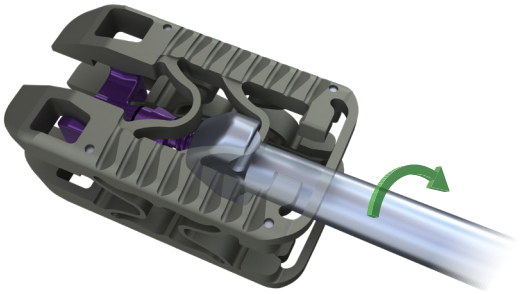
▸ Fig. 83

Implantation of the FlareHawk Interbody Fusion System in PLIF:

The steps described above are the same except a PLIF surgical approach is used, and two total Implant assemblies are placed in parallel within the disc space in a straight anterior-posterior direction. Since two Implants are being placed, it is important to make sure enough space is available to expand both Implants.



Shell Retriever fully seated in the Shell ▸ Fig. 82a



Rotate instrument 90⁰ to grab flexors. ▸ Fig. 82b

Ensure tip of Shell Retriever is parallel with the Shell and endplates ▸ Fig. 83

II-1-0005 Slap Hammer

II-1-0276 Shell Retriever

FLAREHAWK9 INSTRUMENT CATALOG

All instrumentation compatible with TiHawk9 and TiHawk11

Part Numbers	Description
ASY-00484	FlareHawk9 Instrument Tray Base
ASY-00410	Integrity Implants Universal Lid
ASY-00485	FlareHawk9 Insertion Instrumentation Tray
II-1-0372	Fixed T- Handle
II-1-0045	Impact Cap
CMP-00546	Short Impactor
CMP-00547	Tall Impactor
II-1-0328	Fixed Hudson T-Handle
II-1-0073	Insertion Instrument
ASY-00308	FH9 29mm Lock Gauge
ASY-00417	FH9 25mm Lock Gauge
II-1-0015	Guide Pin Wrench
II-1-0431	Bone Funnel (Repeater)
II-1-0435	Bone Tamp (Repeater)
II-1-0434	Bone Funnel Crucible (Repeater)
II-1-0038	Bone Funnel
II-1-0042	Bone Tamp
ASY-00486	FlareHawk9 Auxilliary Instrument Tray
ASY-00499	Cannula and Obturator Tray
CMP-00077	Cannula Assembly Short
CMP-00078	Cannula Assembly Tall
ASY-00006	Cannula Obturator Short
ASY-00008	Cannula Obturator Tall
CMP-01023	Fixed Small Inline Handle
CMP-01024	Fixed Small Teardrop Handle
ASY-00143	Expandable Trial, 0 degree
ASY-00337	Expandable Trial, 9 degree
II-1-0005	Slap Hammer
II-1-0458	Split Shim Removal Tool
II-1-0276	Shell Retriever
ASY-00489	FlareHawk9 Universal Instrument Tray
ASY-00414	Shaver and Distractor Tray Base
ASY-00419	0 Shaver and Distractor Tray
ASY-00420	9 and 15 Distractor Tray
ASY-00421	General Instrument Tray
ASY-00433	Universal Lid
II-1-0328	Fixed Hudson Handle
1-IFU-0150	FlareHawk IFU
ASY-00316	Insertion Instrument

FLAREHAWK9 INSTRUMENT CATALOG (CONTINUED)

All instrumentation compatible with TiHawk9 and TiHawk11

Part Numbers	Description
CMP-00698	7mm x 29mm, 0 Degree Shaver
CMP-00699	8mm x 29mm, 0 Degree Shaver
CMP-00700	9mm x 29mm, 0 Degree Shaver
CMP-00701	10mm x 29mm, 0 Degree Shaver
CMP-00702	11mm x 29mm, 0 Degree Shaver
CMP-00703	12mm x 29mm, 0 Degree Shaver
CMP-00704	13mm x 29mm, 0 Degree Shaver
CMP-00705	14mm x 29mm, 0 Degree Shaver
CMP-00688	7mm x 29mm, 0 Degree Distractor
CMP-00689	8mm x 29mm, 0 Degree Distractor
CMP-00690	9mm x 29mm, 0 Degree Distractor
CMP-00691	10mm x 29mm, 0 Degree Distractor
CMP-00692	11mm x 29mm, 0 Degree Distractor
CMP-00693	12mm x 29mm, 0 Degree Distractor
CMP-00694	13mm x 29mm, 0 Degree Distractor
CMP-00695	14mm x 29mm, 0 Degree Distractor
CMP-00513	11mm x 29mm, 9 degree Distractor
CMP-00514	12mm x 29mm, 9 degree Distractor
CMP-00515	13mm x 29mm, 9 degree Distractor
CMP-00516	14mm x 29mm, 9 degree Distractor
CMP-00534	12mm x 29mm, 15 degree Distractor
CMP-00535	13mm x 29mm, 15 degree Distractor
CMP-00536	14mm x 29mm, 15 degree Distractor
CMP-02456	7mm Shaver, Open
CMP-02457	8mm Shaver, Open
CMP-02458	9mm Shaver, Open
CMP-02459	10mm Shaver, Open
CMP-02460	11mm Shaver, Open
CMP-02461	12mm Shaver, Open
CMP-02462	13mm Shaver, Open
CMP-02463	14mm Shaver, Open

