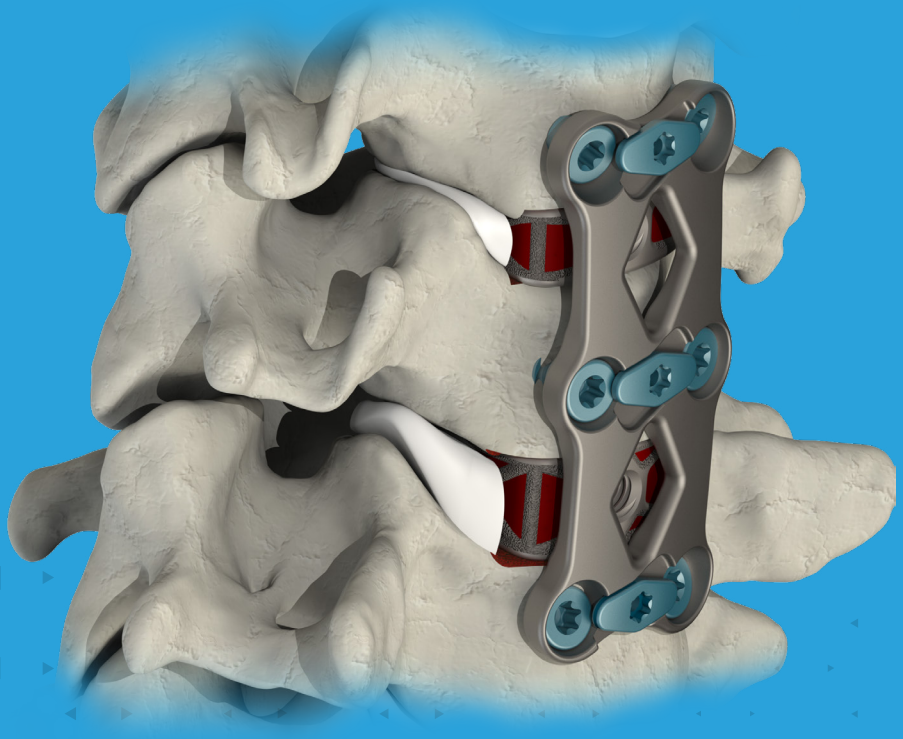
SURGICAL TECHNIQUE GUIDE

CERVICAL SPINE PLATING SOLUTION



4WEB®

TABLE OF CONTENTS

TRUSS IMPLANT TECHNOLOGY™ 3

IMPLANT OVERVIEW 4

SURGICAL PROCEDURE 5

INSTRUMENT CATALOG 12

PLATE & INTERBODY CHART 15

IMPLANT CATALOG 16

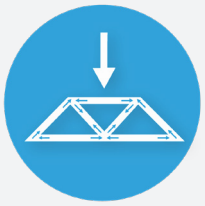
Federal law (USA) restricts these devices to sales by or on the order of a physician. Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the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

The 4WEB Cervical Spine Truss System 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.

INDICATIONS

The CSTS-PS is intended for anterior interbody screw fixation of the cervical spine at levels C2-T1.

The CSTS-PS is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

CONTRAINDICATIONS

The CSTS-PS 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
- Rapid progressive joint disease, bone absorption, osteopenia, and/or osteoporosis
- Known sensitivity to the material
- Any medical or surgical condition which would preclude the potential benefit of surgery

WARNINGS AND PRECAUTIONS

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

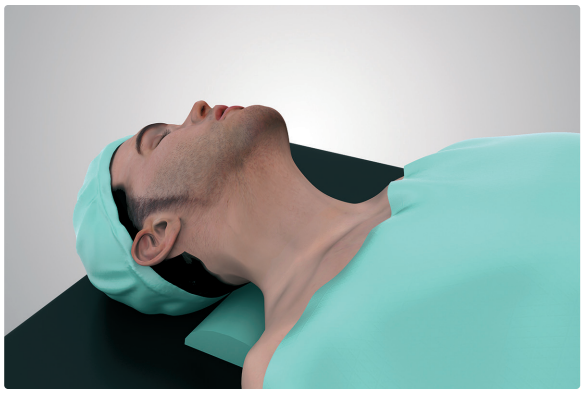


Figure 1

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.

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.

