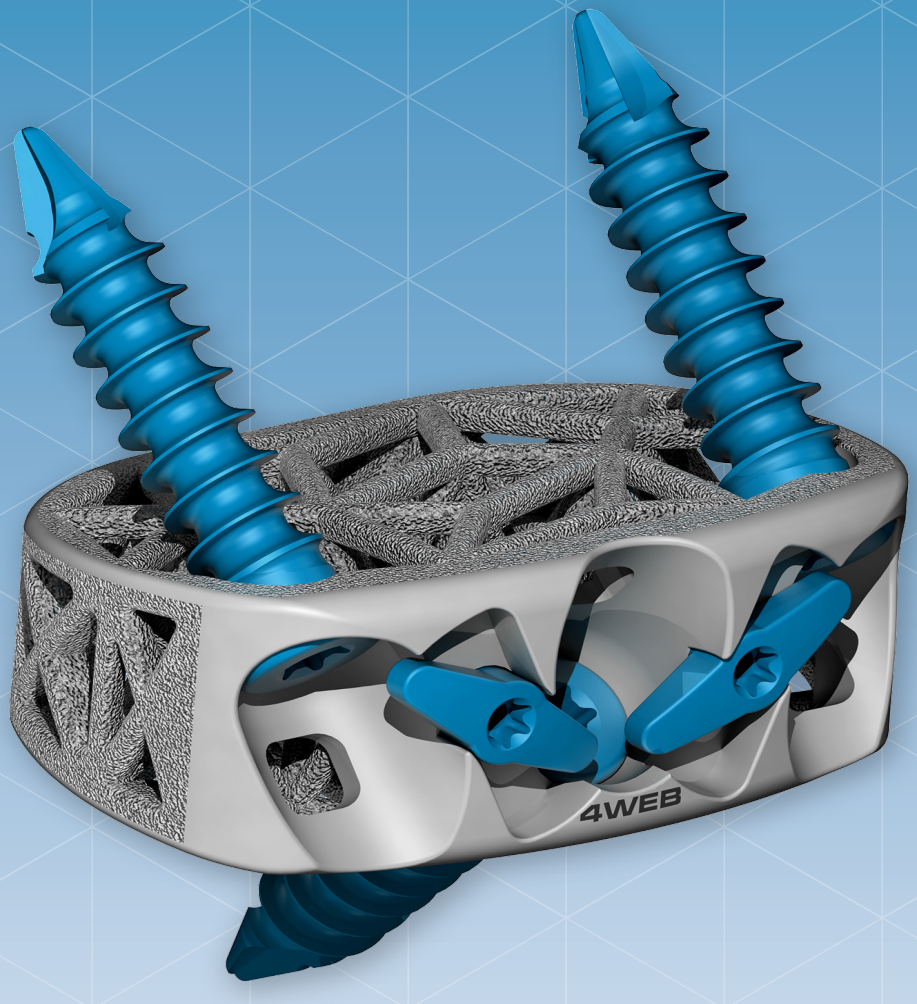
SURGICAL TECHNIQUE GUIDE

STAND ALONE
ANTERIOR SPINE TRUSS SYSTEM



4WEB® MEDICAL

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Federal law (USA) restricts these devices to sales by or on the order of a physician.

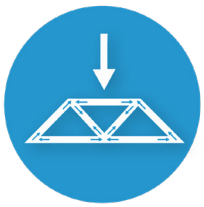
Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedure based on his or her medical training and experience. Prior to use of the system, 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.

