

SURGICAL TECHNIQUE GUIDE

CERVICAL SPINE PLATING SOLUTION

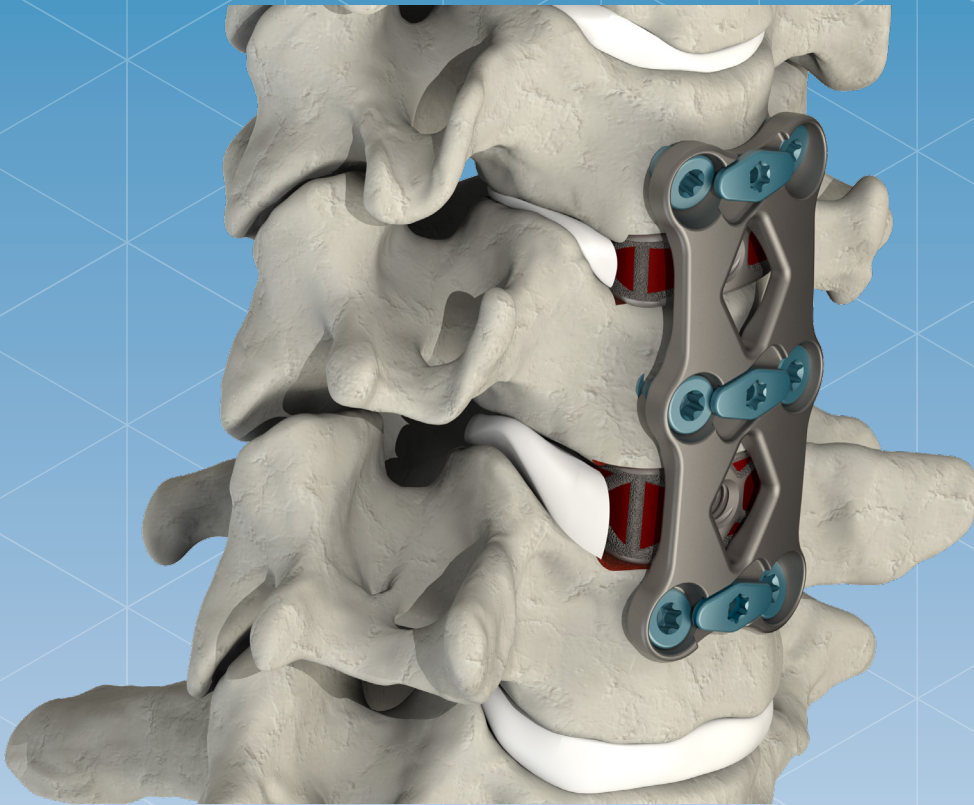


TABLE OF CONTENTS

TRUSS IMPLANT TECHNOLOGY™	3
IMPLANT OVERVIEW	4
SURGICAL PROCEDURE	4
INSTRUMENT CATALOG	11
CSTS PLATE & INTERBODY CHART	14
IMPLANT CATALOG & SPECIFICATIONS	15

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™



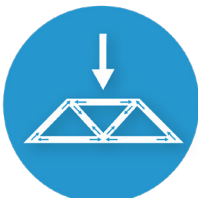
Novel Truss Implant Technology™ provides a Snow Shoe Interface that distributes load across the endplate which minimizes point loading and reduces the risk of subsidence.*



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.^{1,2}



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.¹



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

* Data on file

¹ Lee et al, ORS, 2023 Annual Meeting, Dallas, TX

² Rowe et al, SMISS, AnnualForum'19, p.52

CSTS-PS OVERVIEW

- ▲ The 4WEB Cervical Spine Plating Solution (CSTS-PS) consists of a wide variety of plating configurations to treat one to five levels with several heights per level to address multiple cervical spine pathologies. The plate design features a single-step locking mechanism to prevent screw backout.

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 (Fig. 2).
- ▲ Expose the intervertebral disc space and the adjacent vertebral bodies through a standard anterior approach to the cervical spine.
- ▲ Once the operative level(s) have been exposed, confirm the centerline of the affected level(s) with fluoroscopic imaging.



