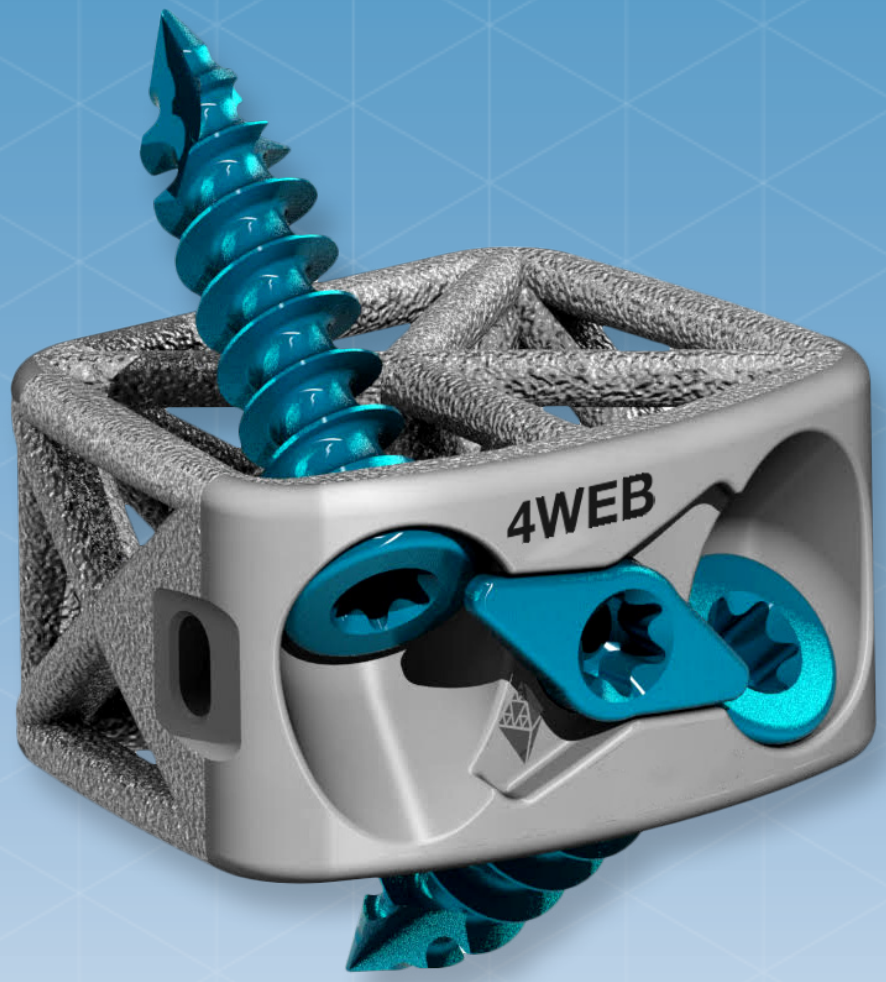
SURGICAL TECHNIQUE GUIDE

CERVICAL SPINE TRUSS SYSTEM™

STAND ALONE



4WEB® MEDICAL

TABLE OF CONTENTS

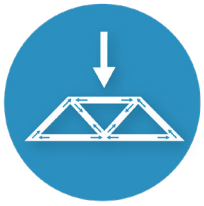
Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedure based on his or her medical training and experience. Prior to use of the system, 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 Design that distributes load across the bone / implant interface minimizing point loading and reduces the risk of subsidence.

4WEB's hierarchical surface roughness spans from the macro to nano scale providing a scaffold for cell adhesion and differentiation. These surface features have shown gene expression of certain osteogenic markers.

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



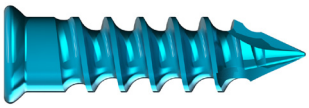
Optimized strain distribution through implant struts delivers a biomechanical stimulus for bone growth.

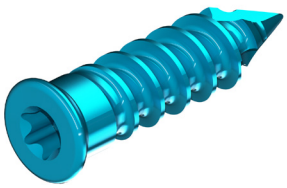
Truss Implant Technology™ limits imaging artifact.

CSTS-SA OVERVIEW

The CSTS-SA is designed to allow fixation screws to be placed through the truss implant and into the adjacent vertebral bodies creating a zero-profile stand-alone construct that removes the need for traditional plate and screw fixation. The device features a single-step locking mechanism that provides surgeon users confidence in the performance of the stand-alone construct. The CSTS-SA is available in multiple footprints, lordotic angles, heights and is delivered in sterile packaging for hospital efficiency and patient safety.

