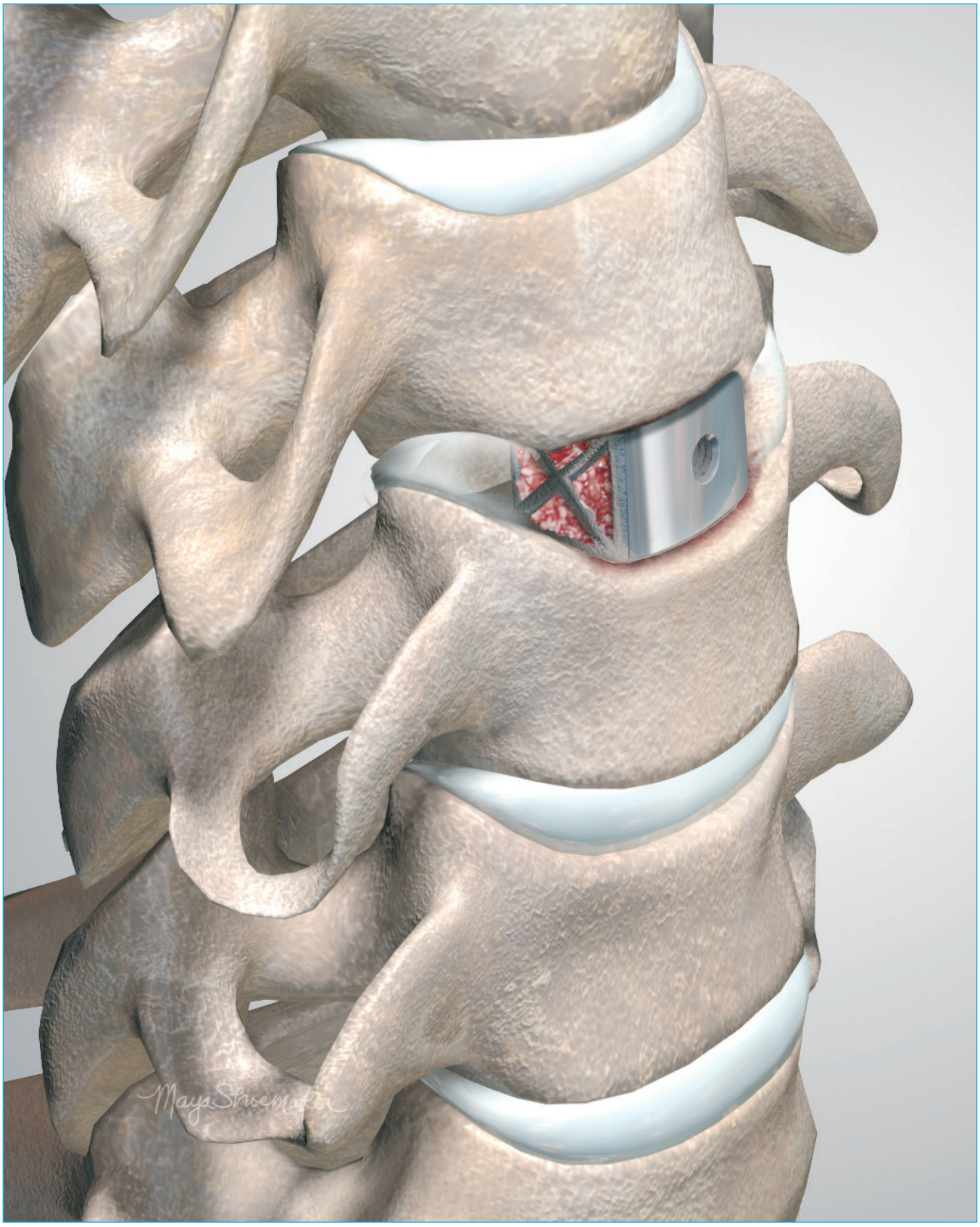
4WEB MEDICAL SURGICAL TECHNIQUE

CERVICAL SPINE TRUSS SYSTEM

4WEB® MEDICAL



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.


