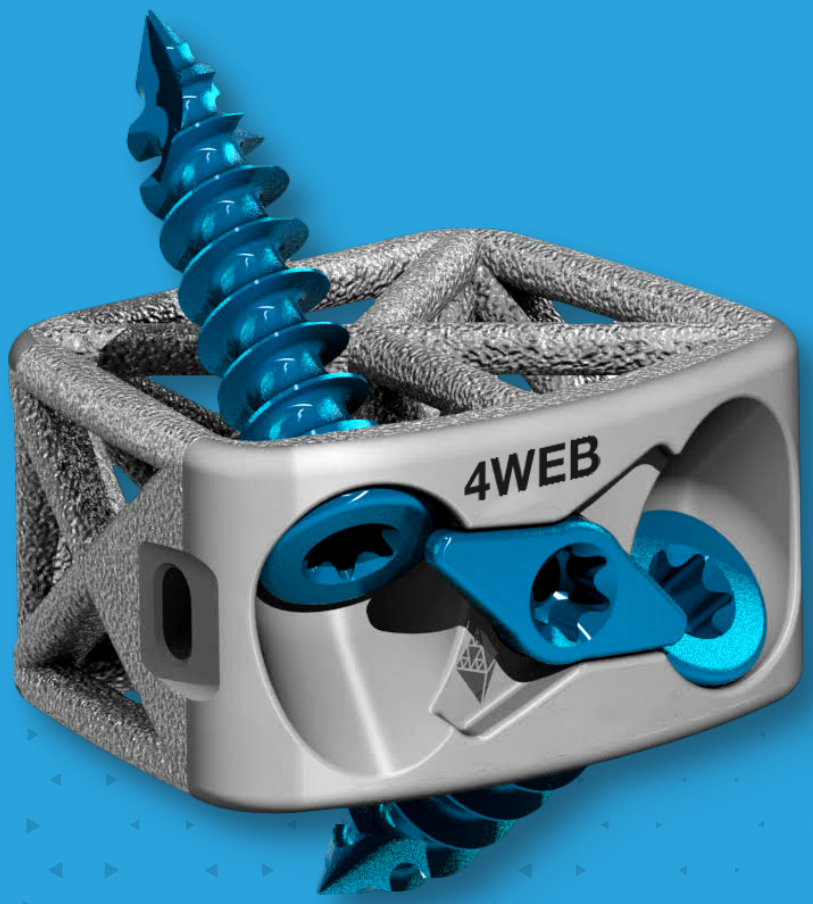
SURGICAL TECHNIQUE GUIDE

CERVICAL SPINE TRUSS SYSTEM STAND ALONE



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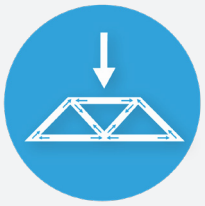
Federal law (USA) restricts these devices to sales by or on the order of a physician. Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the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

The Cervical Spine Truss System - Stand Alone (CSTS-SA) Interbody Fusion Device 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.

INDICATIONS

The 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

WARNINGS AND PRECAUTIONS

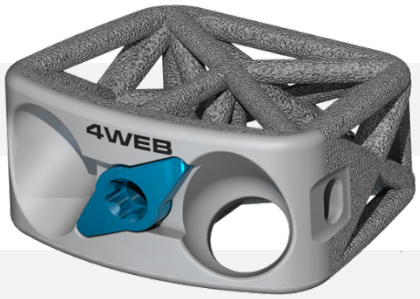
See package insert for warnings, precautions, adverse effects, and other essential product information. Before using the CSTS-SA Instrumentation, verify:

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

For Instructions for Cleaning, Sterilization, Inspection and Maintenance, refer to IFU-CSTS-SA-05 or OUS-IFU-CSTS-SA-13.