Figure 2

DISCECTOMY AND ENDPLATE PREPARATION

- ▲ A Caspar 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.

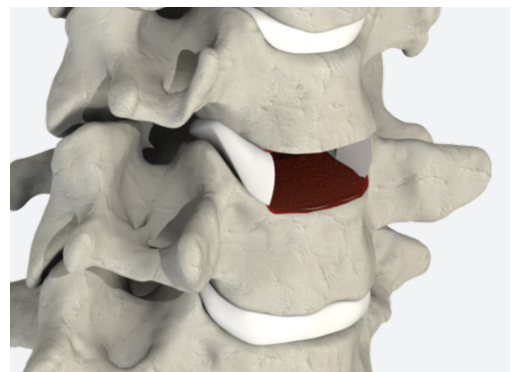


Figure 3

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. The CSTS sizers are sized at a 1:1/measurement ratio with the implants.
- ▲ 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.

IMPLANT PREPARATION

- ▲ Pack the CSTS 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 material into the implant (Fig. 5).

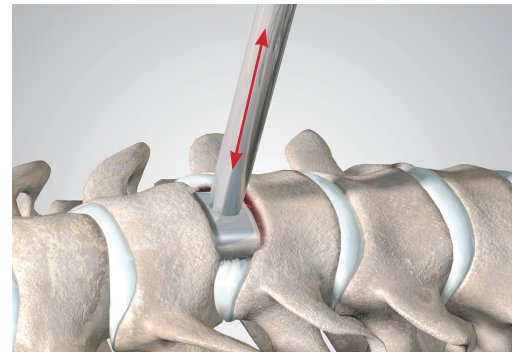


Figure 4

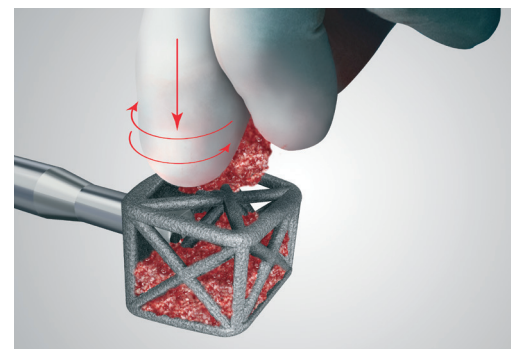


Figure 5

IMPLANT & PLATE INSERTION

- ▲ The CSTS Interbody should be inserted into the disc space first (Fig. 6). Once the CSTS Interbody is in place, select the proper plate size and configuration to accommodate the patient's anatomy. A properly sized plate will bridge the affected segment(s) without overhanging into the adjacent disc space. The appropriate CSTS Plate may be inserted using the CSTS Plate Holder spanning the operative level (Fig. 7).

- ▲ If plate contouring is necessary, place the plate in the Plate Bender and squeeze the handles together to create more lordosis.

NOTE: Due to titanium's notch sensitivity, we do not recommend decreasing the contour if the plate has been over bent. Repeated bending will weaken the plate.

NOTE: Do not bend directly over the locking mechanisms.

SINGLE-STEP INSERTION

- ▲ If a single-step insertion is desired, the appropriate 1-level CSTS Plate and CSTS Interbody may be combined on the back table using the CSTS Plate Combo Inserter (Fig. 8). Once assembled, insert the CSTS Interbody/Plate construct into the disc space and fix the plate into position (Fig. 9).

