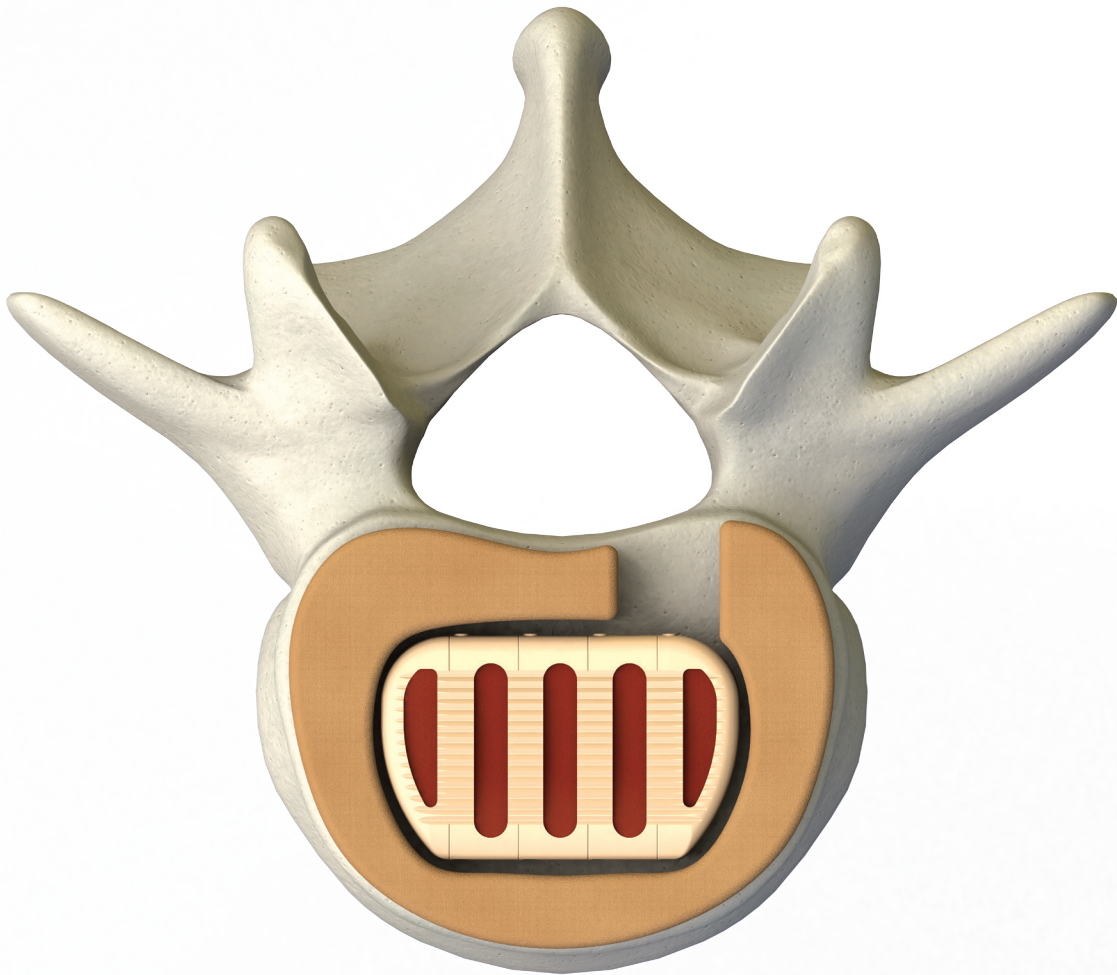


VTI INTERFUSE S™

SURGICAL TECHNIQUE



| *FORWARD THINKING FOR THE BACK.™*

CONTENTS



| | |
|--|-----|
| InterFuse S™ Product Description Indications for Use | 3 |
| X-Ray Marker Locations and Product Specifications | 4 |
| Instrument Set | 5-7 |

STEP ONE: PREOPERATIVE PLANNING

| | |
|---|---|
| Preoperative Planning Patient Positioning | 8 |
|---|---|

STEP TWO: DISC REMOVAL AND ENDPLATE SHAPING

| | |
|--|----|
| Identify Landmarks Distraction | 9 |
| Access Channel Annulotomy and Cortical Rim | 10 |
| Nucleus Removal | 11 |

STEP THREE: DEVICE SIZING AND PREPARATION

| | |
|------------------------------|----|
| Sizing Bone Graft Material | 12 |
|------------------------------|----|

STEP FOUR: IMPLANTATION

| | |
|---|-------|
| A Module Insertion | 13 |
| B Module Insertion | 14 |
| Tail Removal | 15 |
| Maximizing the Footprint | 16 |
| C Module Insertion | 17 |
| Module Disengagement Closure Postoperative Care | 18 |
| Product Listing | 19-21 |

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 ensures 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 three to as many as six segments to provide the best fit possible for each individual patient.

