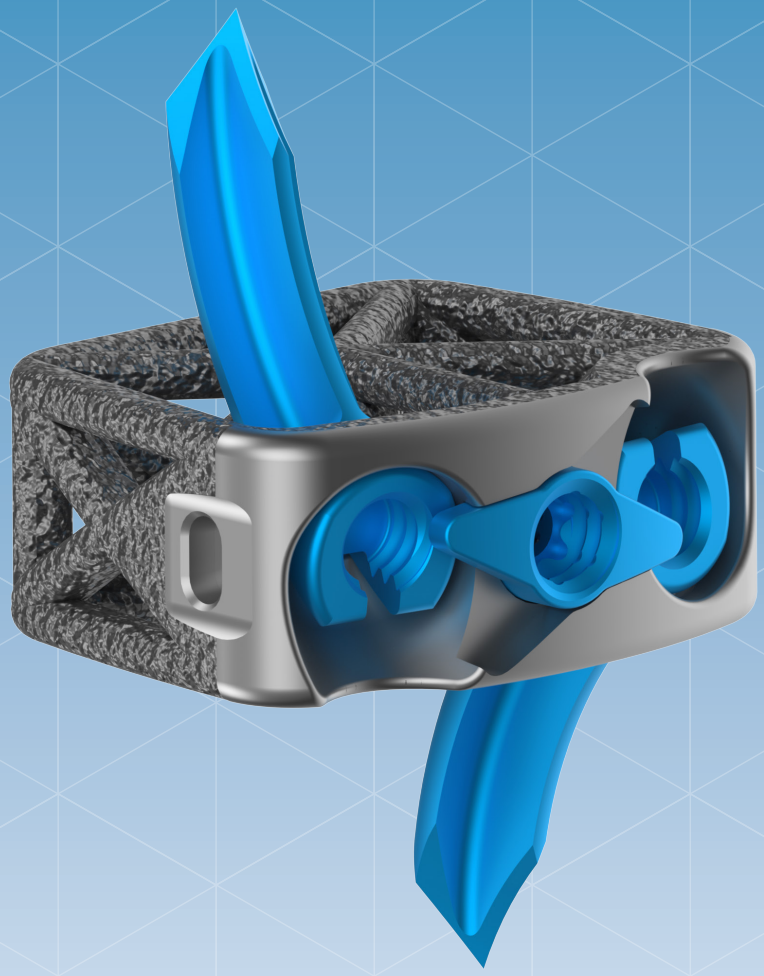
SURGICAL TECHNIQUE GUIDE

CERVICAL SPINE TRUSS SYSTEM

ANCHOR FIXATION

TWO INSERTER VERSION



4WEB® MEDICAL

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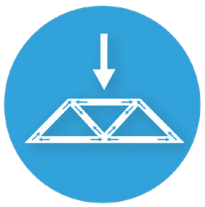
Federal law (USA) restricts these devices to sales by or on the order of a physician. Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the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

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.[1]

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



Distribution of load through the implant struts delivers strain to adjacent cellular material which stimulates a mechanobiologic response.*

Truss Implant design provides maximum strength with a minimal amount of material, which limits imaging artifacts.

[1] Rowe et al, SMISS, AnnualForum'19, p.52 * Data on file

CSTS-SA OVERVIEW

The CSTS-SA is designed to allow fixation screws or anchors* to be placed through the truss implant and into the adjacent vertebral bodies creating a zero-profile construct. The device features a single-step locking mechanism that provides surgeon users confidence in the performance of the 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 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 or fixation anchors 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. When using the CSTS-SA interbody with fixation anchors, the device must be used with supplemental fixation.

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

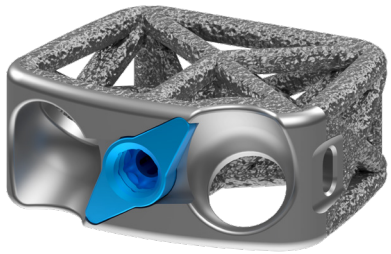
See package insert for warnings, precautions, adverse effects, and other essential product information. Before using the CSTS-SA Instrumentation, verify:

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

For Instructions for Cleaning, Sterilization, Inspection and Maintenance, refer to IFU-CSTS-SAA-05.