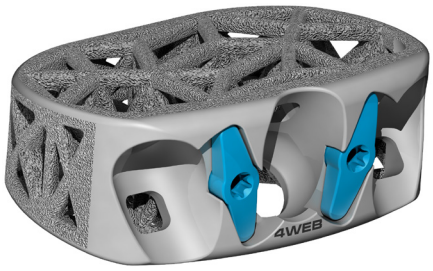
[1] Rowe et al, SMISS, AnnualForum'19, p.52 * Data on file

ASTS-SA OVERVIEW

ASTS-SA has an Advanced Structural Design that incorporates 4WEB Medical's proprietary Truss Implant Technology™. Under normal loading conditions the struts in the truss implant transfer strain to adjacent cellular material which stimulates a mechanobiologic response. The ASTS-SA product 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. Supplemental fixation is not required for implants 20° or less of lordosis but is required for implants greater than 20° of lordosis. Additionally, the device features two single-step locking mechanisms that prevents screw back out and provides surgeon users confidence in the performance of the stand alone construct and procedural efficiency. The Stand Alone Anterior product line provides 45° of screw angulation with 5° of variability and is available in multiple footprints, lordotic angles, and heights. The product is delivered in sterile packaging for hospital efficiency and patient safety.

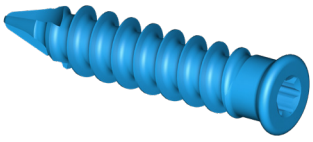
ASTS-SA sizers and instruments are provided non-sterile and require sterilization prior to use.

ASTS-SA IMPLANT SPECIFICATIONS



FOOTPRINT	LORDOSIS	HEIGHT
21 x 34mm	6°,12°	8-16mm
	16°	10-16mm
	20°	12-18mm
	24°	14-20mm
24 x 36mm	6°,12°	8-16mm
	16°	10-16mm
	20°	12-18mm
	24°	14-20mm
27 x 40mm	6°,12°	8-16mm
	16°	10-16mm
	20°	12-18mm
	24°	14-20mm

ASTS-SA SELF DRILLING SCREW SPECIFICATIONS



DIAMETER	LENGTH
ø5.0mm	23, 27, 31mm
ø5.5mm	23, 27, 31mm

SURGICAL PROCEDURE

APPROACH

- Position the patient in the supine position (Fig. 1).
- Perform a standard anterior lumbar approach per surgeon preference.

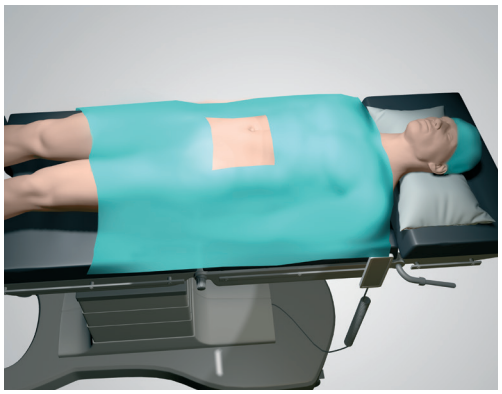


Figure 1

ACCESS AND EXPOSURE

- Locate the correct operative level under fluoroscopic guidance. A lower abdominal transverse incision, left vertical paramedian incision, or other appropriate incision is made depending on the exposure necessary to access the operative level(s).
- 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.

DISCECTOMY AND ENDPLATE PREPARATION

- Perform an annulotomy and subsequent lumbar discectomy within the constraints of the operative window.
- Additional distraction may be applied as desired to increase visualization.
- Remove the superficial layers of the cartilaginous endplates down to bleeding bone while trying to avoid compromising the integrity of the boney endplates (Fig. 2).

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.

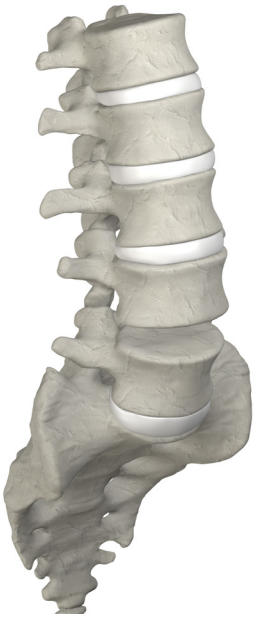


Figure 2

IMPLANT SIZING

- Attach the Straight Inserter to the Quick Connect Handle.
- Select the appropriate sizer and attach it to the Straight Inserter by threading the inserter into the sizer. To secure the sizer to the Straight Inserter turn the knob clockwise. Height, footprint, and lordotic angle measurements are clearly marked on the sizers (Fig. 3).