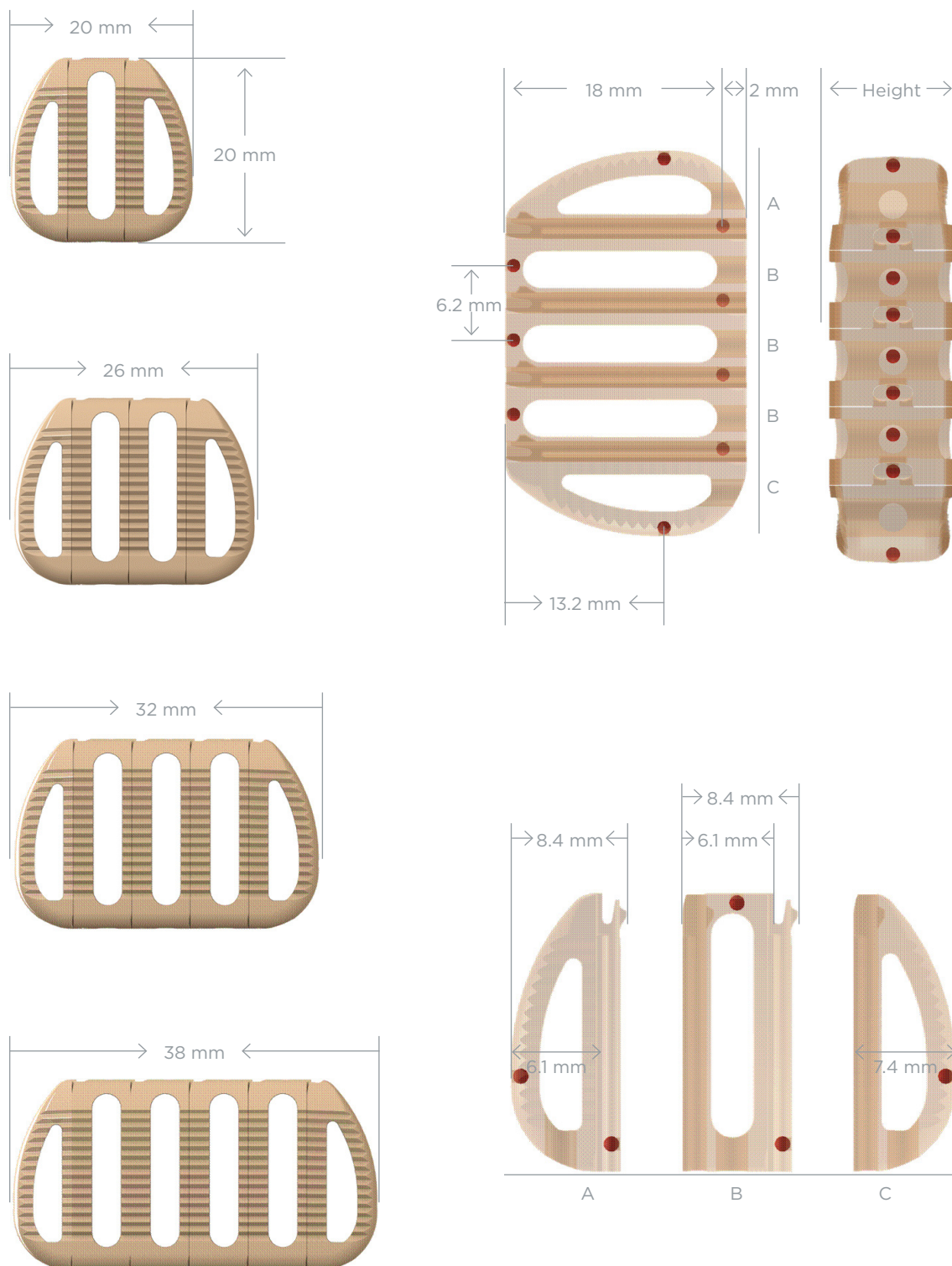
The InterFuse S is available in seven heights (7 mm, 8 mm, 9 mm, 10 mm, 11 mm, 12 mm, 14 mm), one A-P length (20 mm), and two endplate angles (parallel, 5 degree lordotic angle). The device is supplied in 4-module (ABBC) and single B module packages. The device is supplied STERILE.

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 autogenous bone graft and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine.

X-RAY MARKER LOCATION AND PRODUCT SPECIFICATIONS



INSTRUMENT SET*



THREADED INSERTER



INSERTION GUARD



NUCLEUS PROBE

**Instruments are not to scale*



POSITIONING LEVER

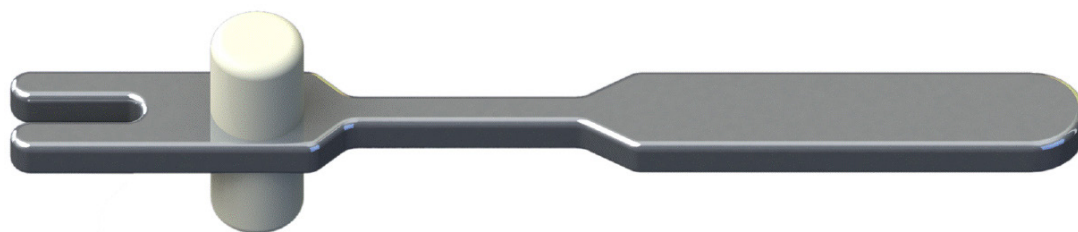


TAIL REMOVAL TOOL

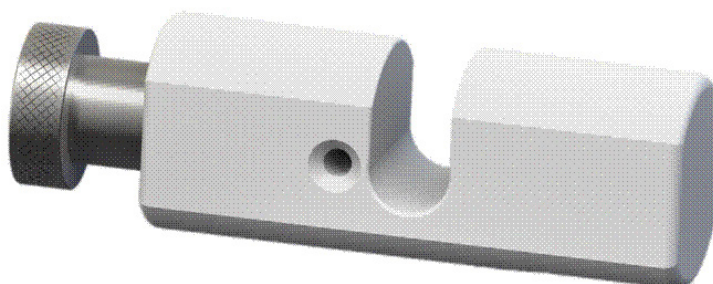


DEVICE SIZER

**Instruments are not to scale*



SLAP HAMMER



TAIL TRACTION TOOL



MODULE DISENGAGEMENT TOOL

**Instruments are not to scale*

STEP ONE

PREOPERATIVE PLANNING

Preoperative planning is recommended to determine the height and lateral width of the VTI InterFuse S device in order to provide the best fit and fill in the patient's disc space. To determine the approximate implant height required for the patient, use sagittal measurements of the intervertebral discs adjacent to the disc being treated (a measurement must be taken from an MRI obtained within the previous six months). For an alternate method, 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. The 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.