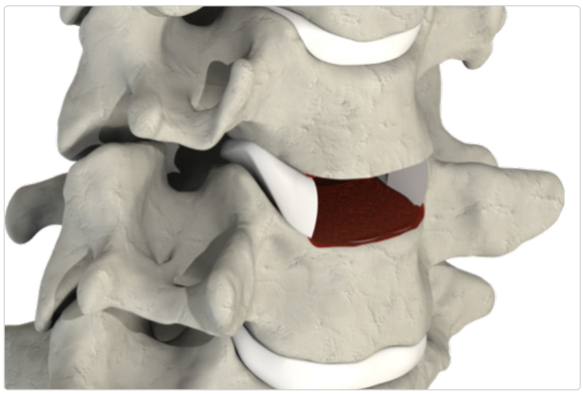


Figure 3

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. 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.

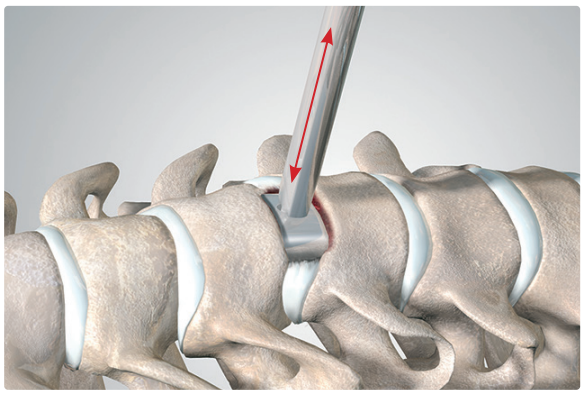


Figure 4

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).

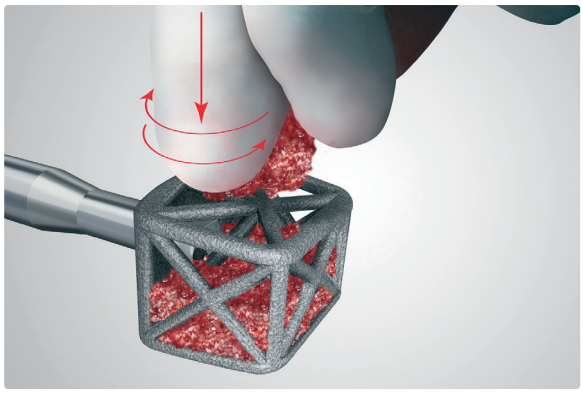


Figure 5

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.

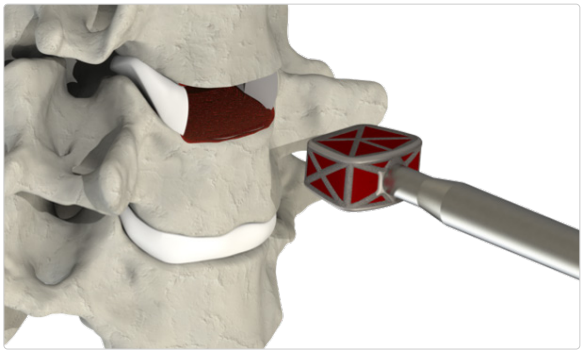


Figure 6

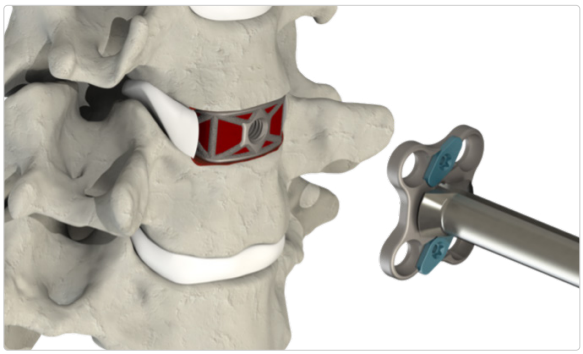


Figure 7

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).

