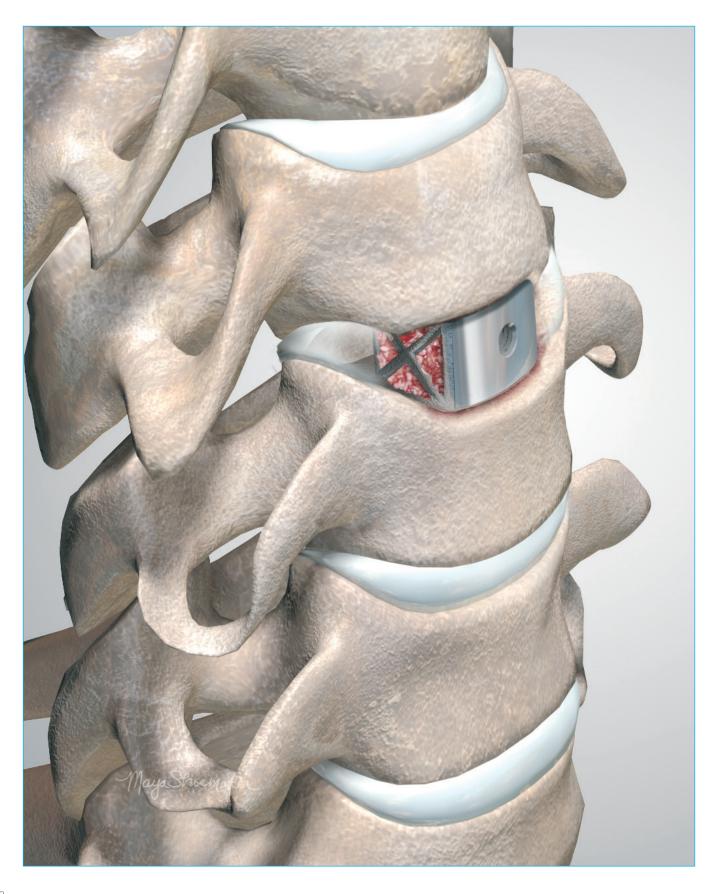
# CERVICAL SPINE TRUSS SYSTEM







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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 OVERVIEW

4WEB Medical's truss implant technology leverages multidisciplinary engineering principles such as truss design, load transfer and adjacent material reaction to produce orthopedic implants that provide structural support with open space throughout the implant for bone growth and fusion.

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.

The CSTS implant family contains two implant footprints (Small and Medium) with multiple heights and lordotic angles. Please refer to pages 11-12 for implant and sizer part numbers and dimensions.





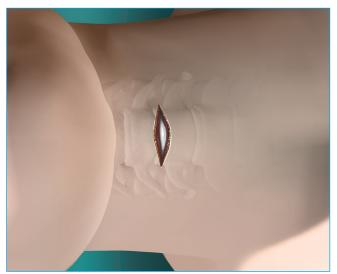
Fig. 1

# 1: 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.





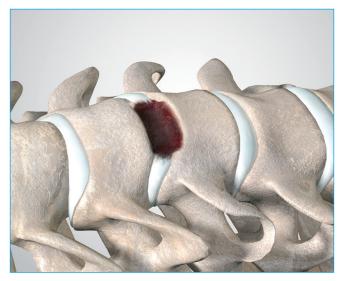


Fig. 3

#### 2: 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.

#### 3: DISCECTOMY AND ENDPLATE PREPARATION

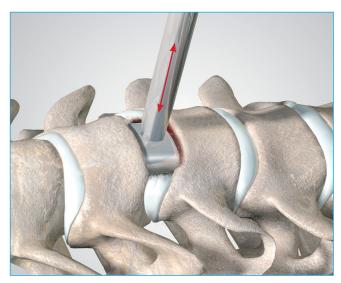
A pin distractor may improve access to the disc space and visualization of potential neual compressive pathology.

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.





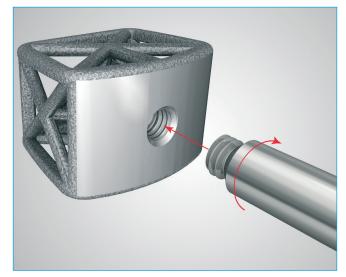


Fig. 5a

#### 4: 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.

**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.

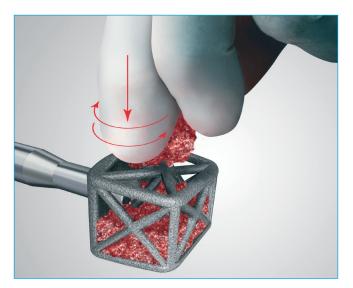
#### 5: IMPLANT PREPARATION

#### 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.





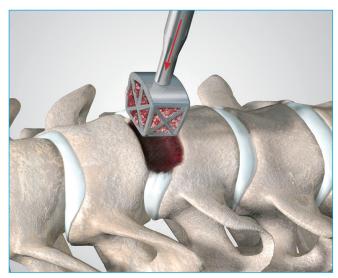


Fig. 6

#### **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. 5b)*.

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.