* When using the CSTS-SA Interbody with fixation anchors, the device must be used with supplemental fixation.

IMPLANT SPECIFICATIONS



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°

ANCHOR SPECIFICATIONS

DIAMETER	LENGTH	
3.5mm	11, 12mm	PRIMARY ANCHOR

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.
- 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.

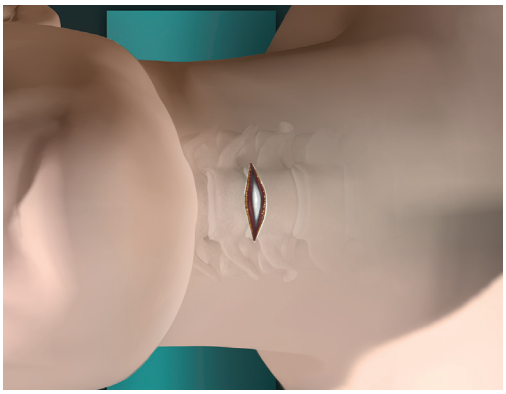


Figure 2

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.

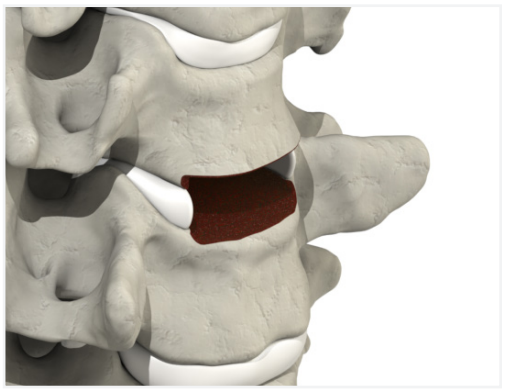


Figure 3

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.

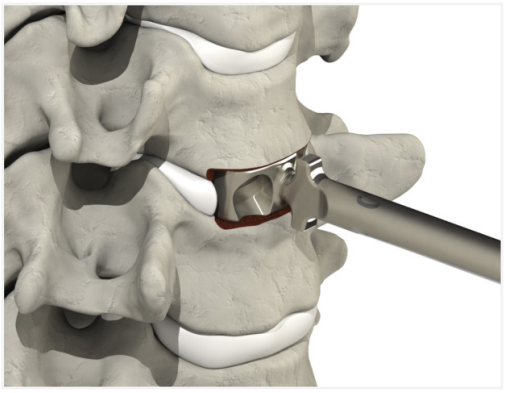


Figure 4

- 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.

ANCHOR TECHNIQUE

- The Anchor Technique uses an Anchor Inserter to insert the implant into the intervertebral disc space and insert two fixation anchors.

INSERTER ASSEMBLY

- The CSTS-SA anchors are provided sterile packaged inside single-use cartridges. Select the anchor cartridge that corresponds to the appropriate sizer. Attach the cartridge to the anchor inserter that corresponds to selected implant footprint by aligning the tab on the cartridge with the slot on the distal end of the Anchor Inserter (Fig. 5).

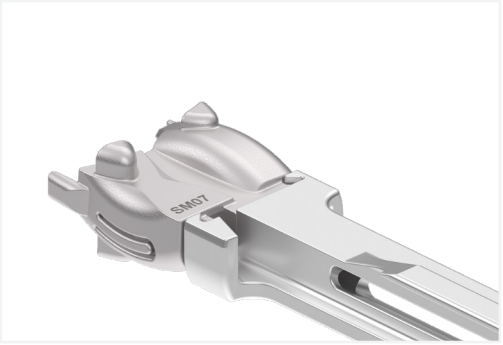


Figure 5

- Insert the Draw Rod into the proximal end of the Anchor Inserter passing through the cartridge (Fig. 6).