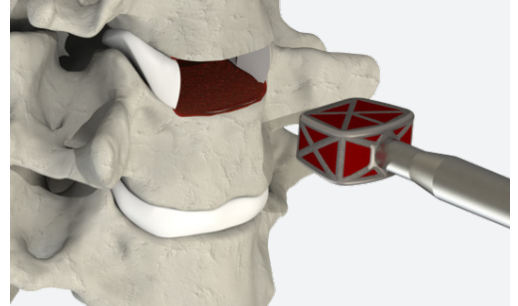


Figure 6

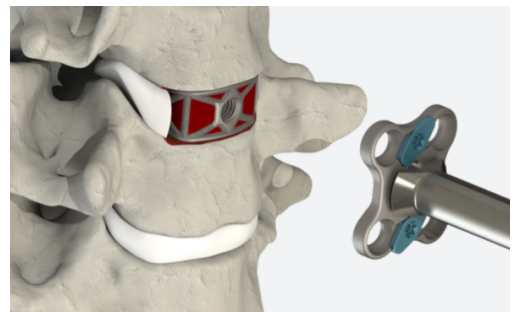


Figure 7

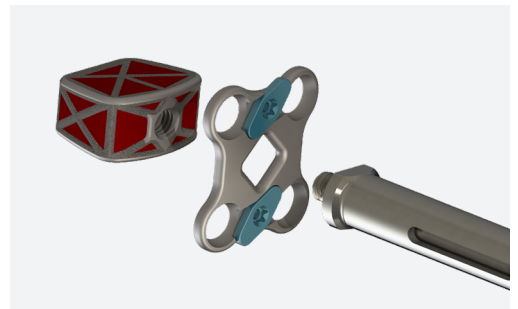


Figure 8

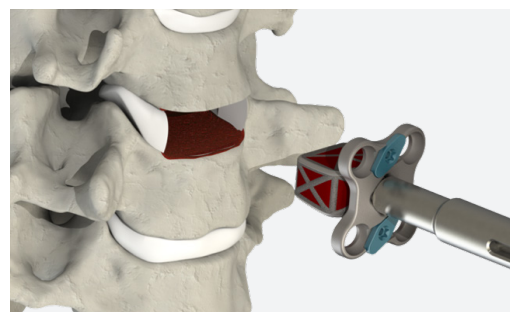


Figure 9

FIXATION PINS (OPTIONAL)

- ▲ Once the plate is placed in the correct position, it can be secured in place using the Fixation Pins (Fig. 10). The Fixation Pins can be placed through any of the screw holes. Use the Driver to insert the Fixation Pins.

NOTE: All Fixation Pins must be removed from the surgical site prior to closure.

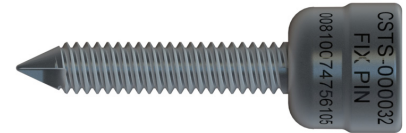


Figure 10

SCREW HOLE PREPARATION

- ▲ The CSTS-PS offers multiple Awl and Drill options to be used with a variable angle or fixed angle driver for screw hole preparation.
- ▲ To use, attach the Handle and insert the distal end of the Awl through the guide as it is placed firmly against the screw hole opening (Fig. 11). Puncture the bone by applying axial force to the end of the Awl Handle. Should a Drill be desired, attach the Handle and prepare the screw hole by rotating the Drill Handle clockwise.

NOTE: The distal end of the awl tip penetrates the vertebral body 10mm when seated (Fig. 12).

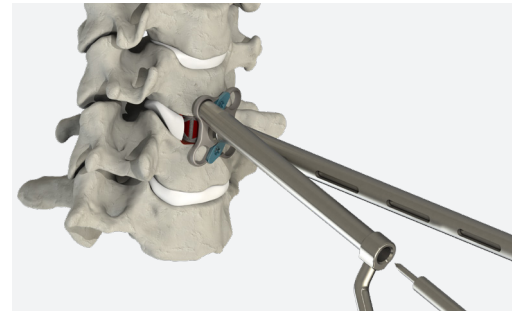


Figure 11

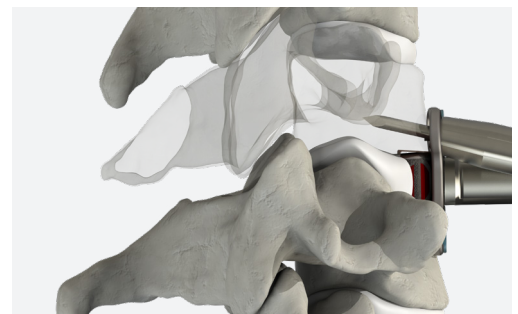


Figure 12

SCREW INSERTION

- ▲ The CSTS-PS offers one driver for both screw insertion and rotating the locking plate. Select the desired Driver and attach the Handle to the proximal end of the Driver. Select the primary screw with the desired length and attach it to the distal end of the Driver. Insert the screw through the screw hole in the plate. Drive the screw until it is fully seated in the plate (Fig. 13).
- ▲ Be careful not to over tighten the screw, which may lead to stripping the bone and inadequate purchase. If the screw purchase into the bone is inadequate, use the larger diameter rescue screw option.

