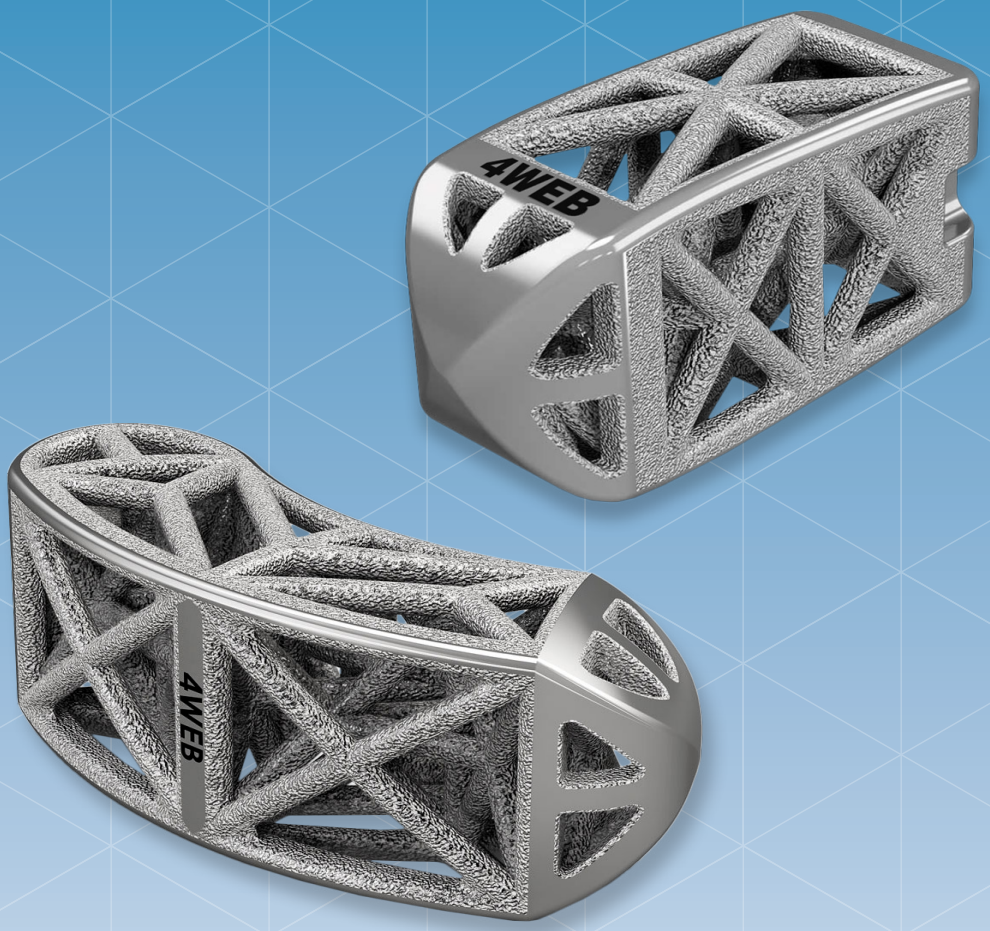
SURGICAL TECHNIQUE GUIDE

# POSTERIOR SPINE TRUSS SYSTEM




4WEB® MEDICAL

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Federal law (USA) restricts these devices to sales by or on the order of a physician.

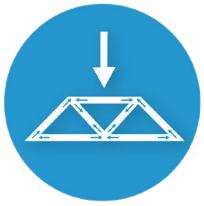
Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedure based on his or her medical training and experience. Prior to use of the system, the surgeon should refer to the product's Instructions For Use (IFU) for complete warnings, precautions, indications, contraindications and adverse effects. IFUs are available by contacting 4WEB MEDICAL, +1 (800) 285-7090.

# TRUSS IMPLANT TECHNOLOGY™

Novel Truss Implant Technology™ provides a Snow Shoe Interface that distributes load across the endplate minimizing point loading and reducing the risk of subsidence.*

Hierarchical surface roughness spans from the macro to nano scale. These surface features have been shown to stimulate increased gene expression of certain osteogenic markers when compared to other interbody surfaces and materials.[1]

Open architecture design allows for greater graft volume and bone growth throughout the entire construct.*



Distribution of load through the implant struts delivers strain to adjacent cellular material which stimulates a mechanobiologic response.

Truss Implant design provides maximum strength with a minimal amount of material, which limits imaging artifacts.

[1] Rowe et al, SMISS, AnnualForum'19, p.52 * Data on file

# PSTS OVERVIEW

The Posterior Spine Truss System (PSTS) consists of two implant designs in a variety of footprints, heights, and lordotic angles to accommodate the patient's anatomy. It is not intended to be used as a stand-alone device and must be used with supplemental fixation. The PSTS implants are provided sterile and may be used in single placement or in pairs.

Sizers and instruments are provided non-sterile and require sterilization prior to use.

# SURGICAL PROCEDURE

## PRE-OPERATIVE PLANNING

- Pre-operative planning with radiographs and other advanced imaging modalities can be helpful in estimating the appropriately sized implants with the goal of restoring disc height and fractional lordosis.
- Determine the surgical approach based on the surgeon's preference (posterior, transforaminal, or oblique).

Note: Implants, sizers, and instrumentation are designed for each of these approaches.

## PATIENT POSITIONING

- Place the patient in the prone position on the operating table (Fig. 1).
- Fluoroscopy can be utilized to aid in patient positioning.

Figure 1

## ACCESS AND EXPOSURE

- Locate the correct operative level under fluoroscopic guidance. Incise the skin and dissect laterally from the midline (Fig. 2).
- Locate the spinous process and the lamina of the appropriate level(s).
- Perform a laminotomy and/or facetectomy as needed to achieve proper discectomy and endplate preparation. Ensure that the neurogenic structures are spared as much as possible.

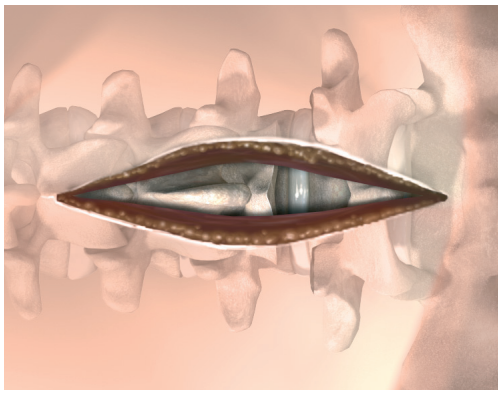


Figure 2

Note: Any bone removed during access and exposure may be used for autologous graft packing.

## DISCECTOMY AND ENDPLATE PREPARATION

- Remove the disc through the laminotomy and/or facetectomy window leaving only the anterior and lateral annulus intact (Fig. 3).
- Remove the superficial layers of the cartilaginous endplates down to bleeding bone.
- Take care to preserve the integrity of the lateral and anterior annular walls to help maintain stability.
- Additional distraction may be applied as desired to increase visualization.

Note: Appropriate cleaning of the endplates is important to provide blood flow to the autologous bone packed inside the implant. Excessive cleaning, on the other hand, can weaken the endplates.

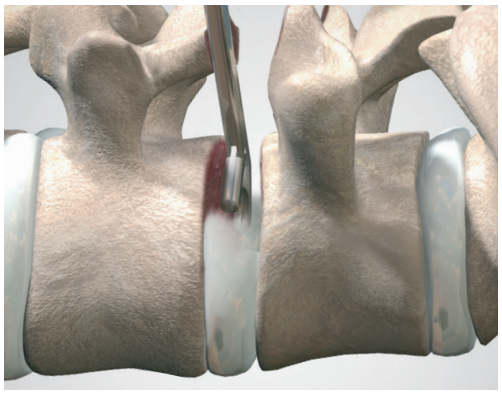


Figure 3

## DISTRACTION

- Distraction provides restoration of the intervertebral disc height and facilitates access to the disc space for preparation of the endplates.
- The longitudinal ligaments and the annulus fibrosus provide stability for the inserted implants. Over distracting of these ligaments could lead to an unstable construct.
- Three distraction methods can be used depending on the pathology and the surgeon's preference:

### 1. Using Paddle Distractors

- Attach an appropriate preoperatively determined paddle distractor to the quick-connect handle. Length and height measurements are clearly marked on the paddle distractors.

