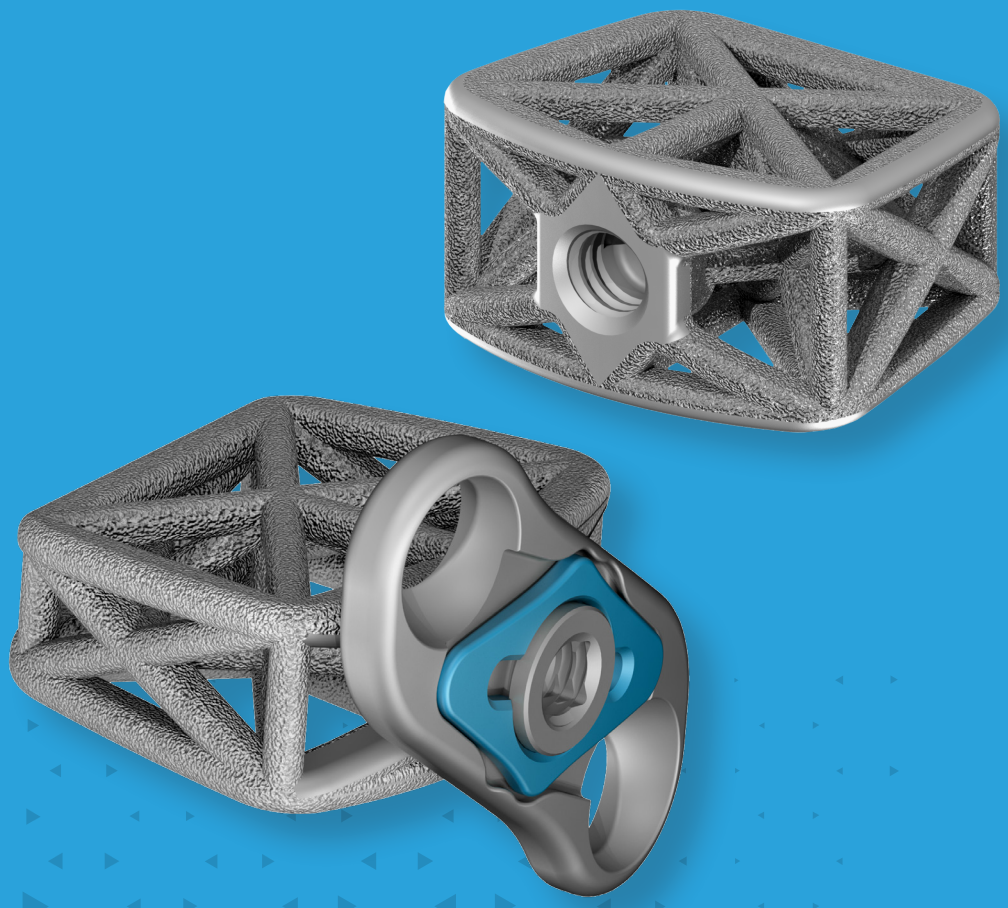
SURGICAL TECHNIQUE GUIDE

CERVICAL SPINE TRUSS SYSTEM WITH STAND ALONE INTEGRATED PLATE



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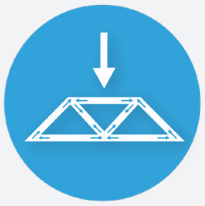
Federal law (USA) restricts these devices to sales by or on the order of a physician. Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the 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 three footprints in a variety of heights and lordotic angles to accommodate the patient's anatomy. If the surgeon determines it is best to use the CSTS Interbody Fusion Device without the CSTS Integrated Plate, it must be used with supplemental fixation. The CSTS Interbody Fusion Devices and CSTS Integrated Plates are provided sterile. CSTS sizers and instruments are provided nonsterile 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 back pain with degeneration of the disc confirmed by patient 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. If the device is being used without the CSTS Integrated Plate, supplemental fixation must be used.

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-CSTS2-05.

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.