Instrument Catalog

Paddle Distractor

(CMP-00688, 689, 690, 691, 692, 693, 694, 695)

Disc Shaver

(CMP-00698, 699, 700, 701, 702, 703, 704, 705)

Open Shaver

(CMP-02456, 57, 58, 59, 60, 61, 62, 63)

Shell Retriever

(II-1-0276)

Impactor

(CMP-00546, 47)

Inserter

(ASY-00316)

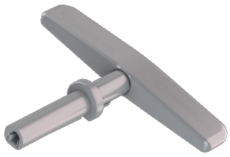
Bone Funnel Assy

(II-1-0038)

Bone Tamp

(II-1-0042)

Instrument Catalog



Guide Pin Wrench
(II-1-0015)

Split Shim Removal Tool
(II-1-0458)

Guide Pin
(FHTA-GP-27-A)

Impaction Cap
(II-1-0045)

Fixed T-Handle
(II-1-0372)

Hudson T-Handle
(II-1-0328)

Inline Handle
(CMP-01023)

Teardrop Handle
(CMP-01024)

Instrument Catalog

Expandable Trial, 0 degree

(ASY-00143)

Expandable Trial, 9 degree

(ASY-00337)

FH9 29mm Lock Gauge

(ASY-00308)

FH9 25mm Lock Gauge

(ASY-00417)

Slap Hammer

(II-1-0005)

Implant Catalog

TIHAWK9 IMPLANT CASE CATALOG

Part Numbers	Description
II-1-0145	Implant Case
CMP-00708	FlareHawk9 25mm Implant Caddy
FHPACS0025TT	Shell, Short 25mm, TiH9
FHPACT0025TT	Shell, Tall 25mm, TiH9
FHPACT0925TT	Shell, Lordotic 25mm, TiH9
FHPAS10023X	Shim, 8mm or 11mm x 25mm, 0 degree, FH9
FHPAS20023X	Shim, 9mm or 12mm x 25mm, 0 degree, FH9
FHPAS30023X	Shim, 10mm or 13mm x 25mm, 0 degree, FH9
FHPAS40023X	Shim, 11mm or 14mm x 25mm, 0 degree, FH9
FHPAS10623X	Shim, 10mm or 12mm x 25mm, 6 degree, FH9
FHPAS20623X	Shim, 11mm or 13mm x 25mm, 6 degree, FH9
FHPAS30623X	Shim, 12mm or 14mm x 25mm, 6 degree, FH9
CMP-00587	29mm Implant Caddy
FHTACS0029TT	Shell, Short 29mm, TiH9
FHTACT0029TT	Shell, Tall 29mm, TiH9
FHTACT0929TT	Shell, Lordotic 29mm, TiH9
FHTAS10027X	Shim, 8mm or 11mm x 29mm, 0 degree, FH9
FHTAS20027X	Shim, 9mm or 12mm x 29mm, 0 degree, FH9
FHTAS30027X	Shim, 10mm or 13mm x 29mm, 0 degree, FH9
FHTAS40027X	Shim, 11mm or 14mm x 29mm, 0 degree, FH9
FHTAS10627X	Shim, 10mm or 12mm x 29mm, 6 degree, FH9
FHTAS20627X	Shim, 11mm or 13mm x 29mm, 6 degree, FH9
FHTAS30627X	Shim, 12mm or 14mm x 29mm, 6 degree, FH9
FHTAGP27A	Guide Pin, 27mm

FLAREHAWK9 IMPLANT CASE CATALOG

Part Numbers	Description
FHPACS0023SB	Shell, Short 25 mm, FlareHawk 9
FHPACT0023SB	Shell, Tall 25 mm, FlareHawk 9
FHPACT0923H	Shell, Lordotic 25 mm, FlareHawk 9
FHTACS0027SB	Shell, Short 29 mm, FlareHawk 9
FHTACT0027SB	Shell, Tall 29 mm, FlareHawk 9
FHTACT0927H	Shell, Lordotic 29 mm, FlareHawk 9