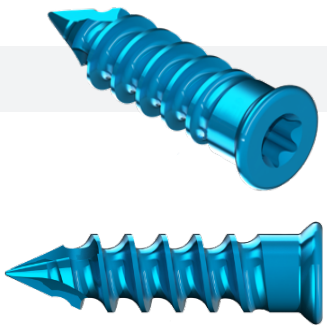
IMPLANT SPECIFICATIONS

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



SELF-DRILLING SCREW SPECIFICATIONS

DIAMETER	LENGTH	
ø3.5mm	12, 14, 16mm	Primary Screw
ø3.8mm	12, 14, 16mm	Rescue Screw



SURGICAL PROCEDURE

APPROACH

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.

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.

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.

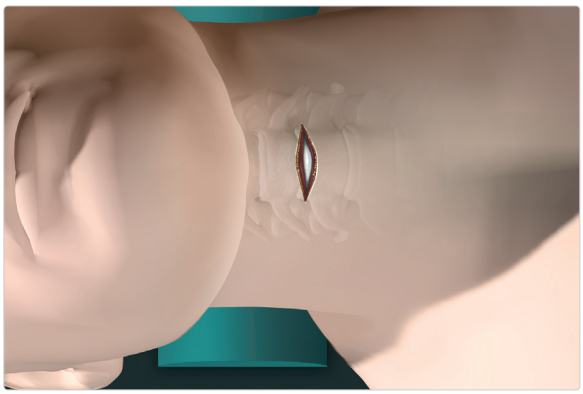


Figure 2

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.

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

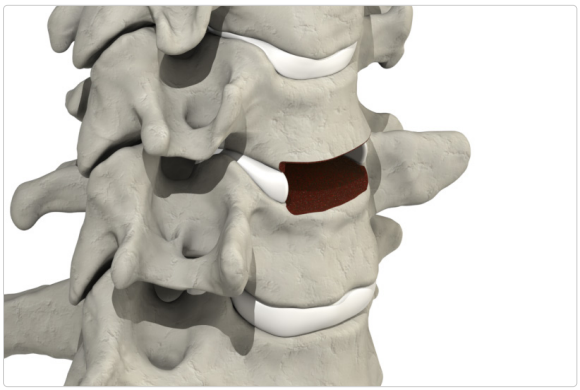


Figure 3

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 or smaller size until a secure fit is achieved.

Remove the sizer from the prepared disc space and select the corresponding implant.

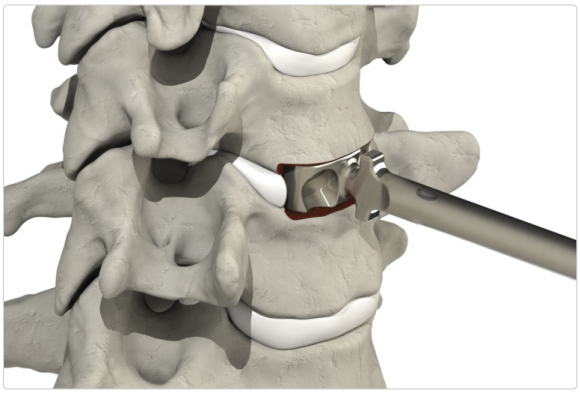


Figure 4

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 INSERTION, SCREW PREPARATION, AND SCREW INSERTION

There are two techniques for inserting the implant and preparing and inserting the screws.

Technique 1 – Guided Inserter Technique

The Guided Technique uses a Guided Inserter with fixed guides to insert the implant into the intervertebral disc space, and to prepare and insert the screws (pages 9-12).

Technique 2 - Freehand Technique

The Freehand Technique uses a Freehand inserter to insert the implant and freehand instruments to prepare and insert the screws (pages 13-16).

Additionally, the following instruments are available:

- Freehand Guide (CSTS-SA-000002) for screw hole preparation and insertion.
- Freehand Awl Guide (CSTS-SA-000027) is available for screw hole preparation only.