Figure 3

- In order to maintain disc height and ensure segment stabilization select a sizer height that provides a secure fit. Start with the smallest height, progressing to taller heights until the desired fit is achieved.
- Carefully impact the sizer into the disc space (Fig. 4). Check the correct fit of the sizer with the aid of fluoroscopy and palpation.

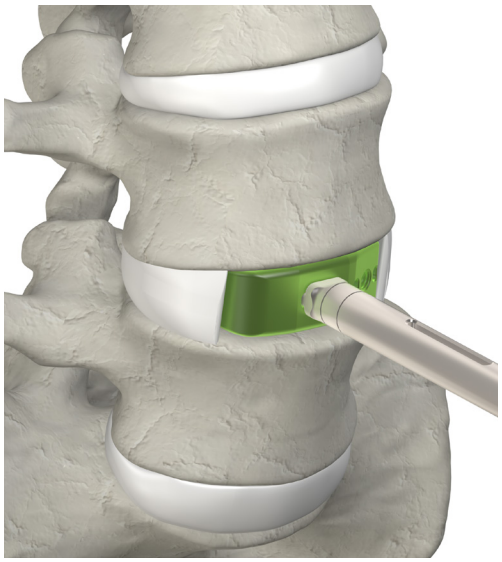


Figure 4

NOTE: The ASTS-SA sizers are designed with a 1:1 measurement ratio to the implants. 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 three techniques for inserting the implant and preparing and inserting the screws.

Technique 1 – Guided Inserter Technique:

- The Guided Technqiue uses a Guided Inserter with fixed guides to insert the implant into the intervertebral disc space, and to prepare and insert the screws (pages 10-14). There are two Guided Inserters to accommodate implant height: 10-12mm Guided Inserter and 14-20mm Guided Inserter. There is no Guided Inserter to accommodate the 8mm implant.

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 15-19).

Technique 3 - Freehand Insertion and Guided Screw Preparation & Insertion Technique:

- This technique uses a Freehand Inserter and Freehand Guide (ASTS-SA-100008) for screw hole preparation and insertion (pages 20-25), alternately the Freehand Awl Guide (ASTS-SA-100009) for screw hole preparation only.

NOTE: Self Drilling Screws will not pass through the Freehand Awl Guide.

TECHNIQUE 1 – GUIDED INSERTER TECHNIQUE

Inserter Assembly:

- Attach the Guided Inserter to the Quick Connect Handle. To attach the implant to the Guided Inserter, match the guide holes of the inserter up to the screw holes of the implant (Fig. 5). It is recommended to align the two hole side of the Guided Inserter first and then tighten the knob clockwise until the one-hole side of the Guided Inserter securely engages the implant. If the Guided Inserter is open wider than the inserter pockets of the corresponding implant, rotate the Guided Inserter knob counterclockwise prior to engaging with the implant.

Figure 5

Implant Insertion:

- Select the implant that corresponds to the appropriate sizer and attach it to the appropriate Guided Inserter.

NOTE: 10-12mm height implants will fit with the 10-12mm Guided Inserter. 14-20mm height implants will fit the 14-20mm Guided Inserter.

- Pack the implant with autologous and/or allogenic bone graft (Fig. 6). 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).