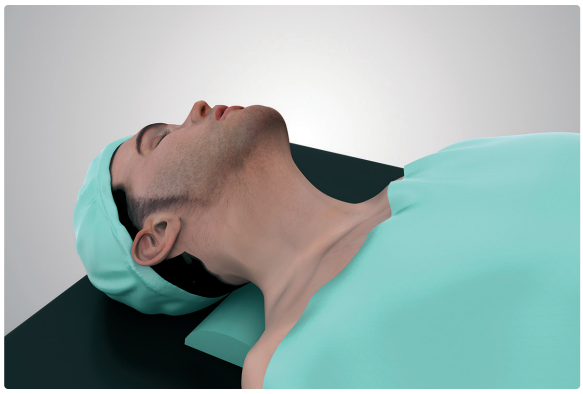


Figure 1

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.

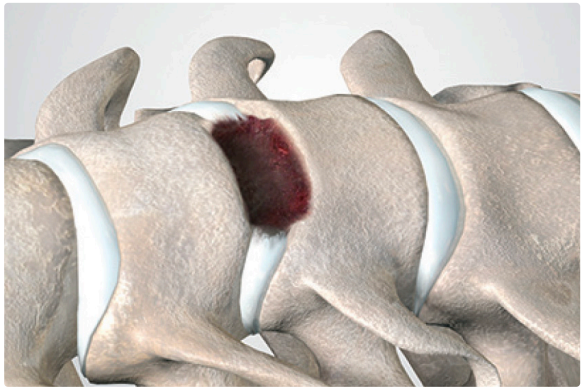


Figure 3

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.

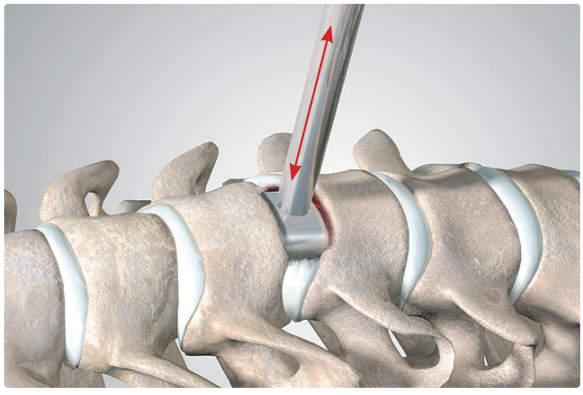


Figure 4

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 – WITH INTEGRATED PLATE

Attaching the Integrated Plate Inserter:

CSTS implants are provided in a sterile package. Select the implant that corresponds to the appropriate sizer. Open the implant package using proper sterile technique.

Select the proper plate size to accommodate the patient's anatomy as well as the CSTS Interbody. For proper plate height in relation to the CSTS Interbody, refer to page 21. The CSTS Integrated Plates are available in two depth configurations to allow for the interbody to be flush with the plate or two millimeters recessed.

To assemble the Integrated Plate and CSTS Interbody, spin the Integrated Plate a half turn into the threads of the Interbody. Ensure the prongs of the Integrated Plate are aligned with the cutouts in the CSTS Interbody. Using the Plate Assembly Driver and the Cervical Handle-AO, tighten the CSTS Integrated Plate to the CSTS Interbody until fully seated (Fig. 5).

Note: Use caution not to over-tighten the Integrated Plates as too much torque may strip the drive feature.

Insert the Draw Rod into the Integrated Plate Inserter. Align the tabs of the Integrated Plate Inserter with the Anti-Backout Plate. Thread the shaft into the CSTS Integrated Plate until two-finger tight. Overtightening of the Draw Rod may result in difficulty removing the Draw Rod after locking the Anti-Backout Plate.

Note: The CSTS Integrated Plate is currently available in the US only.