STEP TWO

DISC REMOVAL AND ENDPLATE SHAPING

IDENTIFY LANDMARKS

- Create 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

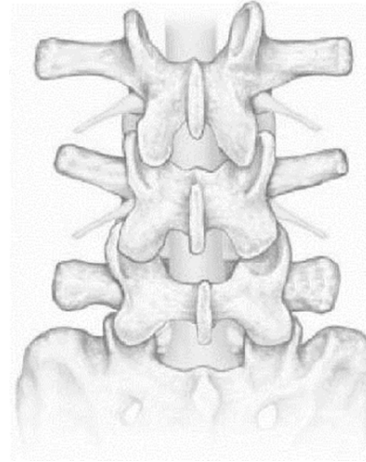


Fig. 1

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
- Hold distraction with pedicle rods if distractor removal is desired

- Alternatively, place a spreader at the lamina or base of the spinous process (Fig. 2)
- Distraction may be maintained with screws and rods following use of the spreader

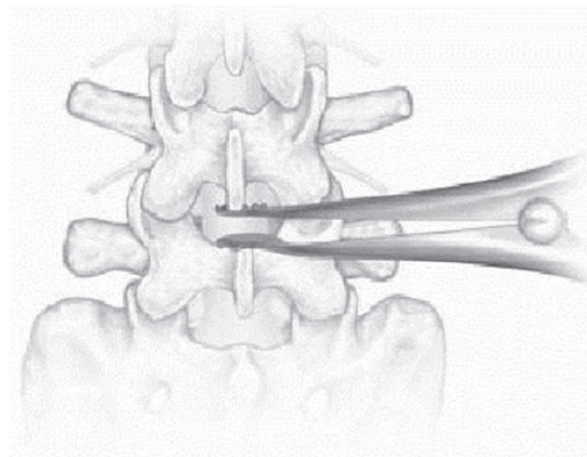


Fig. 2

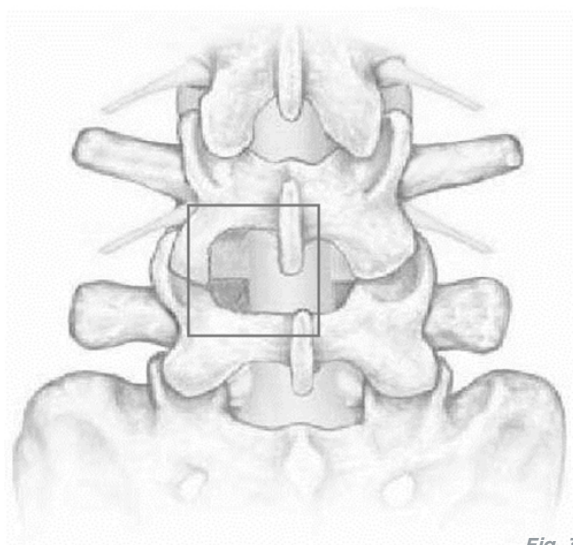


Fig. 3

ACCESS CHANNEL

- Create an access channel to the annulus by performing a laminectomy and medial facetectomy (Fig. 3)
- Extending the laminectomy to the medial border of the inferior facet ensures sufficient access to the disc space for nucleus removal and device implantation

ANNULOTOMY AND CORTICAL RIM

- Continue the access channel through the posterior annulus and cortical rim (blue circle in Fig. 4)
- Create a rectangular annulotomy using a #11 blade (Fig. 5a and 5b)
- Shape the corners of the cortical rim to ensure the access is rectangular (green square in Fig. 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

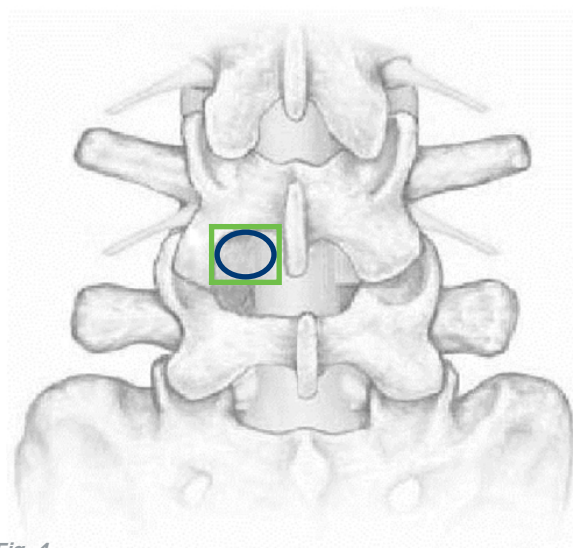


Fig. 4

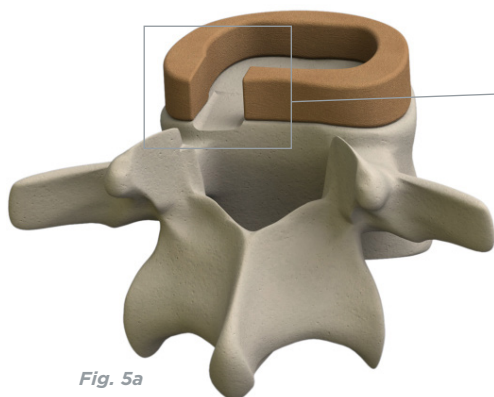


Fig. 5a

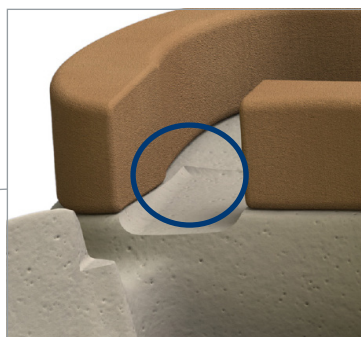


Fig. 5b

TIPS FOR SUCCESS

Do not extend the access channel into the central endplates. Doing so will create a ridge that can impede 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. 6) to check for 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

