

InterFuse S™

Surgical Technique Manual

Distribuidor exclusivo em Portugal:



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INTERFUSE S PRODUCT DESCRIPTION

The VTI InterFuse S Intervertebral Body Fusion Device is an implant that combines the large vertebral endplate contact area characteristic of many ALIF devices with the ability for implantation through a less invasive surgical approach. The unique design of the InterFuse S incorporates an anatomical shape that assures contact with the peripheral margins of the vertebral endplate; contacting the endplate margins is critical to proper loading and reduces the risk of subsidence. The interlocking design provides the necessary structural support and endplate contact area while the open caudal and cephalad spaces accommodate new bone growth and fusion.

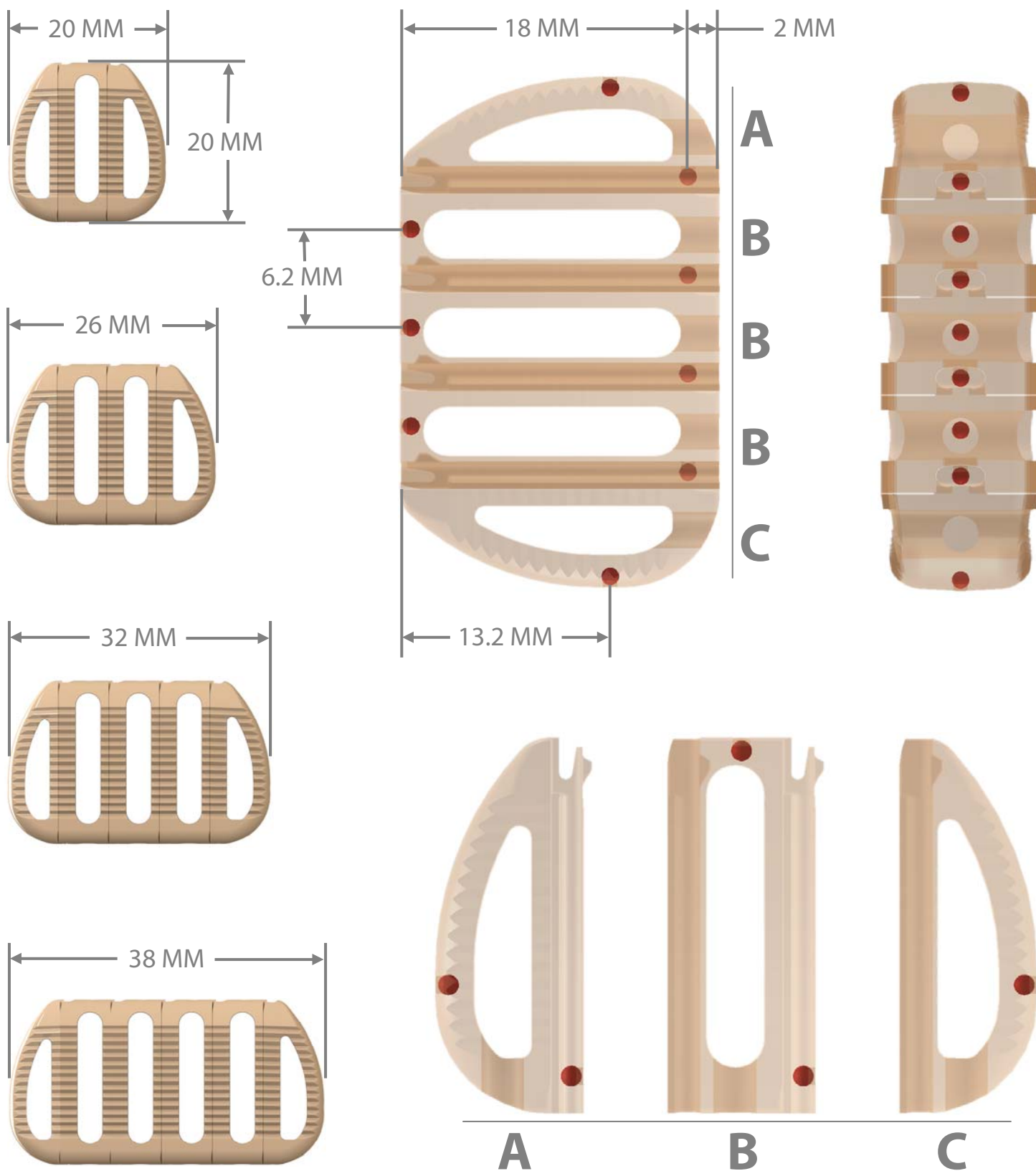
The InterFuse S is made of radiolucent PEEK-Optima® to provide structural strength with nearly the same stiffness of cortical bone while maintaining the ability to assess fusion progress radiographically. The InterFuse S incorporates tantalum markers to aid in visualizing the device during intraoperative and postoperative radiographic assessment. The unique rail-and-slot design using stainless steel tails assures proper placement and alignment of each segment. The InterFuse S allows for the use of as few as three to as many as six segments to provide the best fit possible for each individual patient.

The InterFuse S is available in six heights (7mm, 8mm, 9mm, 10mm, 12mm, 14mm), one A-P length (20mm), and two endplate angles (parallel, 5° lordotic angle). The device is supplied in 4-module (ABBC) and single B module packages. The device is supplied STERILE. A set of instruments is supplied for implantation of this device.

INDICATIONS FOR USE

The InterFuse S Intervertebral Body Fusion Device is indicated for intervertebral spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The InterFuse S device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The InterFuse S device is indicated for use with bone graft and to be used with supplemental internal spinal fixation systems that have been cleared for in the lumbosacral spine.