FOOTPRINT	HEIGHT	LORDOSIS
12 x 15mm	5 -10mm	0°,7°
	11-12mm special order only*	0°,7°
14 x 17mm	5-10mm	0°,7°
	11-12mm special order only*	0°,7°





DIAMETER	LENGTH	
3.5mm	12,14,16mm	PRIMARY SCREW
3.8mm	12,14,16mm	RESCUE SCREW

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 may be placed either transversely or longitudinally, based on surgeon preference, to aid in neck extension.

Figure 1

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

- Fluoroscopy may be utilized to aid in patient positioning.

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.

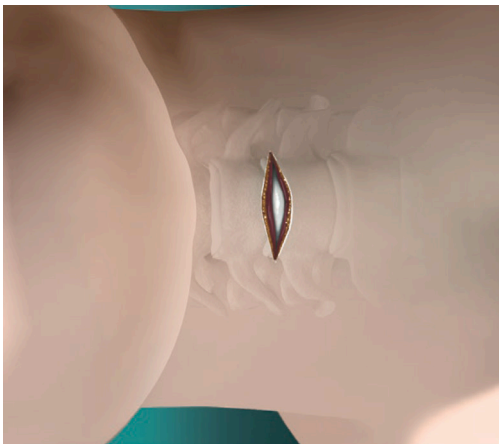


Figure 2

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

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.

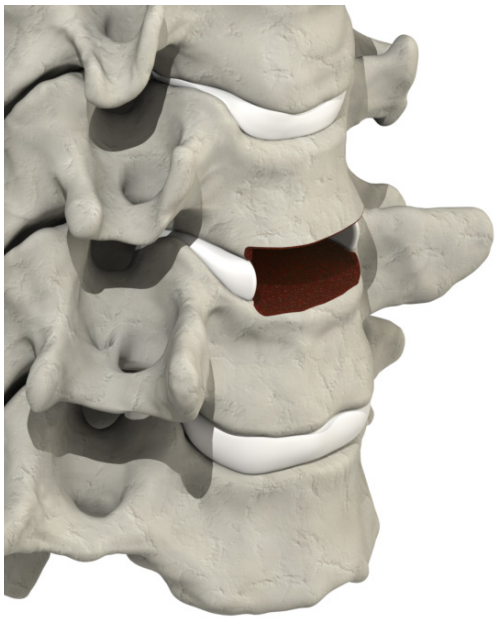


Figure 3

NOTE: Appropriate cleaning of the endplates is important to provide blood flow to the autologous bone packed inside the implant.

NOTE: Use caution when preparing endplates as excessive cleaning can weaken endplates.

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 or 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.

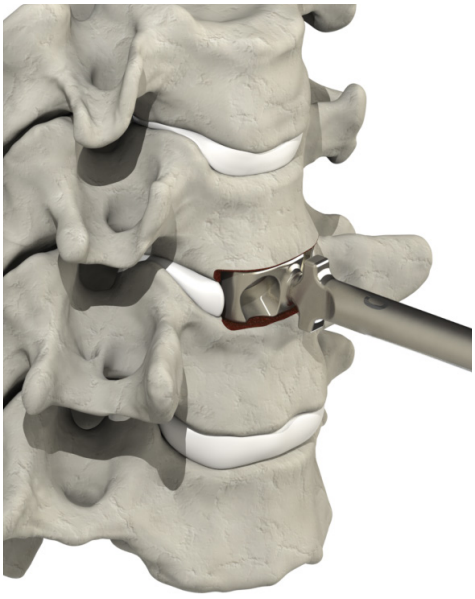


Figure 4

INSERTER ASSEMBLY

- Slide the Guide Sleeve (Fig. 5.1) over the proximal end of the Guided Inserter corresponding to the selected implant height.
- Thread the Guide Sleeve until the arms of the Guided Inserter (Fig. 5.2) collapse around the side of the implant.
- Attach the Cervical Handle (Fig. 5.3) to the Guided Inserter.

Figure 5.1

Figure 5.2

Figure 5.3

IMPLANT PREPARATION

Attaching Implant to Inserter:

CSTS-SA implants are provided in a sterile package.

- Select the implant that corresponds to the appropriate sizer. Open the implant package using proper sterile technique.

