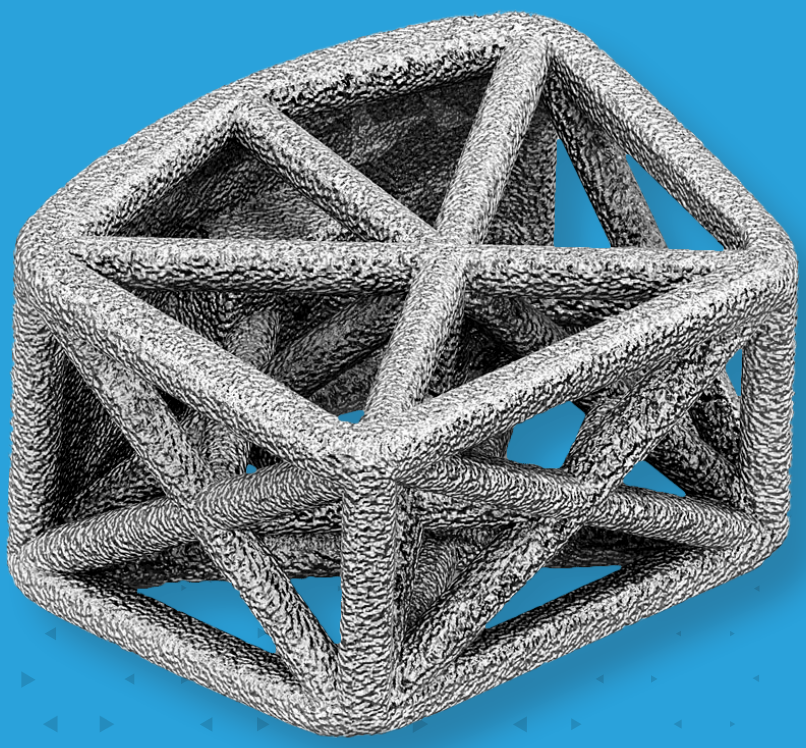
SURGICAL TECHNIQUE GUIDE

CERVICAL SPINE TRUSS SYSTEM



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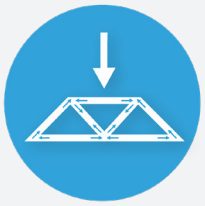
Federal law (USA) restricts these devices to sales by or on the order of a physician. Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the 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® at +1(800) 285-7090.

TRUSS IMPLANT TECHNOLOGY™

Novel Truss Implant Technology™ provides a Snow Shoe Interface that distributes load across the endplate which minimizes point loading and reduces the risk of subsidence.[1]

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.[2, 3]

Open architecture design allows for greater graft volume and bone growth throughout the entire construct.[1]



Distribution of load through the implant struts delivers strain to adjacent cellular material which stimulates a mechanobiologic response.[2]

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

[1] Data on file
[2] Lee et al., ORS, 2023 Annual Meeting, Dallas, TX
[3] Rowe et al., SMISS, Annual Forum '19, p.52

CSTS OVERVIEW

The Cervical Spine Truss System (CSTS) contains two footprints in a variety of 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.

CSTS implants, sizers and instruments are provided non-sterile and require sterilization prior to use.

INDICATIONS

The CSTS Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine at one level or two contiguous disc levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. CSTS Interbody Fusion Devices are used as an adjunct to fusion in the cervical spine and are placed via an anterior approach at the C2 to T1 disc levels using autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation.

CONTRAINDICATIONS

The CSTS 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

See package insert for warnings, precautions, adverse effects, and other essential product information. Before using the CSTS Instrumentation, verify:

- Instruments have maintained design integrity; and,
- Proper size configurations are available.

For Instructions for Cleaning, Sterilization, Inspection and Maintenance, refer to IFU-CSTS-04.

SURGICAL PROCEDURE

PATIENT POSITIONING

Place the patient in a supine position on the operating table (Fig. 1). Ensure that the neck of the patient is in neutral lordosis. A shoulder roll can be placed either transversely or longitudinally, based on surgeon preference, to aid in neck extension.

When treating C6–C7 make sure that the shoulders do not limit the fluoroscopic imaging. Caudal traction to the shoulders can be gently applied using adhesive tape. Ensure that the superior and inferior vertebrae adjacent to the affected level are completely visible.

Fluoroscopy can be utilized to aid in patient positioning.

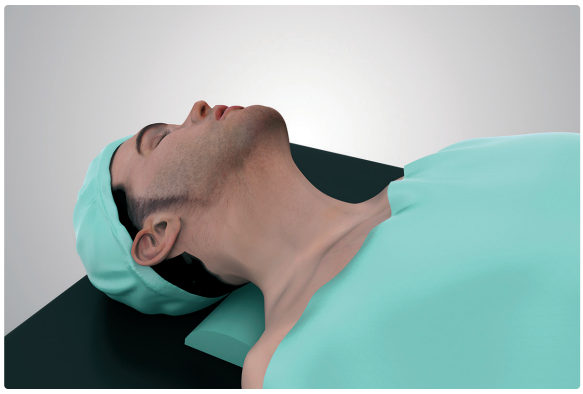


Figure 1

ACCESS AND EXPOSURE

Locate the correct operative level under fluoroscopic guidance. Make a skin incision and dissect to the appropriate level. Expose the intervertebral disc and the adjacent vertebral bodies through a standard anterior approach to the cervical spine (Fig. 2).