X-RAY MARKER LOCATIONS AND PRODUCT SPECIFICATIONS



INSTRUMENT SET

Threaded Inserter

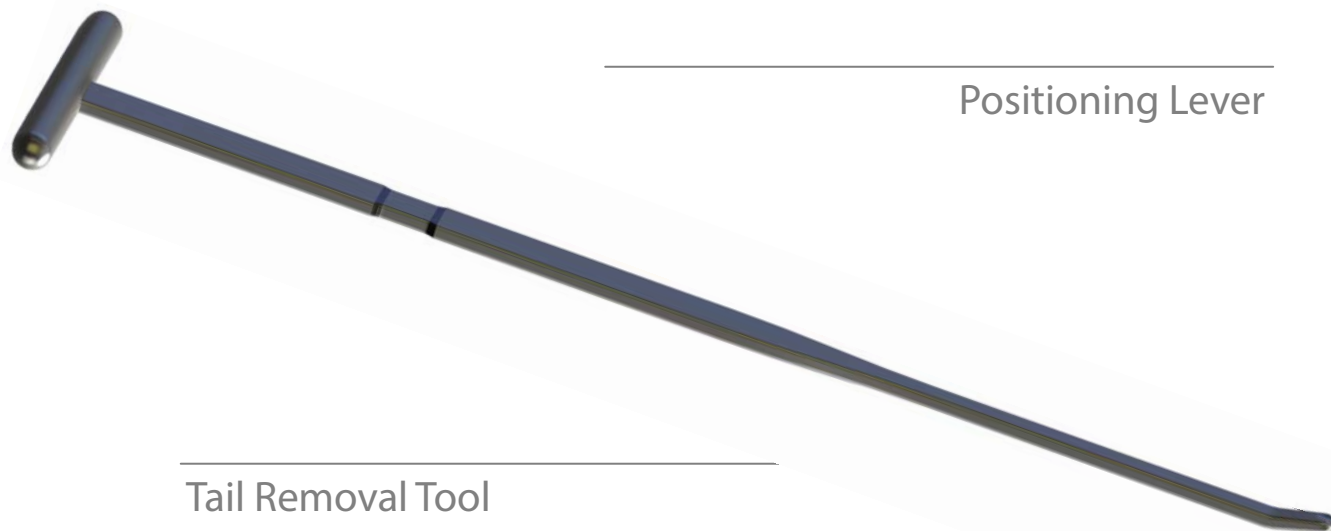


Insertion Guard



Nucleus Probe





Positioning Lever

Tail Removal Tool



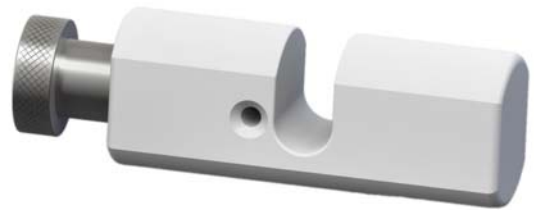
Device Sizer



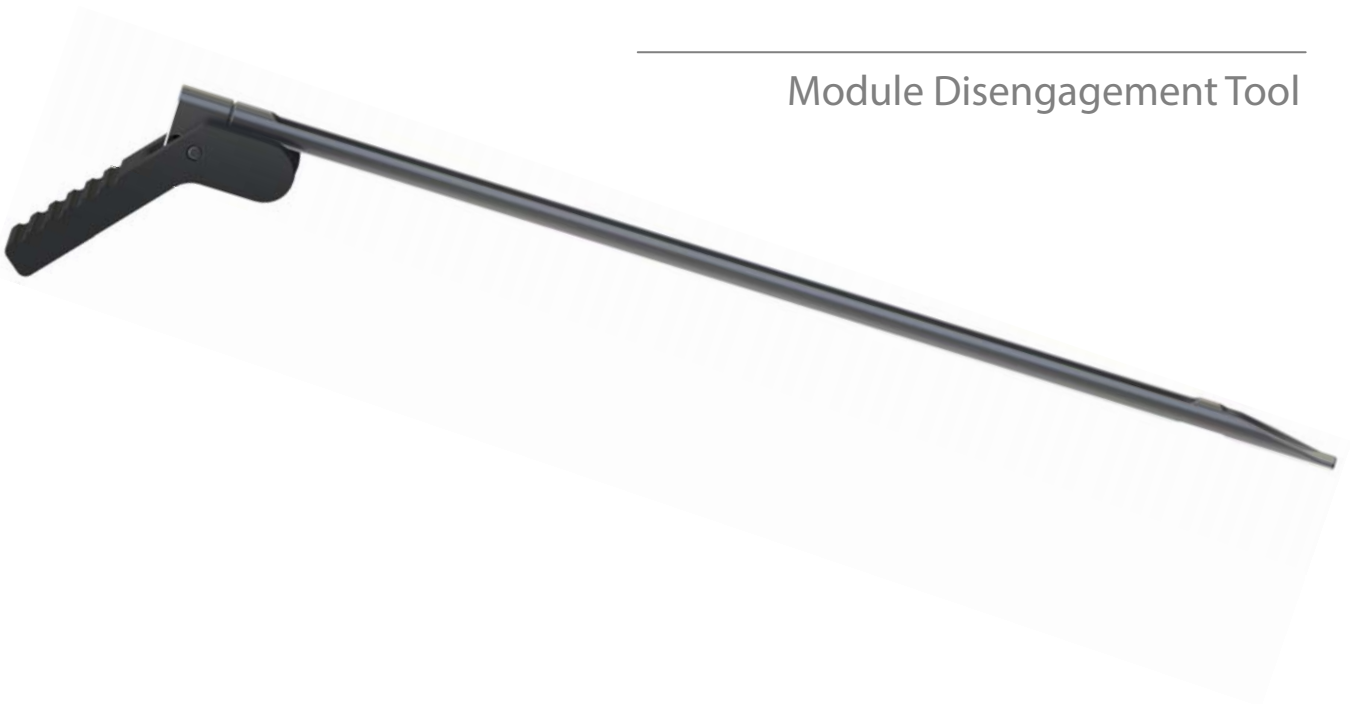
Slap Hammer



Tail Traction Tool



Module Disengagement Tool



STEP 1 — PREOPERATIVE PLANNING

Preoperative planning is recommended for determining the height and lateral width of the VTI InterFuse S device that will most likely provide the best fit and fill in the patient's disc space. Determine the approximate implant height required for the patient by using sagittal measurements of the intervertebral discs adjacent to the disc being treated. A measurement must be taken from an MRI obtained within the previous 6 months. An alternate method is to use digitally-aided lateral radiographs. Select the device height that most closely matches, but does not exceed, the disc height of the adjacent levels. The implant must fit securely between the endplates when the segment is fully distracted. It is essential to use the tallest possible implant, as determined by the preoperative planning, to maximize segmental stability.

Next, determine the approximate InterFuse S device width expected to be implanted from the patient's A-P MRI or radiograph. Select the number of InterFuse S modules to be used in order for the InterFuse S device to maximize contact with the peripheral margins of the endplates once assembled in-vivo.

Due to variations in radiographic magnification, these measurements provide only an estimate of the ideal implant size. Final device sizing must be performed just prior to implant insertion using the sizing instruments provided. Actual lateral dimension of the InterFuse S device is determined intraoperatively by the ability to insert modules effectively.

PATIENT POSITIONING

The patient is positioned prone on a lumbar frame that promotes suitable exposure and restores sagittal alignment. Use of c-arm intraoperative radiographic equipment is recommended to assure operative site selection, confirm the precise position of the InterFuse S device and minimize surgical exposure. Positioning of the patient on the surgical table can be used to obtain additional distraction of the disc space.

STEP 2 — DISC REMOVAL AND ENDPLATE SHAPING

Identify Landmarks

- Perform a midline or paramedian incision and identify anatomical landmarks.
- If a pedicle screw system is used, place screws prior to implantation. They may be used for temporary disc distraction during implant insertion.
- If a facet screw system is used, lateral exposure only to the facets may be used.