4WEB

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.

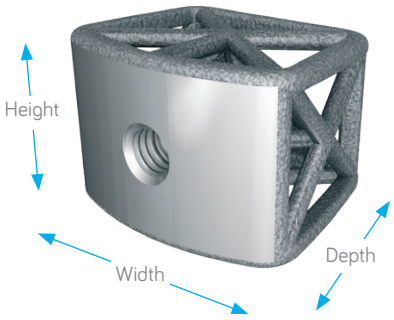


Fig. 1

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.

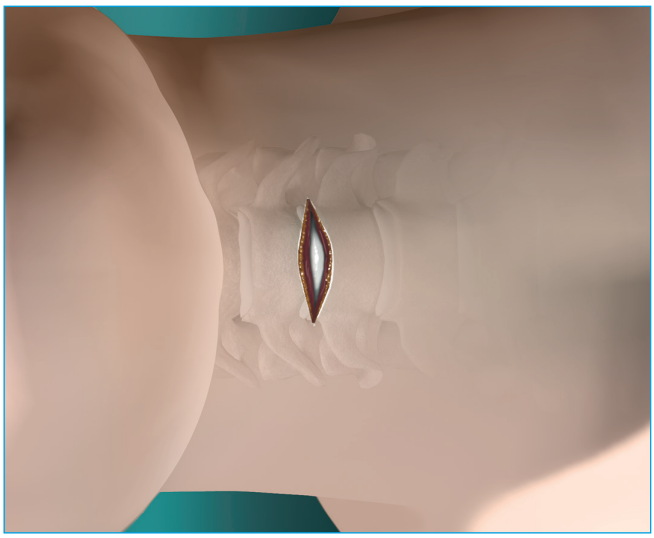


Fig. 2

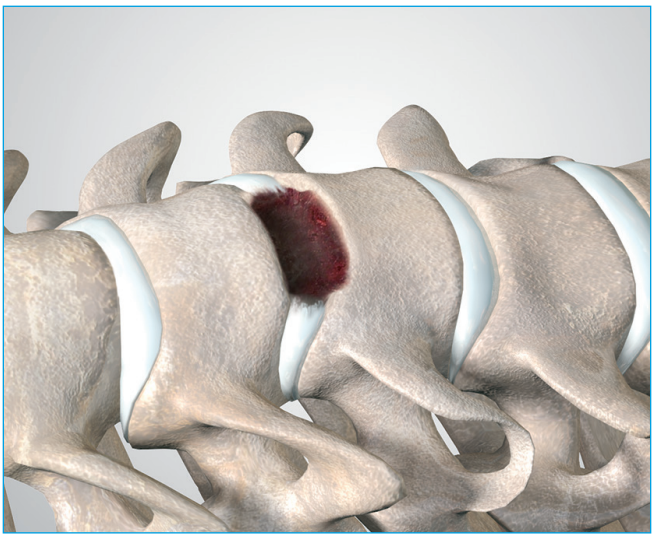


Fig. 3

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.