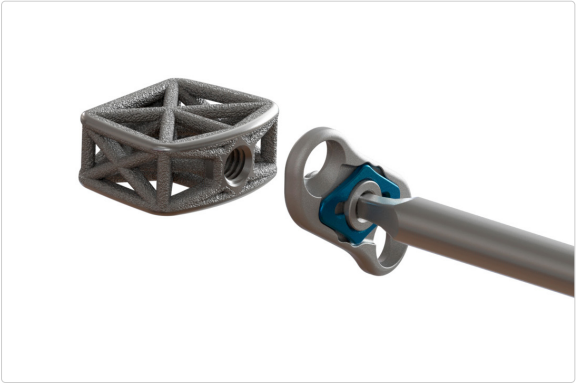


Figure 5

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.

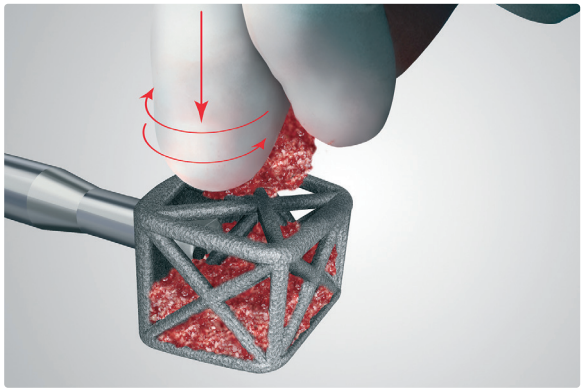


Figure 6

Implant Insertion Using the Integrated Plate Inserter:

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

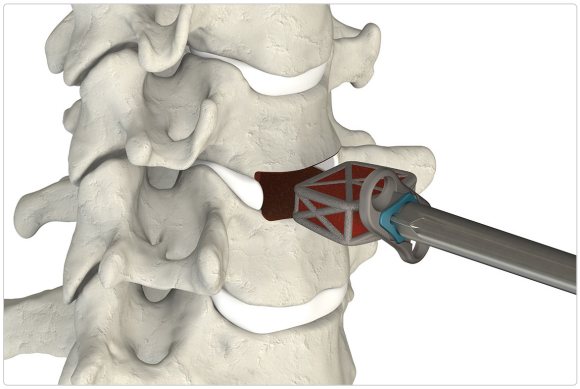


Figure 7

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.

Screw Hole Preparation:

If using the CSTS Integrated Plates, prepare the screw holes using one of the following methods:

- **Awl:** Align the Straight Awl within the corresponding hole on the CSTS Integrated plates and prepare the screw entry hole.
- **Drill:** Align the Straight Drill within the corresponding hole on the CSTS Integrated plates and prepare the screw entry hole (Fig. 8 & 9).

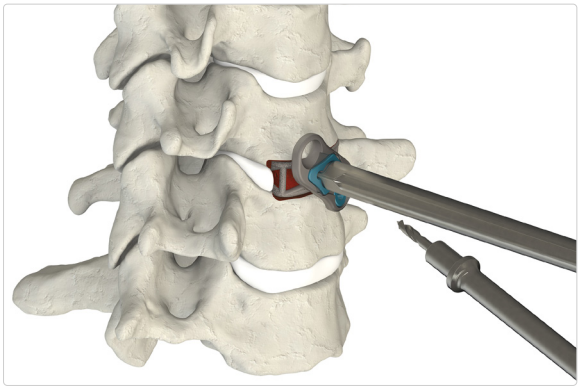


Figure 8

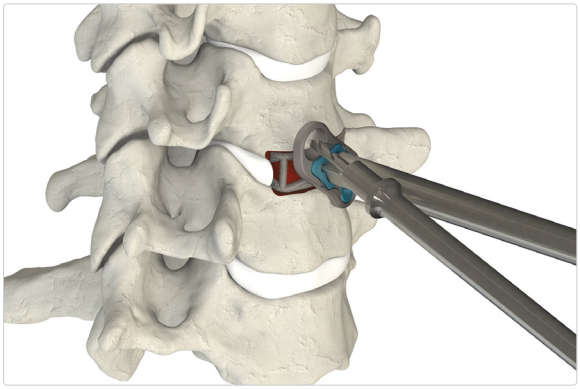


Figure 9

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 the Straight Driver. The Straight Driver uses a press-fit to retain the screws (Fig. 10).