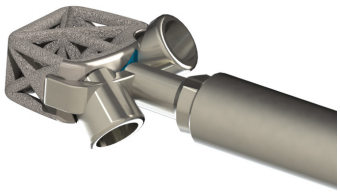


Figure 6.1

- Attach the implant to either the Guided Inserter or Freehand Inserter depending on preferred technique (Fig. 6.1 and 6.2).

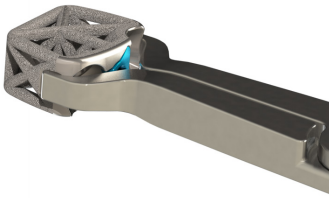


Figure 6.2

Packing Implant:

- Pack the implant with autologous and/or allogenic bone graft. For best results, cut or morselize the bone graft 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 graft particles into the implant (Fig. 6.3 and 6.4).

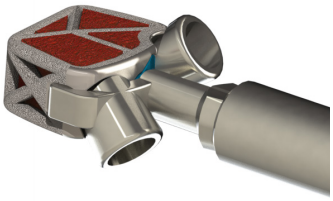


Figure 6.3

- Once packing has been completed through the top web structure, turn the implant over and repeat the placement of graft into the bottom web structure. Pack autologous and/or allogenic bone graft into the implant as appropriate.

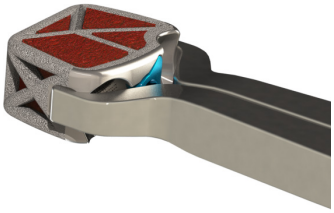


Figure 6.4

IMPLANT INSERTION

- Introduce the implant into the prepared intervertebral space and tap it into place with a mallet (Fig. 7.1 and 7.2). Confirm the proper placement of the implant using fluoroscopy.

- Once the implant is in the proper position, the Freehand Inserter may be disengaged and removed if desired. For guided screw insertion leave the Guided Inserter attached during screw preparation and insertion.

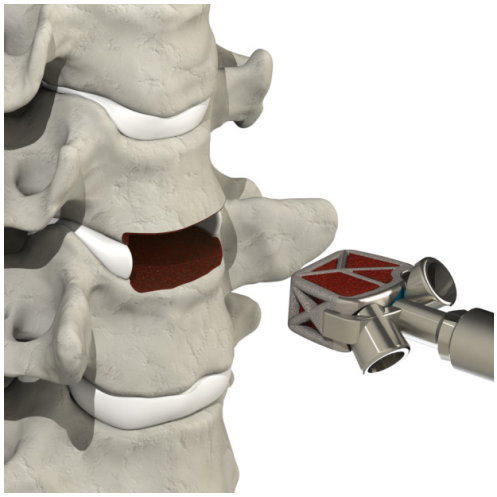


Figure 7.1

Implant Positioning:

- If the implant needs to be positioned further into the prepared space once the Freehand Inserter is detached, gently tap the implant with the tamp provided in the instrument tray.

- Verify final placement of the implant with fluoroscopic imaging.

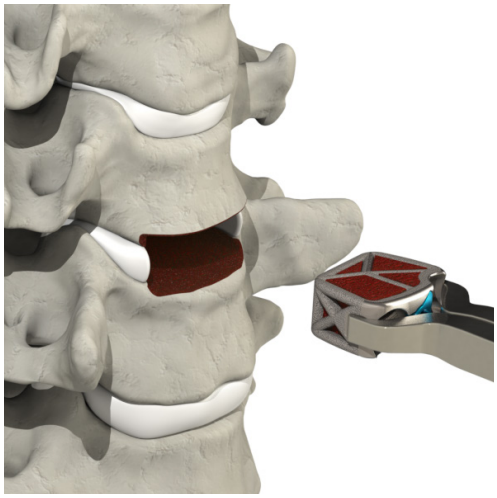


Figure 7.2

SCREW PREPARATION

Prepare the screw holes using one of the following methods, which may be performed with or without the Guided Inserter attached depending on preferred technique.

Screw Hole Preparation:

- Straight/Angled Awl

  Using the implant as a guide or the freehand guide, align either the Straight Awl or Angled Awl assembly within the corresponding hole on the implant and prepare the screw entry hole (Fig.8.1).

- Straight/Angled Drill

  Using the implant as a guide, align either the Straight Drill or Angled Drill assembly within the corresponding hole on the implant and prepare the screw entry hole (Fig.8.2).