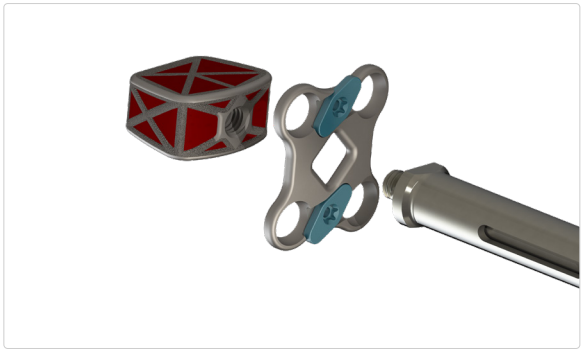


Figure 8

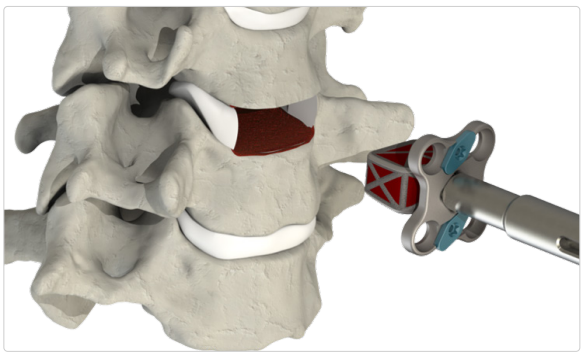


Figure 9

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.

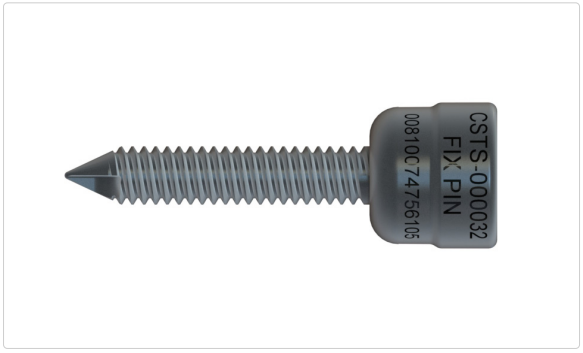


Figure 10

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).

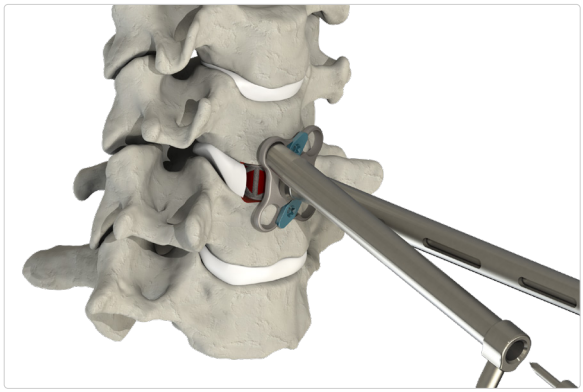


Figure 11

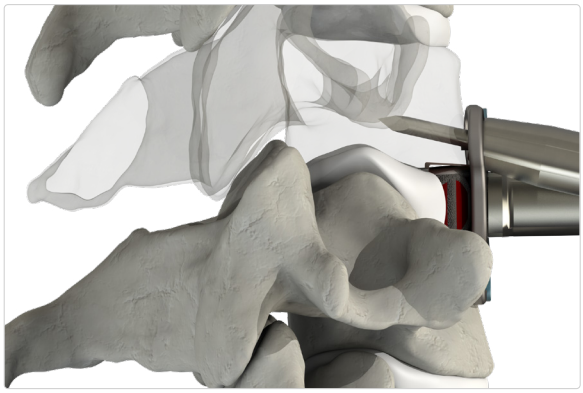


Figure 12

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.

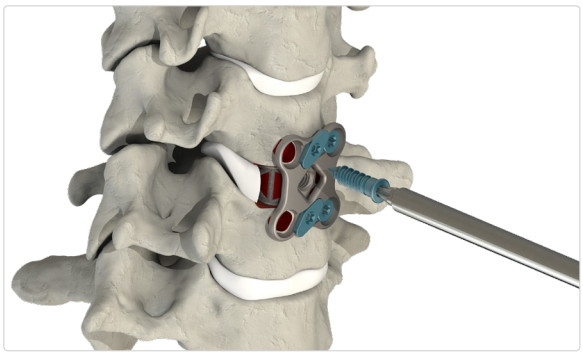


Figure 13

LOCKING THE ANTI-BACKOUT PLATE

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

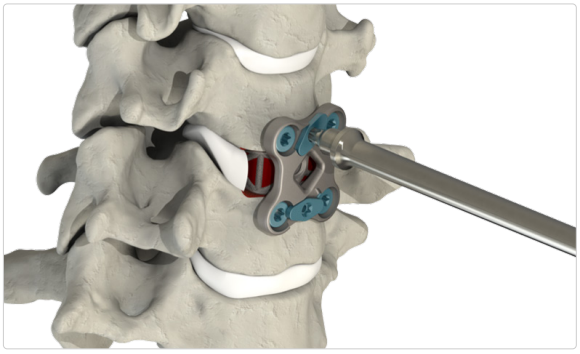


Figure 14

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).