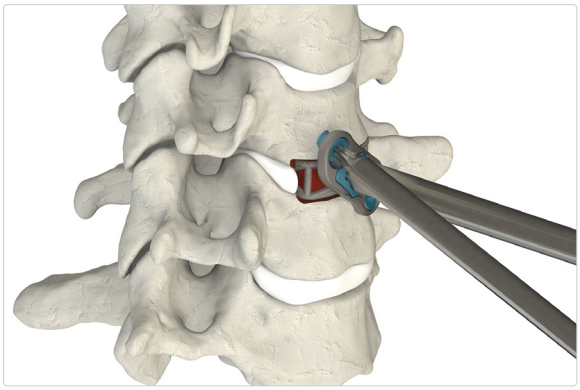


Figure 10

Locking the Anti-Backout Plate:

Rotate the Anti-Backout Plate using the Integrated Plate Inserter to approximately 30° clockwise to lock the Screws into the Integrated Plate. The wings of the Anti-Backout Plate will stop against the recess on the anterior face of the Integrated Plate (Fig. 11).

Disengage the Draw Rod by rotating the proximal knob counter-clockwise and removing the Draw Rod from the Integrated Plate Inserter.

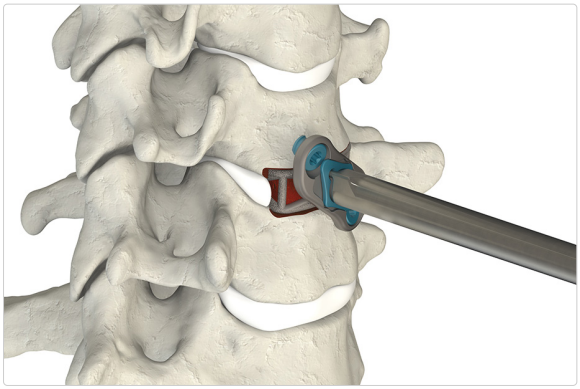


Figure 11

IMPLANT PREPARATION – WITHOUT INTEGRATED PLATE

Attaching Implant Inserter:

CSTS 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 inserter (Fig. 12). Ensure the shoulder of the inserter is fully seated against the implant and no threads are visible.

Be careful not to over-tighten.

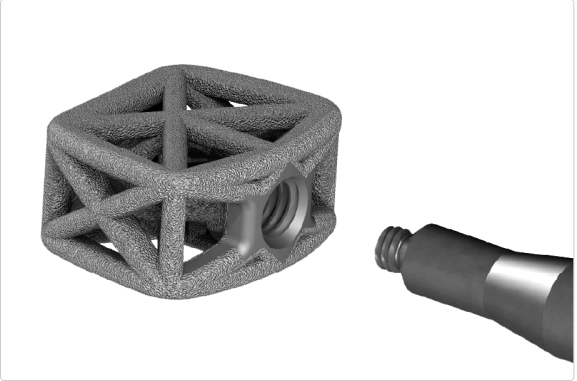


Figure 12

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. 13).

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.

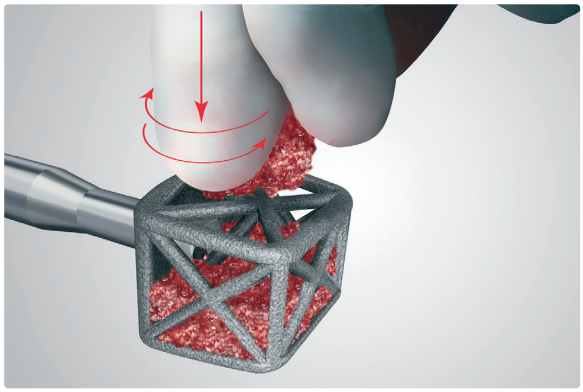


Figure 13

Implant Insertion Using the Inserter:

Introduce the implant into the prepared intervertebral space and tap it into place with a mallet (Fig. 14). Confirm the proper placement of the implant using fluoroscopy.