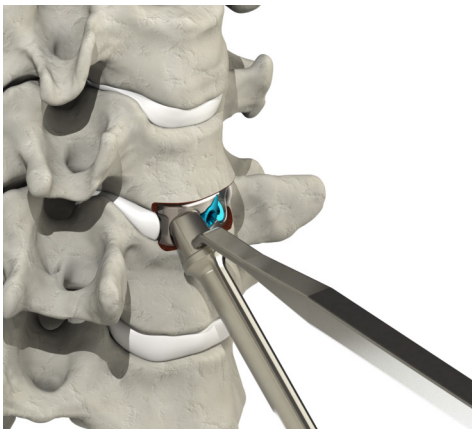


Figure 8.1

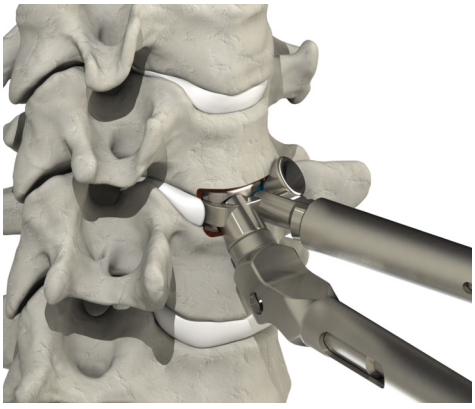


Figure 8.2

SCREW INSERTION AND LOCKING

Screw Insertion:

- Select the appropriate length screw based on the patient's anatomy. Screws are provided in a sterile package with two screws per package. Open the screw package using proper sterile technique.

- Insert the Screws using either the Straight Driver or the Angled Driver (Fig. 9.1, 9.2). Both drivers have self-retaining screw heads.

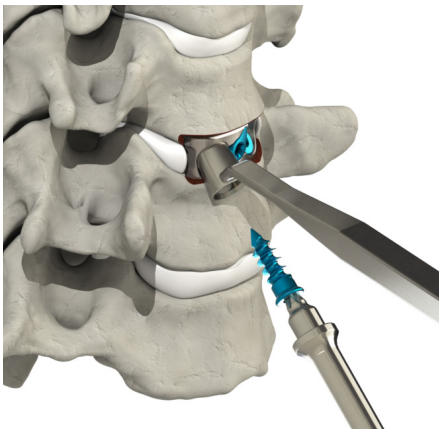


Figure 9.1

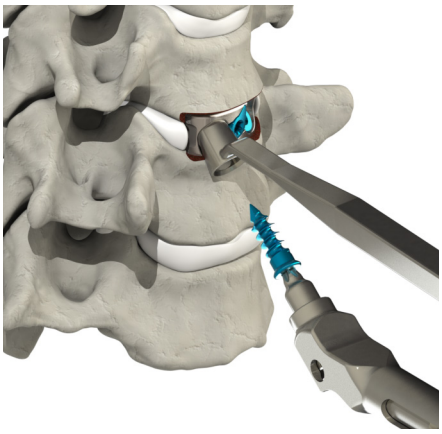


Figure 9.2

Screw Locking:

- Remove the Implant Inserter if it is still attached to the implant.

- Rotate the Locking Plate with the Straight Driver to approximately 90° clockwise to lock the Screws into the Implant Assembly (Fig. 9.3). The wings of the Locking Plate will stop against the recess on the anterior face of the interbody.

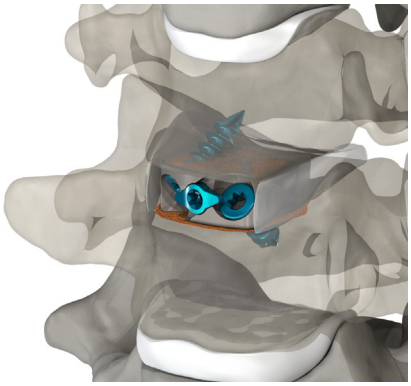


Figure 9.3

IMPLANT REMOVAL

If implant removal is necessary, rotate the Locking Plate counterclockwise approximately 90°, until the Screws are no longer retained.

Remove the screws using either the Straight Driver or the Angled Driver.

If implant removal is required, the intervertebral space should be distracted in the same manner as for implant placement (Fig. 10). Once distracted, the implant may be removed by using either the Guided Inserter or Freehand Inserter.

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.