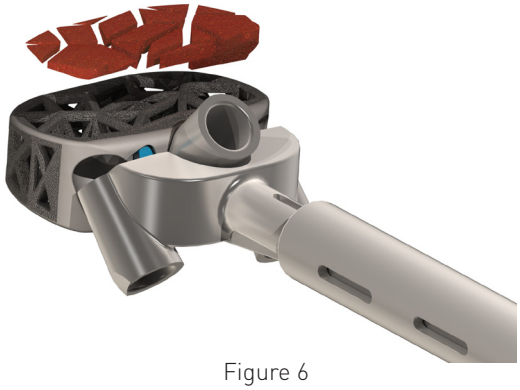


Figure 6

- Insert the implant into the disc space (Fig. 7 and 8). Use fluoroscopy to confirm proper position and placement of the implant.

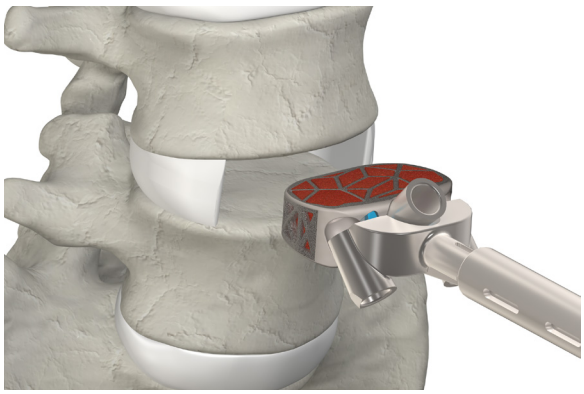


Figure 7

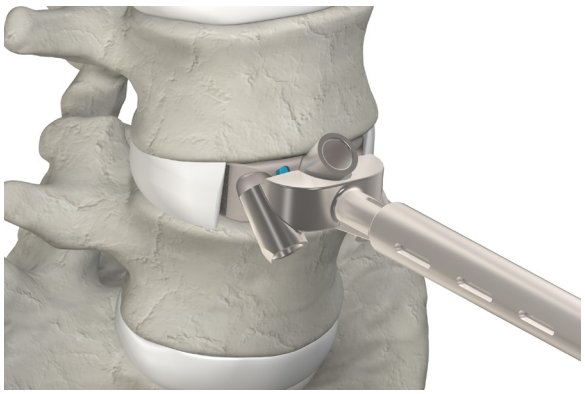


Figure 8

Screw Hole Preparation:

- It is recommended to use either the Straight Awl (ASTS-SA-100004) or Fixed Angle Awl (ASTS-SA-100005) with the Guided Inserters. The Straight Punch Awl (ASTS-SA-100006) and Angled Punch Awl (ASTS-SA-100007) are designed to be used independent of the Guided Inserters. Select the desired Awl and attach the Quick Connect Handle at the end of the instrument.

- Insert the distal end of an awl through the Guided Inserter and apply axial force to the handle to puncture the cortical bone of the vertebral body (Fig. 9).

- Repeat this step through all three guide holes in the inserter.

- Surgeon preference can be used to determine implant and screw orientation (2 up / 1 down or 1 up / 2 down). It is recommended that the same screw/implant orientation is used for multi-level procedures.

Note: The Straight and Angled Awl provide a maximum of 11.6mm of bone penetration when the awl is fully deployed through the Guided Inserter into the implant screw hole (Fig. 10).

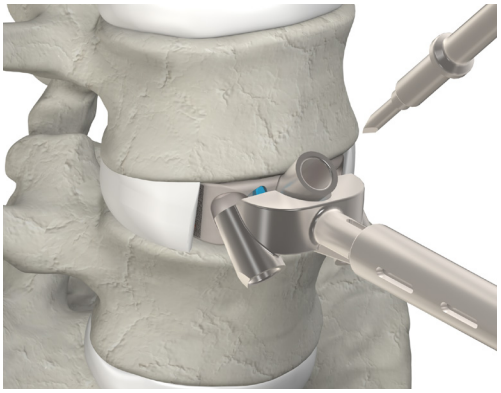


Figure 9

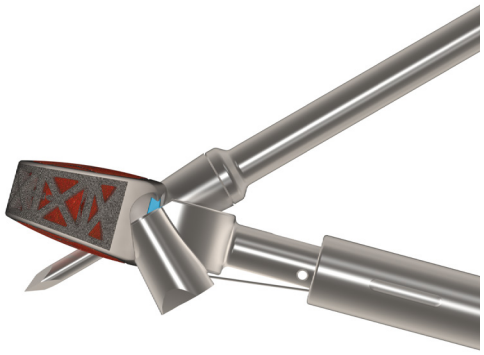


Figure 10

Screw Insertion:

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

- Depending on the angle and position of the implant, select the desired driver and attach the Ratcheting Handle or Quick Connect Handle to the proximal end of the instrument.

- Select the desired length screw and fix it to the distal end of the desired driver. 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 all three screws (Fig. 12).

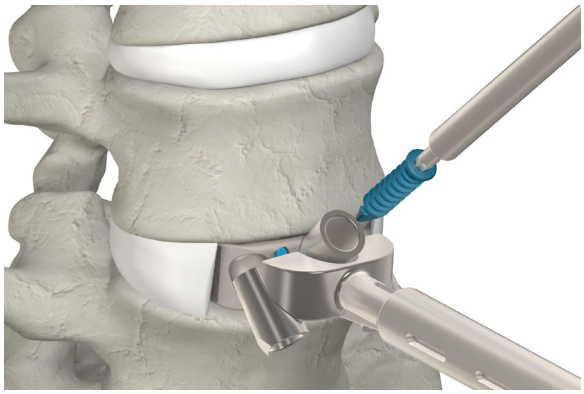


Figure 11

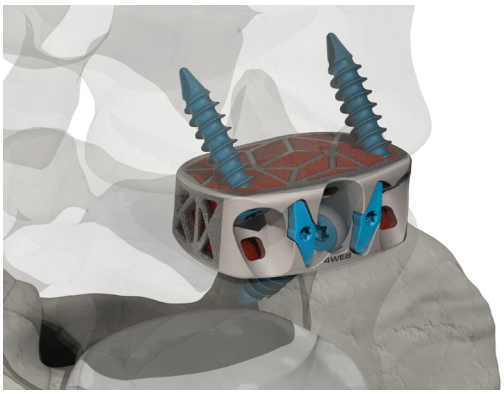


Figure 12

Locking the Anti-Backout Plates:

- Remove the Guided Inserter from the implant by twisting the knob counter clockwise to release the outer shaft.

- Use the Anti Back Out Plate Driver to rotate the two Locking Plates approximately 90° (Fig. 13). The wings of the Locking Plate will stop against the recess on the anterior face of the interbody (Fig. 14).

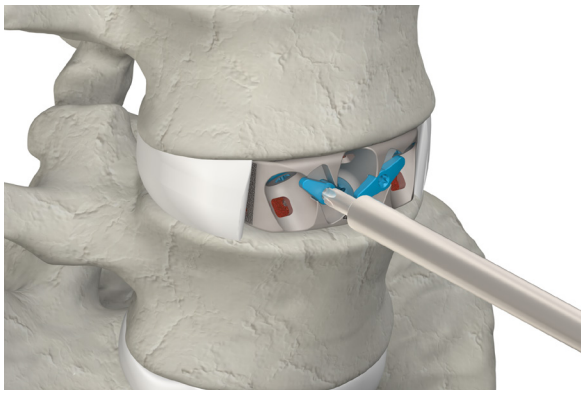


Figure 13

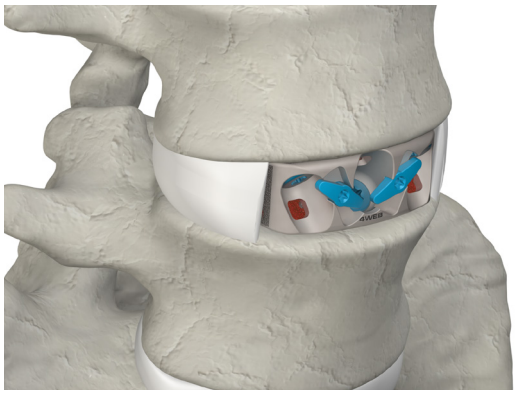


Figure 14

Final Implant Position:

- Inspect implant for correct position and assembly and confirm with fluoroscopy (Fig. 15).