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

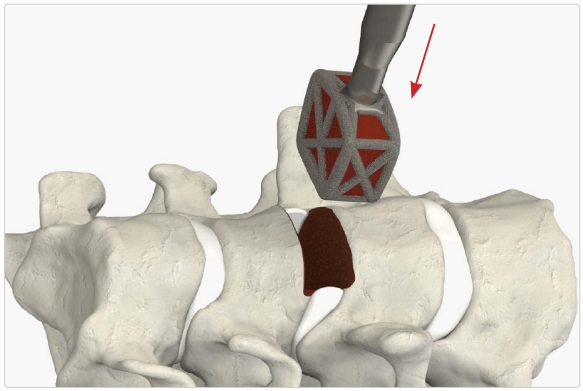


Figure 14

IMPLANT REMOVAL

If implant removal is necessary and an integrated plate was used, remove the screws using the Straight Driver.

The intervertebral space should be distracted in the same manner as for implant placement (Fig. 15). Once distracted, the implant may be removed.

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.

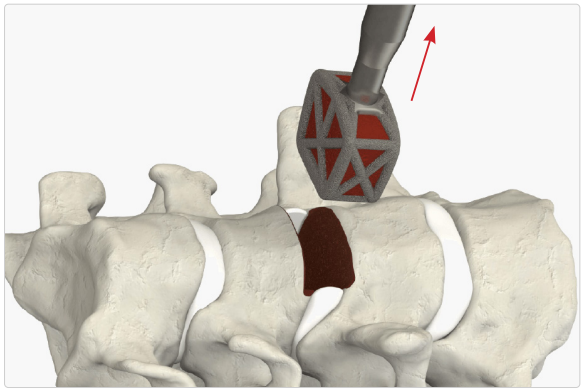


Figure 15

INSTRUMENT CATALOG

PART NUMBER	DESCRIPTION
CSTS-SMXX (05-12) -S	SIZER, SMALL, 5MM-12MM

CSTS-MDXX (05-12) -S	SIZER, MEDIUM, 5MM-12MM

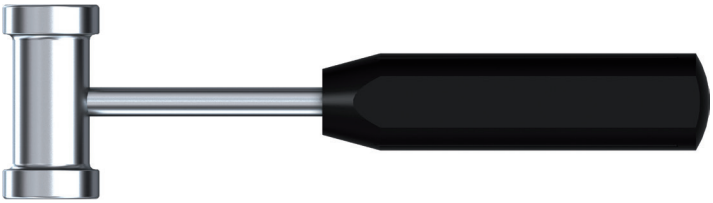
CSTS-SA-LGXX (05-12) -S	SIZER, LARGE, 5MM-12MM