TECHNIQUE 1 – GUIDED INSERTER TECHNIQUE

Guided Inserter Assembly:

Attach the Cervical Handle to the Inner Shaft (Fig. 5).

Insert the Inner Shaft construct into the Guide corresponding to the selected implant (Fig. 6).

Thread the Inner Shaft into the implant until there is secure fit (Fig. 7).

Figure 5

Figure 6

Implant Preparation:

CSTS-SA implants are provided in a sterile package.

Attaching Implant to Inserter

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

Attach the implant to the Guided Inserter (Fig. 8).

Figure 7

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.

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.

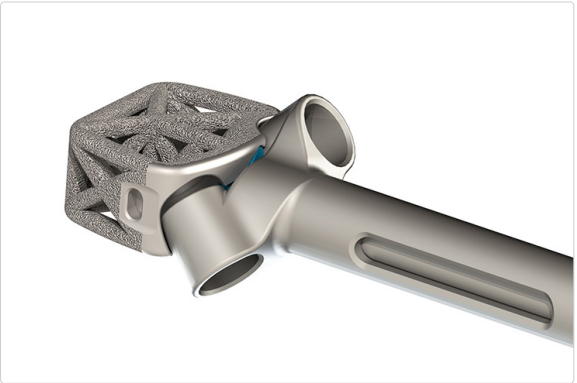


Figure 8

Implant Insertion:

Introduce the implant into the prepared intervertebral space and tap it into place with a mallet (Fig. 9). Confirm the proper placement of the implant using fluoroscopy.

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.

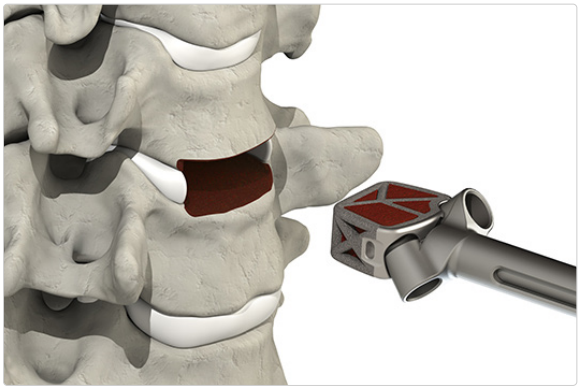


Figure 9

Screw Hole Preparation and Insertion:

Screw Hole Preparation

It is recommended to use either the Straight Awl, Straight Drill, Fixed Angled Awl, or Variable Angle Drill with the Guided Inserters.

Select the desired awl or drill and attach the Quick Connect Handle at the end of the instrument. Insert the distal end of the awl or drill through the Guided Inserter to puncture the cortical bone of the vertebral body (Fig. 10). Repeat this step through both guide holes in the inserter.

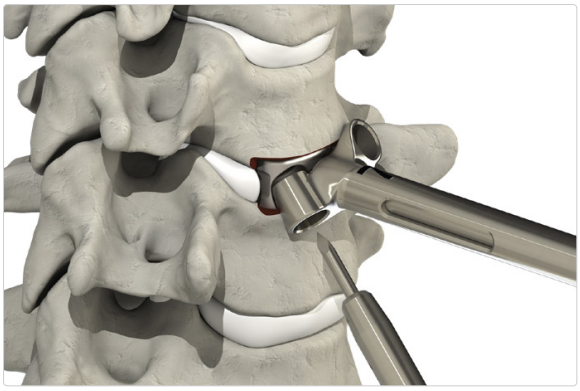


Figure 10

Screw Insertion

The CSTS-SA System offers two drivers: It is recommended to use either the Straight Driver or Variable Angle Driver for the Guided Technique. All drivers have a self-retaining screw feature.

Select the desired screw length screw and fix it to the distal end of the desired driver. Screws are provided in a sterile package with two screws per package.

Note: Ensure that the distal tip of the driver is seated securely in the screw before use.