Once the operative level(s) have been exposed, confirm the centerline of the affected level(s) with fluoroscopic imaging.

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

Figure 2

DISCECTOMY AND ENDPLATE PREPARATION

A pin distractor may improve access to the disc space and visualization of potential neural compressive pathology.

Perform an annulotomy and subsequent discectomy between the uncovertebral joints and posterior longitudinal ligament as necessary (Fig. 3).

Remove the superficial layers of the cartilaginous endplates down to bleeding bone.

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.

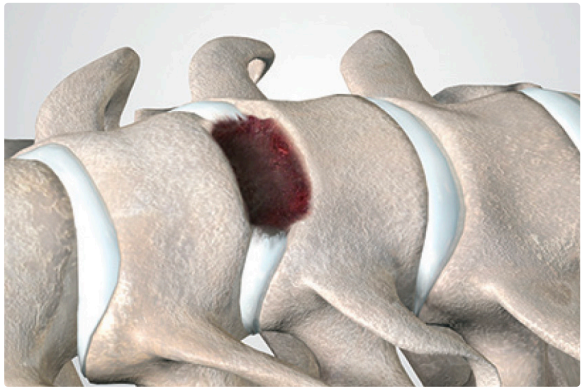


Figure 3

IMPLANT SIZING

Select the appropriate sizer by footprint, height and lordotic angle (Fig. 4). Height, footprint, and angle measurements are clearly marked on the sizers.

Carefully impact the sizer into the 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.

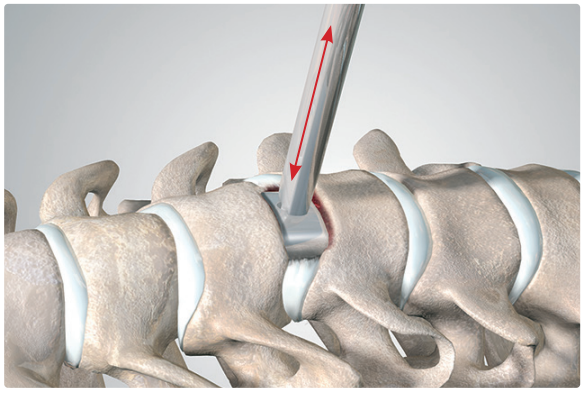


Figure 4

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:

CSTS implants are provided in a caddie found in the instrument tray. Select the implant that corresponds to the appropriate sizer.

Attach the implant to the inserter (Fig. 5a). Ensure the shoulder of the inserter is fully seated against the implant and no threads are visible.

Be careful not to over-tighten.

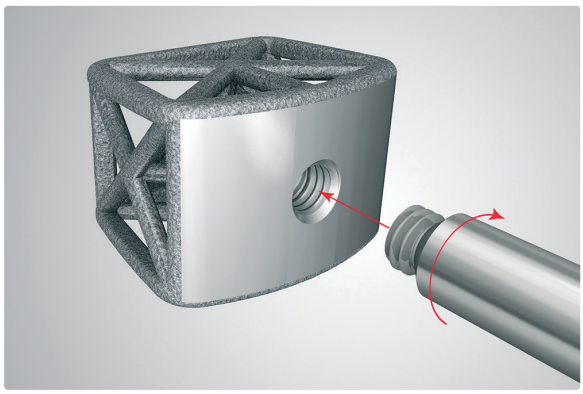


Figure 5

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. 6).

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.

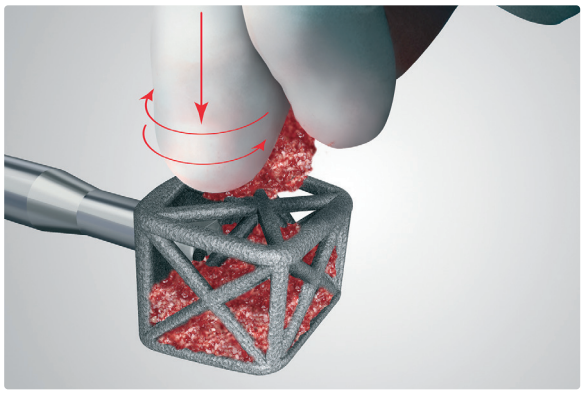


Figure 6

IMPLANT INSERTION

Introduce the implant into the prepared intervertebral space and tap it into place with a mallet (Fig. 7). Confirm the proper placement of the implant using fluoroscopy.

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

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.