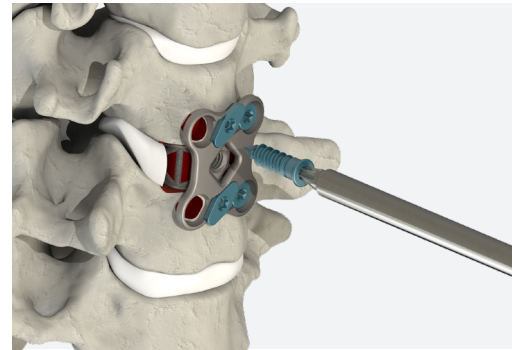


Figure 13

LOCKING THE ANTI-BACKOUT PLATE

- ▲ After placement of the screws, rotate the Anti-Backout Plates with the Driver (Fig. 14).

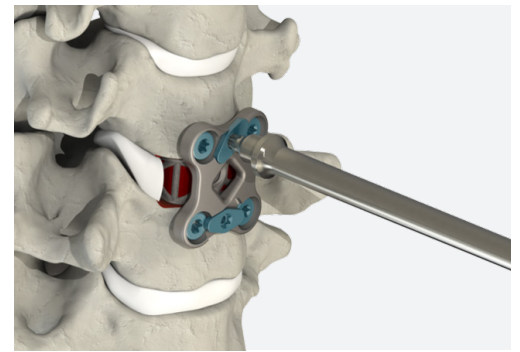


Figure 14

FINAL IMPLANT POSITION

- ▲ Visually inspect CSTS Plate for correct position and confirm with fluoroscopy. Ensure the plate is aligned via the midline of the vertebral body (Fig. 15).

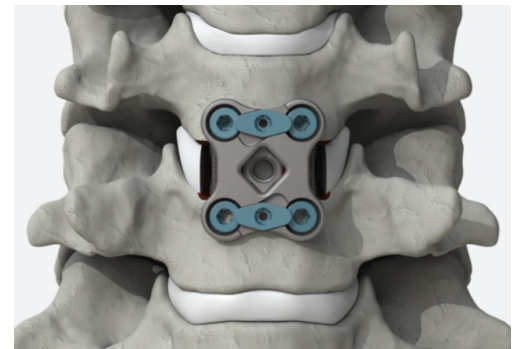


Figure 15

IMPLANT REMOVAL/REVISION

- ▲ If Plate removal is necessary, rotate the Anti-Backout Plates until the screws are no longer retained (Fig. 16). Remove the screws using the Driver and remove the Plate using the Plate Inserter (Fig. 17).
- ▲ If interbody removal is required, the intervertebral space should be distracted in the same manner as for interbody insertion. Once distracted, the interbody may be removed by using the CSTS Inserter (Fig. 18).