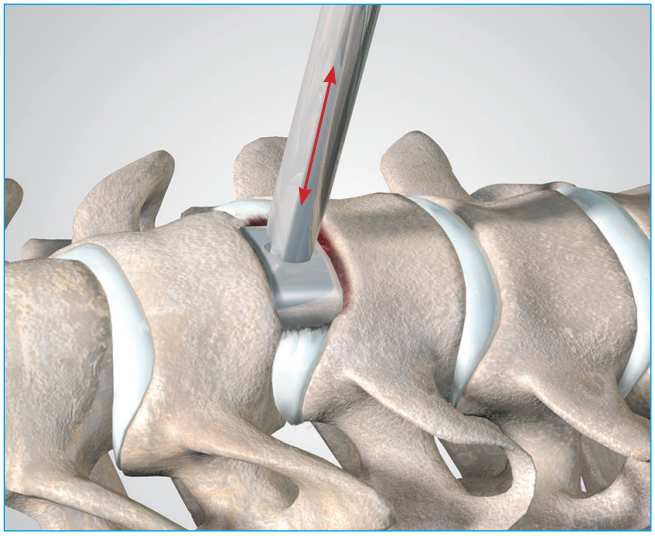


Fig. 4

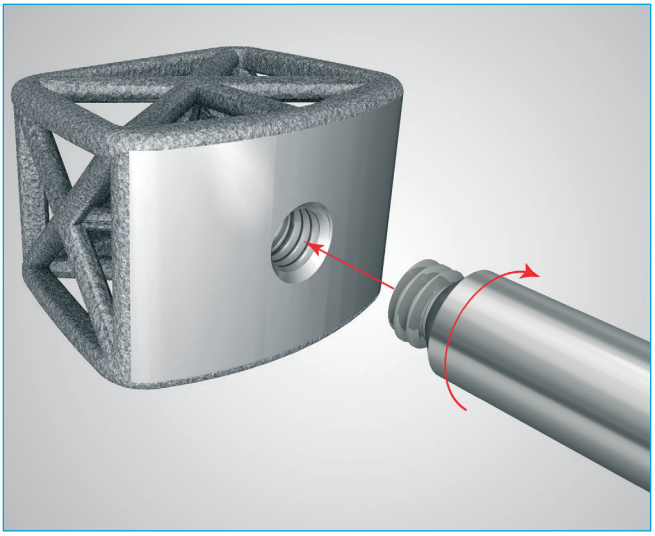


Fig. 5a

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.

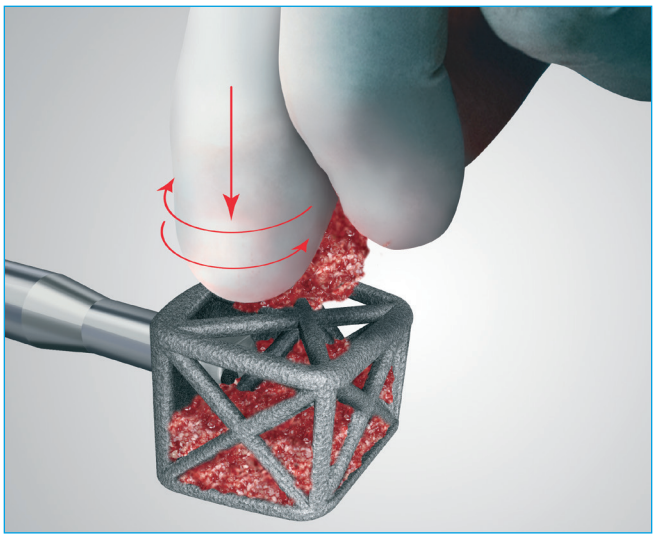


Fig. 5b

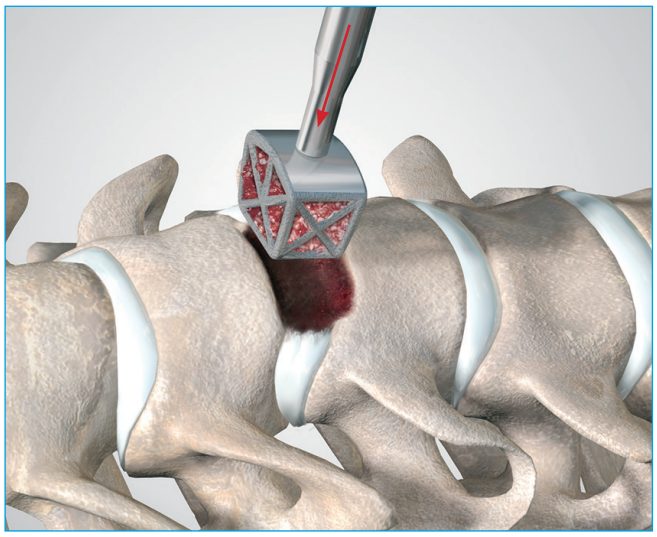


Fig. 6

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.