# 6: IMPLANT INSERTION

Introduce the implant into the prepared intervertebral space and tap it into place with a mallet *(Fig.6)*. 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.

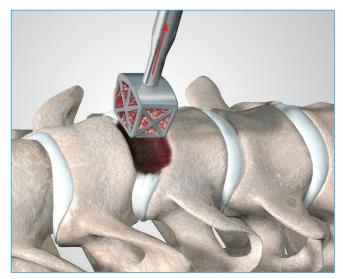
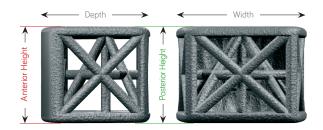


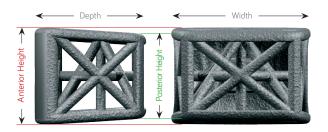
Fig. 7

# 7: IMPLANT REMOVAL

If implant removal is required, the intervertebral space should be distracted in the same manner as for implant placement *(Fig. 7)*. 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.





# CSTS IMPLANT - 11 X 14mm (SM) - 0 DEGREE

Part Number	Anterior Height (mm)	Posterior Height (mm)	Gradt Volume (cc)
CSTS-SM0005	5.0	5.0	0.31
CSTS-SM0006	6.0	6.0	0.41
CSTS-SM0007	7.0	7.0	0.51
CSTS-SM0008	8.0	8.0	0.61
CSTS-SM0009	9.0	9.0	0.72
CSTS-SM0010	10.0	10.0	0.82
CSTS-SM0011	11.0	11.0	0.92
CSTS-SM0012	12.0	12.0	1.03

# CSTS IMPLANT - 11 X 14mm (SM) - 7 DEGREE

Part Number	Anterior Height (mm)	Posterior Height (mm)	Gradt Volume (cc)
CSTS-SM0705	5.0	3.7	0.24
CSTS-SM0706	6.0	4.7	0.34
CSTS-SM0707	7.0	5.7	0.44
CSTS-SM0708	8.0	6.7	0.54
CSTS-SM0709	9.0	7.7	0.64
CSTS-SM0710	10.0	8.7	0.75
CSTS-SM0711	11.0	9.7	0.85
CSTS-SM0712	12.0	10.7	0.96

# CSTS IMPLANT - 14 X 17mm (MD) - 0 DEGREE

CSTS-MD0005	5.0	5.0	0.59
CSTS-MD0006	6.0	6.0	0.76
CSTS-MD0007	7.0	7.0	0.94
CSTS-MD0008	8.0	8.0	1.11
CSTS-MD0009	9.0	9.0	1.29
CSTS-MD0010	10.0	10.0	1.47
CSTS-MD0011	11.0	11.0	1.65
CSTS-MD0012	12.0	12.0	1.83

# CSTS IMPLANT - 14 X 17mm (MD) - 7 DEGREE

CSTS-MD0705	5.0	3.3	0.45
CSTS-MD0706	6.0	4.3	0.61
CSTS-MD0707	7.0	5.3	0.78
CSTS-MD0708	8.0	6.3	0.96
CSTS-MD0709	9.0	7.3	1.13
CSTS-MD0710	10.0	8.3	1.31
CSTS-MD0711	11.0	9.3	1.49
CSTS-MD0712	12.0	10.3	1.66





# CSTS SIZER - 11 X 14mm (SM):

Part Number	Height (mm)
CSTS-SMXX05-S	5
CSTS-SMXX06-S	6
CSTS-SMXX07-S	7
CSTS-SMXX08-S	8
CSTS-SMXX09-S	9
CSTS-SMXX10-S	10
CSTS-SMXX11-S	11
CSTS-SMXX12-S	12

# CSTS SIZER - 14 X 17mm (MD):

Part Number	Height (mm)
CSTS-MDXX05-S	5
CSTS-MDXX06-S	6
CSTS-MDXX07-S	7
CSTS-MDXX08-S	8
CSTS-MDXX09-S	9
CSTS-MDXX10-S	10
CSTS-MDXX11-S	11
CSTS-MDXX12-S	12



**ROUND BONE TAMP (9.5")** - CSTS-000020



DOUBLE SIDED RASP (9.5") - CSTS-000400



MALLET - CSTS-000060



CSTS INSERTER - CSTS-000011

CSTS INSERTER LONG - CSTS-000012



4WEB MEDICAL
2801 Network Blvd, Suite 620
Frisco, TX USA 75034
+1 (800) 285-7090 | 4WEBMEDICAL.com

**CE** 0344