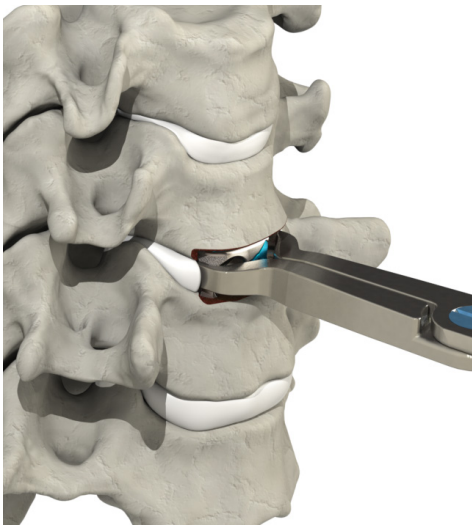
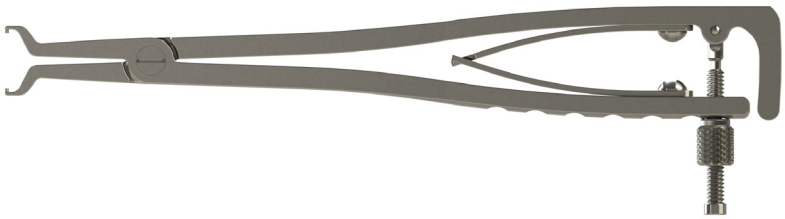


Figure 10

INSTRUMENT CATALOG

PART NUMBER	DESCRIPTION
CSTS-SA-000001	FREEHAND INSERTER



CSTS-SA-000002	FREEHAND GUIDE

CSTS-SA-000004	STRAIGHT AWL

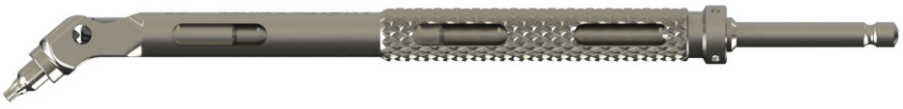
CSTS-SA-000006	FIXED ANGLE AWL

PART NUMBER	DESCRIPTION
CSTS-SA-000008	STRAIGHT DRILL

CSTS-SA-000009	FIXED ANGLE DRILL

CSTS-SA-000011	STRAIGHT DRIVER

CSTS-SA-000012	FIXED ANGLE DRIVER



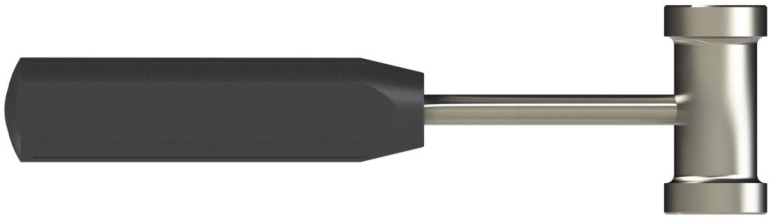
CSTS-SA-GD00 (05-12)	GUIDED INSERTER 5-12 MM