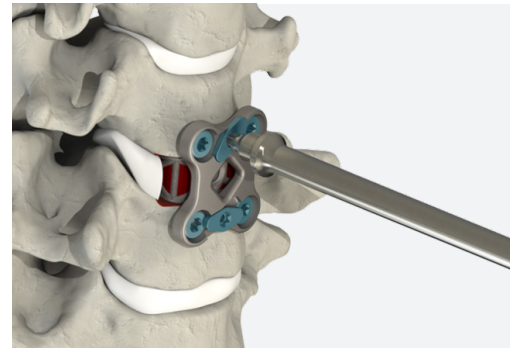


Figure 16

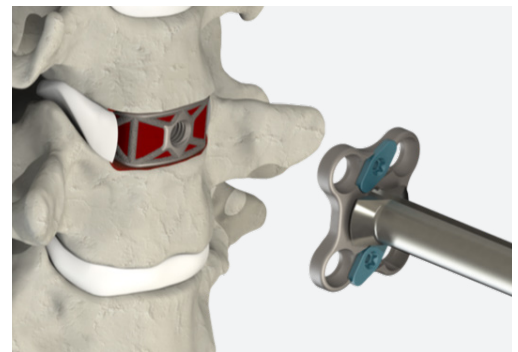


Figure 17

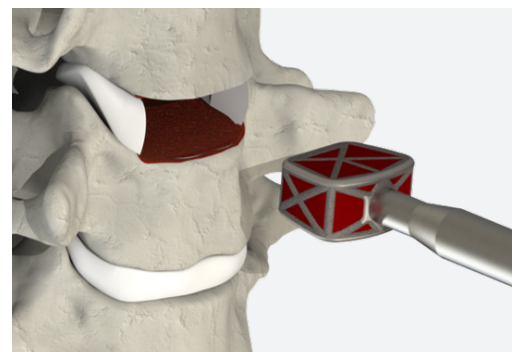


Figure 18

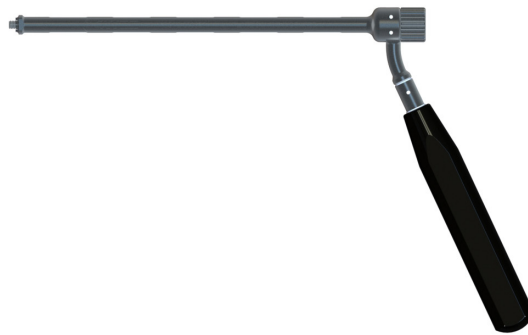
INSTRUMENT CATALOG

PART NUMBER	DESCRIPTION
-------------	-------------

CSTS-000024	Freehand Plate Inserter
-------------	-------------------------



CSTS-000025	Plate Combo Inserter
-------------	----------------------



CSTS-000026	CSTS-PS Driver
-------------	----------------



CSTS-000027	CSTS-PS Awl
-------------	-------------



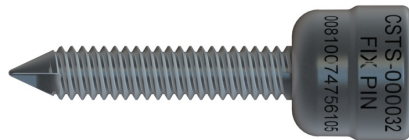
PART NUMBER	DESCRIPTION
CSTS-000029	CSTS-PS Fixed Drill/Awl Guide