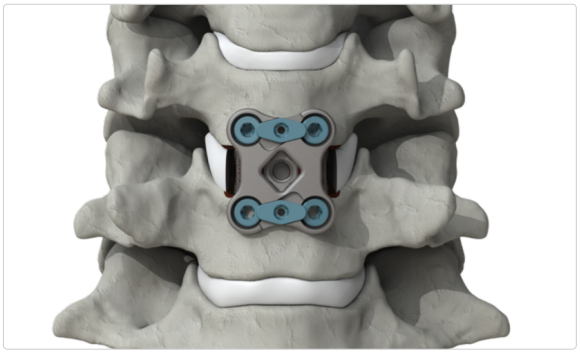


Figure 15

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).

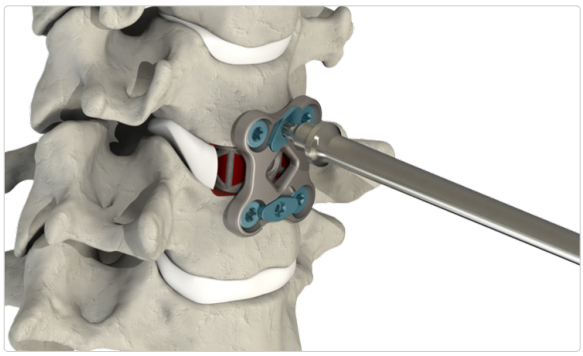


Figure 16

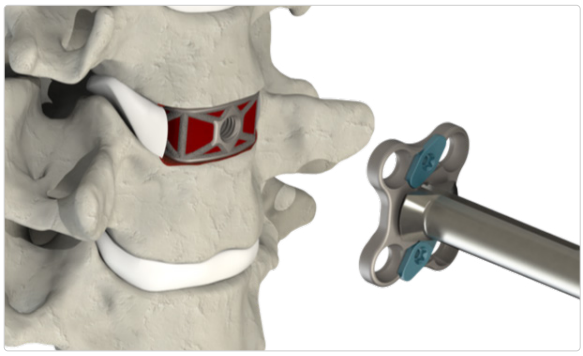


Figure 17

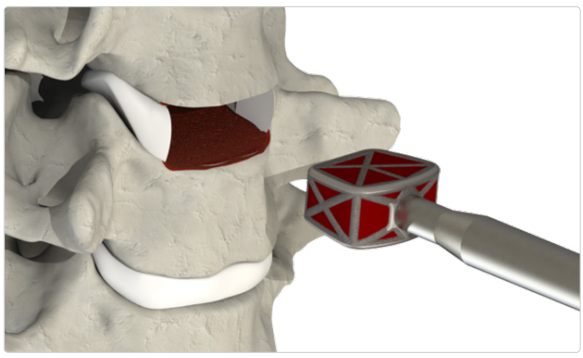
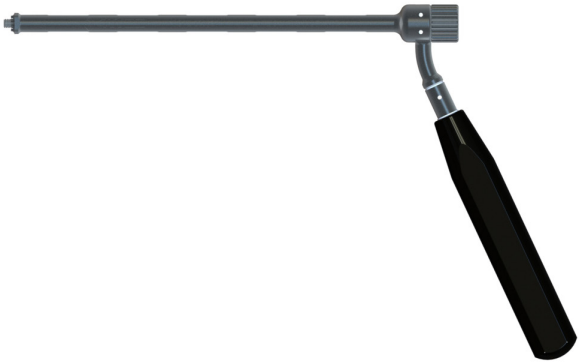