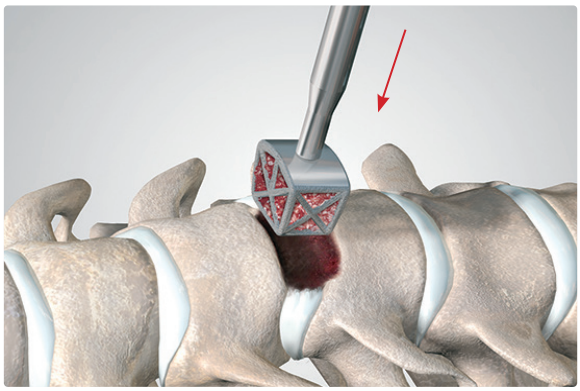


Figure 7

IMPLANT REMOVAL

If implant removal is required, the intervertebral space should be distracted in the same manner as for implant placement (Fig. 8). Once distracted, the implant may be removed by using the insertion tool.

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.

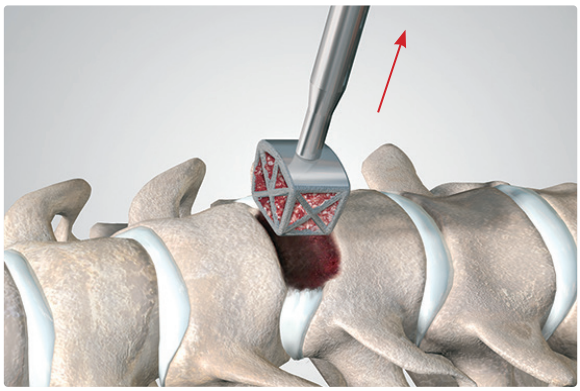


Figure 8

INSTRUMENT CATALOG

PART NUMBER	DESCRIPTION
CSTS-SMXX (05-12)-S	CSTS SIZER - 11 X 14MM (SM)

CSTS-MDXX (05-12)-S	CSTS SIZER - 14 X 17MM (MD)

763-9504-0	ROUND BONE TAMP (9.5")

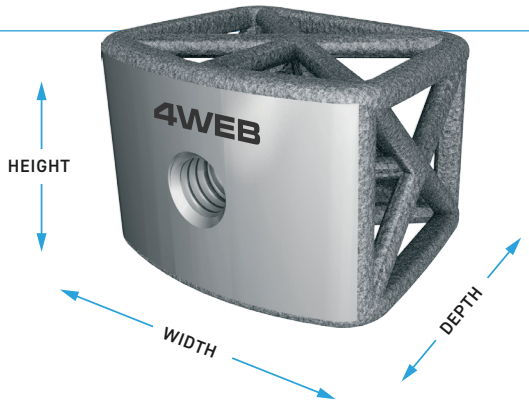
765-0909-0	DOUBLE SIDED RASP (8.5")'

761-9017-0	MALLET

PART NUMBER	DESCRIPTION
CSTS-000011	CSTS INSERTER

CSTS-000012	CSTS INSERTER LONG

IMPLANT CATALOG



INTERBODY DEVICES

CATALOG NUMBER	FOOTPRINT D x W x H	LORDOSIS
CSTS-SM0005	11 x 14 x 5mm	0°
CSTS-SM0006	11 x 14 x 6mm	0°
CSTS-SM0007	11 x 14 x 7mm	0°
CSTS-SM0008	11 x 14 x 8mm	0°
CSTS-SM0009	11 x 14 x 9mm	0°
CSTS-SM0010	11 x 14 x 10mm	0°
CSTS-SM0011	11 x 14 x 11mm	0°
CSTS-SM0012	11 x 14 x 12mm	0°
CSTS-MD0005	14 x 17 x 5mm	0°
CSTS-MD0006	14 x 17 x 6mm	0°
CSTS-MD0007	14 x 17 x 7mm	0°
CSTS-MD0008	14 x 17 x 8mm	0°
CSTS-MD0009	14 x 17 x 9mm	0°
CSTS-MD0010	14 x 17 x 10mm	0°
CSTS-MD0011	14 x 17 x 11mm	0°
CSTS-MD0012	14 x 17 x 12mm	0°

CATALOG NUMBER	FOOTPRINT D x W x H	LORDOSIS
CSTS-SM0705	11 x 14 x 5mm	7°
CSTS-SM0706	11 x 14 x 6mm	7°
CSTS-SM0707	11 x 14 x 7mm	7°
CSTS-SM0708	11 x 14 x 8mm	7°
CSTS-SM0709	11 x 14 x 9mm	7°
CSTS-SM0710	11 x 14 x 10mm	7°
CSTS-SM0711	11 x 14 x 11mm	7°
CSTS-SM0712	11 x 14 x 12mm	7°
CSTS-MD0705	14 x 17 x 5mm	7°
CSTS-MD0706	14 x 17 x 6mm	7°
CSTS-MD0707	14 x 17 x 7mm	7°
CSTS-MD0708	14 x 17 x 8mm	7°
CSTS-MD0709	14 x 17 x 9mm	7°
CSTS-MD0710	14 x 17 x 10mm	7°
CSTS-MD0711	14 x 17 x 11mm	7°
CSTS-MD0712	14 x 17 x 12mm	7°

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