CSTS-000031	CSTS-PS Awl Guide
-------------	-------------------



CSTS-000032	CSTS-PS Fixation Pin
-------------	----------------------



PART NUMBER	DESCRIPTION
CSTS-000033	CSTS-PS Plate Bender



CSTS-000028	CSTS-PS 12mm Drill
-------------	--------------------



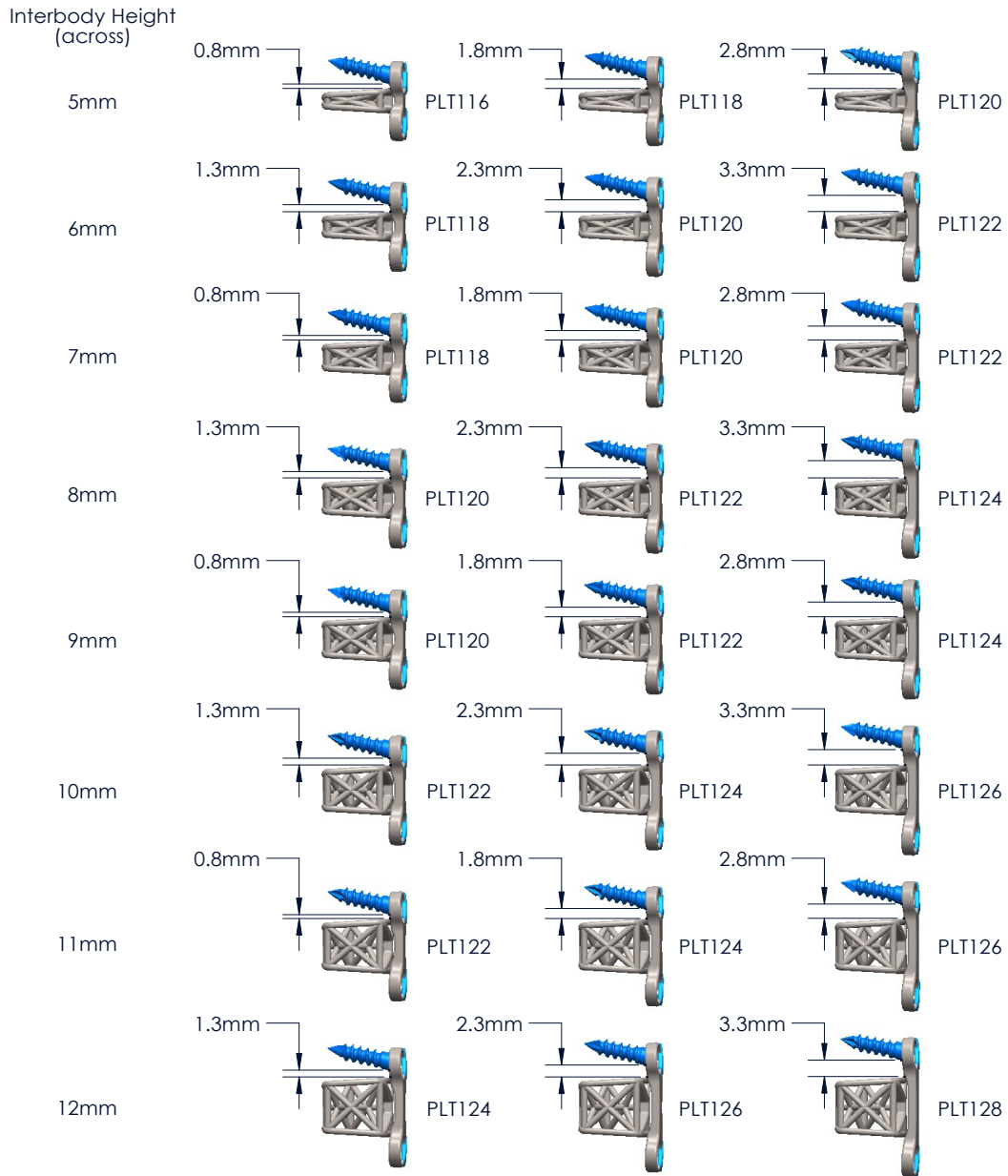
CSTS-000034	CSTS-PS 14mm Drill
-------------	--------------------