Figure 18

INSTRUMENT CATALOG

PART NUMBER	DESCRIPTION
CSTS-000024	FREEHAND PLATE INSERTER

CSTS-000025	PLATE COMBO INSERTER



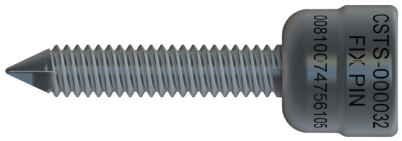
CSTS-000026	CSTS-PS DRIVER

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



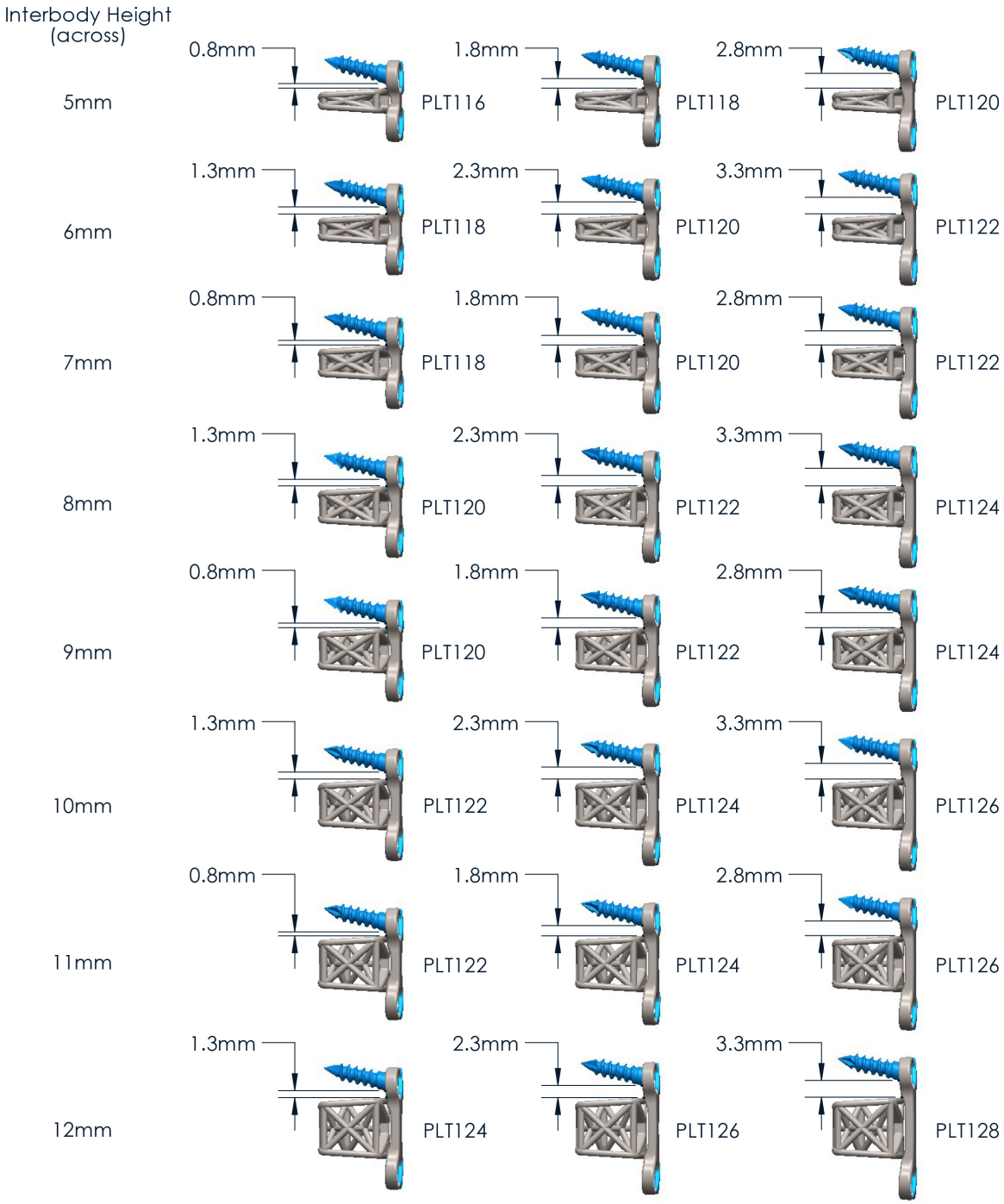
PART NUMBER	DESCRIPTION
CSTS-000033	CSTS-PS PLATE BENDER