CSTS-SA-SMXX (05-12)-S	SIZER, SM, 5MM-12MM

PART NUMBER	DESCRIPTION
CSTS-SA-XX (05-12) -S	SIZER, MD, 5MM-12MM

CSTS-000016	CERVICAL TAMP

761-9017-0	CERVICAL MALLET

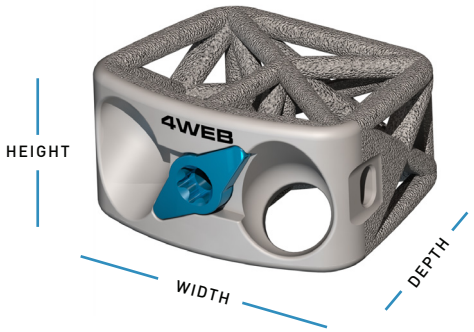


CSTS-SA-GD0000	GUIDE SLEEVE

1HJ1-C01	CERVICAL HANDLE - AO

IMPLANT CATALOG

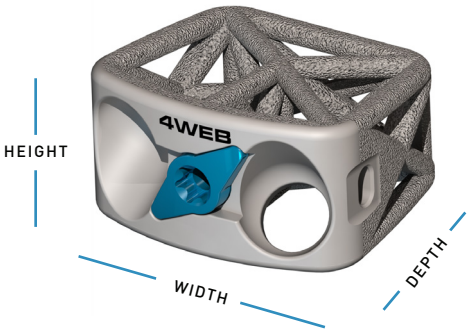
INTERBODY DEVICES



CATALOG NUMBER	FOOTPRINT D x W x H	LORDOSIS
CSTS-SA-SM0005-SP	12 x 15 x 5 MM	0°
CSTS-SA-SM0006-SP	12 x 15 x 6 MM	0°
CSTS-SA-SM0007-SP	12 x 15 x 7 MM	0°
CSTS-SA-SM0008-SP	12 x 15 x 8 MM	0°
CSTS-SA-SM0009-SP	12 x 15 x 9 MM	0°
CSTS-SA-SM0010-SP	12 x 15 x 10 MM	0°
CSTS-SA-SM0011-SP	12 x 15 x 11 MM	0°
CSTS-SA-SM0012-SP	12 x 15 x 12 MM	0°
CSTS-SA-SM0705-SP	12 x 15 x 5 MM	7°
CSTS-SA-SM0706-SP	12 x 15 x 6 MM	7°
CSTS-SA-SM0707-SP	12 x 15 x 7 MM	7°
CSTS-SA-SM0708-SP	12 x 15 x 8 MM	7°
CSTS-SA-SM0709-SP	12 x 15 x 9 MM	7°
CSTS-SA-SM0710-SP	12 x 15 x 10 MM	7°
CSTS-SA-SM0711-SP	12 x 15 x 11 MM	7°
CSTS-SA-SM0712-SP	12 x 15 x 12 MM	7°

IMPLANT CATALOG

INTERBODY DEVICES



CATALOG NUMBER	FOOTPRINT D x W x H	LORDOSIS
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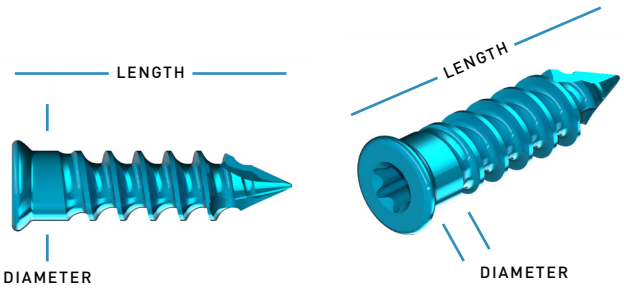
CSTS-SA-MD0006-SP	14 x 17 x 6 MM	0°
CSTS-SA-MD0007-SP	14 x 17 x 7 MM	0°
CSTS-SA-MD0008-SP	14 x 17 x 8 MM	0°
CSTS-SA-MD0009-SP	14 x 17 x 9 MM	0°
CSTS-SA-MD0010-SP	14 x 17 x 10 MM	0°
CSTS-SA-MD0011-SP	14 x 17 x 11 MM	0°
CSTS-SA-MD0012-SP	14 x 17 x 12 MM	0°
CSTS-SA-MD0705-SP	14 x 17 x 5 MM	7°
CSTS-SA-MD0706-SP	14 x 17 x 6 MM	7°
CSTS-SA-MD0707-SP	14 x 17 x 7 MM	7°
CSTS-SA-MD0708-SP	14 x 17 x 8 MM	7°
CSTS-SA-MD0709-SP	14 x 17 x 9 MM	7°
CSTS-SA-MD0710-SP	14 x 17 x 10 MM	7°
CSTS-SA-MD0711-SP	14 x 17 x 11 MM	7°
CSTS-SA-MD0712-SP	14 x 17 x 12 MM	7°

IMPLANT CATALOG

SCREWS



CATALOG NUMBER	DIAMETER, LENGTH	
CSCR-3512-SD-SP	Ø3.5MM, L 12MM	SELF-DRILLING
CSCR-3514-SD-SP	Ø3.5MM, L 14MM	SELF-DRILLING
CSCR-3516-SD-SP	Ø3.5MM, L 16MM	SELF-DRILLING
CSCR-3812-SD-SP	Ø3.8MM, L 12MM	SELF-DRILLING
CSCR-3814-SD-SP	Ø3.8MM, L 14MM	SELF-DRILLING
CSCR-3816-SD-SP	Ø3.8MM, L 16MM	SELF-DRILLING