Insert the screw through the Guide Hole on the Guided Inserter into in the implant (Fig 11). Drive the screw until it is fully seated in the implant. Repeat this step for both screws.

Note: It is recommended to only use the Straight Driver when there is direct in-line access to the screws.

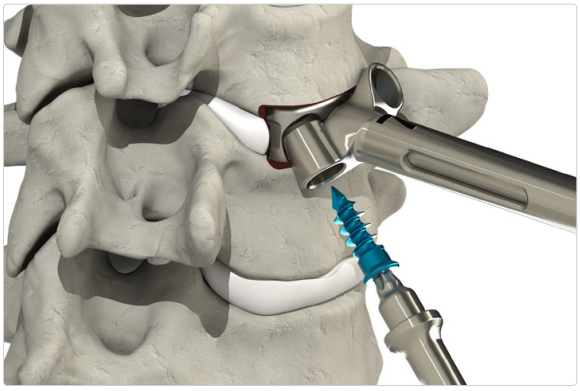


Figure 11

Locking The Anti-Backout Plate:

ABP Locking

Remove the Guided Inserter if it is still attached to the implant.

Rotate the Anti-Backout Plate with the Straight Driver to approximately 90° clockwise to lock the screws into the implant assembly (Fig. 12). The wings of the Locking Plate will stop against the recess on the anterior face of the interbody.

Figure 12

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. 13). 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.

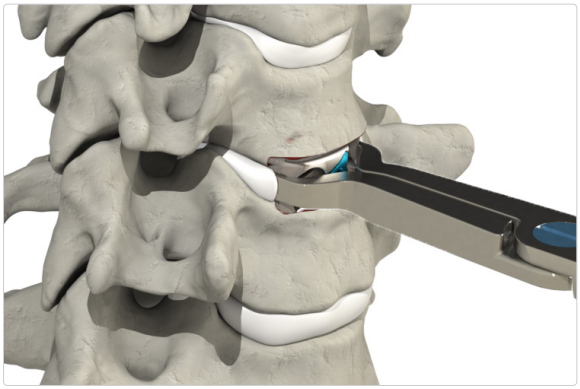


Figure 13

TECHNIQUE 2 – FREEHAND TECHNIQUE

Implant Preparation:

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.

Attach the implant to the Freehand Inserter (Fig. 14).

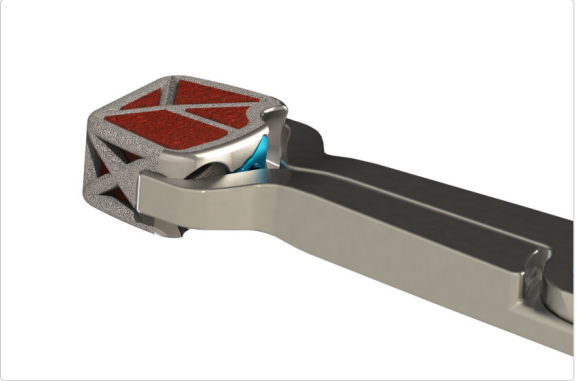


Figure 14

Implant Insertion:

Insert the implant into the disc space (Fig. 15). Use fluoroscopy to confirm proper position and placement of the implant. A tamp is provided in the system for additional implant positioning. Remove the Freehand Inserter from the implant.

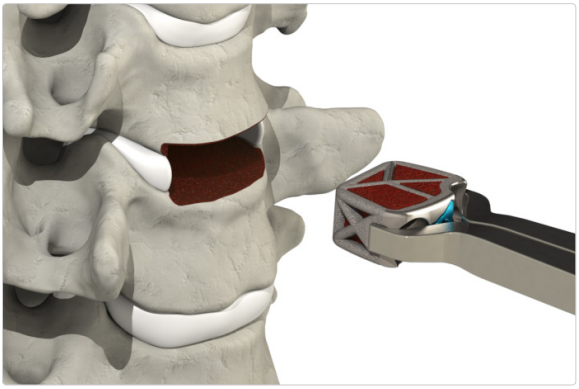


Figure 15

Screw Hole Preparation:

Freehand Guide Screw Preparation

The CSTS-SA System offers a straight and angled punch awl as well as a straight and variable angle drill for screw hole preparation. Select the desired punch awl or drill and connect the Quick Connect Handle to the end of the instrument. Insert the distal end of the awl or drill through the screw hole of the implant or through the freehand guide. Apply an axial force to the handle to puncture the cortical bone of the vertebral body (Fig. 16). Repeat this step through the opposite implant screw hole.

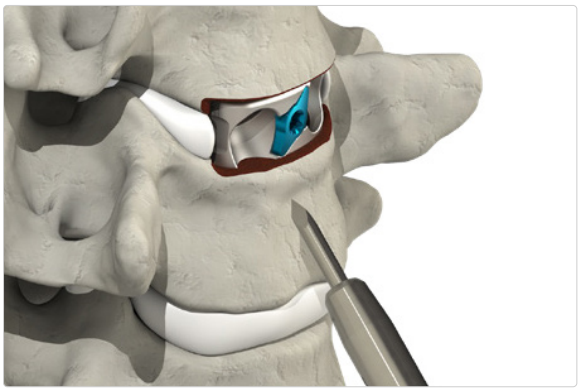


Figure 16

Punch Awl Preparation

The CSTS-SA System offers two punch awls: Straight Punch Awl and Angled Punch Awl. Select the desired awl and attached the Quick Connect Handles to the end of the instrument. Insert the distal end of the awl through the screw hole in the implant and apply axial force to the handle to puncture the cortical bone of the vertebral body (Fig. 16). Repeat this step through both screw bone holes.

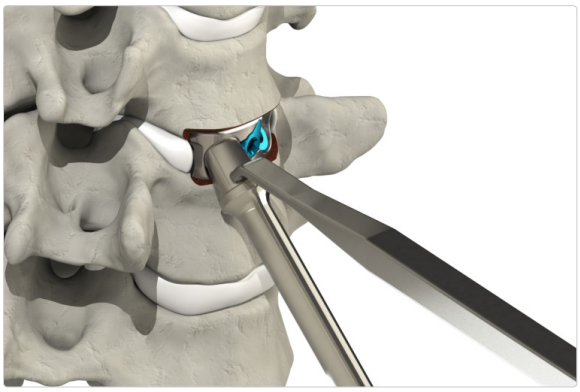


Figure 17

Select the desired awl or drill and attach the Quick Connect Handle at the end of the instrument. Insert the distal end of the awl or drill through the desired guide to puncture the cortical bone of the vertebral body (Fig. 17). Repeat this step through both guide holes in the inserter.

Screw Insertion:

The CSTS-SA System offers two drivers: the Straight Driver or Variable Angle Driver. All drivers have a self-retaining screw feature. Depending on the angle and position of the implant, select the desired driver and attach the Quick Connect Handle to the proximal end of the instrument.

Select the desired screw length screw and fix it to the distal end of the desired driver. Screws are provided in a sterile package with two screws per package.

Insert the screw through the Screw Hole into the implant (Fig. 18). Drive the screw until it is fully seated in the implant. Repeat this step for both screws.

Note: It is recommended to only use the Straight Driver when there is direct in-line access to the screws to avoid damaging the driver tip.

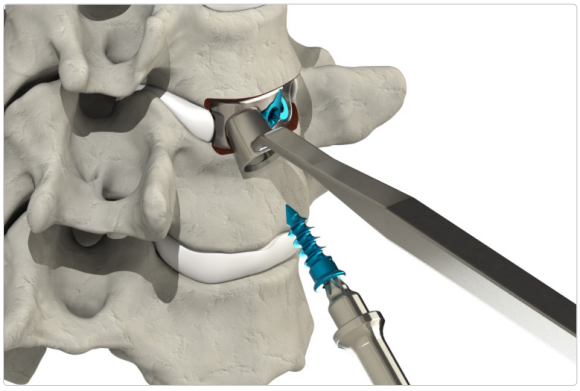


Figure 18

Locking the Anti-Backout Plate:

Rotate the Locking Plate with the Straight Driver to approximately 90° clockwise to lock the screws into the Implant Assembly (Fig. 19). The wings of the Locking Plate will stop against the recess on the anterior face of the interbody.