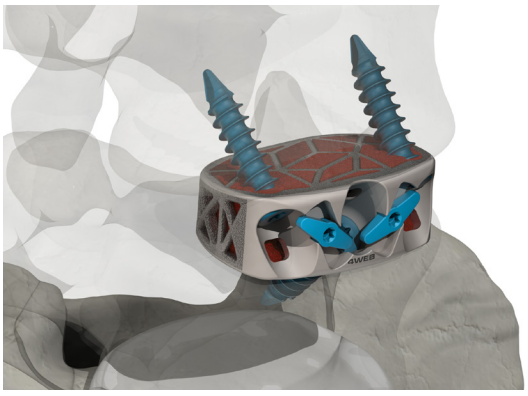


Figure 15

TECHNIQUE 2 – FREEHAND TECHNIQUE

Inserter Assembly:

- Attach the Freehand Inserter to the Quick Connect Handle (Fig. 16). To secure the Freehand Inserter to the implant turn the knob clockwise until a secure fit is achieved. If the prongs of the Freehand Inserter are open wider than the screw holes, rotate the knob counterclockwise prior to engaging with the implant.

Figure 16

Implant Insertion:

- Once the appropriate implant has been sized and selected, attach it to the inserter. For implant heights 8-12mm the Freehand Inserter engages through the screw holes. For implant heights 14-20mm the Freehand Inserter engages through the inserter cut outs.

- Pack the implant with autologous and/or allogenic bone graft (Fig. 17). 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).

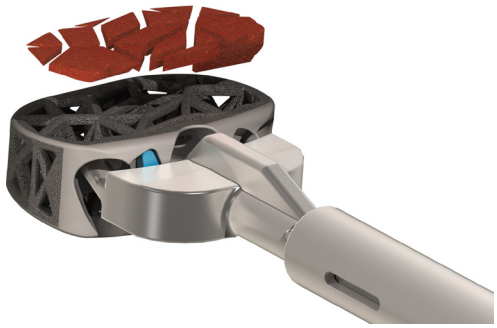


Figure 17

- Insert the implant into the disc space (Fig. 18 and 19). Use fluoroscopy to confirm proper position and placement of the implant.

- Remove the Freehand Inserter from the implant by twisting the knob counterclockwise to disengage the prongs from the implant.

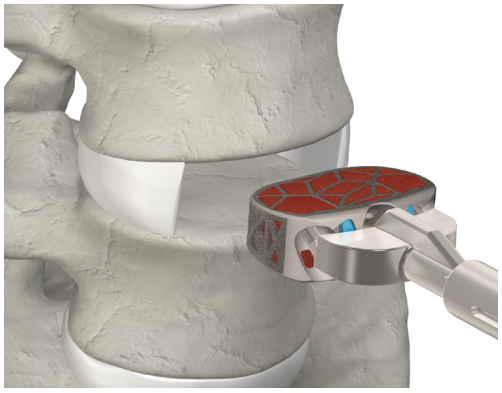


Figure 18

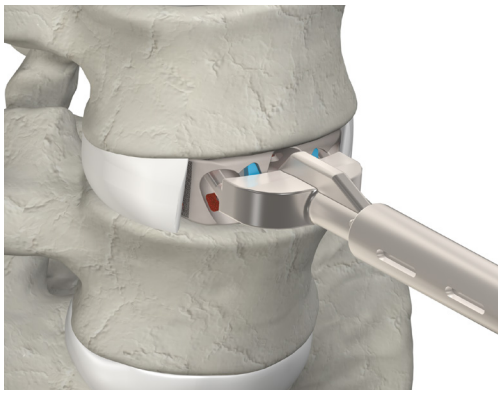


Figure 19

Implant Positioning:

- Additional implant positioning can be achieved using a tamp (Fig. 20). Two tamps are available in this system: ASTS-SA Tamp (ASTS-SA 100010) and ASTS-SA Guided Tamp (ASTS-SA100011).