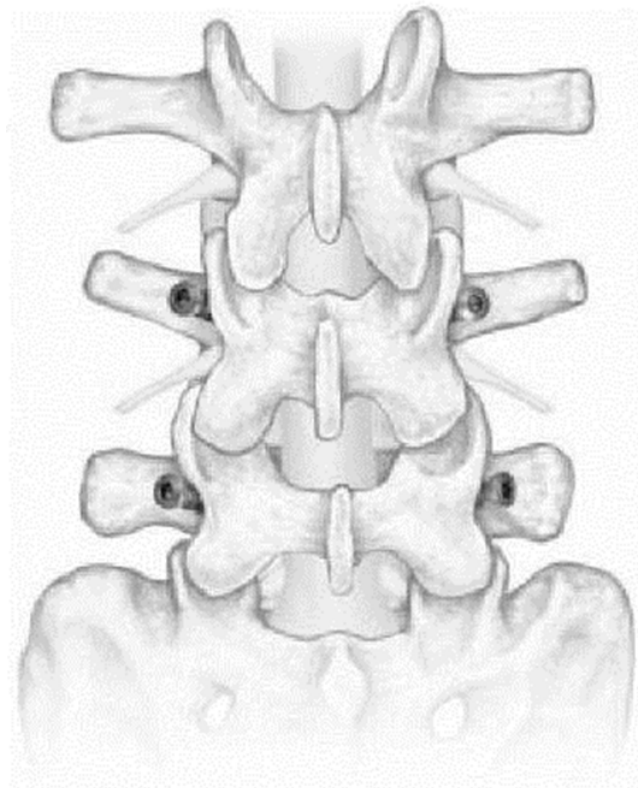


Fig 1

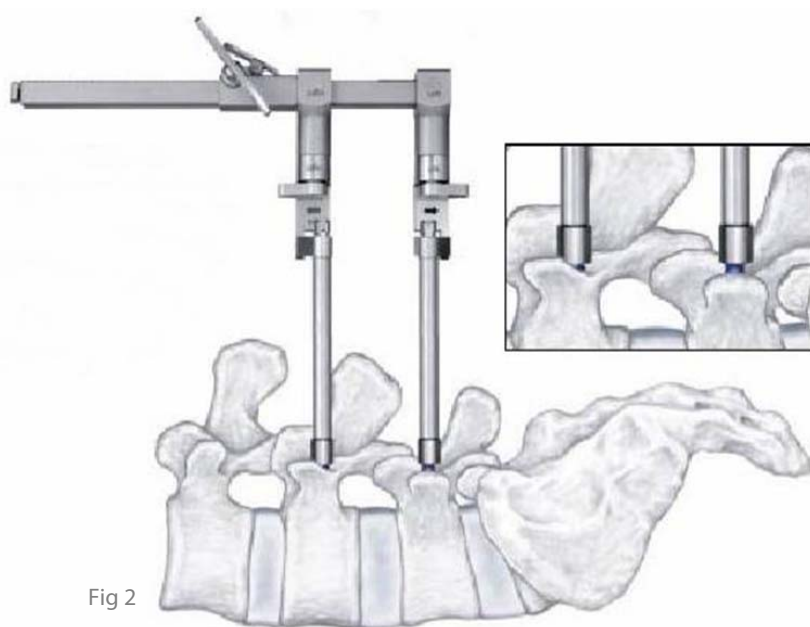


Fig 2

Distraction

- Parallel distraction of the disc provides easier insertion of modules and ensures sufficient device height.
- Distraction can be applied between pedicle screw heads using a lateral distractor (Fig 2).
- Apply distraction after pedicle rods if distractor removal is desired.

(continued on page 10)

Distraction (*continued*)

- Alternatively, place a spreader at the lamina or base of the spinous process (Fig 3). Distraction may be maintained with screws and rods following use of the spreader.

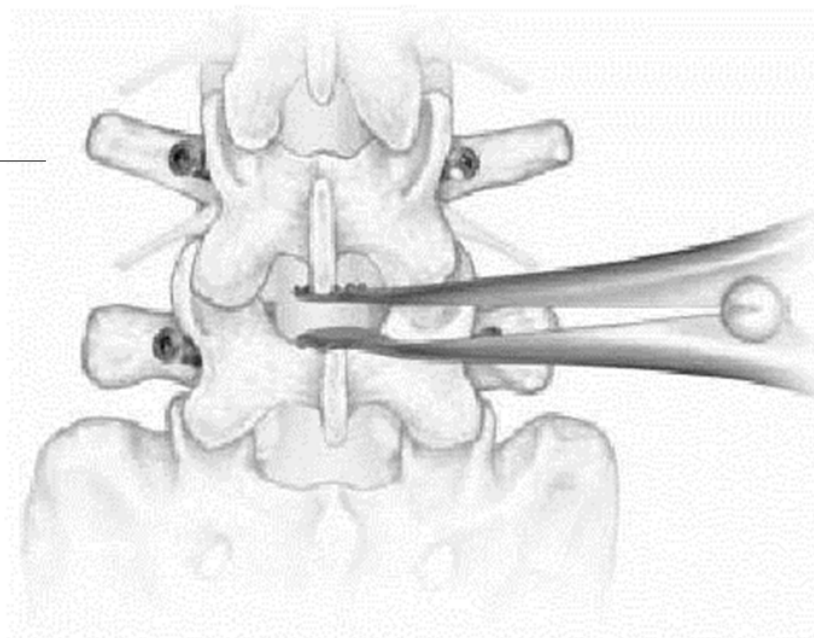


Fig 3

Access Channel

- Create an access to the annulus by performing a laminectomy and medial facetectomy.
- Extending the laminectomy to the medial border of the inferior facet ensures sufficient access to the disc space for nucleus removal and device implantation.

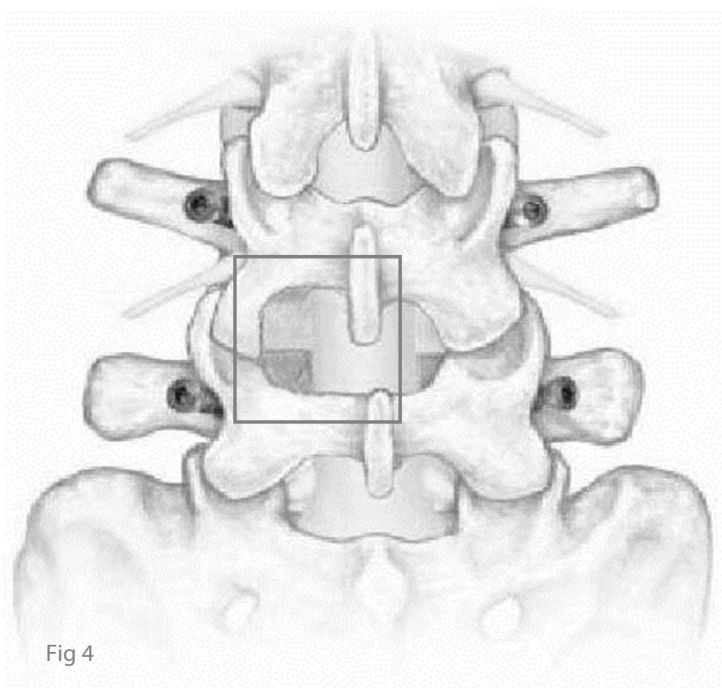


Fig 4

Annulotomy and Cortical Rim

- Continue the access channel through the posterior annulus and cortical rim (blue circle in Figure 5).
- Create a rectangular annulotomy using a #11 blade (Figures 6a and 6b).
- Shape the corners of the cortical rim to ensure the access is rectangular (red square in Figure 5). If a paddle shaver is used to create the access channel, Kerrison rongeurs are useful for squaring the corners.
- Use a Device Sizer to determine whether the access channel is sufficient.