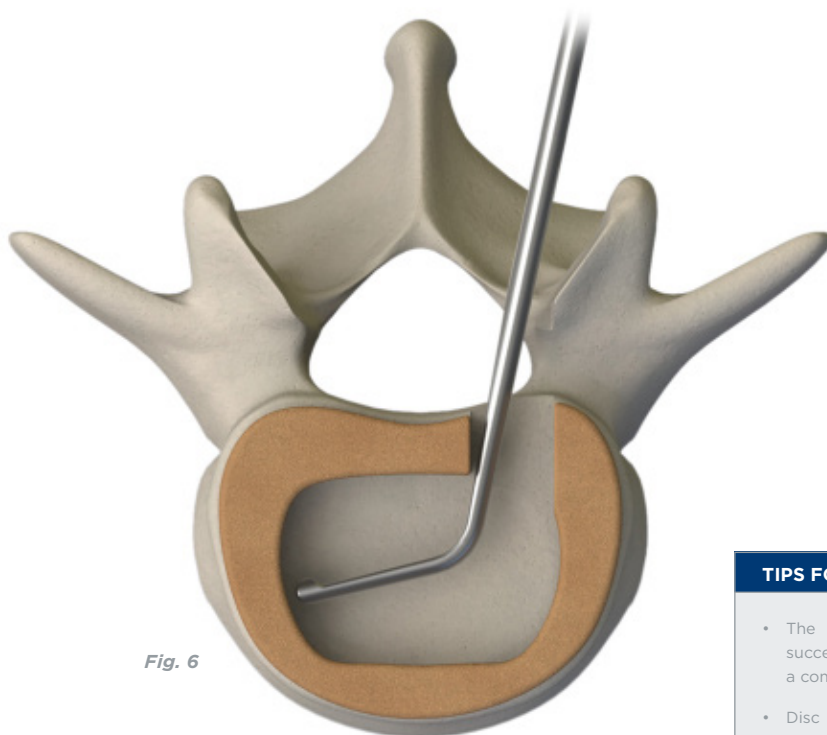


Fig. 6

TIPS FOR 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

STEP THREE

DEVICE SIZING AND PREPARATION

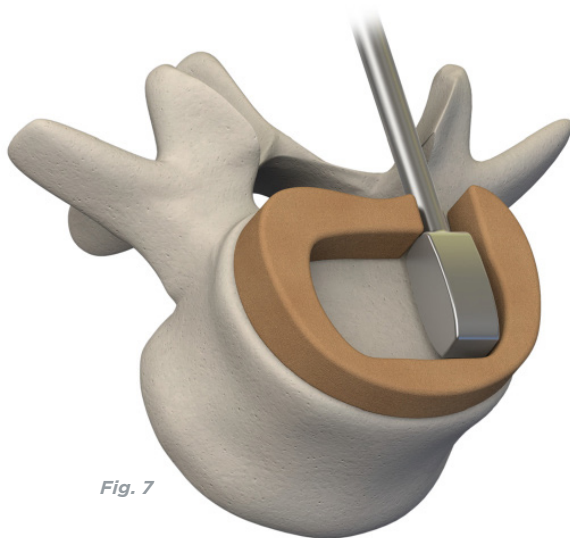


Fig. 7

SIZING

- Use Device Sizers (Fig. 7) 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

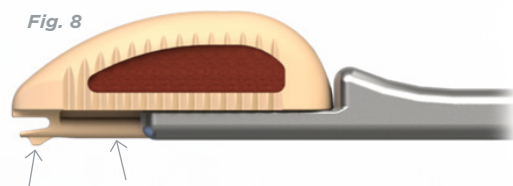
(A list of available device sizes can be found on pg. 20)

BONE GRAFT MATERIAL

Place bone graft material in the bone growth hole of each module (Fig. 8)

Bone graft volume (in cc) for each device is located in the "Bone Graft Volume (cc)" table below

Fig. 8



TIPS FOR SUCCESS

Ensure that no bone graft material is in the implant's rail or lock (see arrows in Fig. 8). Material in these areas can interfere with engagement and locking of the modules.

BONE GRAFT VOLUME (cc)

| HEIGHT | 3 MODULES | 4 MODULES | 5 MODULES | 6 MODULES |
|--------|-----------|-----------|-----------|-----------|
| 7 mm | 0.7 cc | 1.0 cc | 1.3 cc | 1.6 cc |
| 8 mm | 0.8 cc | 1.2 cc | 1.5 cc | 1.9 cc |
| 9 mm | 0.9 cc | 1.3 cc | 1.7 cc | 2.1 cc |
| 10 mm | 1.0 cc | 1.5 cc | 1.9 cc | 2.4 cc |
| 11 mm | 1.1 cc | 1.6 cc | 2.1 cc | 2.6 cc |
| 12 mm | 1.2 cc | 1.8 cc | 2.3 cc | 2.8 cc |
| 14 mm | 1.5 cc | 2.1 cc | 2.7 cc | 3.3 cc |

STEP FOUR

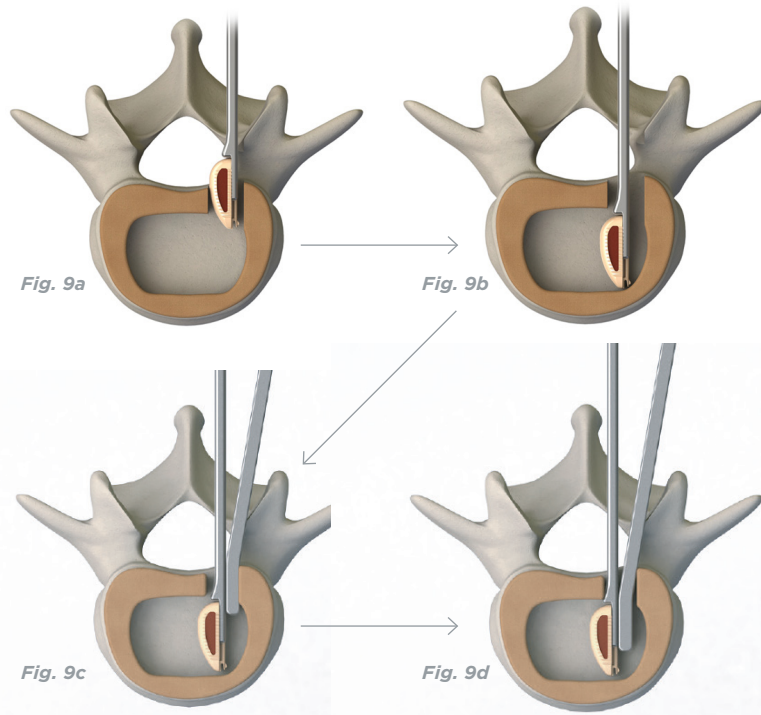
IMPLANTATION

A MODULE INSERTION

- Using an Insertion Guard insert the A module (Fig. 9a and 9b)
- 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 (Fig. 9c and 9d)
- The facet can be used as a fulcrum