Figure 6

- 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 CSTS-SA implant to the Anchor Inserter by threading the Cartridge Draw Rod into the threaded hole of the CSTS-SA interbody's Anti-Backout Plate (Fig. 7).

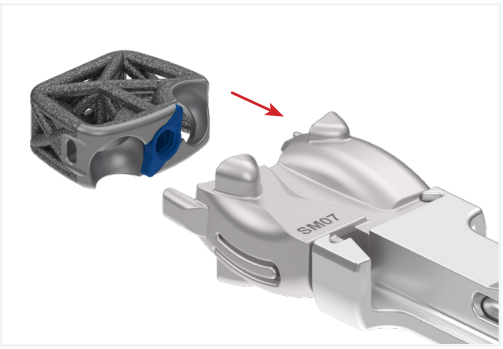


Figure 7

IMPLANT PREPARATION

- 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. 8).

- 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.

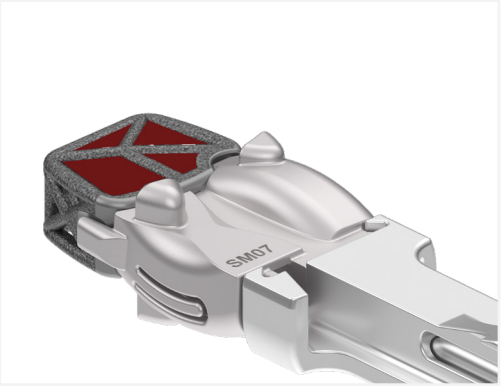


Figure 8

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.

- Once the implant is in the proper position, leave the Anchor Inserter attached during fixation anchor insertion.

- Verify final placement of the implant with fluoroscopic imaging.

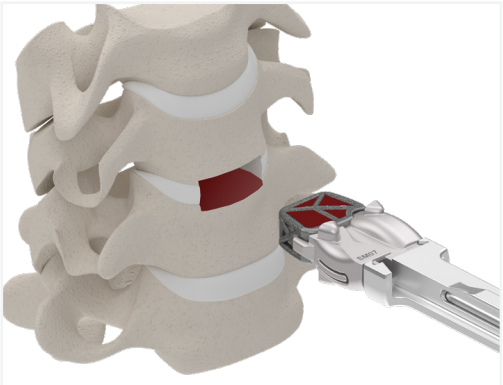


Figure 9

ANCHOR INSERTION AND LOCKING

- Insert the Anchor Tamps into the square openings on the proximal end of the Anchor Inserter, with the side labelled "OUT" facing outward, until the distal tip of the Anchor Tamps is in contact with the head of the Fixation Anchor (Fig. 10).

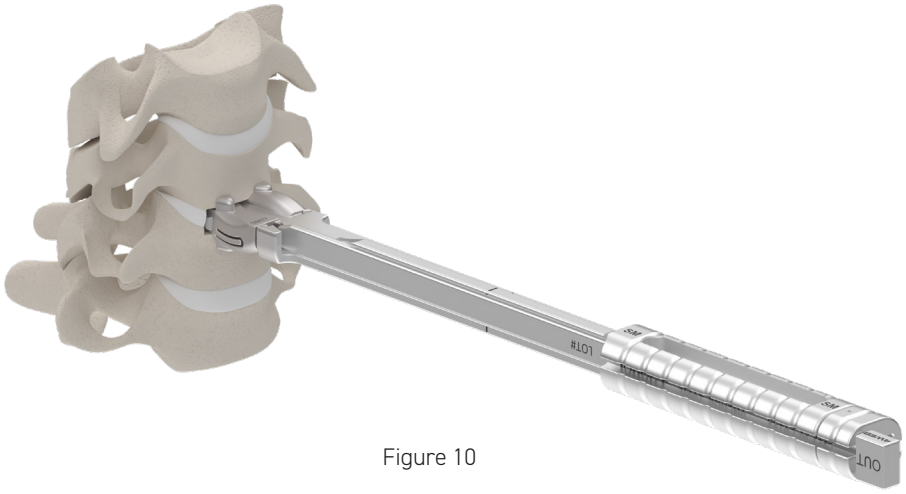


Figure 10

- Using a mallet, gently tap the proximal end of the Anchor Tamps to advance the Fixation Anchor into the vertebral bodies. Continue advancing the Anchor Tamps until they are flush with the proximal body of the Anchor Inserter.