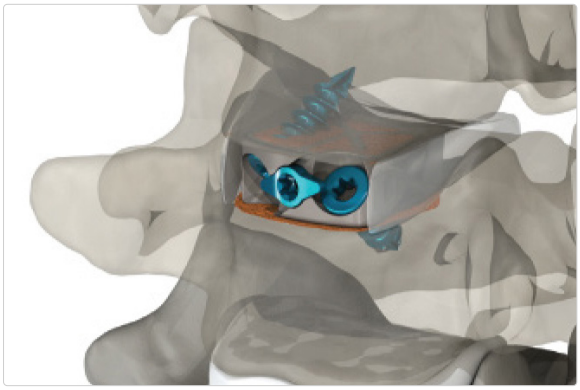


Figure 19

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. 20). 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.

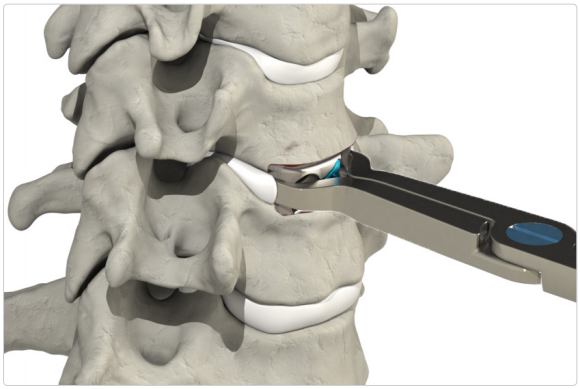
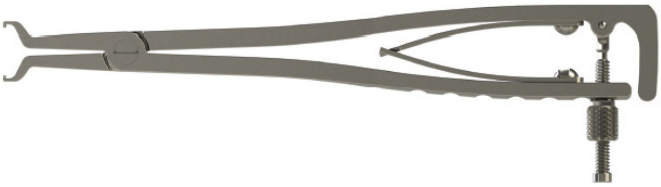


Figure 20

INSTRUMENT CATALOG

PART NUMBER	DESCRIPTION
CSTS-SA-000001	Freehand Inserter



CSTS-SA-000025	Straight Awl

CSTS-SA-000020	Angled Awl

CSTS-SA-000002	Freehand Guide

CSTS-SA-000027	Freehand Awl Guide

PART NUMBER	DESCRIPTION
CSTS-SA-ML0000	Midline Inserter Threaded Shaft

CSTS-SA-000024	Variable Angle Drill

CSTS-SA-000021	Straight Punch Awl

CSTS-SA-000022	Angled Punch Awl

CSTS-SA-MLSM10	Midline Inserter, Small, 5mm-10mm

PART NUMBER	DESCRIPTION
CSTS-SA-MLMD10	Midline Inserter, Medium, 5mm-10mm

CSTS-SA-000026	Straight Drill

CSTS-SA-000013	Straight Driver

CSTS-SA-000023	Variable Angle Driver

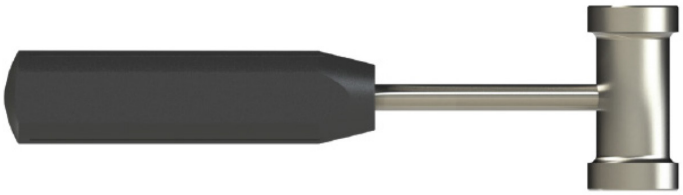
CSTS-SA-000012	Fixed Angle Driver *(available by special order only)*