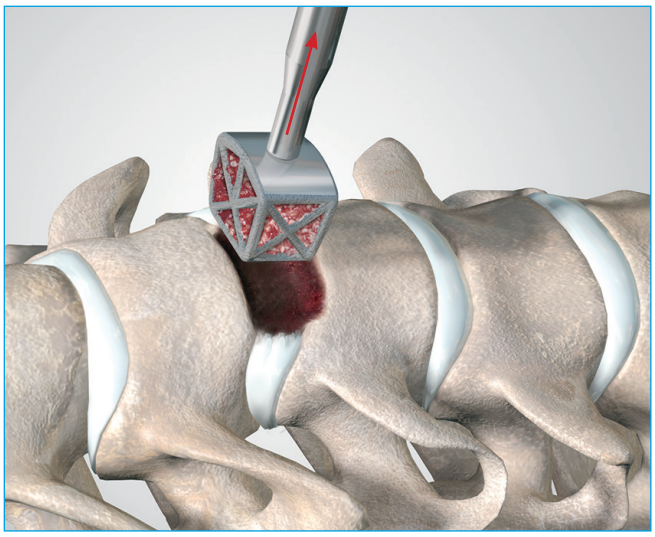
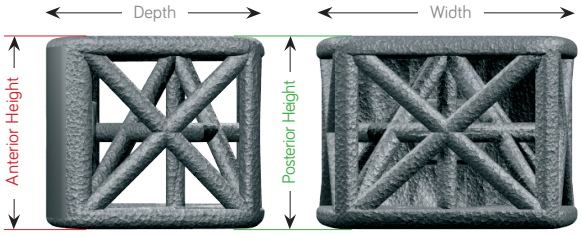


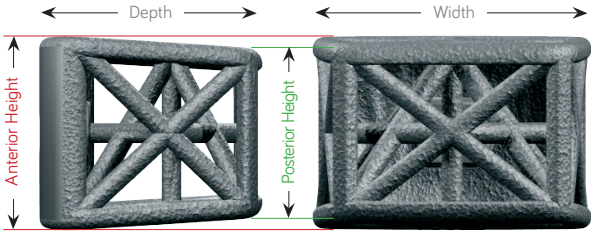
Fig. 7

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

Indications:

The Cervical Spine Truss System (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 C-2 to T-1 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 Cervical STS 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:

- Smoking
- Gross obesity
- Three or more levels to be fused
- Symptomatic cardiac disease
- Pregnancy
- Previous fusion attempts at the involved level(s)
- Spondylolisthesis or retrolisthesis
- Significant loss of bone stock as seen with osteoporosis or osteomalacia
- Conditions requiring chronic corticosteroid use
- Active drug abuse

The CSTS Interbody Fusion Device is for single use only.

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

All implants, 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 cervical spine fusion procedures should implant this device.

Operative Precautions:

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

Each CSTS 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.

Implantation of the CSTS Interbody Fusion Device must be used with supplemental fixation.

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 surgery in general: reactions to anesthesia, the anesthetic or other medications; bleeding; infection; blood vessel damage; nerve or soft tissue damage; atelectasis; pneumonia; hematoma; seroma; wound dehiscence or incisional hernia; embolism; anemia; colitis; thrombophlebitis; heart attack; stroke; or death.
- Adverse events related to spine surgery specifically: dural tear and CSF leak; nerve damage leading to radiculopathy, myelopathy, paraparesis, paresthesia or paralysis; meningitis; vertebral body damage or fracture; or ligament damage.
- Adverse events related to the device: implant crack or fracture, failure to achieve fusion, implant migration, dislodgment 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 CSTS 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 CSTS 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 28mm from the CSTS Interbody Fusion Device when imaged with a gradient echo pulse sequence and a 3 T MR system.

Packaging:

All CSTS Interbody Fusion Devices and ancillary instrumentation are 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.

SEE INSTRUCTIONS FOR USE (IFU-CSTS-04) FOR CLEANING AND STERILIZATION

NOTES:

4WEB MEDICAL

2801 Network Blvd, Suite 620

Frisco, TX USA 75034

+1 (800) 285-7090 | 4WEBMEDICAL.com

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