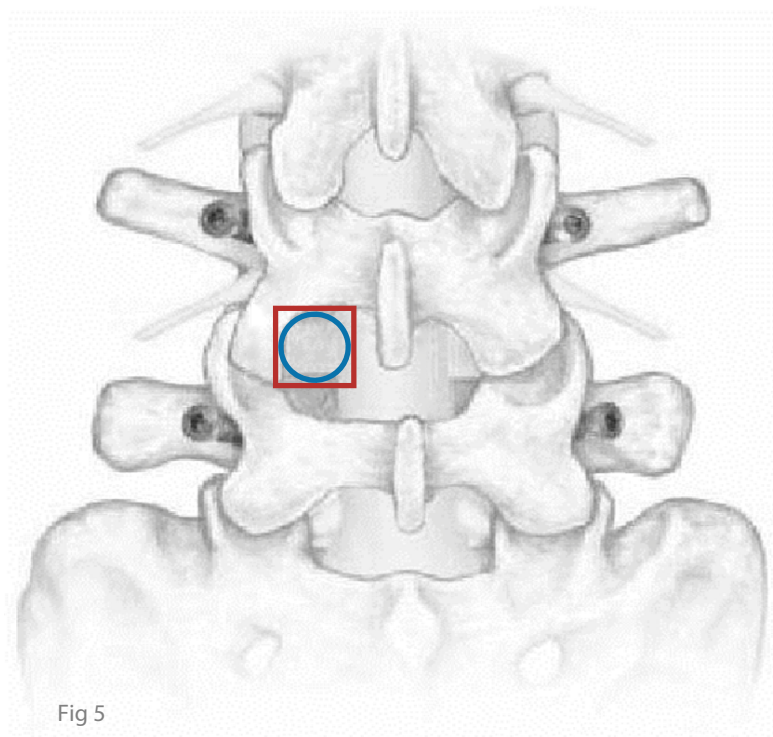


Fig 5

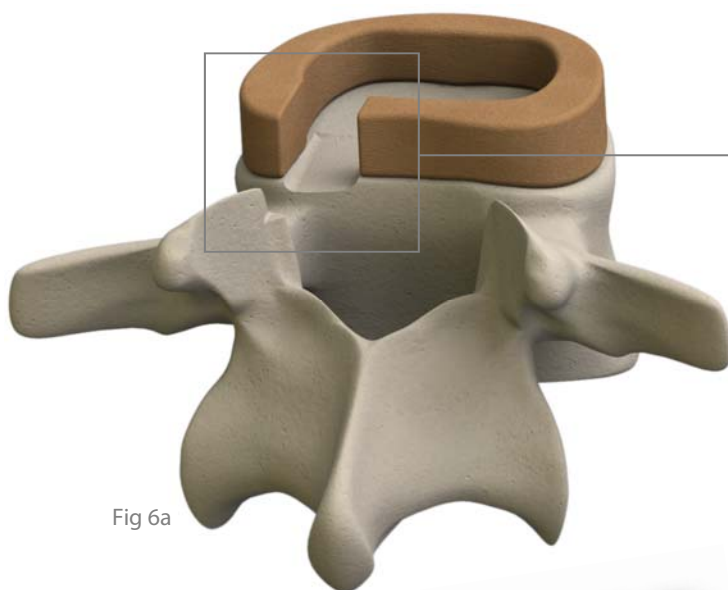


Fig 6a



Fig 6b

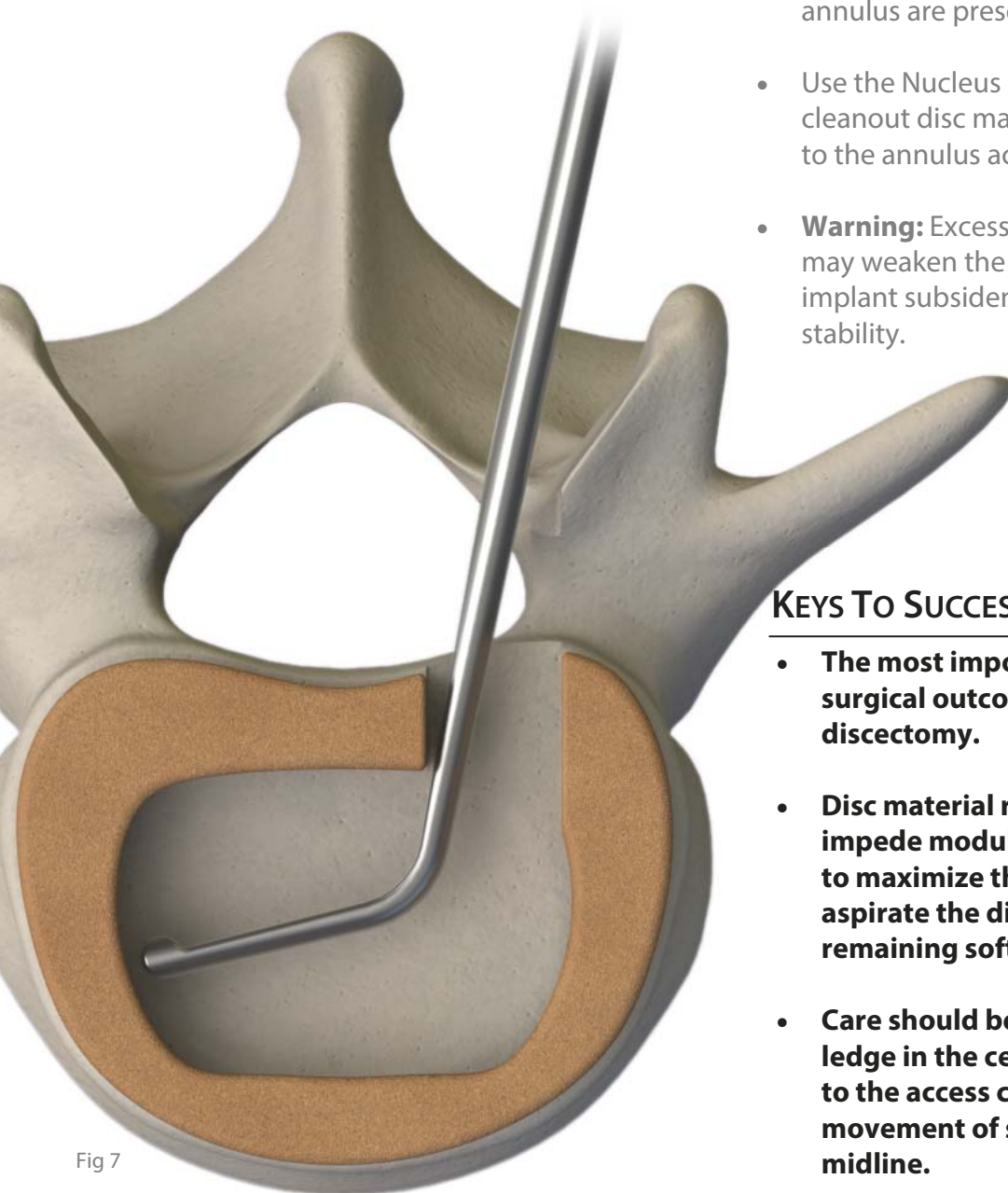


KEYS TO SUCCESS

- **Do not extend the access channel into the central endplates. Doing so will create a ridge that will prevent lateral movement of the modules into the disc space.**