PART NUMBER	DESCRIPTION
CSTS-SA-SMXX (05-12)-S	Sizer, Small, 5mm-12mm

CSTS-SA-MDXX (05-12)-S	Sizer, Medium, 5mm-12mm

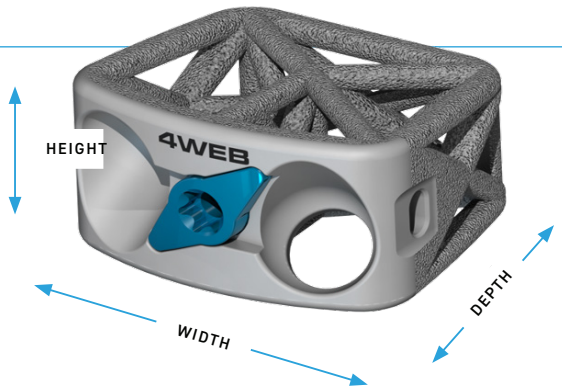
CSTS-000016	Cervical Tamp

CSTS-000018	Cervical Mallet



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 5mm	0°
CSTS-SA-SM0006-SP	12 x 15 x 6mm	0°
CSTS-SA-SM0007-SP	12 x 15 x 7mm	0°
CSTS-SA-SM0008-SP	12 x 15 x 8mm	0°
CSTS-SA-SM0009-SP	12 x 15 x 9mm	0°
CSTS-SA-SM0010-SP	12 x 15 x 10mm	0°
CSTS-SA-SM0011-SP	12 x 15 x 11mm	0°
CSTS-SA-SM0012-SP	12 x 15 x 12mm	0°
CSTS-SA-MD0005-SP	14 x 17 x 5mm	0°
CSTS-SA-MD0006-SP	14 x 17 x 6mm	0°
CSTS-SA-MD0007-SP	14 x 17 x 7mm	0°
CSTS-SA-MD0008-SP	14 x 17 x 8mm	0°
CSTS-SA-MD0009-SP	14 x 17 x 9mm	0°
CSTS-SA-MD0010-SP	14 x 17 x 10mm	0°
CSTS-SA-MD0011-SP	14 x 17 x 11mm	0°
CSTS-SA-MD0012-SP	14 x 17 x 12mm	0°

CATALOG NUMBER	FOOTPRINT D x W x H	LORDOSIS
CSTS-SA-SM0705-SP	12 x 15 x 5mm	7°
CSTS-SA-SM0706-SP	12 x 15 x 6mm	7°
CSTS-SA-SM0707-SP	12 x 15 x 7mm	7°
CSTS-SA-SM0708-SP	12 x 15 x 8mm	7°
CSTS-SA-SM0709-SP	12 x 15 x 9mm	7°
CSTS-SA-SM0710-SP	12 x 15 x 10mm	7°
CSTS-SA-SM0711-SP	12 x 15 x 11mm	7°
CSTS-SA-SM0712-SP	12 x 15 x 12mm	7°
CSTS-SA-MD0705-SP	14 x 17 x 5mm	7°
CSTS-SA-MD0706-SP	14 x 17 x 6mm	7°
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CSTS-SA-MD0708-SP	14 x 17 x 8mm	7°
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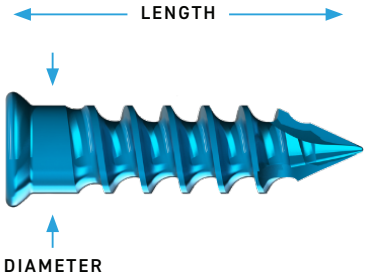

SCREWS

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

2801 NETWORK BLVD. SUITE 620
FRISCO, TX 75034
4WEBMEDICAL.COM
INFO@4WEBMEDICAL.COM
800.285.7090
ST-CSTS-SA-01 | REV F 06-2025