- Insert a small paddle distractor horizontally into the intervertebral space and rotate the instrument vertically to distract the space (Fig. 4). Sequentially insert the paddle distractors increasing in height until the desired height is obtained.

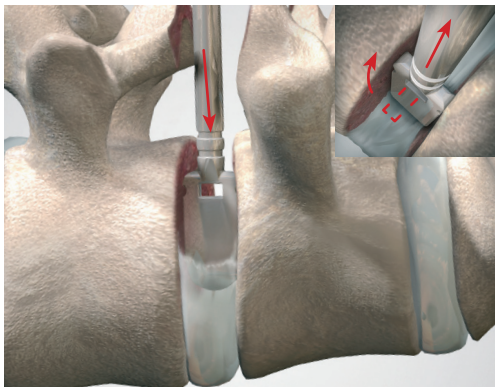


Figure 4

### 2. Using Implant Sizers

- Attach an appropriate preoperatively determined sizer to the quick-connect handle. Length and height measurements are clearly marked on the implant sizers.

- Insert the sizer horizontally into the intervertebral space and rotate the instrument vertically to distract the space (Fig. 5). Sequentially insert the sizers increasing in height until the desired height is obtained.

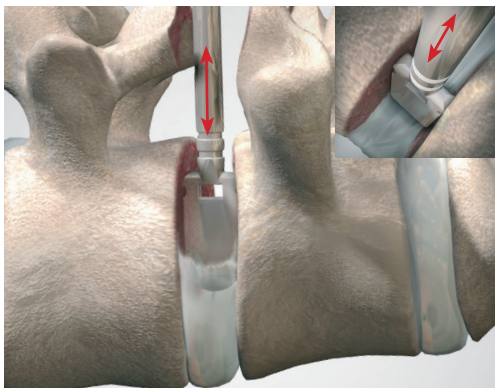


Figure 5

- Proceed to Step 7 for implant preparation.

### 3. Using Lamina Spreaders (not shown)

- This distraction method temporarily opens the posterior disc space, providing better access for decompression and the insertion of the implant.

## IMPLANT SIZING

### Curved Sizers:

- After distraction has been achieved, attach a suitable implant sizer to the quick-connect handle. Length and height measurements are clearly marked on the curved sizers (Fig. 6).

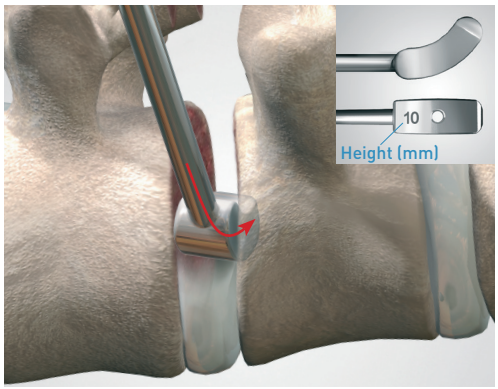



Figure 6

- Carefully impact the sizer into the contralateral disc space. Check the correct fit of the sizer with the aid of fluoroscopy and palpation.
- There is an open cavity in the anterior wall of the sizer head for midline orientation (Fig. 6).
- If the sizer is too loose or too tight, try the next larger/smaller size until a secure fit is achieved.
- Remove the sizer from the prepared disc space and select the corresponding implant.

## Straight Sizers:

- After distraction has been achieved, attach a suitable implant sizer to the quick-connect handle. Length and height measurements are clearly marked on the straight sizers (Fig. 7).
- Carefully impact the sizer into the contralateral disc space. Check the correct fit of the sizer with the aid of fluoroscopy and palpation.
- If the sizer is too loose or too tight, try the next larger/smaller size until a secure fit is achieved.
- Remove the sizer from the prepared disc space and select the corresponding implant.

Note: Although over distraction of the disc space is to be avoided, the largest implant that can be safely implanted in the disc space is generally the optimal implant size. Maximizing the implant surface with the vertebral endplates and providing an appropriate amount of preload through disc space distraction will help to create a stable environment conducive to new bone formation.

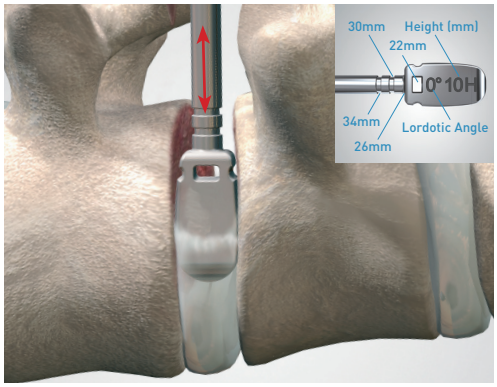



Figure 7

## IMPLANT PREPARATION

### Attaching Implant Inserter:

- PSTS implants are provided in a sterile package. Select the implant that corresponds to the appropriate sizer. Open the implant package using proper sterile technique.
- Attach the implant to the inserter (Fig. 8). Ensure the prongs are fully seated and no threads are visible.
- Be careful not to over-tighten.

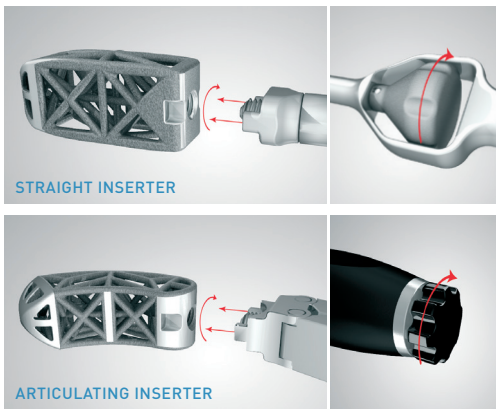



Figure 8

### Packing Implant:

- Pack the implant with autologous and/or allogenic bone graft. For best results, cut or morselize the autologous bone into 1–2mm sized particles. Place the morselized bone into the top or bottom web structure (top and bottom are interchangeable). In a downward, circular motion, massage the bone particles into the implant (Fig. 9).
- Once packing has been completed through the top web structure, turn the implant over and repeat the placement of bone into the bottom web structure. Pack autologous bone into the implant as appropriate.

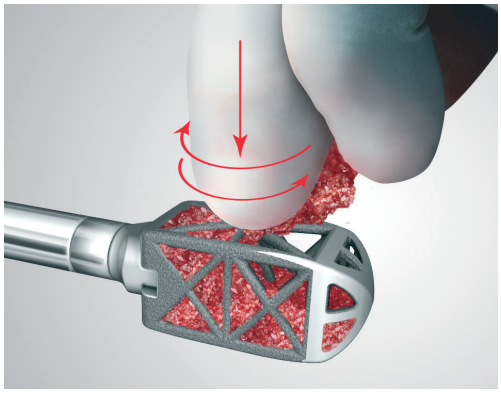


Figure 9

## IMPLANT INSERTION

- Introduce the implant into the prepared intervertebral space and tap it into place with a mallet (Fig. 10 or 11). Confirm the proper placement of the implant using fluoroscopy.

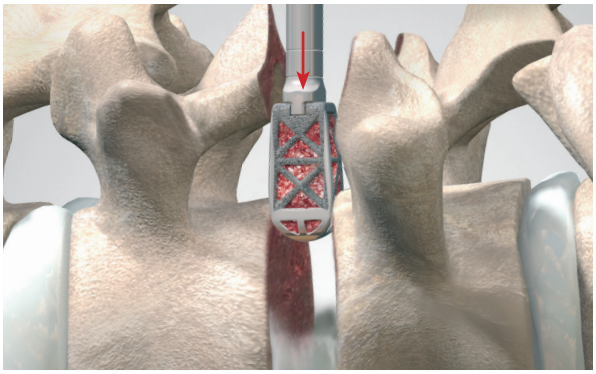


Figure 10

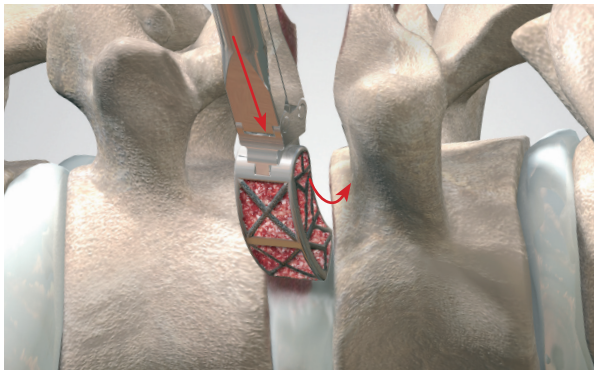


Figure 11

- Once the implant is in the proper position, disengage and remove the inserter.

- If an "insert-and-rotate" insertion technique is preferred, a PSTS-000015 inserter is required. To employ this technique, the surgeon first inserts the implant with the lateral aspects of the PSTS cage in the cranial-caudal orientation. The lateral aspects of the cage can be differentiated from the superior and inferior faces of the cage by looking at the truss structure (Fig. 12 & 13). Once the proper position of the cage in the disc space is confirmed under fluoroscopy, the implant can then be rotated 90° so that the superior and inferior faces of the implant are in the cranial/caudal direction. The implant inserter can then be disengaged from the implant. If the implant needs to be positioned further into the prepared space, gently tap the implant with the tamp provided in the instrument tray.

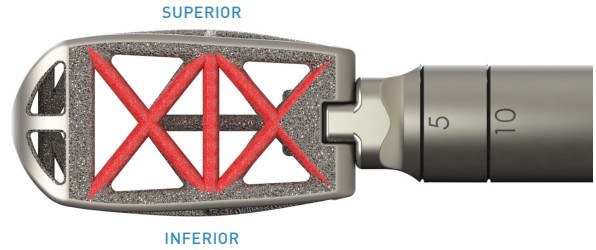



Figure 12

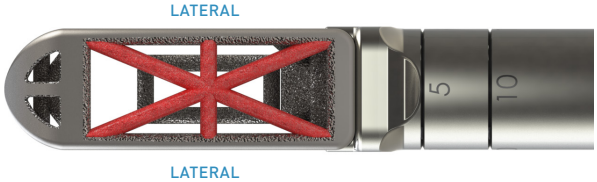



Figure 13

## Curved Articulating Inserter:

- Introduce the implant into the prepared interbody space. Advance the implant into the disc space by tapping on the proximal end of the inserter. Once the implant is fully within the disc space, begin gradual articulation of the implant by rotating the articulating steering module clockwise in between tapping until the articulation has reached 40º or anterior placement of the implant has been achieved (Fig. 14).

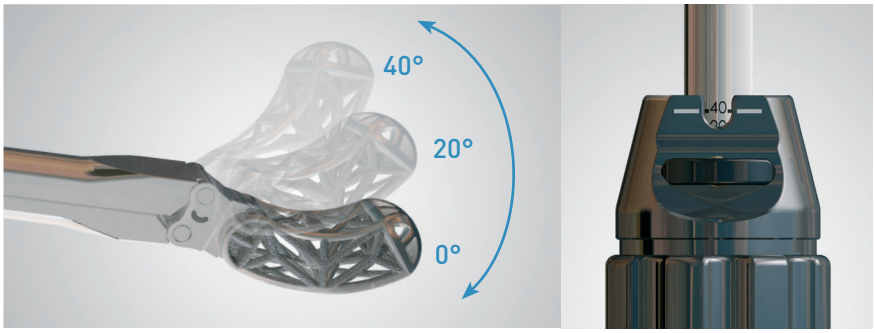



Figure 14

- Once the implant is in the proper position, disengage and remove the inserter.

NOTE: The buttons on the articulating inserter are for disassembly only.

## Implant Positioning:

- If the implant needs to be positioned further into the prepared space, gently tap the implant with the tamp provided in the instrument tray.
- Verify final placement of the implant with fluoroscopic imaging.
- Although surgical techniques will vary from physician to physician, three commonly found implant orientations are illustrated at right (Fig. 15).

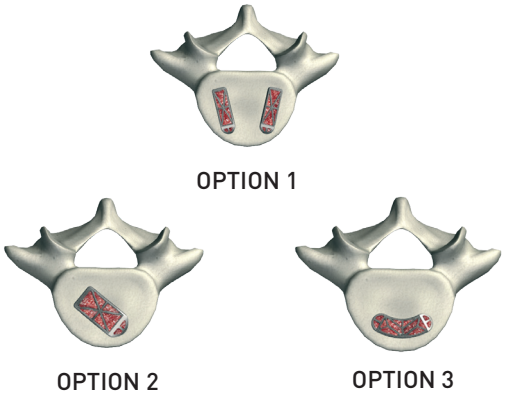



Figure 15

## IMPLANT REMOVAL

- If implant removal is required, the intervertebral space should be distracted in the same manner as for implant placement. Once distracted, the implant may be removed by using the insertion tool (Fig. 16).

- The implant should be disengaged from the superior and inferior endplates with the surgeon's preferred technique. The surgeon should apply slight back-pressure in order to remove the implant.

- If greater force is required, use the slap hammer provided in the instrument tray to remove the implant.

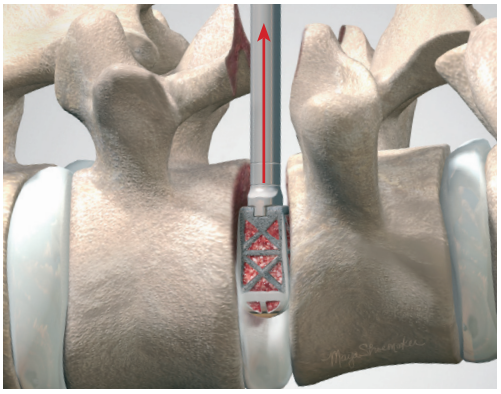


Figure 16

# INSTRUMENT CATALOG

### PADDLE SHAVER

| PART NUMBER | SIZE (MM) |
|---|---|
| PSTS-000300 | 6 |
| PSTS-000301 | 7 |
| PSTS-000302 | 8 |
| PSTS-000303 | 9 |
| PSTS-000304 | 10 |
| PSTS-000305 | 11 |
| PSTS-000306 | 12 |
| PSTS-000307 | 13 |
| PSTS-000308 | 14 |
| PSTS-000309 | 15 |

### DISTRACTOR

| PART NUMBER | SIZE (MM) |
|---|---|
| PSTS-SM0006-26D | 6 |
| PSTS-SM0007-26D | 7 |
| PSTS-SM0008-26D | 8 |
| PSTS-SM0009-26D | 9 |
| PSTS-SM00010-26D | 10 |
| PSTS-SM00011-26D | 11 |
| PSTS-SM00012-26D | 12 |
| PSTS-SM00013-26D | 13 |
| PSTS-SM00014-26D | 14 |
| PSTS-SM00015-26D | 15 |

### STRAIGHT SIZER

| PART NUMBER | SIZE (MM) | DEGREE |
|---|---|---|
| PSTS-SM0006-26S | 9 x 26 x 6 | 0° |
| PSTS-SM0008-26S | 9 x 26 x 8 | 0° |
| PSTS-SM0010-26S | 9 x 26 x 10 | 0° |
| PSTS-SM0012-26S | 9 x 26 x 12 | 0° |
| PSTS-SM0014-26S | 9 x 26 x 14 | 0° |
| PSTS-SM0608-26S | 9 x 26 x 8 | 6° |
| PSTS-SM0609-26S | 9 x 26 x 9 | 6° |
| PSTS-SM0610-26S | 9 x 26 x 10 | 6° |
| PSTS-SM0611-26S | 9 x 26 x 11 | 6° |
| PSTS-SM0612-26S | 9 x 26 x 12 | 6° |

### CURVED SIZER

| PART NUMBER | SIZE (MM) | DEGREE |
|---|---|---|
| TSTS-MD0007-27S | 10 x 27 x 7 | 0° |
| TSTS-MD0009-27S | 10 x 27 x 9 | 0° |
| TSTS-MD0011-27S | 10 x 27 x 11 | 0° |
| TSTS-MD0013-27S | 10 x 27 x 13 | 0° |
| TSTS-MD0015-27S | 10 x 27 x 15 | 0° |
| TSTS-MD0607-27S | 10 x 27 x 7 | 6° |
| TSTS-MD0608-27S | 10 x 27 x 8 | 6° |
| TSTS-MD0609-27S | 10 x 27 x 9 | 6° |
| TSTS-MD0610-27S | 10 x 27 x 10 | 6° |
| TSTS-MD0611-27S | 10 x 27 x 11 | 6° |

## STRAIGHT SIZER (CONT.)

| PART NUMBER | SIZE (MM) | DEGREE |
|---|---|---|
| PSTS-SM0613-26S | 9 x 26 x 13 | 6° |
| PSTS-SM0614-26S | 9 x 26 x 14 | 6° |
| PSTS-SM1210-26S | 9 x 26 x 10 | 12° |
| PSTS-SM1211-26S | 9 x 26 x 11 | 12° |
| PSTS-SM1212-26S | 9 x 26 x 12 | 12° |
| PSTS-SM1213-26S | 9 x 26 x 13 | 12° |
| PSTS-SM1214-26S | 9 x 26 x 14 | 12° |
| PSTS-MD0608-26S | 11 x 26 x 8 | 6° |
| PSTS-MD0609-26S | 11 x 26 x 9 | 6° |
| PSTS-MD0610-26S | 11 x 26 x 10 | 6° |
| PSTS-MD0611-26S | 11 x 26 x 11 | 6° |
| PSTS-MD0612-26S | 11 x 26 x 12 | 6° |
| PSTS-MD0613-26S | 11 x 26 x 13 | 6° |
| PSTS-MD0614-26S | 11 x 26 x 14 | 6° |
| PSTS-MD1210-26S | 11 x 26 x 10 | 12° |
| PSTS-MD1211-26S | 11 x 26 x 11 | 12° |
| PSTS-MD1212-26S | 11 x 26 x 12 | 12° |
| PSTS-MD1213-26S | 11 x 26 x 13 | 12° |
| PSTS-MD1214-26S | 11 x 26 x 14 | 12° |

## CURVED SIZER (CONT.)

| PART NUMBER | SIZE (MM) | DEGREE |
|---|---|---|
| TSTS-MD0612-27S | 10 x 27 x 12 | 6° |
| TSTS-MD0613-27S | 10 x 27 x 13 | 6° |
| TSTS-MD0614-27S | 10 x 27 x 14 | 6° |
| TSTS-MD0615-27S | 10 x 27 x 15 | 6° |
| TSTS-MD0007-32S | 10 x 32 x 7 | 0° |
| TSTS-MD0009-32S | 10 x 32 x 9 | 0° |
| TSTS-MD0011-32S | 10 x 32 x 11 | 0° |
| TSTS-MD0013-32S | 10 x 32 x 13 | 0° |
| TSTS-MD0015-32S | 10 x 32 x 15 | 0° |
| TSTS-MD0607-32S | 10 x 32 x 7 | 6° |
| TSTS-MD0608-32S | 10 x 32 x 8 | 6° |
| TSTS-MD0609-32S | 10 x 32 x 9 | 6° |
| TSTS-MD0610-32S | 10 x 32 x 10 | 6° |
| TSTS-MD0611-32S | 10 x 32 x 11 | 6° |
| TSTS-MD0612-32S | 10 x 32 x 12 | 6° |
| TSTS-MD0613-32S | 10 x 32 x 13 | 6° |
| TSTS-MD0614-32S | 10 x 32 x 14 | 6° |
| TSTS-MD0615-32S | 10 x 32 x 15 | 6° |

## LONG HANDLE CURETTES (15")

STRAIGHT CURETTE
PSTS-000100

LATERAL LEFT ANGLE CURETTE
PSTS-000104

ANGLED CURETTE
PSTS-000101

STRAIGHT CONE RING CURETTE
PSTS-000105

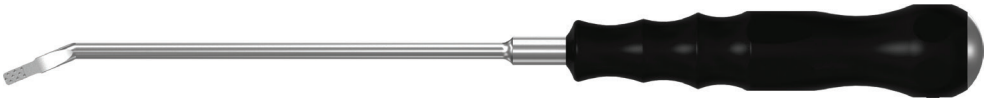
REVERSE ANGLED CURETTE
PSTS-000102

ANGLED CONE RING CURETTE
PSTS-000106

LATERAL RIGHT ANGLE CURETTE
PSTS-000103

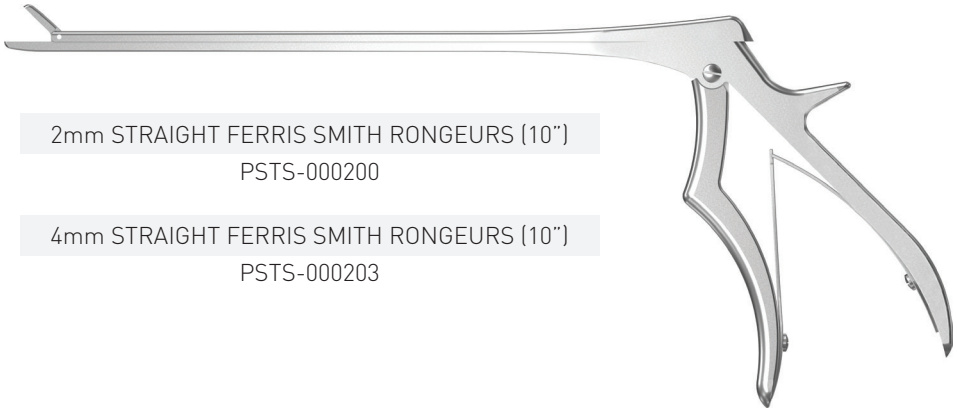
DOWN PUSHING CURETTE
PSTS-000107

PSTS-000600 STRAIGHT LONG OSTEOTOME (3/8")



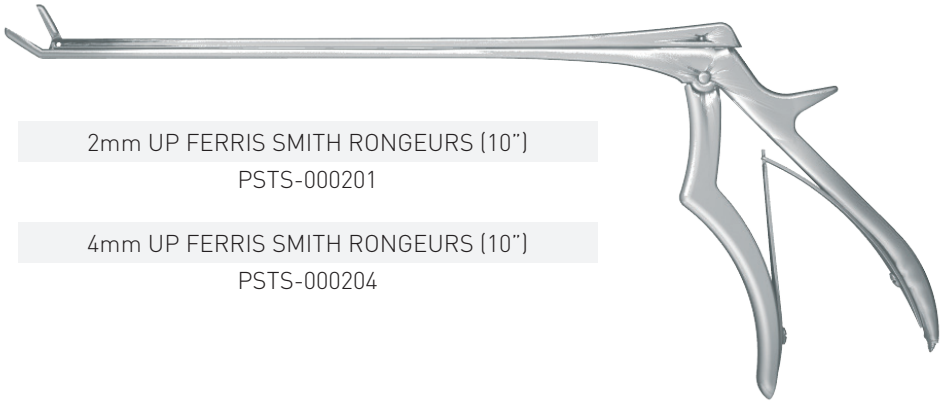
PSTS-000400 DOUBLE-SIDED ANGLED RASP

PSTS-000401 SINGLE-SIDED STRAIGHT RASP



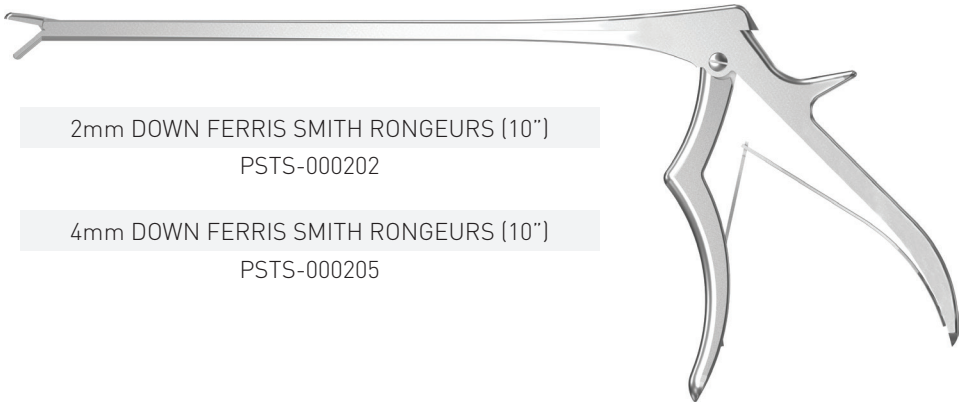
2mm STRAIGHT FERRIS SMITH RONGEURS (10")
PSTS-000200

4mm STRAIGHT FERRIS SMITH RONGEURS (10")
PSTS-000203



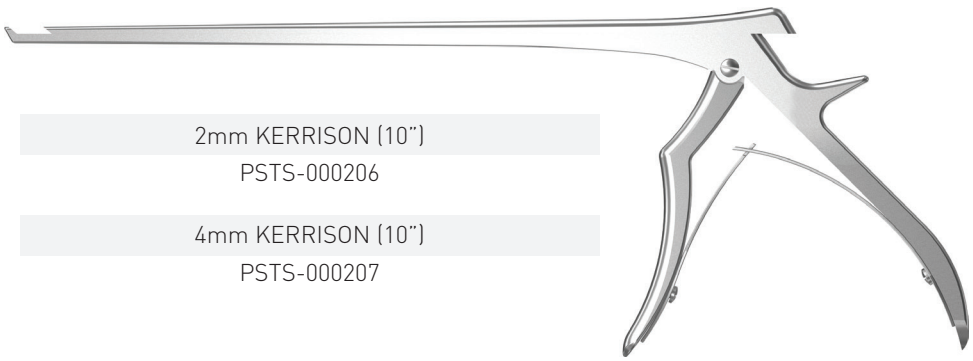
2mm UP FERRIS SMITH RONGEURS (10")
PSTS-000201

4mm UP FERRIS SMITH RONGEURS (10")
PSTS-000204



2mm DOWN FERRIS SMITH RONGEURS (10")
PSTS-000202

4mm DOWN FERRIS SMITH RONGEURS (10")
PSTS-000205



2mm KERRISON (10")
PSTS-000206

4mm KERRISON (10")
PSTS-000207

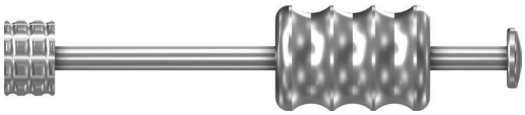
SILICONE T-HANDLE
PSTS-000010

WITH IMPACTION CAP
PSTS-000012


SILICONE STRAIGHT HANDLE
PSTS-000013

SLOTTED MALLOT
PSTS-000060

SILICONE STRAIGHT HANDLE
w/ SLAP HAMMER ATTACHMENT
PSTS-000011



SLAP HAMMER
PSTS-000050

ARTICULATING INSERTER
TSTS-000004

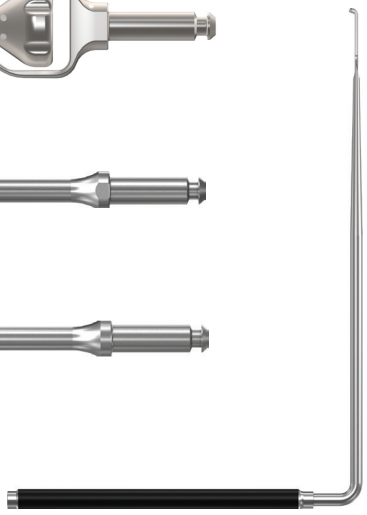
STRAIGHT INSERTER
PSTS-000004

INSERT-AND-ROTATE STRAIGHT INSERTER
PSTS-000015

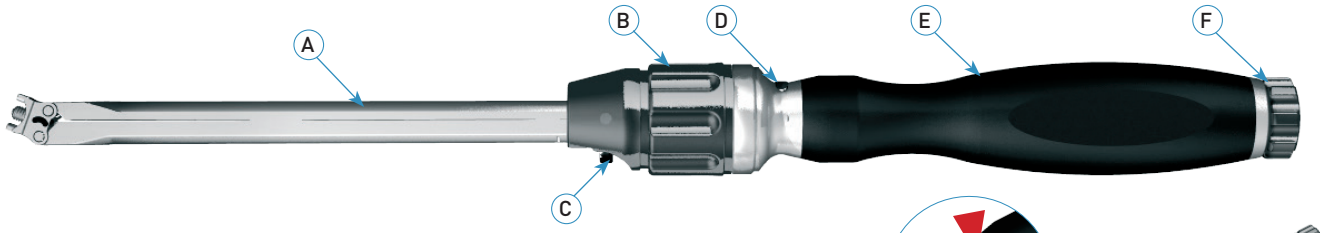
QC INSERTER SHORT
PSTS-000003

STRAIGHT TAMP SHORT
PSTS-000022

8mm BAYONET SCOVILLE RETRACTOR 6" FROM BEND
PSTS-000501



8mm 90° SCOVILLE RETRACTOR
7" FROM BEND
PSTS-000500




### The Curved Articulating Inserter body is comprised of the following parts:

A) Instrument body shaft
B) Implant steering module
C) Quick-release button for implant steering module
D) Inner shaft quick-release button
E) Handle
F) Implant locking knob on inner shaft

### Articulating Inserter Disassembly:

1. Press the quick-release button (D) located under the handle (Fig. 17) to release and remove the inner shaft locked into the instrument body (Fig. 18). The inner shaft is a component which consists of a U-joint with a threaded distal end (Fig. 19).

2. Rotate the implant steering module (B) clockwise until the module comes to a complete stop (approximately 40°) (Fig. 20).

3. Press the quick-release button located on the steering module (C) and push the module towards the distal end and unscrew the module until it freely slides along the instrument body shaft (A) (Fig. 21).

4. Pull the implant steering module off the distal end of the instrument body shaft (Fig. 22).

5. Manipulate the instrument body shaft carefully and do not force the articulation (Fig. 23).

### Articulating Inserter Reassembly:

To reassemble, follow the disassembly instructions in reverse order.

When sliding the implant steering module (B) onto the distal end of the instrument body shaft (A), ensure the graduation window on the implant steering module is facing the same direction as the etched graduation on the instrument body shaft.

Once seated, screw the implant steering module counter-clockwise until it comes to a complete stop.

Insert the inner shaft into the proximal end of the instrument body thread first, ensuring the tip of the inserter is perpendicular to the shaft (approximately 20°).

Press the quick-release button (D) to fully engage and secure the inner shaft within the instrument body. The threaded end of the inner shaft will appear between the prongs on the distal tip of the instrument (Fig. 24).

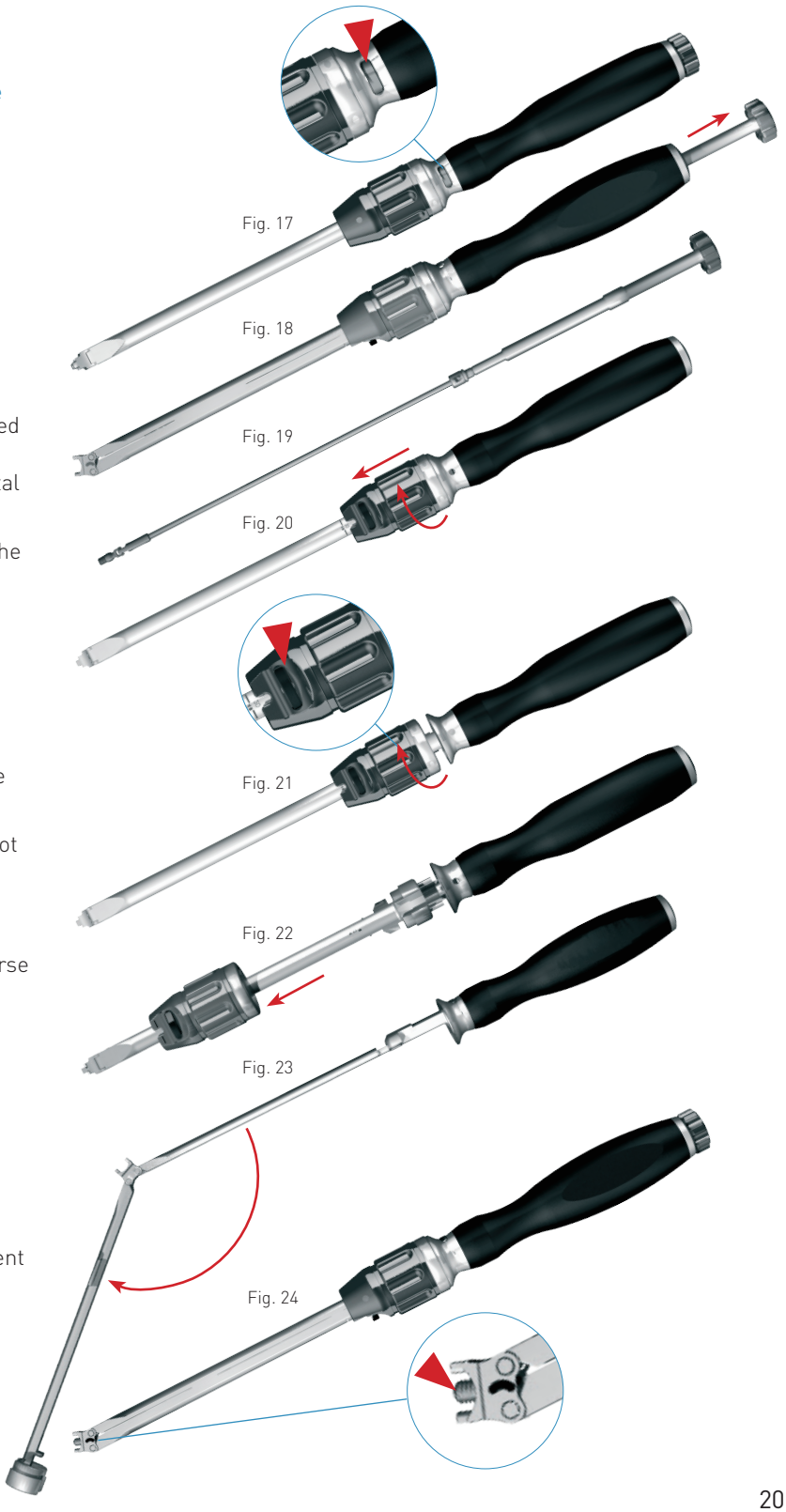


Fig. 17

Fig. 18

Fig. 19

Fig. 20

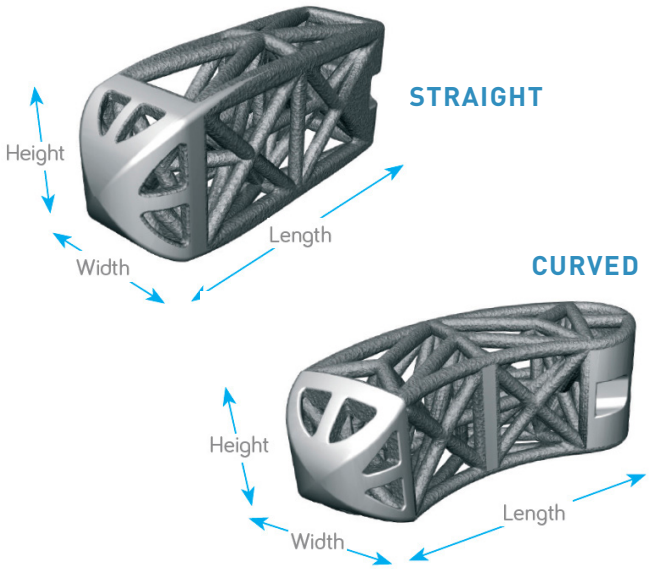
Fig. 21

Fig. 22

Fig. 23

Fig. 24

# IMPLANT CATALOG & SPECIFICATIONS




## INTERBODY DEVICES

| CATALOG NUMBER | FOOTPRINT W x L x H | LORDOSIS |
|---|---|---|
| STRAIGHT | | |
| PSTS-SM0006-22-SP | 9 x 22 x 6mm | 0° |
| PSTS-SM0008-22-SP | 9 x 22 x 8mm | 0° |
| PSTS-SM0010-22-SP | 9 x 22 x 10mm | 0° |
| PSTS-SM0012-22-SP | 9 x 22 x 12mm | 0° |
| PSTS-SM0014-22-SP | 9 x 22 x 14mm | 0° |
| PSTS-SM0608-22-SP | 9 x 22 x 8mm | 6° |
| PSTS-SM0609-22-SP | 9 x 22 x 9mm | 6° |
| PSTS-SM0610-22-SP | 9 x 22 x 10mm | 6° |
| PSTS-SM0611-22-SP | 9 x 22 x 11mm | 6° |
| PSTS-SM0612-22-SP | 9 x 22 x 12mm | 6° |
| PSTS-SM0613-22-SP | 9 x 22 x 13mm | 6° |
| PSTS-SM0614-22-SP | 9 x 22 x 14mm | 6° |
| PSTS-SM1210-22-SP | 9 x 22 x 10mm | 12° |
| PSTS-SM1211-22-SP | 9 x 22 x11mm | 12° |
| PSTS-SM1212-22-SP | 9 x 22 x 12mm | 12° |

| CATALOG NUMBER | FOOTPRINT W x L x H | LORDOSIS |
|---|---|---|
| PSTS-SM1213-22-SP | 9 x 22 x 13mm | 12° |
| PSTS-SM1214-22-SP | 9 x 22 x 14mm | 12° |
| PSTS-SM0006-26-SP | 9 x 26 x 6mm | 0° |
| PSTS-SM0008-26-SP | 9 x 26 x 8mm | 0° |
| PSTS-SM0010-26-SP | 9 x 26 x 10mm | 0° |
| PSTS-SM0012-26-SP | 9 x 26 x 12mm | 0° |
| PSTS-SM0014-26-SP | 9 x 26 x 14mm | 0° |
| PSTS-SM0608-26-SP | 9 x 26 x 8mm | 6° |
| PSTS-SM0609-26-SP | 9 x 26 x 9mm | 6° |
| PSTS-SM0610-26-SP | 9 x 26 x 10mm | 6° |
| PSTS-SM0611-26-SP | 9 x 26 x 11mm | 6° |
| PSTS-SM0612-26-SP | 9 x 26 x 12mm | 6° |
| PSTS-SM0613-26-SP | 9 x 26 x 13mm | 6° |
| PSTS-SM0614-26-SP | 9 x 26 x 14mm | 6° |
| PSTS-SM1210-26-SP | 9 x 26 x 10mm | 12° |
| PSTS-SM1211-26-SP | 9 x 26 x 11mm | 12° |
| PSTS-SM1212-26-SP | 9 x 26 x 12mm | 12° |
| PSTS-SM1213-26-SP | 9 x 26 x 13mm | 12° |
| PSTS-SM1214-26-SP | 9 x 26 x 14mm | 12° |
| PSTS-MD0608-26-SP | 11 x 26 x 8mm | 6° |
| PSTS-MD0609-26-SP | 11 x 26 x 9mm | 6° |
| PSTS-MD0610-26-SP | 11 x 26 x 10mm | 6° |
| PSTS-MD0611-26-SP | 11 x 26 x 11mm | 6° |
| PSTS-MD0612-26-SP | 11 x 26 x 12mm | 6° |

| CATALOG NUMBER | FOOTPRINT W x L x H | LORDOSIS |
|---|---|---|
| PSTS-MD0613-26-SP | 11 x 26 x 13mm | 6° |
| PSTS-MD0614-26-SP | 11 x 26 x 14mm | 6° |
| PSTS-MD1210-26-SP | 11 x 26 x 10mm | 12° |
| PSTS-MD1211-26-SP | 11 x 26 x 11mm | 12° |
| PSTS-MD1212-26-SP | 11 x 26 x 12mm | 12° |
| PSTS-MD1213-26-SP | 11 x 26 x 13mm | 12° |
| PSTS-MD1214-26-SP | 11 x 26 x 14mm | 12° |
| CURVED | | |
| TSTS-MD0007-27-SP | 10 x 27 x 7mm | 0° |
| TSTS-MD0009-27-SP | 10 x 27 x 9mm | 0° |
| TSTS-MD0011-27-SP | 10 x 27 x 11mm | 0° |
| TSTS-MD0013-27-SP | 10 x 27 x 13mm | 0° |
| TSTS-MD0015-27-SP | 10 x 27 x 15mm | 0° |
| TSTS-MD0607-27-SP | 10 x 27 x 7mm | 6° |
| TSTS-MD0608-27-SP | 10 x 27 x 8mm | 6° |
| TSTS-MD0609-27-SP | 10 x 27 x 9mm | 6° |
| TSTS-MD0610-27-SP | 10 x 27 x 10mm | 6° |
| TSTS-MD0611-27-SP | 10 x 27 x 11mm | 6° |
| TSTS-MD0612-27-SP | 10 x 27 x 12mm | 6° |
| TSTS-MD0613-27-SP | 10 x 27 x 13mm | 6° |
| TSTS-MD0614-27-SP | 10 x 27 x 14mm | 6° |
| TSTS-MD0615-27-SP | 10 x 27 x 15mm | 6° |
| TSTS-MD0007-32-SP | 10 x 32 x 7mm | 0° |
| TSTS-MD0009-32-SP | 10 x 32 x 9mm | 0° |

| CATALOG NUMBER | FOOTPRINT W x L x H | LORDOSIS |
|---|---|---|
| TSTS-MD0011-32-SP | 10 x 32 x 11mm | 0° |
| TSTS-MD0013-32-SP | 10 x 32 x 13mm | 0° |
| TSTS-MD0015-32-SP | 10 x 32 x 15mm | 0° |
| TSTS-MD0607-32-SP | 10 x 32 x 7mm | 6° |
| TSTS-MD0608-32-SP | 10 x 32 x 8mm | 6° |
| TSTS-MD0609-32-SP | 10 x 32 x 9mm | 6° |
| TSTS-MD0610-32-SP | 10 x 32 x 10mm | 6° |
| TSTS-MD0611-32-SP | 10 x 32 x 11mm | 6° |
| TSTS-MD0612-32-SP | 10 x 32 x 12mm | 6° |
| TSTS-MD0613-32-SP | 10 x 32 x 13mm | 6° |
| TSTS-MD0614-32-SP | 10 x 32 x 14mm | 6° |
| TSTS-MD0615-32-SP | 10 x 32 x 15mm | 6° |

**Not all sizes are available in all markets. Please refer to your country of origin's sales sheet for a complete product offering.*

**POSTERIOR SPINE TRUSS SYSTEM (PSTS) INTERBODY FUSION DEVICE**

**INSTRUCTIONS FOR USE**

**PLEASE READ CAREFULLY**

**CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALES BY OR ON THE ORDER OF A PHYSICIAN.**

**INTENDED USE:**
The Posterior Spine Truss System (PSTS) Interbody Fusion Device is designed to provide mechanical support to the lumbar spine while biologic fusion takes place.

**DEVICE DESCRIPTION:**
The device is an open architecture truss design mathematically formulated to provide structural support with open space throughout the implant for bone growth and fusion. The 4WEB additive manufacturing process provides a hierarchical surface roughness. The implant is made from Ti6Al4V alloy.

The device is available in a variety of sizes and lordotic angles to accommodate the patient's anatomy.

**INDICATIONS FOR USE:**
The Posterior Spine Truss System (PSTS) Interbody Fusion Device is indicated for use 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. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

**CONTRAINDICATIONS:**
The PSTS Interbody Fusion Device should not be implanted in patients with:
- An active infection at the operative site or other active systemic infections
- Tumor involvement at the operative site
- Prior fusion at the level(s) to be treated
- Known sensitivity to the material

**WARNINGS AND PRECAUTIONS:**
Safety and effectiveness have not been established in the following conditions:
- Gross obesity
- Three or more levels to be fused
- Symptomatic cardiac disease
- Pregnancy
- Previous fusion attempts at the involved level(s)
- Spondylolisthesis or retrolisthesis greater than Grade I
- Significant loss of bone stock as seen with osteoporosis or osteomalacia
- Conditions requiring chronic corticosteroid use
- Active drug abuse

The PSTS Interbody Fusion Device is for single use only.

Bending or fracture of the implants or instruments can occur if not handled properly.

All sizers and instrumentation are provided non-sterile and must be steam sterilized prior to use.

No implant should be reused if it has come in contact with blood or other bodily fluids.

All implants, sizers and instrumentation should be inspected prior to use for possible damage or defects. Any damaged or defective component should not be used and should be returned to 4WEB.

Interbody fusion devices are intended to provide mechanical support while biologic fusion occurs. In the event of pseudoarthrosis or delayed fusion, the risk of implant migration, loosening or breakage increases. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

Only surgeons trained in lumbar spine fusion procedures should implant this device.

**OPERATIVE PRECAUTIONS:**
The surgeon is to be thoroughly familiar with the PSTS Interbody Fusion Device, methods of application, instruments and surgical technique. Correct positioning of the PSTS Interbody Fusion Device relative to the vertebrae should be checked intraoperatively with x-ray. The size (and more particularly the height) of the PSTS Interbody Fusion Device must be chosen on the basis of the patient's anatomy and desired correction.

Each PSTS Interbody Fusion Device is to be filled with autologous and/or allograft bone to promote bone fusion (See Surgical Technique Manual for complete details). The implants are for single-implant use only. An explanted implant must never be re-implanted. Stresses and fracture, even though not noticeable by visual inspection, may have been created during initial implantation.

Following implantation, the product number and manufacturing lot number of the device that has been implanted must be reported in the patient's surgical file.

**POTENTIAL ADVERSE EVENTS:**
Potential adverse events may be related to surgery in general, spine surgery specifically or the device. These may include, but are not limited to the following:
- Adverse events related to any surgery: reactions to anesthesia, the anesthetic or other medications; bleeding; infection; ileus; blood vessel damage; nerve or soft tissue damage; atelectasis; pneumonia; hematoma; seroma; wound dehiscence or incisional hernia; urologic problems; embolism; anemia; colitis; thrombophlebitis; heart attack; stroke; or death.
- Adverse events related specifically to spine surgery: dural tear and CSF leak; nerve damage leading to radiculopathy, myelopathy, paraparesis, paresthesia or paralysis; meningitis; vertebral body damage or fracture; ligament damage; fractured sacrum; or retrograde ejaculation.
- Adverse events related to the device: implant crack or fracture, failure to achieve fusion, implant migration, dislodgement, or metal sensitivity to a foreign body, including possible tumor formation. Additional surgery may be necessary for implant removal, repositioning or replacement. Additional stabilization at the implanted level or surgery at another disc level may be necessary if non-union or anatomic change at an adjacent level develops.

**POSTOPERATIVE CARE:**
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
- Detailed instructions on the use and limitations of the device must be given to the patient. The patient must be warned that loosening, and / or breakage of the device(s) are complications which may occur as result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine.
- The patient must be advised not to smoke or consume alcohol during period of the bone fusion process.
- The patient must be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- It is critical that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and / or break, the devices must be revised and / or removed immediately before serious injury occurs.
- Any retrieved devices are not to be used in another surgical procedure.

**MRI SAFETY INFORMATION:**
Non-clinical testing has demonstrated the PSTS Interbody Fusion Device is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:
- Static magnetic field of 3 T or 1.5 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤ 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, non-clinical testing results indicate the PSTS Interbody Fusion Device produces a maximum temperature rise of no more than 5.0°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 28 mm from the PSTS Interbody Fusion Device when imaged with a gradient echo pulse sequence and a 3 T MR system.

**PACKAGING:**
PSTS Interbody Fusion Device is provided sterile and is clearly labeled as such in an unopened sterile package provided by 4WEB. The contents are considered sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised.

**Implants supplied sterilized from 4WEB must not be re-sterilized.**

Posterior STS ancillary instrumentation is provided non-sterile and is supplied in a tray that is used for steam sterilization prior to use in the operating room. In the case of instrument restock, individual items will be sent in a plastic bag, labeled for that device.

Storage conditions must maintain the integrity of the implants, associated ancillary instruments and their respective packaging. The condition of all implants and instruments must be checked before use. Damaged products must not be used and should be returned to 4WEB.

**INFORMATION FOR CLEANING AND STERILIZATION OF SURGICAL INSTRUMENTS:**

CAUTION: THESE INSTRUCTIONS DO NOT APPLY TO SINGLE-USE DEVICES.

The instruments used to implant the PSTS Interbody Fusion Device do not have an indefinite functional life. All reusable instruments are subjected to repeated stresses related to bone contact, impaction, routing, cleaning, and sterilization processes. Instruments should be carefully inspected before use to ensure that they are fully functional.

All ancillary instruments of the PSTS Interbody Fusion Device are delivered non-sterile and therefore, must be decontaminated, cleaned and sterilized prior to surgical use. Decontamination reduces the population of microorganisms and facilitates the subsequent cleaning stage. Strict compliance with the instructions for use pertaining to decontamination and cleaning is mandatory, particularly the concentration and exposure time requirements. Thorough rinsing with water must be conducted following decontamination and cleaning.

- Decontamination: Each hospital must use their own validated decontamination procedures.
- Cleaning: Wash instruments in a LANCER type (or equivalent) washing machine with the appropriate cleaning products, rinse, and dry. Any product which may alter the material is prohibited, i.e. bleach, formalin, hypochlorite solutions, saline solution, etc.

The reprocessing instructions provided have been validated as being capable of preparing reusable 4WEB instruments. It is the responsibility of the reprocessor to ensure that the reprocessing is actually performed using appropriate equipment, materials, and personnel to achieve the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the reprocessor from these instructions should be evaluated for effectiveness and potential adverse consequences.

**WARNINGS:**
- Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents and equipment used.
- Do not exceed 140° C (284° F) during reprocessing steps.
- Highly alkaline conditions can damage products with aluminum parts.
- Avoid exposure to hypochlorite solutions, as these will promote corrosion.
- Scratches or dents can result in breakage.
- For instruments produced by another manufacturer, reference the manufacturer's instructions for use.
- Care should be taken to remove any debris, tissue or bone fragments that may collect on the instrument.

**LIMITATIONS ON REPROCESSING:**
- End of useful life is generally determined by wear or damage in surgical use.
- Carefully inspect instruments between uses to verify proper functioning and configuration.
- Damaged instruments must be replaced to prevent potential patient injury such as loss of metal fragments into the surgical site.

**DECONTAMINATION CONSIDERATIONS — CREUTZFELDT-JAKOB DISEASE (CJD):**
- Under certain classifications of risk, the World Health Organization (WHO) or local regulatory authorities recommend special CJD (Creutzfeldt-Jakob Disease) inactivation processing procedures. For use of this product outside the United States, consult WHO and local regulations for further information.

**REPROCESSING INSTRUCTIONS**
**CARE AT THE POINT OF USE:**
- Use purified water obtained via ultra-filtration, RO, DI and/or distilled.
- Thoroughly clean instruments as soon as possible after use. If cleaning must be delayed, immerse instruments in a compatible pH neutral detergent solution and purified water to prevent drying and encrustation of surgical soil.
- Avoid prolonged exposure to saline to minimize the chance of corrosion.
- Remove excessive soil with a disposable low lint wipe.

**CLEANING:**
ALL INSTRUMENTS
- Instructions for instruments requiring disassembly for cleaning may be found in the Surgical Technique Manual (ST-PSTS-01).
- Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions (1oz Enzol, or equivalent, per gallon of purified water). **Note:** the enzyme solution must be changed on a regular basis.
- Soak soiled instruments for 5 minutes in the enzymatic solution.
- Use a soft bristle brush to remove all traces of blood and debris; pay close attention to any hard-to-reach areas, textured surfaces, or crevices.
- Rinse the instrument thoroughly with purified water.
- Dry the instrument immediately after final rinse.
- Clean using the "INSTRUMENTS" cycle in a validated washer disinfector and a pH neutral cleaning agent intended for use in automated cleaning. The cleaning cycle should incorporate enzymatic pre-wash, wash, rinse, thermal rinse, and drying steps.
- Place heavier instruments on the bottom of containers. Do not place heavy instruments on top of delicate instruments.
- For instruments with concave surfaces, such as curettes, place instrument with the concave surface facing downward to facilitate draining.

**CLEANING INSPECTION:**
- Inspect all instruments to verify that all visible debris is removed during cleaning and prior to sterilization. If debris is still visible after cleaning, repeat the cleaning process.

**MAINTENANCE INSPECTION AND FUNCTIONAL TESTING:**
- Visually inspect all instruments to ensure no damage and wear.
- Ensure there are no cracked handles and shafts are secure in handles.
- Ensure long instruments are free of any bending and distortion.
- Ensure instrument tips are free of defects or burrs.
- Ensure complex instruments with moving parts function appropriately.

**WRAPPING:**
WRAPPING TECHNIQUE
- Use instrument trays to contain instruments that are provided in sets.
- Biological or Chemical Indicators (BIs or CIs) used for monitoring the performance of sterilization processes should be placed in the middle racks within wrapped trays. They should be tested according to the BI or CI manufacturer's directions.
- Double wrap instruments in accordance with local procedures, using standard wrapping techniques such as those described in ANSI/AAMI ST79.
- Use only FDA-cleared wraps.
- Label the contents of the wrapped tray using an indelible marker or other sterilization compatible label system.
- Allow 1 inch of free space between the instrument tray and the inside of the container lid for effective processing.

**STERILIZATION:**
- Use a validated, properly maintained and calibrated steam sterilizer.
- Effective steam sterilization can be achieved using the following cycle to achieve an SAL of $10^{-6}$.

| Cycle | Temperature | Duration | Dry Time |
|---|---|---|---|
| Gravity | 121° C (250° F) | 30 min | 45 min |
| Prevacuum | 132° C (270° F) | 4 min | 45 min |

**NOTE:** STERILIZATION DOES NOT REPLACE DECONTAMINATION OR CLEANING. ONLY A CLEAN PRODUCT CAN BE CORRECTLY STERILIZED. ONLY STERILE IMPLANTS AND INSTRUMENTS MAY BE USED FOR SURGERY.

**PRODUCT COMPLAINTS:**
Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any PSTS products should notify 4WEB, or, where applicable, their distributor.

**SURGICAL TECHNIQUE MANUAL:**
To receive additional copies of the Surgical Technique Manual (ST-PSTS-01), contact your local sales representative or the company at the address below.

**USA:**
4WEB Medical
2801 Network Blvd. Suite 620
Frisco, TX USA 75034
T +1(800) 285-7090
F +1(972) 488-1816

**OUTSIDE USA:**
4WEB EU B.V.
Industrieweg 13b
1566JN Assendelft, The Netherlands
T +31 20 708 45 45
F +31 20 708 45 65
CE 0344

**Standard: ISO 15223-1, Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied.**

| Symbol | Ref. Number | Title | Description of Symbol |
|---|---|---|---|
|  | 5.4.4 | Caution | Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. |
|  | 5.4.2 | Do not re-use | Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. |
|  | 5.4.3 | Consult instructions for use | Indicates the need for the user to consult the instructions for use. |
|  | 5.1.5 | Lot number | Indicates the manufacturer's lot number so that a specific medical device can be identified. |
|  | 5.1.6 | Catalog number | Indicates the manufacturer's catalog number so that the medical device can be identified. |
|  | 5.1.1 | Manufacturer | Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42 EEC, and 98/79 EC. |
|  | 5.1.3 | Date of manufacture | Indicates the date when the medical device was manufactured. |
|  | 5.1.4 | Use-by date | Indicates the date after which the medical device is not to be used. |
|  | 5.2.4 | Sterile | Sterilized using irradiation. Indicates a medical device that has been sterilized using irradiation. |
|  | 5.2.6 | Do not resterilize | Indicates a medical device that is not to be resterilized. |
|  | 5.2.8 | Do not use if package is damaged | Indicates a medical device that should not be used if the package has been damaged or opened. |

| | | | |
|---|---|---|---|
|  | ASTM F2503-13 | MR Conditional | Medical device that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. |
|  | 21 CFR 801.109 | Prescription only | Requires prescription in the United States. |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4WEBMEDICAL.COM
INFO@4WEBMEDICAL.COM
800.285.7090
ST-PSTS-01 | REV D