Nucleus Removal

- Completely remove the disc nucleus and endplate cartilage.
- Pay special attention to removal of disc material contralateral and ipsilateral to the annulus access. In addition, remove any posterior osteophytes medial to the annulotomy.
- Ensure that the anterior and lateral walls of the annulus are preserved during cleanout.
- Use the Nucleus Probe (Fig 7) to ensure proper cleanout disc material ipsilateral and contralateral to the annulus access.
- **Warning:** Excessive removal of subchondral bone may weaken the vertebral endplate and result in implant subsidence and loss of segmental stability.



KEYS TO SUCCESS

- **The most important aspect of a successful surgical outcome is performing a complete discectomy.**
- **Disc material remaining within the cavity will impede module insertion and limit the ability to maximize the device footprint. Irrigate and aspirate the disc space to ensure any remaining soft tissue is removed.**
- **Care should be taken not to create a bony ledge in the central portion of the disc medial to the access channel. This will impair movement of subsequent modules across the midline.**

Fig 7

STEP 3 — DEVICE SIZING AND PREPERATION

Sizing

- Use Device Sizers (Fig 8) to determine final implant size.
- Final height is determined when the Device Sizer fits securely but does not require use of the slap hammer for removal.
- The curved face of the Sizer must be contacting the endplates.

A list of available device sizes can be found on page 21.

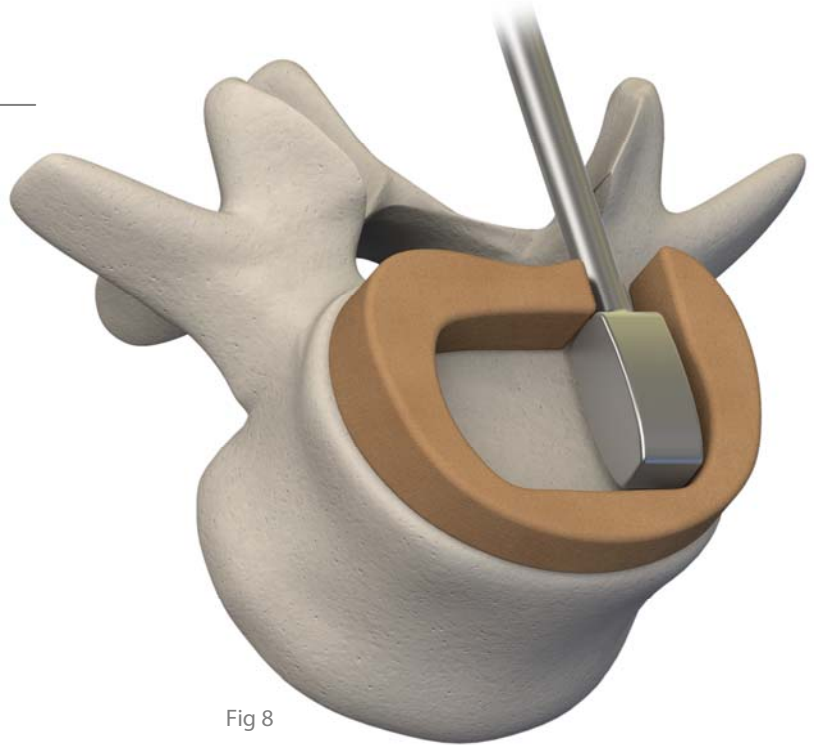


Fig 8

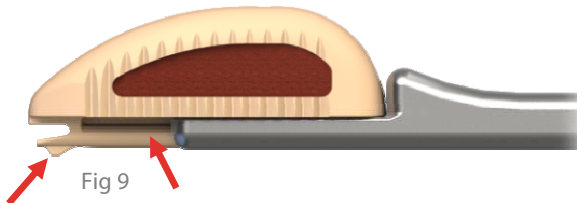


Fig 9

Bone Graft Material

- Place bone graft material in the bone growth hole of each module (Fig 9).
- Bone graft volume (in cc) for each device is located in the "Bone Graft Volume (cc)" table below.

Bone Graft Volume (cc)

Thickness	3 Module	4 Module	5 Module	6 Module
7 mm	.710	1.011	1.313	1.615
8 mm	.816	1.164	1.512	1.860
9 mm	.923	1.317	1.711	2.105
10 mm	1.029	1.469	1.909	2.350
12 mm	1.243	1.775	2.307	2.839
14 mm	1.456	2.080	2.704	3.329

KEYS TO SUCCESS

- **Ensure that no bone graft material is in the implant's rail or lock (see arrows in Fig 9). Material in these areas can interfere with engagement and locking of the modules.**



