

## INTERFUSE S™ - INTERBODY FUSION DEVICE

### INSTRUMENTS



**Nucleus Probe** -Used to verify completeness of nucleotomy.



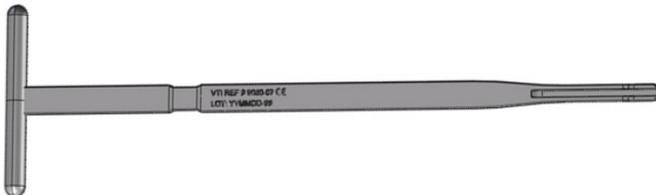
**Device Sizer (Trial)** - Represents the A/P and thickness of an implant module. Used to determine the correct size implant prior to opening packaging.



**Threaded Inserter** - The Threaded Inserter attaches to the PEEK implant modules and is used to place the implant components during implantation. Distal end of tail should align with top marker ring of the inserter. The inserter is hand tightened loosely.



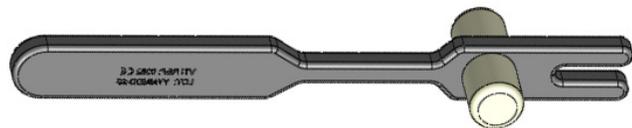
**Insertion Guard** - An alternative to the Threaded Inserter which provides greater torsional control during module insertion and assembly. Prevents tail breakage when using Positioning Lever.



**Positioning Lever** - Used to move/position inserted implant assembly medially using a “walk it over” motion to safely and effectively position the implant.



**Tail Removal Tool** - Once a module is assembled the Tail Removal Tool is slid over the adjacent tail until it is flush with the posterior surface of the implant and the distal end of tail is even with the top of the tool. The instrument is rotated and the tail is removed.



**Slap Hammer** - Mallet that may be used gently during insertion and removal of implant modules.



**Tail Traction Tool** - The Tail Traction Tool provides a method for tensioning the adjacent tail when inserting subsequent implant modules. The instrument is slid over the tail of the previously placed module and the thumb screw is tightened. Traction is applied to the handle to react the thrust force during module insertion.

**Module Disengagement Tool** - The Module Disengagement Tool is used to separate locked implant modules. A Threaded Inserter is attached to the module to be removed and the Module Disengagement Tool is mated to the adjacent module. The lever is used to provide a disassembly force without stressing the annulus or requiring the use of a mallet.

## IMPLANT MODULES

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A – PEEK oval with metal tail; 1st module to be implanted

B – PEEK rectangle with metal tail; next one to four modules to be implanted

C – PEEK oval without tail; last module to be implanted

## SURGICAL PROCEDURE— SUMMARY

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### DISTRACTION, DISCECTOMY AND NUCLEOTOMY

Prior to beginning the InterFuse implantation, the surgeon will need to obtain parallel distraction of the disc space and complete the discectomy/nucleotomy per the Surgical Technique (VTI document MS 4043). **BE SURE A DISCECTOMY / NUCLEOTOMY INSTRUMENT SET IS AVAILABLE FOR THE CASE.** An auxiliary discectomy instrument set is available from VTI. Discectomy instruments are NOT included in the standard InterFuse instrument tray. The Nucleus Probe should be used to evaluate discectomy. Distraction strategies include: Positioning, predistraction and hold with screws and rods, distraction off of rods, interspinous spreader (available on request).

### SIZING

Implant sizers labeled by device height (7, 8, 9, 10, 12, 14mm) and A-P length (20mm) corresponding to implant sizes. An appropriate sizer height will fit snugly in the disc space, but it will not require a Slap Hammer for removal from the disc space.

### BONE GRAFT PLACEMENT

Place bone graft material in the bone growth hole of each module. Ensure that no bone graft material is in the module's rail or lock; material in these areas can interfere with engagement and locking of the modules.

### IMPLANTING MODULES

- ◆ While the surgeon is implanting the A module, prepare the next B module by attaching it to the Insertion Guard and packing the bone growth cavity with bone graft material.
- ◆ Once the A module is inserted use the Positioning Lever to move the module medially. Keep the Insertion Guard in conjunction with Positioning Lever to prevent tail breakage.
- ◆ After the A module is positioned inside the disc space, the surgeon will remove the Insertion Guard. The surgeon will use the Insertion Guard to advance the B module along the tail of the A module and into the disc space. Insert the tail of the A module into the slot of the B module so it will slide along the tail.
- ◆ The modules will be properly aligned when a snap lock is felt or heard and the ends of the tails are in alignment. A small mallet may be used on the Threaded Inserter to ensure the modules are engaged by gently tapping the modules into place. **DO NOT USE A Mallet ON THE INSERTION GUARD UNTIL THE ADJACENT TAIL IS PAST THE POSTERIOR END OF THE PREVIOUS MODULES,** as evidenced when the tail of the previous module is beyond the black marker on the Insertion Guard.
- ◆ Using the Tail Traction Tool, place counter traction on the tail of the previous module while pushing the Insertion Guard forward to facilitate engagement of the implant modules.
- ◆ All additional B modules will be inserted using the same methods used for the first two modules.

### TAIL REMOVAL

Place the end of the Tail Removal Tool over the tail of the A module tail and slide the instrument down to the rear of the implant, making sure it has reached the junction of the tail and implant. Rotate the Tail Removal Tool to remove the tail. Once the surgeon has cut the tail of the module, the detached tail must be removed from the Tail Removal Tool.

### IMPLANT C MODULE

The C module does not have a tail, so a Threaded Inserter must be used for inserting the C module. Make sure to align the Threaded Inserter parallel to the slotted side of the implant when screwing in.