CSTS-SA-XX (SM, MD, LG) 12 ZZ (05-12) -S	SIZER, 12 DEGREE

PART NUMBER	DESCRIPTION
CSTS-000016	CERVICAL TAMP

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

761-9017-0	MALLET



CSTS-000011	CSTS INSERTER *(Available in CSTS2-020000)*

CSTS-000012	CSTS LONG INSERTER *(Available in CSTS2-020000)*

PART NUMBER	DESCRIPTION
CSTS-000021	CSTS SHORT INSERTER *(Available in CSTS-SA-011000)*

CSTS-000022	CSTS LONG INSERTER *(Available in CSTS-SA-011000)*

CSTS-000041	INTEGRATED PLATE INSERTER

CSTS-SA-000025	STRAIGHT AWL

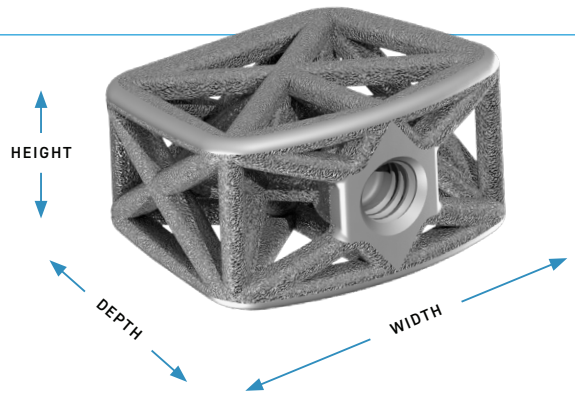
CSTS-SA-000026	STRAIGHT DRILL

PART NUMBER	DESCRIPTION
CSTS-SA-000013	STRAIGHT DRIVER

CSTS-000038	ASSEMBLY DRIVER

1HJ1-C01	CERVICAL HANDLE - AO

IMPLANT CATALOG



INTERBODY DEVICES

	CATALOG NUMBER	FOOTPRINT D x W x H	LORDOSIS	GRAFT VOLUME (CC)	ANTERIOR HEIGHT (MM)	POSTERIOR HEIGHT (MM)
	SMALL					
	CSTS2-SM0005-SP	12 x 15 x 5mm	0°	0.3	5.0	5.0
	CSTS2-SM0006-SP	12 x 15 x 6mm	0°	0.5	6.0	6.0
	CSTS2-SM0007-SP	12 x 15 x 7mm	0°	0.6	7.0	7.0
	CSTS2-SM0008-SP	12 x 15 x 8mm	0°	0.7	8.0	8.0
	CSTS2-SM0009-SP	12 x 15 x 9mm	0°	0.8	9.0	9.0
	CSTS2-SM0010-SP	12 x 15 x 10mm	0°	1.0	10.0	10.0
*	CSTS2-SM0011-SP	12 x 15 x 11mm	0°	1.1	11.0	11.0
*	CSTS2-SM0012-SP	12 x 15 x 12mm	0°	1.2	12.0	12.0
	CSTS2-SM0705-SP	12 x 15 x 5mm	7°	0.3	5.0	3.7
	CSTS2-SM0706-SP	12 x 15 x 6mm	7°	0.4	6.0	4.7
	CSTS2-SM0707-SP	12 x 15 x 7mm	7°	0.5	7.0	5.7
	CSTS2-SM0708-SP	12 x 15 x 8mm	7°	0.6	8.0	6.7
	CSTS2-SM0709-SP	12 x 15 x 9mm	7°	0.7	9.0	7.7
	CSTS2-SM0710-SP	12 x 15 x 10mm	7°	0.9	10.0	8.7
*	CSTS2-SM0711-SP	12 x 15 x 11mm	7°	1.0	11.0	9.7
*	CSTS2-SM0712-SP	12 x 15 x 12mm	7°	1.1	12.0	10.7
	CSTS2-SM1206-SP	12 x 15 x 6mm	12°	0.31	6.0	3.7
	CSTS2-SM1207-SP	12 x 15 x 7mm	12°	0.42	7.0	4.7