STEP 4 — IMPLANTATION

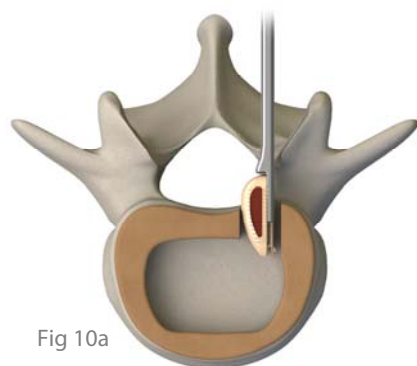


Fig 10a

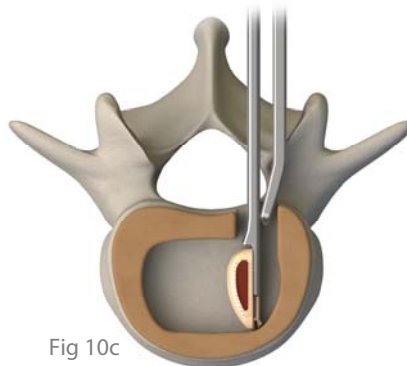


Fig 10c

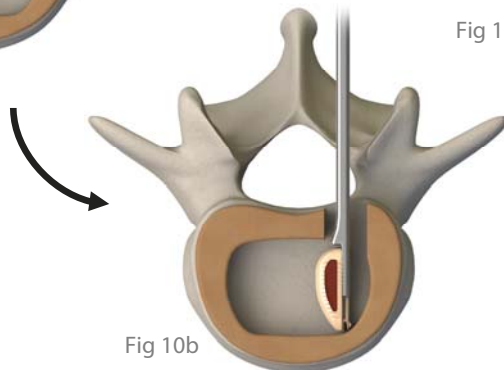


Fig 10b

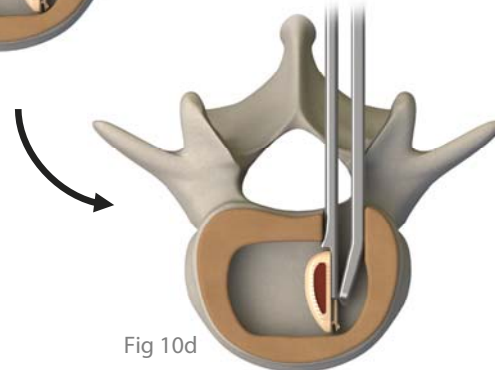


Fig 10d

A Module Insertion

- Using either a Threaded Inserter or an Insertion Guard, insert the A module. (Figures 10a and 10b shown using an Insertion Guard.)
- Take special care to ensure that the curved portion is oriented medially and the serrated edges are contacting the vertebral endplates.
- Once the A module is through the annulotomy, use the Positioning Lever to move the module medially (Figures 10c and 10d).
- While using the Positioning Lever, the facet can be used as a fulcrum.
- The Tail of the A module should be protruding from the disc space.
- Remove the Threaded Inserters / Insertion Guard

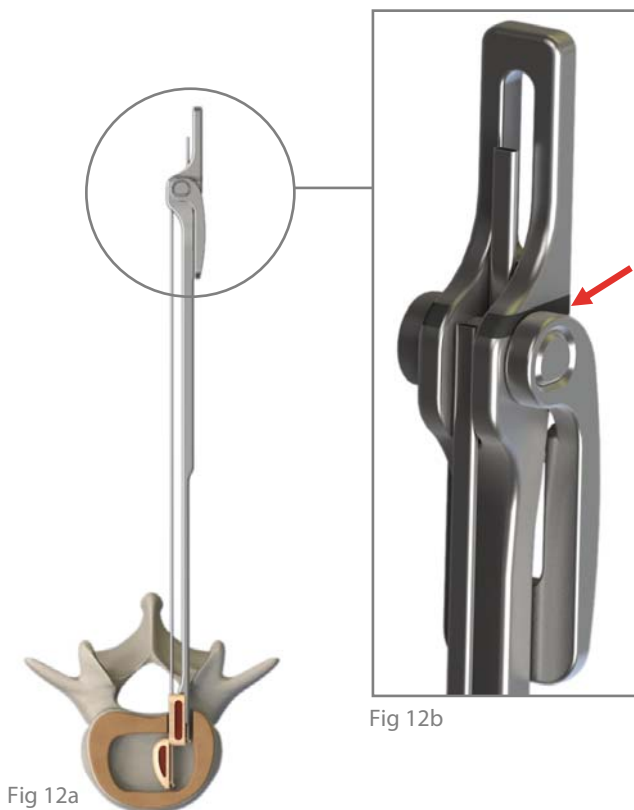
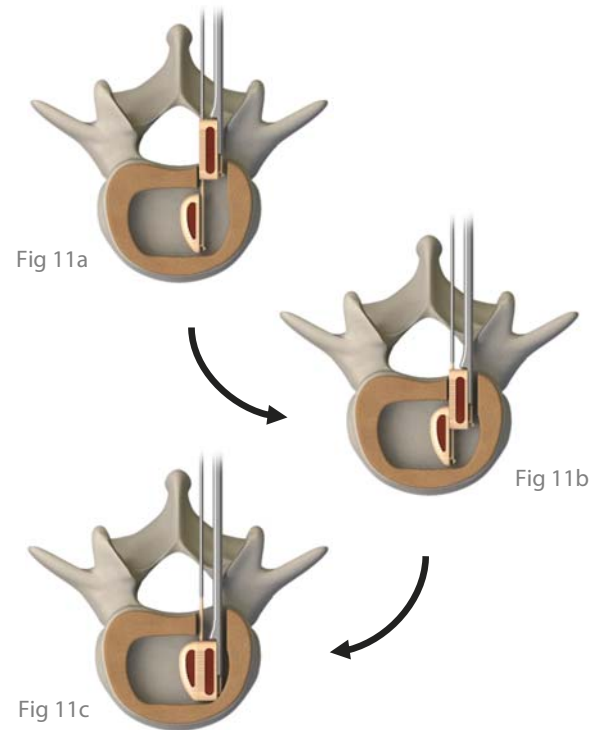
KEYS TO SUCCESS

- **The first A module should be able to enter the disc space smoothly and without resistance.**
- **Resistance to placement of the A module may indicate additional cleanout is required.**
- **X-Ray imaging may be used throughout the procedure to visualize proper module placement and construct positioning.**



B Module Insertion

- Insert the Tail of the A module in to the anterior aspect of the slot of the B Module.
- Carefully slide the B module along the tail of the A module until it is completely within the disc space (figures 11a through 11c).
- **THE MODULES MUST BE PARALLEL TO ONE ANOTHER PRIOR TO THE B MODULE ENGAGING THE A MODULE TO PREVENT PRE-MATURE REMOVAL OF THE TAIL.**
- A mallet may be used to help engage the B module. Do not to use a mallet until the tail of the previous segment is flush with the hammer-safe line (denoted by the red arrow in Fig 12b).
- The Tail Traction Tool may also be used to engage the B module.



- The Insertion Guard (Fig 12a) has a special window cut out of the top of the instrument that aids in determining if the modules are fully engaged.
- The B module is fully engaged when both of the tails are flush with one another.
- The tails will be visible through the window of the Insertion Guard.
- The Insertion Guard may be removed at this point.

Tail Removal

- In order to remove the tail of each module, slide the Tail Removal Tool over the tail and down into the disc space.
- Ensure that the tails are parallel to and flush with one another (Fig 13).
- The Tail Removal Tool must be flush with the implant (Fig 14) so as not to leave any excess material behind that could disturb the healing process.
- Remove the tail by rotating the Tail Removal Tool 360 degrees.
- Slide both the Tail Removal Tool and the disengaged tail out of the disc space.