TIHAWK9 STERILE PACK IMPLANT CASE CATALOG

Part Numbers	Description
ASY-00718	FlareHawk Sterile Pack Field Distribution Soft Case
FHPACS0025TTS	Shell, Short 25mm, TiH9 Sterile
FHPACT0025TTS	Shell, Tall 25mm, TiH9 Sterile
FHPACT0925TTS	Shell, Lordotic 25mm, TiH9 Sterile
FHPAS100259S	Shim, 8mm or 11mm x 25mm, 0 degree, FH9 Sterile
FHPAS200259S	Shim, 9mm or 12mm x 25mm, 0 degree, FH9 Sterile
FHPAS300259S	Shim, 10mm or 13mm x 25mm, 0 degree, FH9 Sterile
FHPAS400259S	Shim, 11mm or 14mm x 25mm, 0 degree, FH9 Sterile
FHPAS106259S	Shim, 10mm or 12mm x 25mm, 6 degree, FH9 Sterile
FHPAS206259S	Shim, 11mm or 13mm x 25mm, 6 degree, FH9 Sterile
FHPAS306259S	Shim, 12mm or 14mm x 25mm, 6 degree, FH9 Sterile
FHTACS0029TTS	Shell, Short 29mm, TiH9 Sterile
FHTACT0029TTS	Shell, Tall 29mm, TiH9 Sterile
FHTACT0929TTS	Shell, Lordotic 29mm, TiH9 Sterile
FHTAS100299S	Shim, 8mm or 11mm x 29mm, 0 degree, FH9 Sterile
FHTAS200299S	Shim, 9mm or 12mm x 29mm, 0 degree, FH9 Sterile
FHTAS300299S	Shim, 10mm or 13mm x 29mm, 0 degree, FH9 Sterile
FHTAS400299S	Shim, 11mm or 14mm x 29mm, 0 degree, FH9 Sterile
FHTAS106299S	Shim, 10mm or 12mm x 29mm, 6 degree, FH9 Sterile
FHTAS206299S	Shim, 11mm or 13mm x 29mm, 6 degree, FH9 Sterile
FHTAS306299S	Shim, 12mm or 14mm x 29mm, 6 degree, FH9 Sterile

TIHAWK11 STERILE PACK IMPLANT CASE CATALOG

Part Numbers	Description
ASY-00718	FlareHawk Sterile Pack Field Distribution Soft Case
FHTGCS0023TTS	Shell, Short 23 mm, TiH11 Sterile
FHTGCT0023TTS	Shell, Tall 23 mm, TiH11 Sterile
FHTGCT0923TTS	Shell, Lordotic 23 mm, TiH11 Sterile
FHTGCS0025TTS	Shell, Short 25 mm, TiH11 Sterile
FHTGCT0025TTS	Shell, Tall 25 mm, TiH11 Sterile
FHTGCT0925TTS	Shell, Lordotic 25 mm, TiH11 Sterile
FHTGS000251S	Shim, 7 mm or 10 mm x 23 mm/ 25 mm, 0 degree, FH11 Sterile
FHTGS100251S	Shim, 8 mm or 11 mm x 23 mm/ 25 mm, 0 degree, FH11 Sterile
FHTGS200251S	Shim, 9 mm or 12 mm x 23 mm/ 25 mm, 0 degree, FH11 Sterile
FHTGS300251S	Shim, 10 mm or 13 mm x 23 mm/ 25 mm, 0 degree, FH11 Sterile
FHTGS400251S	Shim, 11 mm or 14 mm x 23 mm/ 25 mm, 0 degree, FH11 Sterile
FHTGS106251S	Shim, 10 mm or 12 mm x 23 mm/ 25 mm, 6 degree, FH11 Sterile
FHTGS206251S	Shim, 11 mm or 13 mm x 23 mm/ 25 mm, 6 degree, FH11 Sterile
FHTGS306251S	Shim, 12 mm or 14 mm x 23 mm/ 25 mm, 6 degree, FH11 Sterile
FHTGCS0029TTS	Shell, Short 29 mm, TiH11 Sterile
FHTGCT0029TTS	Shell, Tall 29 mm, TiH11 Sterile
FHTGCT0929TTS	Shell, Lordotic 29 mm, TiH11 Sterile
FHTGS000291S	Shim, 7 mm or 10 mm x 29 mm, 0 degree, FH11 Sterile
FHTGS100291S	Shim, 8 mm or 11 mm x 29 mm, 0 degree, FH11 Sterile
FHTGS200291S	Shim, 9 mm or 12 mm x 29 mm, 0 degree, FH11 Sterile
FHTGS300291S	Shim, 10 mm or 13 mm x 29 mm, 0 degree, FH11 Sterile
FHTGS400291S	Shim, 11 mm or 14 mm x 29 mm, 0 degree, FH11 Sterile
FHTGS106291S	Shim, 10 mm or 12 mm x 29 mm, 6 degree, FH11 Sterile
FHTGS206291S	Shim, 11 mm or 13 mm x 29 mm, 6 degree, FH11 Sterile
FHTGS306291S	Shim, 12 mm or 14 mm x 29 mm, 6 degree, FH11 Sterile

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.

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 aluminum 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 mm^2/mm^3. 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.

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.

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.

Integrity Implants Inc.
354 Hiatt Drive
Palm Beach Gardens, FL
33418 USA
Phone: 800 201 9300
or 561 529 3861
Email: customerservice@
integrityimplants.com

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

Notes

MINIMALLY INVASIVE SURGICAL TECHNIQUE MANUAL

Accelus

TiHAWK

FlareHawk Interbody Fusion System

Multi-Directional Expansion | Minimal Insertion Profile | Maximum Graft Delivery

TiHAWK9™ FLAREHAWK9 TiHAWK11™

Accelus

PHONE 800.201.9300 | +1.561.529.3861
EMAIL customerservice@accelusinc.com
WEB www.accelusinc.com

INTEGRITY IMPLANTS INC.
354 Hiatt Drive
Palm Beach Gardens, FL 33418 USA

STM-00018 RevD