* By request only

	CATALOG NUMBER	FOOTPRINT D x W x H	LORDOSIS	GRAFT VOLUME (CC)	ANTERIOR HEIGHT (MM)	POSTERIOR HEIGHT (MM)
	CSTS2-SM1208-SP	12 x 15 x 8mm	12°	0.54	8.0	5.7
	CSTS2-SM1209-SP	12 x 15 x 9mm	12°	0.67	9.0	6.7
	CSTS2-SM1210-SP	12 x 15 x 10mm	12°	0.79	10.0	7.7
*	CSTS2-SM1211-SP	12 x 15 x 11mm	12°	0.92	11.0	8.7
*	CSTS2-SM1212-SP	12 x 15 x 12mm	12°	1.05	12.0	9.7
	MEDIUM					
	CSTS2-MD0005-SP	14 x 17 x 5mm	0°	0.5	5.0	5.0
	CSTS2-MD0006-SP	14 x 17 x 6mm	0°	0.7	6.0	6.0
	CSTS2-MD0007-SP	14 x 17 x 7mm	0°	0.9	7.0	7.0
	CSTS2-MD0008-SP	14 x 17 x 8mm	0°	1.0	8.0	8.0
	CSTS2-MD0009-SP	14 x 17 x 9mm	0°	1.2	9.0	9.0
	CSTS2-MD0010-SP	14 x 17 x 10mm	0°	1.4	10.0	10.0
*	CSTS2-MD0011-SP	14 x 17 x 11mm	0°	1.6	11.0	11.0
*	CSTS2-MD0012-SP	14 x 17 x 12mm	0°	1.8	12.0	12.0
	CSTS2-MD0705-SP	14 x 17 x 5mm	7°	0.4	5.0	3.5
	CSTS2-MD0706-SP	14 x 17 x 6mm	7°	0.6	6.0	4.5
	CSTS2-MD0707-SP	14 x 17 x 7mm	7°	0.7	7.0	5.5
	CSTS2-MD0708-SP	14 x 17 x 8mm	7°	0.9	8.0	6.5
	CSTS2-MD0709-SP	14 x 17 x 9mm	7°	1.1	9.0	7.5
	CSTS2-MD0710-SP	14 x 17 x 10mm	7°	1.3	10.0	8.5
*	CSTS2-MD0711-SP	14 x 17 x 11mm	7°	1.4	11.0	9.5
*	CSTS2-MD0712-SP	14 x 17 x 12mm	7°	1.6	12.0	10.5
	CSTS2-MD1206-SP	14 x 17 x 6mm	12°	0.46	6.0	3.3
	CSTS2-MD1207-SP	14 x 17 x 7mm	12°	0.61	7.0	4.3

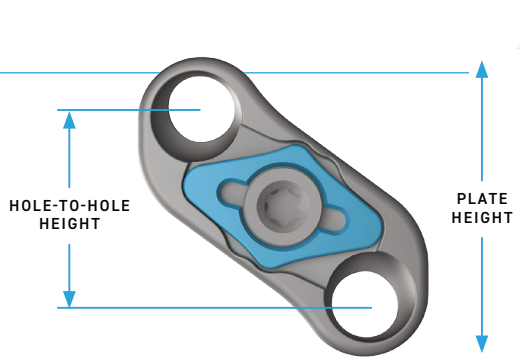
* By request only

	CATALOG NUMBER	FOOTPRINT D x W x H	LORDOSIS	GRAFT VOLUME (CC)	ANTERIOR HEIGHT (MM)	POSTERIOR HEIGHT (MM)
	CSTS2-MD1208-SP	14 x 17 x 8mm	12°	0.78	8.0	5.3
	CSTS2-MD1209-SP	14 x 17 x 9mm	12°	0.96	9.0	6.3
	CSTS2-MD1210-SP	14 x 17 x 10mm	12°	1.14	10.0	7.3
*	CSTS2-MD1211-SP	14 x 17 x 11mm	12°	1.30	11.0	8.3
*	CSTS2-MD1212-SP	14 x 17 x 12mm	12°	1.49	12.0	9.3
	LARGE					
	CSTS2-LG0005-SP	16 x 19 x 5mm	0°	0.73	5.0	5.0
	CSTS2-LG0006-SP	16 x 19 x 6mm	0°	0.94	6.0	6.0
	CSTS2-LG0007-SP	16 x 19 x 7mm	0°	1.17	7.0	7.0
	CSTS2-LG0008-SP	16 x 19 x 8mm	0°	1.40	8.0	8.0
	CSTS2-LG0009-SP	16 x 19 x 9mm	0°	1.66	9.0	9.0
	CSTS2-LG0010-SP	16 x 19 x 10mm	0°	1.89	10.0	10.0
*	CSTS2-LG0011-SP	16 x 19 x 11mm	0°	2.10	11.0	11.0
*	CSTS2-LG0012-SP	16 x 19 x 12mm	0°	2.32	12.0	12.0
	CSTS2-LG0705-SP	16 x 19 x 5mm	7°	0.52	5.0	3.2
	CSTS2-LG0706-SP	16 x 19 x 6mm	7°	0.72	6.0	4.2
	CSTS2-LG0707-SP	16 x 19 x 7mm	7°	0.94	7.0	5.2
	CSTS2-LG0708-SP	16 x 19 x 8mm	7°	1.17	8.0	6.2
	CSTS2-LG0709-SP	16 x 19 x 9mm	7°	1.40	9.0	7.2
	CSTS2-LG0710-SP	16 x 19 x 10mm	7°	1.66	10.0	8.2
*	CSTS2-LG0711-SP	16 x 19 x 11mm	7°	1.87	11.0	9.2
*	CSTS2-LG0712-SP	16 x 19 x 12mm	7°	2.11	12.0	10.2
	CSTS2-LG1206-SP	16 x 19 x 6mm	12°	0.58	6.0	2.9
	CSTS2-LG1207-SP	16 x 19 x 7mm	12°	0.78	7.0	3.9