- **ANCHOR LOCKING:**
  - Remove the Anchor Inserter from the implant.
  - Examine the position of the Fixation Anchors. If the Fixation Anchors are not fully inserted in the CSTS-SA interbody, gently tap the implant with the Anchor Tamp provided in the instrument tray. Attach the Anchor Tamp to the Cervical Handle prior to final adjustment.

- Rotate the Locking Plate with the Straight Driver to approximately 90° clockwise to lock the Fixation Anchors into the Implant Assembly (Fig. 11). The wings of the Locking Plate will stop against the recess on the anterior face of the interbody.

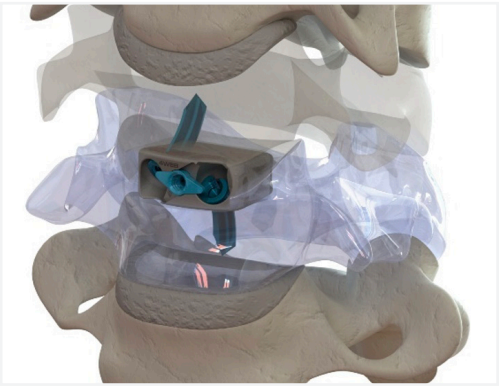


Figure 11

IMPLANT REMOVAL

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

- To remove the Fixation Anchors, a Nail Remover Slap Hammer has been provided. The Nail Removal Slap Hammer has the ability to be in a "locked" state, which does not allow for translation of the proximal handle, and an "unlocked" state, where the handle is free to slide. To lock or unlock the handle, turn the proximal knob on the Nail Removal Slap Hammer when the handle is in the collapsed position (Fig. 12).

Figure 12

- To remove the Fixation Anchors, thread the Nail Remover Slap Hammer into the threads on the head of the Fixation Anchor. Remove the Fixation Anchors by applying backwards pressure using the Nail Remover Slap Hammer (Fig. 13).

- If implant removal is required, the intervertebral space should be distracted in the same manner as for implant placement. 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 (Fig. 14).