GRAFT PACKING VOLUME MATRIX

		GRAFT VOLUME (CC)	GRAFT CONTACT AREA (MM2)
SM, 0°	CSTS-SA-SM0005-SP	0.32	35.8
	CSTS-SA-SM0006-SP	0.38	37.8
	CSTS-SA-SM0007-SP	0.47	39.6
	CSTS-SA-SM0008-SP	0.58	50.8
	CSTS-SA-SM0009-SP	0.69	50.8
	CSTS-SA-SM0010-SP	0.79	50.8
	CSTS-SA-SM0011-SP	0.90	50.8
	CSTS-SA-SM0012-SP	1.01	50.8
SM, 7°	CSTS-SA-SM0705-SP	0.24	35.8
	CSTS-SA-SM0706-SP	0.30	37.8
	CSTS-SA-SM0707-SP	0.39	39.6
	CSTS-SA-SM0708-SP	0.49	50.8
	CSTS-SA-SM0709-SP	0.60	50.8
	CSTS-SA-SM0710-SP	0.71	50.8
	CSTS-SA-SM0711-SP	0.82	50.8
	CSTS-SA-SM0712-SP	0.92	50.8
MD, 0°	CSTS-SA-MD0005-SP	0.52	70.9
	CSTS-SA-MD0006-SP	0.62	72.9
	CSTS-SA-MD0007-SP	0.76	74.7
	CSTS-SA-MD0008-SP	0.91	85.9
	CSTS-SA-MD0009-SP	1.07	85.9
	CSTS-SA-MD0010-SP	1.23	85.9
	CSTS-SA-MD0011-SP	1.38	85.9
	CSTS-SA-MD0012-SP	1.54	85.9
MD, 7°	CSTS-SA-MD0705-SP	0.39	70.9
	CSTS-SA-MD0706-SP	0.48	72.9
	CSTS-SA-MD0707-SP	0.62	74.7
	CSTS-SA-MD0708-SP	0.77	85.9
	CSTS-SA-MD0709-SP	0.93	85.9
	CSTS-SA-MD0710-SP	1.08	85.9
	CSTS-SA-MD0711-SP	1.24	85.9
	CSTS-SA-MD0712-SP	1.40	85.9

CERVICAL SPINE TRUSS SYSTEM - STAND ALONE (CSTS-SA) 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 Cervical Spine Truss System - Stand Alone (CSTS-SA) Interbody Fusion Device is designed to provide mechanical support to the cervical 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. Screws are inserted through the anterior portion of the implant into adjacent vertebral bodies for bony fixation.

INDICATIONS FOR USE:

The Cervical Spine Truss System - Stand Alone (CSTS-SA) 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 and is to be used with two titanium alloy screws which accompany the device. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. CSTS-SA 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.

CONTRAINDICATIONS:

The CSTS-SA 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

4WEB Medical's proprietary Truss Implant Technology™ stimulates a mechanobiologic response that increases gene expression in adjacent cellular material to facilitate fusion.

WARNINGS AND PRECAUTIONS:

Safety and effectiveness have not been established in the following conditions:
- Gross obesity
- Smoking
- 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-SA 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 cervical spine fusion procedures should implant this device.

OPERATIVE PRECAUTIONS:

The surgeon is to be thoroughly familiar with the CSTS-SA Interbody Fusion Device, methods of application, instruments and surgical technique. Correct positioning of the CSTS-SA Interbody Fusion Device relative to the vertebrae should be checked intraoperatively with x-ray. The size (and more particularly the height) of the CSTS-SA Interbody Fusion Device must be chosen on the basis of the patient's anatomy and desired correction. Implantation of the CSTS-SA Interbody Fusion Device must be used with two titanium alloy screws which accompany the device.

Each CSTS-SA 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 CSTS-SA 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-SA 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 CSTS-SA Interbody Fusion Device when imaged with a gradient echo pulse sequence and a 3 T MR system.

PACKAGING:

CSTS-SA 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.

CSTS-SA 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 CSTS-SA 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 CSTS-SA 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
- No instruments provided with the CSTS-SA Interbody Fusion Device require disassembly prior to cleaning.
- 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.

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 CSTS-SA products should notify 4WEB, or, where applicable, their distributor.

SURGICAL TECHNIQUE MANUAL:

To receive additional copies of the Surgical Technique Manual (ST-CSTS-SA-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
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OUTSIDE USA:
4WEB EU B.V.
Industrieweg 13b
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The Netherlands

Standard: ISO 152223-1, 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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