* By request only

	CATALOG NUMBER	FOOTPRINT D x W x H	LORDOSIS	GRAFT VOLUME (CC)	ANTERIOR HEIGHT (MM)	POSTERIOR HEIGHT (MM)
	CSTS2-LG1208-SP	16 x 19 x 8mm	12°	1.00	8.0	4.9
	CSTS2-LG1209-SP	16 x 19 x 9mm	12°	1.25	9.0	5.9
	CSTS2-LG1210-SP	16 x 19 x 10mm	12°	1.49	10.0	6.9
*	CSTS2-LG1211-SP	16 x 19 x 11mm	12°	1.70	11.0	7.9
*	CSTS2-LG1212-SP	16 x 19 x 12mm	12°	1.94	12.0	8.9

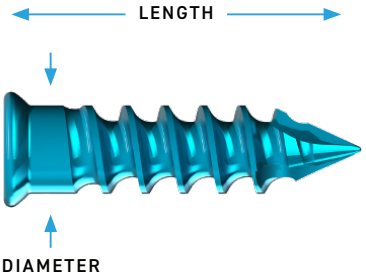
* By request only



INTEGRATED PLATES

	CATALOG NUMBER	PLATE HEIGHT	HOLE-TO-HOLE HEIGHT	OFFSET PLATE	CSTS INTERBODY HEIGHT
	NON-RECESSED				
	CSTS-PLT016-SP	16.5mm	10.4mm	0mm	5mm
	CSTS-PLT017-SP	17.5mm	11.4mm	0mm	6mm
	CSTS-PLT018-SP	18.5mm	12.4mm	0mm	7mm
	CSTS-PLT019-SP	19.5mm	13.4mm	0mm	8mm
	CSTS-PLT020-SP	20.5mm	14.4mm	0mm	9mm
	CSTS-PLT021-SP	21.5mm	15.4mm	0mm	10mm
*	CSTS-PLT022-SP	22.5mm	16.4mm	0mm	11mm
*	CSTS-PLT023-SP	23.5mm	17.4mm	0mm	12mm
	RECESSED				
	CSTS-PLT016-R-SP	16.5mm	10.4mm	2mm	5mm
	CSTS-PLT017-R-SP	17.5mm	11.4mm	2mm	6mm
	CSTS-PLT018-R-SP	18.5mm	12.4mm	2mm	7mm
	CSTS-PLT019-R-SP	19.5mm	13.4mm	2mm	8mm
	CSTS-PLT020-R-SP	20.5mm	14.4mm	2mm	9mm
	CSTS-PLT021-R-SP	21.5mm	15.4mm	2mm	10mm
*	CSTS-PLT022-R-SP	22.5mm	16.4mm	2mm	11mm
*	CSTS-PLT023-R-SP	23.5mm	17.4mm	2mm	12mm

* By request only



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-3518-SD-SP	ø3.5mm, L 18mm	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
CSCR-3818-SD-SP	ø3.8mm, L 18mm	Self-Drilling

2801 NETWORK BLVD. SUITE 620
FRISCO, TX 75034
4WEBMEDICAL.COM
INFO@4WEBMEDICAL.COM
800.285.7090
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