TIPS FOR 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
- Intraoperative c-arm imaging may be used throughout the procedure to visualize proper module placement and construct positioning



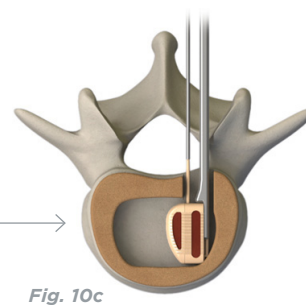
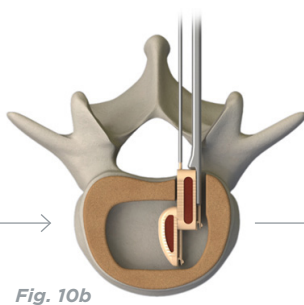
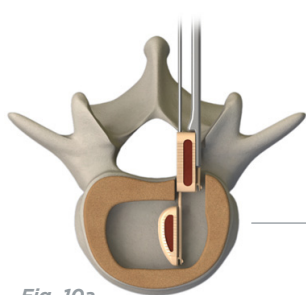
- Place the Positioning Lever alongside the lateral side of the module (Fig. 9c & 9d). The insertion guard should be in place.
- Insert the positioning lever so the tails of the module are between the marked lines (Fig. 10e). This indicates that the instrument is pushing on the body of the module and not on the locking feature.
- Move the positioning lever laterally to move the module(s) medially.



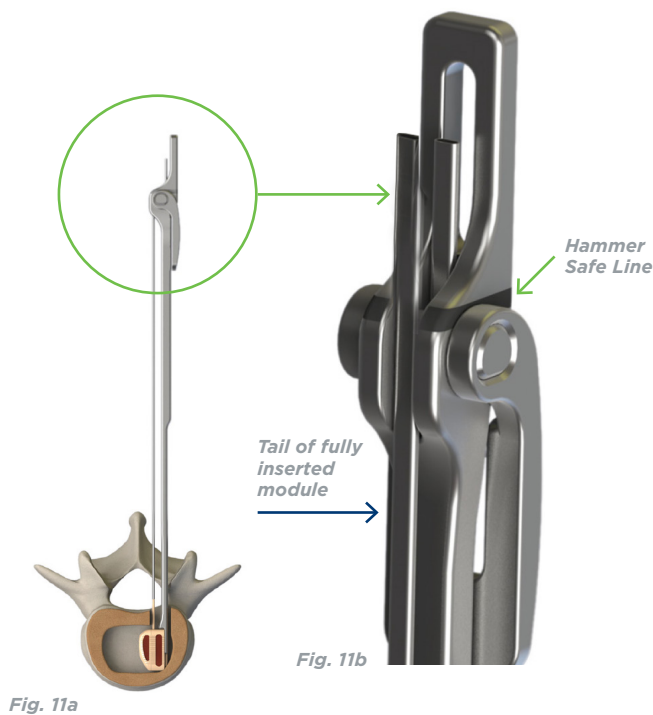
Fig. 9e

B MODULE INSERTION

- Load a B module into the insertion guard and insert the tail of the A module into the distal end 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 (Fig.10a through 10c)
- **The modules must be parallel to one another prior to the B module engaging the A module (this will prevent pre-mature removal of the tail)**
- A mallet may be used to help engage the B module. Hold the lever of the Insertion Guard tight against the body of the Insertion Guard when using a mallet, to ensure the Insertion guard does not come loose. However, do not use a mallet until the tail of the previous segment is at least to the hammer-safe line (denoted by the green arrow in Fig. 11b).



- Confirm engagement of the A and B modules by simultaneously pulling up on the A module's tail while pushing down on the B module's Insertion Guard (the Tail Traction Tool may be used to apply this force).
- The B module is fully engaged when both of the tails are flush with one another.
- Additional confirmation may be checked through C-Arm images.
- The Insertion Guard may be removed at this point.



TAIL REMOVAL

- Ensure that the tails are parallel to and flush with one another (Fig. 12).
- In order to remove the tail of each module, slide the Tail Removal Tool over the tail and down into the disc space.
- The Tail Removal Tool must be flush with the implant (Fig. 13) so as not to leave any excess material behind that could disturb the healing process (Fig. 13).
- 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. 12