CSTS-000035	CSTS-PS 16mm Drill
-------------	--------------------



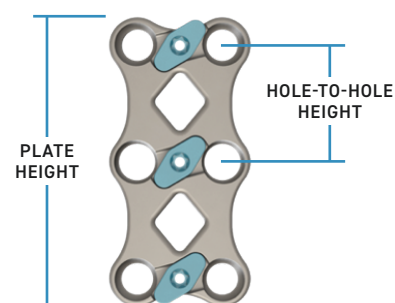
PLATE & INTERBODY CHART



IMPLANT CATALOG

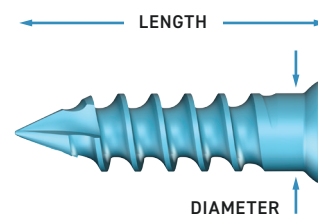
PLATES

CATALOG #	PLATE HEIGHT	HOLE-TO-HOLE HEIGHT	CATALOG #	PLATE HEIGHT	HOLE-TO-HOLE HEIGHT	CATALOG #	PLATE HEIGHT	HOLE-TO-HOLE HEIGHT
1-LEVEL PLATES			3-LEVEL PLATES			5-LEVEL PLATES		
CSTS-PLT116-NS	16mm	10mm	CSTS-PLT342-NS	42mm	36mm	CSTS-PLT576-NS	76mm	69mm
CSTS-PLT118-NS	18mm	12mm	CSTS-PLT345-NS	45mm	39mm	CSTS-PLT579-NS	79mm	72mm
CSTS-PLT120-NS	20mm	14mm	CSTS-PLT348-NS	48mm	42mm	CSTS-PLT582-NS	82mm	75mm
CSTS-PLT122-NS	22mm	16mm	CSTS-PLT351-NS	51mm	45mm	CSTS-PLT585-NS	85mm	78mm
CSTS-PLT124-NS	24mm	18mm	CSTS-PLT354-NS	54mm	48mm	CSTS-PLT588-NS	88mm	81mm
CSTS-PLT126-NS	26mm	20mm	CSTS-PLT357-NS	57mm	51mm	CSTS-PLT591-NS	91mm	84mm
CSTS-PLT128-NS	28mm	22mm	CSTS-PLT360-NS	60mm	54mm	CSTS-PLT594-NS	94mm	87mm
CSTS-PLT130-NS	30mm	24mm	CSTS-PLT363-NS	63mm	57mm	CSTS-PLT597-NS	97mm	90mm
CSTS-PLT132-NS	32mm	26mm	CSTS-PLT366-NS	66mm	60mm	CSTS-PLT5100-NS	100mm	93mm
CSTS-PLT134-NS	34mm	28mm	CSTS-PLT369-NS	69mm	63mm	CSTS-PLT5103-NS	103mm	96mm
CSTS-PLT136-NS	36mm	30mm	CSTS-PLT372-NS	72mm	66mm	CSTS-PLT5106-NS	106mm	99mm
2-LEVEL PLATES			4-LEVEL PLATES			CSTS-PLT5109-NS	109mm	102mm
CSTS-PLT224-NS	24mm	18mm	CSTS-PLT460-NS	60mm	54mm	CSTS-PLT5112-NS	112mm	105mm
CSTS-PLT226-NS	26mm	20mm	CSTS-PLT463-NS	63mm	57mm	CSTS-PLT5115-NS	115mm	108mm
CSTS-PLT228-NS	28mm	22mm	CSTS-PLT466-NS	66mm	60mm			
CSTS-PLT230-NS	30mm	24mm	CSTS-PLT469-NS	69mm	63mm			
CSTS-PLT232-NS	32mm	26mm	CSTS-PLT472-NS	72mm	66mm			
CSTS-PLT234-NS	34mm	28mm	CSTS-PLT475-NS	75mm	69mm			
CSTS-PLT236-NS	36mm	30mm	CSTS-PLT478-NS	78mm	72mm			
CSTS-PLT238-NS	38mm	32mm	CSTS-PLT481-NS	81mm	75mm			
CSTS-PLT240-NS	40mm	34mm	CSTS-PLT484-NS	84mm	78mm			
CSTS-PLT242-NS	42mm	36mm	CSTS-PLT487-NS	87mm	81mm			
CSTS-PLT244-NS	44mm	38mm	CSTS-PLT490-NS	90mm	84mm			
CSTS-PLT246-NS	46mm	40mm	CSTS-PLT493-NS	93mm	87mm			
CSTS-PLT248-NS	48mm	42mm						



SELF-DRILLING SCREW SPECIFICATIONS

SCREW DIAMETER	LENGTH	
3.5mm	12, 14, 16, 18mm	PRIMARY SCREW
3.8mm	12, 14, 16, 18mm	RESCUE SCREW
CATALOG #	DIAMETER, LENGTH *	
CSCR-3512-SD-SP	Ø3.5mm, L 12mm	
CSCR-3514-SD-SP	Ø3.5mm, L 14mm	
CSCR-3516-SD-SP	Ø3.5mm, L 16mm	
CSCR-3518-SD-SP	Ø3.5mm, L 18mm	
CSCR-3812-SD-SP	Ø3.8mm, L 12mm	
CSCR-3814-SD-SP	Ø3.8mm, L 14mm	
CSCR-3816-SD-SP	Ø3.8mm, L 16mm	
CSCR-3818-SD-SP	Ø3.8mm, L 18mm	



*25° maximum angulation with 6° of conical variability



2801 NETWORK BLVD. SUITE 620

FRISCO, TX 75034

4WEBMEDICAL.COM

INFO@4WEBMEDICAL.COM

800.285.7090

ST-CSTS-PS-01 | REV C