Fig 13

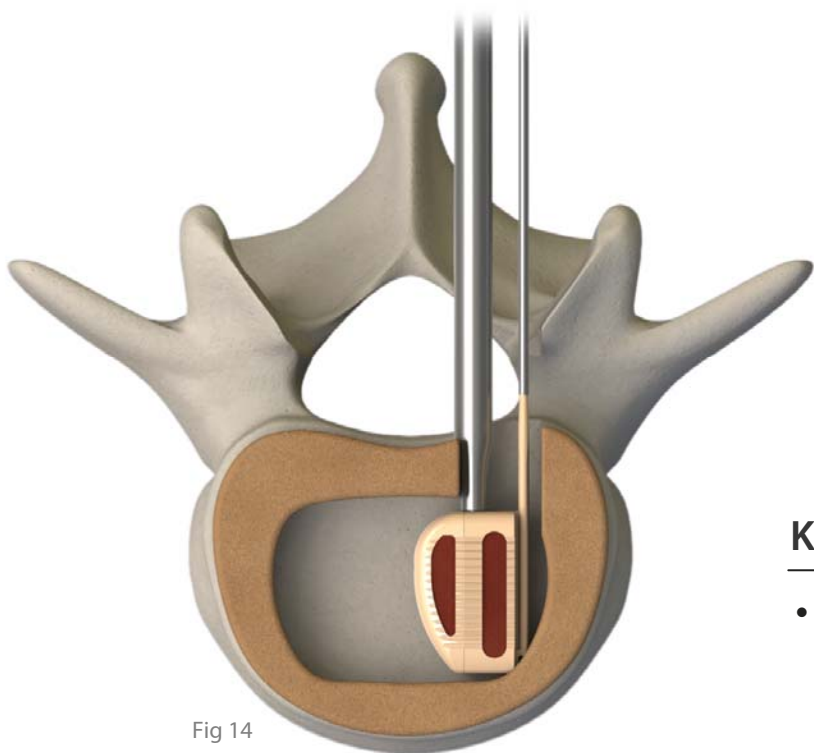


Fig 14



KEYS TO SUCCESS

- **Use of a nerve root retractor is strongly recommended during tail removal.**

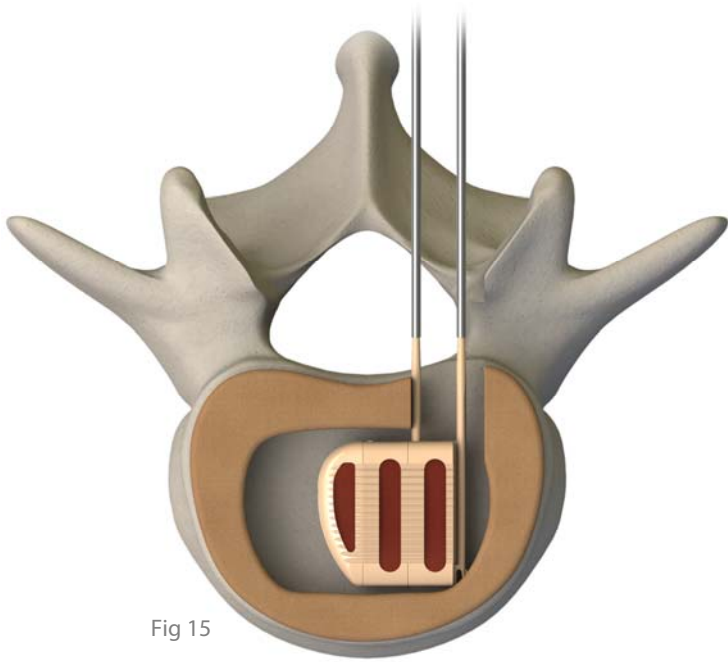


Fig 15

Maximizing the Footprint

- Each additional B module is inserted by repeating the procedure outlined in the “B Module Insertion” and “Tail Removal” sections (pages 15 - 16).
- Prior to inserting the final C module make sure there is no additional room for extra B modules. The implant must be as snug as possible.

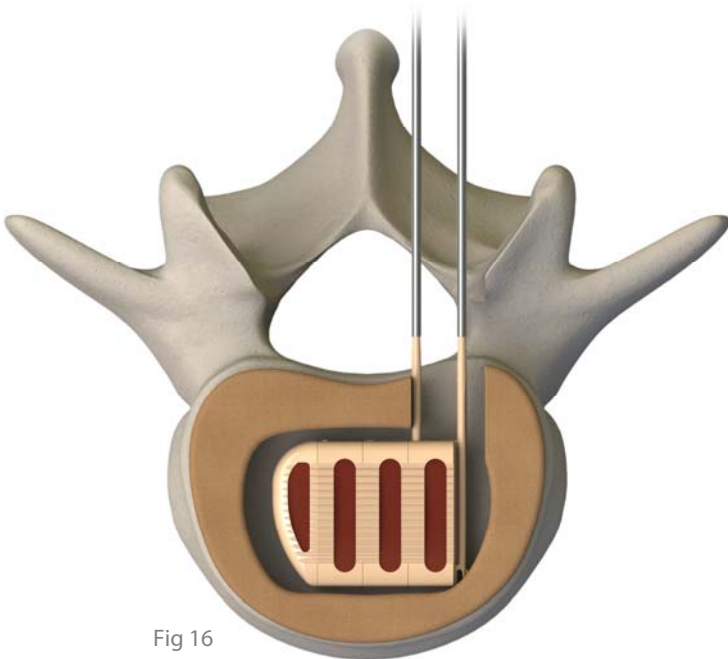
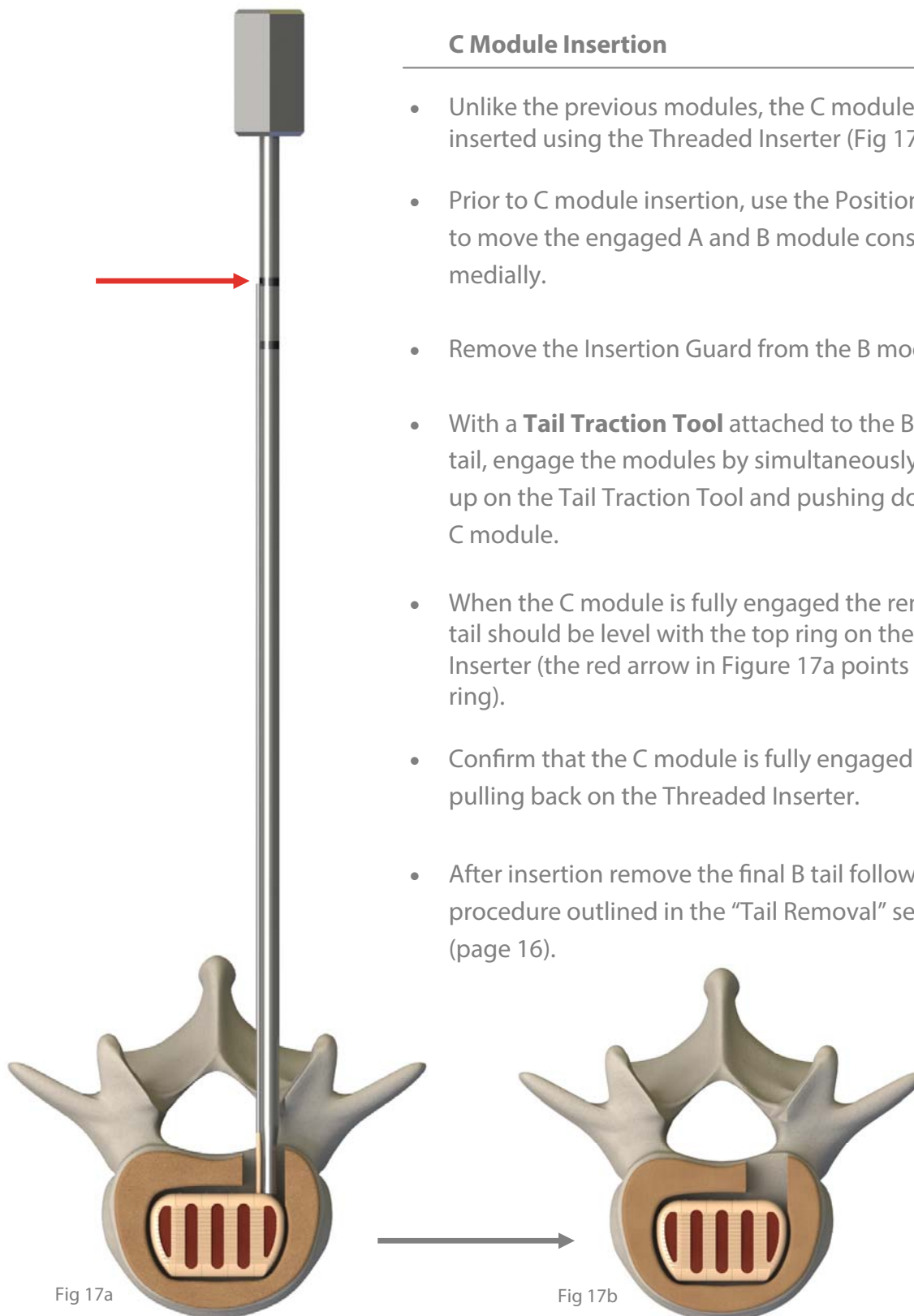