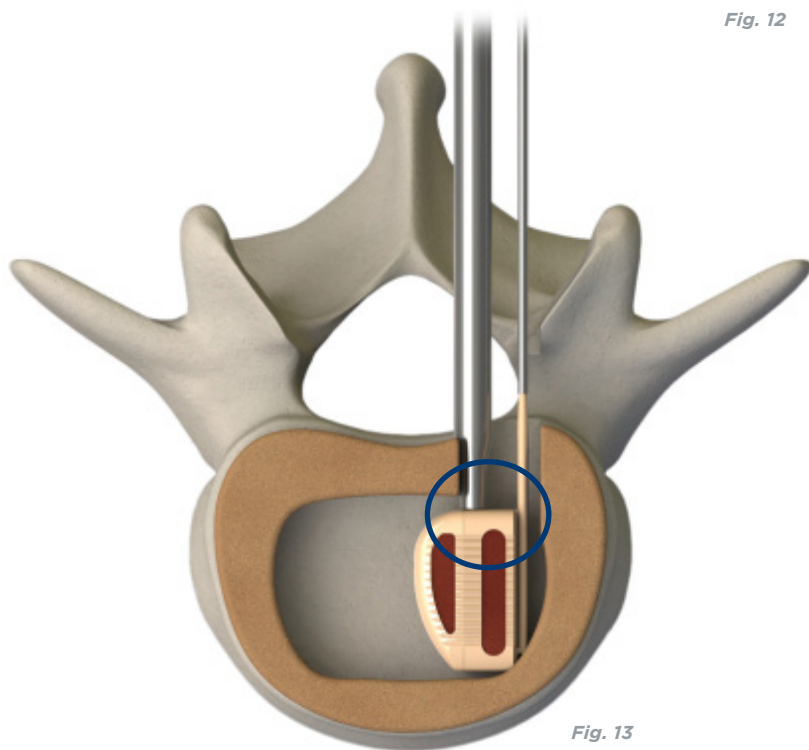


Fig. 13

TIPS FOR SUCCESS

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

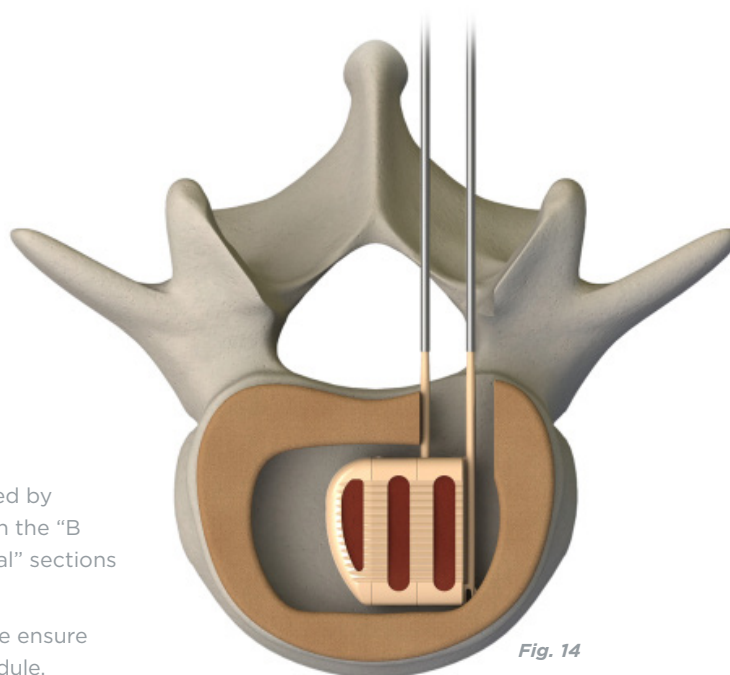


Fig. 14

MAXIMIZING THE FOOTPRINT

- Each additional B module is inserted by repeating the procedure outlined in the “B Module Insertion” and “Tail Removal” sections (pgs. 14 - 15).
- Prior to inserting the final B module ensure there is additional room for a C module.
- The implant should fill as much of the disc space as possible.

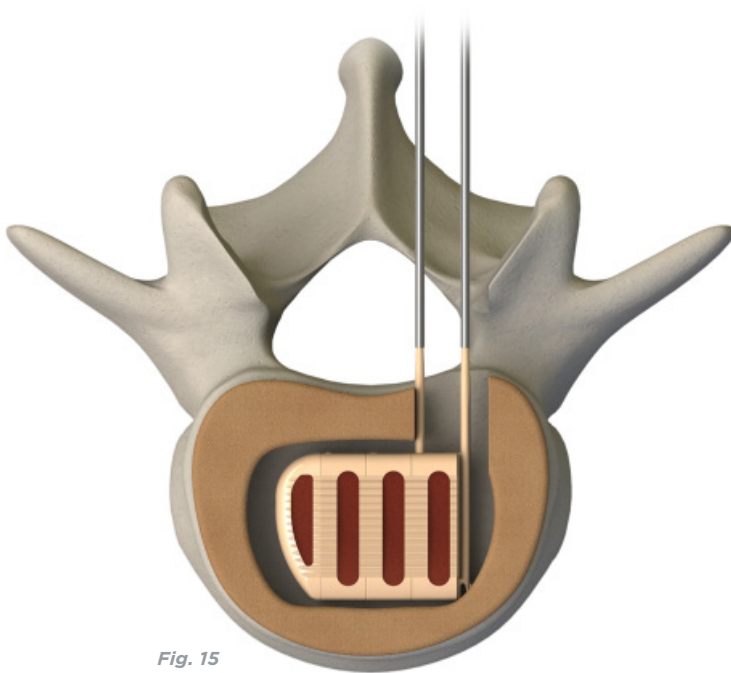
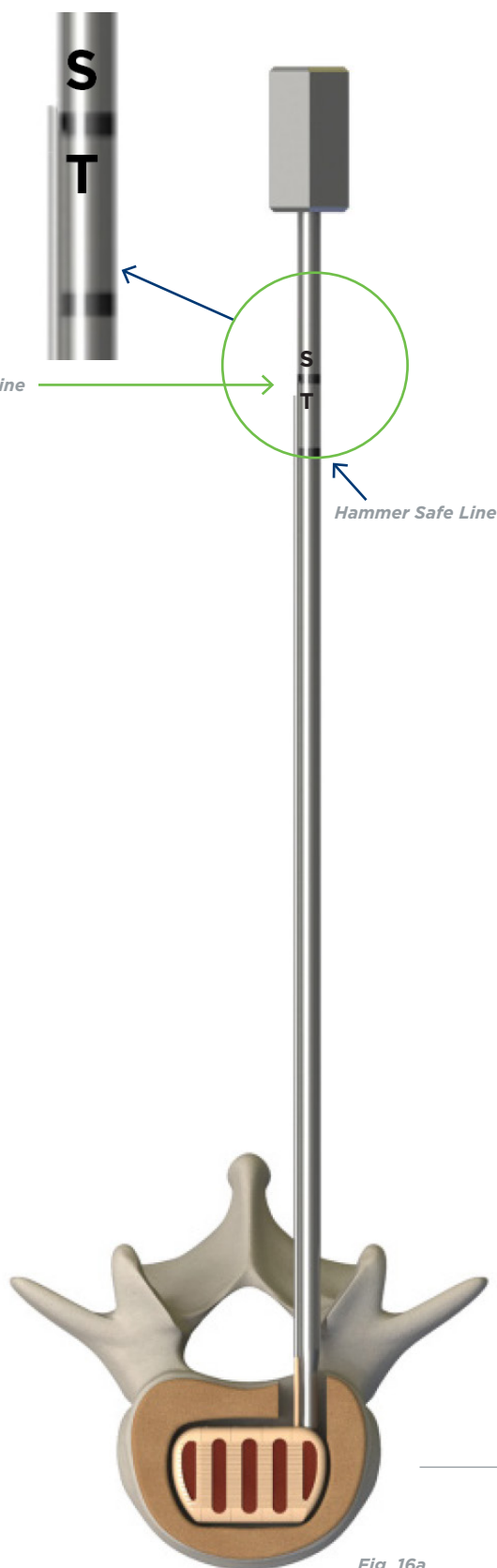