CSTS-000028	CSTS-PS 12MM DRILL

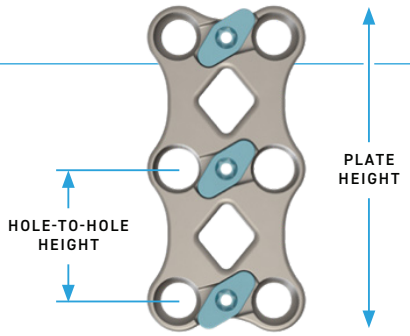
CSTS-000034	CSTS-PS 14MM DRILL

CSTS-000035	CSTS-PS 16MM DRILL

PLATE & INTERBODY CHART



IMPLANT CATALOG

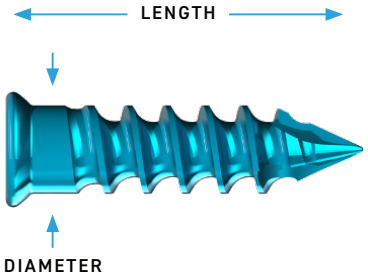


PLATES

CATALOG NUMBER	PLATE HEIGHT	HOLE-TO-HOLE HEIGHT
1-LEVEL PLATES		
CSTS-PLT116-NS	16mm	10mm
CSTS-PLT118-NS	18mm	12mm
CSTS-PLT120-NS	20mm	14mm
CSTS-PLT122-NS	22mm	16mm
CSTS-PLT124-NS	24mm	18mm
CSTS-PLT126-NS	26mm	20mm
CSTS-PLT128-NS	28mm	22mm
CSTS-PLT130-NS	30mm	24mm
CSTS-PLT132-NS	32mm	26mm
CSTS-PLT134-NS	34mm	28mm
CSTS-PLT136-NS	36mm	30mm
2-LEVEL PLATES		
CSTS-PLT224-NS	24mm	18mm
CSTS-PLT226-NS	26mm	20mm
CSTS-PLT228-NS	28mm	22mm
CSTS-PLT230-NS	30mm	24mm
CSTS-PLT232-NS	32mm	26mm
CSTS-PLT234-NS	34mm	28mm

CATALOG NUMBER	PLATE HEIGHT	HOLE-TO-HOLE HEIGHT
CSTS-PLT236-NS	36mm	30mm
CSTS-PLT238-NS	38mm	32mm
CSTS-PLT240-NS	40mm	34mm
CSTS-PLT242-NS	42mm	36mm
CSTS-PLT244-NS	44mm	38mm
CSTS-PLT246-NS	46mm	40mm
CSTS-PLT248-NS	48mm	42mm
3-LEVEL PLATES		
CSTS-PLT342-NS	42mm	36mm
CSTS-PLT345-NS	45mm	39mm
CSTS-PLT348-NS	48mm	42mm
CSTS-PLT351-NS	51mm	45mm
CSTS-PLT354-NS	54mm	48mm
CSTS-PLT357-NS	57mm	51mm
CSTS-PLT360-NS	60mm	54mm
CSTS-PLT363-NS	63mm	57mm
CSTS-PLT366-NS	66mm	60mm
CSTS-PLT369-NS	69mm	63mm
CSTS-PLT372-NS	72mm	66mm
4-LEVEL PLATES		
CSTS-PLT460-NS	60mm	54mm
CSTS-PLT463-NS	63mm	57mm

CATALOG NUMBER	PLATE HEIGHT	HOLE-TO-HOLE HEIGHT
CSTS-PLT466-NS	66mm	60mm
CSTS-PLT469-NS	69mm	63mm
CSTS-PLT472-NS	72mm	66mm
CSTS-PLT475-NS	75mm	69mm
CSTS-PLT478-NS	78mm	72mm
CSTS-PLT481-NS	81mm	75mm
CSTS-PLT484-NS	84mm	78mm
CSTS-PLT487-NS	87mm	81mm
CSTS-PLT490-NS	90mm	84mm
CSTS-PLT493-NS	93mm	87mm
5-LEVEL PLATES		
CSTS-PLT576-NS	76mm	69mm
CSTS-PLT579-NS	79mm	72mm
CSTS-PLT582-NS	82mm	75mm
CSTS-PLT585-NS	85mm	78mm
CSTS-PLT588-NS	88mm	81mm
CSTS-PLT591-NS	91mm	84mm
CSTS-PLT594-NS	94mm	87mm
CSTS-PLT597-NS	97mm	90mm
CSTS-PLT5100-NS	100mm	93mm
CSTS-PLT5103-NS	103mm	96mm
CSTS-PLT5106-NS	106mm	99mm
CSTS-PLT5109-NS	109mm	102mm
CSTS-PLT5112-NS	112mm	105mm
CSTS-PLT5115-NS	115mm	108mm



SCREWS

DIAMETER	LENGTH	
ø3.5mm	12, 14, 16, 18mm	Primary Screw
ø3.8mm	12, 14, 16, 18mm	Rescue Screw

CATALOG NUMBER	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
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