Fig 16



KEYS TO SUCCESS

- **Maximizing the implant footprint minimizes the risk of subsidence by distributing endplate load more evenly.**
- **The InterFuse S is capable of achieving an ALIF-sized footprint or greater.**



C Module Insertion

- Unlike the previous modules, the C module *must* be inserted using the Threaded Inserter (Fig 17a).
- Prior to C module insertion, use the Positioning Lever to move the engaged A and B module construct medially.
- Remove the Insertion Guard from the B module.
- With a **Tail Traction Tool** attached to the B module tail, engage the modules by simultaneously pulling up on the Tail Traction Tool and pushing down on the C module.
- When the C module is fully engaged the remaining B tail should be level with the top ring on the Threaded Inserter (the red arrow in Figure 17a points to the top ring).
- Confirm that the C module is fully engaged by gently pulling back on the Threaded Inserter.
- After insertion remove the final B tail following the procedure outlined in the “Tail Removal” section (page 16).

Fig 17a

Fig 17b



CLOSURE

- A routine wound closure is performed following completion of the InterFuse S device implantation

POSTOPERATIVE CARE

- Routine monitoring of the vital signs, and of the hemodynamic and neurologic status of the patient
- Pain medication
- NG tubes and/or Foley catheters, if used, are discontinued within 24 - 48 hours
- Diet is restricted to small amounts of liquids until return of bowel function is completed
- The patient is encouraged to ambulate as soon as possible. The individual surgeon determines activity level for the patient
- External bracing is to be used per each surgeon's discretion
- Attention to the posterior fixation to include adjusting down the rod separation on the pedicle screws to attain desired sagittal alignment

PRODUCT LISTING

Catalog Number	Implant (Height x A-P Length)	Catalog Number	Implant (Height x A-P Length)
9076-07-20-0	07mm x 20mm – Parallel	9076-07-20-5	07mm x 20mm – 5° Angle
9076-08-20-0	08mm x 20mm – Parallel	9076-08-20-5	08mm x 20mm – 5° Angle
9076-09-20-0	09mm x 20mm – Parallel	9076-09-20-5	09mm x 20mm – 5° Angle
9076-10-20-0	10mm x 20mm – Parallel	9076-10-20-5	10mm x 20mm – 5° Angle
9076-12-20-0	12mm x 20mm – Parallel	9076-12-20-5	12mm x 20mm – 5° Angle
9076-14-20-0	14mm x 20mm – Parallel	9076-14-20-5	14mm x 20mm – 5° Angle
9076-07-20-0-B	07mm x 20mm – Parallel	9076-07-20-5-B	07mm x 20mm – 5° Angle
9076-08-20-0-B	08mm x 20mm – Parallel	9076-08-20-5-B	08mm x 20mm – 5° Angle
9076-09-20-0-B	09mm x 20mm – Parallel	9076-09-20-5-B	09mm x 20mm – 5° Angle
9076-10-20-0-B	10mm x 20mm – Parallel	9076-10-20-5-B	10mm x 20mm – 5° Angle
9076-12-20-0-B	12mm x 20mm – Parallel	9076-12-20-5-B	12mm x 20mm – 5° Angle
9076-14-20-0-B	14mm x 20mm – Parallel	9076-14-20-5-B	14mm x 20mm – 5° Angle

IMPLANT INSTRUMENT SET

DISC PREP SET (OPTIONAL)

Catalog Number	Instrument	Catalog Number	Instrument
9078-07-20	Device Sizer, 07mm x 20mm	9087-02	Long Ring Cone Curette #2 Angled
9078-08-20	Device Sizer, 08mm x 20mm	9087-03	15" Ring Cone Curette #2 Lateral Angled
9078-09-20	Device Sizer, 09mm x 20mm	9087-04	Long Curette #2 Angled
9078-10-20	Device Sizer, 10mm x 20mm	9087-05	15" Curette #2 Angled Right
9078-12-20	Device Sizer, 12mm x 20mm	9087-06	15" Curette #2 Angled Left
9078-14-20	Device Sizer, 14mm x 20mm	9087-07/08	Curved Rongeur
9079	Threaded Inserter	9087-09	Long Curette #2 Reverse Angled
9080-01	Positioning Lever - Convex		
9080-07	Positioning Lever – Flat		
9082	Slap Hammer		
9085	Nucleus Probe		
9090	Tail Removal Tool		
9105-02	Insertion Guard		
9116	Tail Traction Tool		
9118-01	Module Disengagement Tool		

Please refer to the InterFuse S Interbody Fusion Device package insert for further information on:

- CONTRAINDICATIONS
- WARNINGS & PRECAUTIONS
- INSTRUMENT CLEANING & STERILIZATION

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

The InterFuse S Interbody Fusion Device Surgical Technique is presented to demonstrate the surgical technique utilized by Jesse P. Butler, M.D., Illinois Bone & Joint, Chicago, IL, Paul Asdourian, M.D., Greater Chesapeake Orthopedic Associates, Baltimore, MD, and Neill M. Wright M.D., Washington University School of Medicine, St. Louis, MO. Vertebral Technologies, Inc., as the manufacturer of this device, does not practice medicine and does not recommend this product or any specific surgical technique for use on any specific patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each specific patient.

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Notes:
