SURGICAL TECHNIQUE GUIDE

POSTERIOR SPINE TRUSS SYSTEM





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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 TECHNOLOGYTM



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.



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.





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.

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



Figure 2

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.

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.
- 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).
- 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.



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.



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 40° or anterior placement of the implant has been achieved (Fig. 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 backpressure 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

DISTRACTOR

PART NUMBER	SIZE (MM)	PART NUMBER	SIZE (MM)
PSTS-000300	6	PSTS-SM0006-26D	6
PSTS-000301	7	PSTS-SM0007-26D	7
PSTS-000302	8	PSTS-SM0008-26D	8
PSTS-000303	9	PSTS-SM0009-26D	9
PSTS-000304	10	PSTS-SM00010-26D	10
PSTS-000305	11	PSTS-SM00011-26D	11
PSTS-000306	12	PSTS-SM00012-26D	12
PSTS-000307	13	PSTS-SM00013-26D	13
PSTS-000308	14	PSTS-SM00014-26D	14
PSTS-000309	15	PSTS-SM00015-26D	15



STRAIGHT SIZER

CURVED SIZER

PART NUMBER	SIZE (MM)	DEGREE	PART NUMBER	SIZE (MM)	DEGREE
PSTS-SM0006-26S	9 x 26 x 6	0°	TSTS-MD0007-27S	10 x 27 x 7	0°
PSTS-SM0008-26S	9 x 26 x 8	0°	TSTS-MD0009-27S	10 x 27 x 9	0°
PSTS-SM0010-26S	9 x 26 x 10	0°	TSTS-MD0011-27S	10 x 27 x 11	0°
PSTS-SM0012-26S	9 x 26 x 12	0°	TSTS-MD0013-27S	10 x 27 x 13	0°
PSTS-SM0014-26S	9 x 26 x 14	0°	TSTS-MD0015-27S	10 x 27 x 15	0°
PSTS-SM0608-26S	9 x 26 x 8	6°	TSTS-MD0607-27S	10 x 27 x 7	6°
PSTS-SM0609-26S	9 x 26 x 9	6°	TSTS-MD0608-27S	10 x 27 x 8	6°
PSTS-SM0610-26S	9 x 26 x 10	6°	TSTS-MD0609-27S	10 x 27 x 9	6°
PSTS-SM0611-26S	9 x 26 x 11	6°	TSTS-MD0610-27S	10 x 27 x 10	6°
PSTS-SM0612-26S	9 x 26 x 12	6°	TSTS-MD0611-27S	10 x 27 x 11	6°



STRAIGHT SIZER (CONT.)

CURVED SIZER (CONT.)

PART NUMBER	SIZE (MM)	DEGREE	PART NUMBER	SIZE (MM)	DEGREE
PSTS-SM0613-26S	9 x 26 x 13	6°	TSTS-MD0612-27S	10 x 27 x 12	6°
PSTS-SM0614-26S	9 x 26 x 14	6°	TSTS-MD0613-27S	10 x 27 x 13	6°
PSTS-SM1210-26S	9 x 26 x 10	12°	TSTS-MD0614-27S	10 x 27 x 14	6°
PSTS-SM1211-26S	9 x 26 x 11	12°	TSTS-MD0615-27S	10 x 27 x 15	6°
PSTS-SM1212-26S	9 x 26 x 12	12°	TSTS-MD0007-32S	10 x 32 x 7	0°
PSTS-SM1213-26S	9 x 26 x 13	12°	TSTS-MD0009-32S	10 x 32 x 9	0°
PSTS-SM1214-26S	9 x 26 x 14	12°	TSTS-MD0011-32S	10 x 32 x 11	0°
PSTS-MD0608-26S	11 x 26 x 8	6°	TSTS-MD0013-32S	10 x 32 x 13	0°
PSTS-MD0609-26S	11 x 26 x 9	6°	TSTS-MD0015-32S	10 x 32 x 15	0°
PSTS-MD0610-26S	11 x 26 x 10	6°	TSTS-MD0607-32S	10 x 32 x 7	6°
PSTS-MD0611-26S	11 x 26 x 11	6°	TSTS-MD0608-32S	10 x 32 x 8	6°
PSTS-MD0612-26S	11 x 26 x 12	6°	TSTS-MD0609-32S	10 x 32 x 9	6°
PSTS-MD0613-26S	11 x 26 x 13	6°	TSTS-MD0610-32S	10 x 32 x 10	6°
PSTS-MD0614-26S	11 x 26 x 14	6°	TSTS-MD0611-32S	10 x 32 x 11	6°
PSTS-MD1210-26S	11 x 26 x 10	12°	TSTS-MD0612-32S	10 x 32 x 12	6°
PSTS-MD1211-26S	11 x 26 x 11	12°	TSTS-MD0613-32S	10 x 32 x 13	6°
PSTS-MD1212-26S	11 x 26 x 12	12°	TSTS-MD0614-32S	10 x 32 x 14	6°
PSTS-MD1213-26S	11 x 26 x 13	12°	TSTS-MD0615-32S	10 x 32 x 15	6°
PSTS-MD1214-26S	11 x 26 x 14	12°			













 (\mathbf{A})

B

(C

D

E

(F)

- 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).



IMPLANT CATALOG & SPECIFICATIONS



INTERBODY DEVICES

CATALOG NUMBER	FOOTPRINT W x L x H		
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×L×H	LORDOSIS	
TSTS-MD0011-32-SP	10 x 32 x 11mm	٥°	
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.



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