Fig. 15

TIPS FOR SUCCESS

- Maximizing the implant footprint minimizes the risk of subsidence by distributing endplate load more evenly



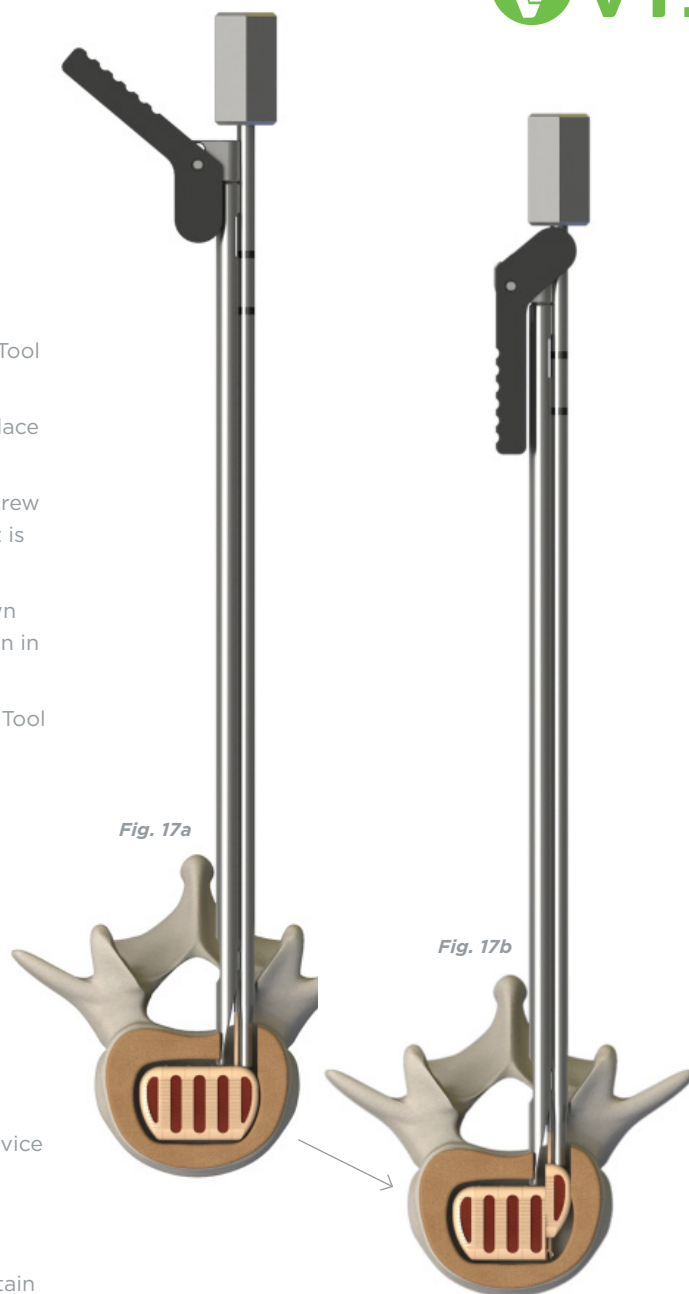
C MODULE INSERTION

- Prior to C module insertion, use the Positioning Lever to move the engaged A and B module construct medially.
- Fully thread the C module onto the threaded inserter.
- Insert the B module tail into the C module slot.
- Carefully slide the C module along the tail of the B module until it is completely within the disc space (Fig 16a)
- A mallet may be used to insert the C module. Do not mallet until the B module tail is past the hammer safe line (Fig 16a).
- **(OPTIONAL)** 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 even with or past the top of the edge the top ring on the Threaded Inserter (the green arrow in Fig. 16a points to the top ring)
- Confirm that the C module is fully engaged by gently pulling back on the Threaded Inserter
- Module alignment should also be verified by reviewing the marker bead location using intraoperative C-arm (see pg. 3 for x-ray marker locations)
- If needed, a 3D bead placement model is available to help correlate the marker bead locations to the device
- After insertion remove the final B tail following the procedure outlined in the "Tail Removal" section (pg. 15)



MODULE DISENGAGEMENT

- If at any point one module needs to be removed, use the Module Disengagement Tool
- Prior to use of the Module Disengagement Tool, ensure a Nerve Root Retractor is in place to protect the exiting nerve rootlet
- To use the Module Disengagement Tool, screw the Threaded Inserter into the module that is to be removed
- Slide the Module Disengagement Tool down the length of the previous module as shown in (Fig. 17a)
- While holding the Module Disengagement Tool against the Threaded Inserter, depress the lever to disengage the module (Fig. 17b)



CLOSURE

- A routine wound closure is performed following completion of the InterFuse S device implantation
- Prior to closure, attention to the posterior fixation should include adjusting down the rod separation on the pedicle screws to attain desired sagittal alignment

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 hour
- 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