Figure 13

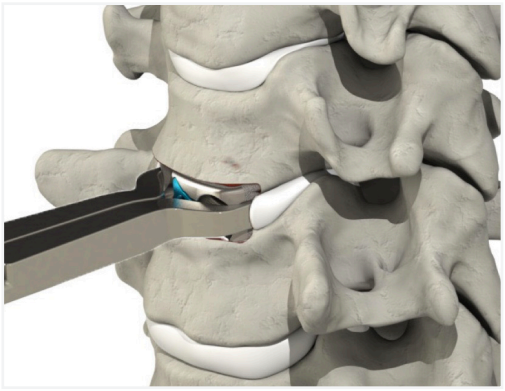


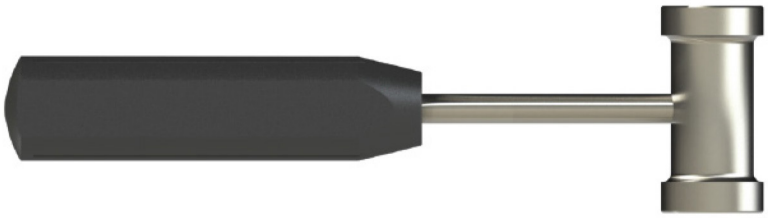
Figure 14

INSTRUMENT CATALOG

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

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

CSTS-000018	Cervical Mallet



1HJ1-C01	Cervical Handle - AO

CSTS-SA-000043	Nail Remover Slap Hammer

PART NUMBER	DESCRIPTION
CSTS-SA-000046	Anchor Finishing Tamp

CSTS-SA-000068	Anchor Inserter, Small

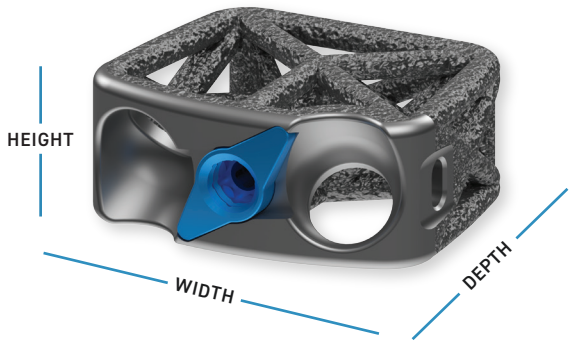
CSTS-SA-000069	Anchor Inserter, Medium

CSTS-SA-CATXX	Anchor Tamp

CSTS-SA-000060	Draw Rod

IMPLANT CATALOG

INTERBODY DEVICES

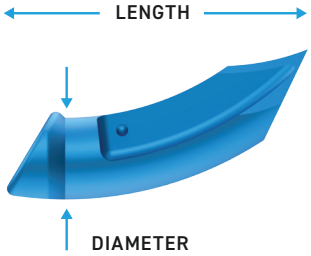


CATALOG #	FOOTPRINT (D, W, H)	LORDOSIS
0 DEGREE		
CSTS-SA-SM0005-SP	12 x 15 x 5mm	0°
CSTS-SA-SM0006-SP	12 x 15 x 6mm	0°
CSTS-SA-SM0007-SP	12 x 15 x 7mm	0°
CSTS-SA-SM0008-SP	12 x 15 x 8mm	0°
CSTS-SA-SM0009-SP	12 x 15 x 9mm	0°
CSTS-SA-SM0010-SP	12 x 15 x 10mm	0°
CSTS-SA-MD0005-SP	14 x 17 x 5mm	0°
CSTS-SA-MD0006-SP	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°
7 DEGREE		
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°

CATALOG #	FOOTPRINT (D, W, H)	LORDOSIS
CSTS-SA-SM0709-SP	12 x 15 x 9mm	7°
CSTS-SA-SM0710-SP	12 x 15 x 10mm	7°
CSTS-SA-MD0705-SP	14 x 17 x 5mm	7°
CSTS-SA-MD0706-SP	14 x 17 x 6mm	7°
CSTS-SA-MD0707-SP	14 x 17 x 7mm	7°
CSTS-SA-MD0708-SP	14 x 17 x 8mm	7°
CSTS-SA-MD0709-SP	14 x 17 x 9mm	7°
CSTS-SA-MD0710-SP	14 x 17 x 10mm	7°

IMPLANT CATALOG

FIXATION ANCHORS



ANCHOR DIAMETER	LENGTH	
3.5mm	11, 12mm	PRIMARY ANCHOR
CATALOG #	**DIAMETER, LENGTH**	**FITS WITH INTERBODY**
CSTS-SA-ACSM05-SP	Ø3.5mm, L 11mm	Small, 5mm
CSTS-SA-ACSM06-SP	Ø3.5mm, L 11mm	Small, 6mm
CSTS-SA-ACSM07-SP	Ø3.5mm, L 11mm	Small, 7mm
CSTS-SA-ACSM08-SP	Ø3.5mm, L 11mm	Small, 8mm
CSTS-SA-ACSM09-SP	Ø3.5mm, L 11mm	Small, 9mm
CSTS-SA-ACSM10-SP	Ø3.5mm, L 11mm	Small, 10mm
CSTS-SA-ACMD05-SP	Ø3.5mm, L 12mm	Medium, 5mm
CSTS-SA-ACMD06-SP	Ø3.5mm, L 12mm	Medium, 6mm
CSTS-SA-ACMD07-SP	Ø3.5mm, L 12mm	Medium, 7mm
CSTS-SA-ACMD08-SP	Ø3.5mm, L 12mm	Medium, 8mm
CSTS-SA-ACMD09-SP	Ø3.5mm, L 12mm	Medium, 9mm
CSTS-SA-ACMD10-SP	Ø3.5mm, L 12mm	Medium, 10mm

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

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