PRODUCT LISTING

| INTERFUSE S™ IMPLANT SYSTEM - FOUR PACK | |
|---|-------------------------------|
| Catalog Number | Implant (Height x A-P Length) |
| 9076-07-20-0 | 07mm x 20mm - Parallel |
| 9076-08-20-0 | 08mm x 20mm - Parallel |
| 9076-09-20-0 | 09mm x 20mm - Parallel |
| 9076-10-20-0 | 10mm x 20mm - Parallel |
| 9076-11-20-0 | 11mm x 20mm - Parallel |
| 9076-12-20-0 | 12mm x 20mm - Parallel |
| 9076-14-20-0 | 14mm x 20mm - Parallel |
| 9076-07-20-5 | 07mm x 20mm - 5° Angle |
| 9076-08-20-5 | 08mm x 20mm - 5° Angle |
| 9076-09-20-5 | 09mm x 20mm - 5° Angle |
| 9076-10-20-5 | 10mm x 20mm - 5° Angle |
| 9076-11-20-5 | 11mm x 20mm - 5° Angle |
| 9076-12-20-5 | 12mm x 20mm - 5° Angle |
| 9076-14-20-5 | 14mm x 20mm - 5° Angle |

| INTERFUSE S™ IMPLANT SYSTEM - SINGLE B | |
|--|-------------------------------|
| Catalog Number | Implant (Height x A-P Length) |
| 9076-07-20-0-B | 07mm x 20mm - Parallel |
| 9076-08-20-0-B | 08mm x 20mm - Parallel |
| 9076-09-20-0-B | 09mm x 20mm - Parallel |
| 9076-10-20-0-B | 10mm x 20mm - Parallel |
| 9076-11-20-0-B | 11mm x 20mm - Parallel |
| 9076-12-20-0-B | 12mm x 20mm - Parallel |
| 9076-14-20-0-B | 14mm x 20mm - Parallel |
| 9076-07-20-5-B | 07mm x 20mm - 5° Angle |
| 9076-08-20-5-B | 08mm x 20mm - 5° Angle |
| 9076-09-20-5-B | 09mm x 20mm - 5° Angle |
| 9076-10-20-5-B | 10mm x 20mm - 5° Angle |
| 9076-11-20-5-B | 11mm x 20mm - 5° Angle |
| 9076-12-20-5-B | 12mm x 20mm - 5° Angle |
| 9076-14-20-5-B | 14mm x 20mm - 5° Angle |

PRODUCT LISTING CONT



| INTERFUSE® INSTRUMENTATION TRAY | |
|---------------------------------|--------------------------------|
| Catalog Number | Description |
| 9078-07 | Device Sizer, 7mm x 20mm |
| 9078-08 | Device Sizer, 8mm x 20mm |
| 9078-09 | Device Sizer, 9mm x 20mm |
| 9078-10 | Device Sizer, 10mm x 20mm |
| 9078-11 | Device Sizer, 11mm x 20mm |
| 9078-12 | Device Sizer, 12mm x 20mm |
| 9078-14 | Device Sizer, 14mm x 20mm |
| 9079 | Threaded Inserter |
| 9080-05 | Positioning Lever - Concave |
| 9082 | Slap Hammer |
| 9085-01 | Nucleus Probe |
| 9086 | Instrument Tray |
| 9090 | Tail Removal Tool |
| 9105-02 | Insertion Guard |
| 9116 | Tail Traction Tool |
| 9118-01 | Module Disengagement Tool |
| 9130-01 | Nerve Root Retractor |
| 9130-03 | Bayoneted Nerve Root Retractor |

| COMPREHENSIVE DISC PREP INSTRUMENTATION TRAY | |
|--|--|
| Catalog Number | Description |
| 9135-01 | Bayoneted Angled Forward Gouge |
| 9135-02 | MIS Angled Backward Gouge |
| 9135-03 | MIS Left Bent Oval Curette |
| 9135-04 | MIS Right Bent Oval Curette |
| 9135-07 | MIS Right Bent Ring Curette |
| 9135-09 | Angled Forward Gouge |
| 9135-10 | Angled Backward Gouge |
| 9135-11 | Left Bent Oval Curette |
| 9135-12 | Right Bent Oval Curette |
| 9135-14 | Bent Hooked Gouge |
| 9135-15 | Right Bent Ring Curette |
| 9139-01 | Straight Endplate Rasp |
| 9139-02 | Bent Endplate Rasp |
| 9140 | Comprehensive Disc Prep Tray |
| 9141-01 or 9141-02 | Straight Pituitary Rongeur - 3mm or Straight Pituitary Rongeur - 4mm |
| 9141-07 or 9141-08 | Up-Biting Pituitary Rongeur - 3mm or Up-Biting Pituitary Rongeur - 4mm |
| 9141-11 or 9141-12 | 15x25 Curved Pituitary Rongeur - 3mm or 15x25 Curved Pituitary Rongeur - 4mm |
| 9140-20 | 40 degree Kerrison Rongeur - 4mm |
| 9140-21 | 90 degree Kerrison Rongeur - 4mm |

PRODUCT LISTING CONT

| PADDLE SHAVER INSTRUMENT SET | |
|------------------------------|-------------------------------|
| Catalog Number | Description |
| 9092-07 | Paddle Distractor, 07mm |
| 9092-08 | Paddle Distractor, 08mm |
| 9092-09 | Paddle Distractor, 09mm |
| 9092-10 | Paddle Distractor, 10mm |
| 9092-11 | Paddle Distractor, 11mm |
| 9092-12 | Paddle Distractor, 12mm |
| 9092-13 | Paddle Distractor, 13mm |
| 9092-14 | Paddle Distractor, 14mm |
| 9092-15 | Paddle Distractor, 15mm |
| 9114 | T Handle |
| 9128 | Paddle Shaver Instrument Tray |
| 9128-06 | Shaver, Size 6 |
| 9128-07 | Shaver, Size 7 |
| 9128-08 | Shaver, Size 8 |
| 9128-09 | Shaver, Size 9 |
| 9128-10 | Shaver, Size 10 |
| 9128-11 | Shaver, Size 11 |
| 9128-12 | Shaver, Size 12 |
| 9128-13 | Shaver, Size 13 |
| 9128-14 | Shaver, Size 14 |

Please refer to the InterFuse® 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.

For further information, contact:
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Minneapolis, MN 55441
(952) 912-5400

Visit us online at:
vti-spine.com

InterFuse S™ Surgical Technique



NOTES