ASTS-SA Tamp (ASTS-SA 10010)

ASTS-SA Guided Tamp (ASTS-SA 100011)

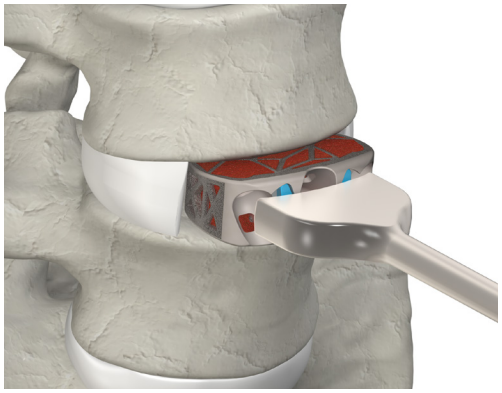


Figure 20

Screw Hole Preparation:

- The ASTS-SA System offers four awls: Straight Awl (ASTS-SA-100004), Fixed Angle Awl (ASTS-SA-100005), Straight Punch Awl (ASTS-SA-100006), and Angled Punch Awl (ASTS-SA-100007). Select the desired awl and attach the Quick Connect Handle 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. 21).

- Repeat this step through all three screw holes.

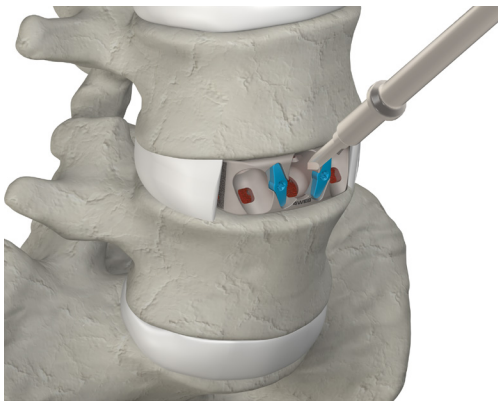


Figure 21

Note: The static awls provide a maximum of 11.6mm of bone penetration when the awl is fully deployed through the screw hole into the vertebral body. The punch awls provide a maximum of 11.6mm of bone penetration when the awl is fully deployed through the screw hole into the vertebral body.

Screw Insertion:

- The ASTS-SA System offers three drivers: ASTS-SA Straight Driver, Variable Angle Driver, Short 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 Ratcheting Handle or Quick Connect Handle to the proximal end of the instrument.

- Select the desired length screw and fix it to the distal end of the desired driver. Insert the screw through the screw hole on the implant (Fig. 22). Drive the screw until it is fully seated in the implant. Repeat this step for all three screws (Fig. 23).

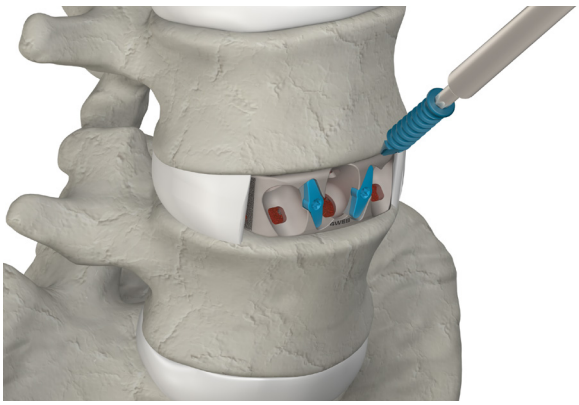


Figure 22

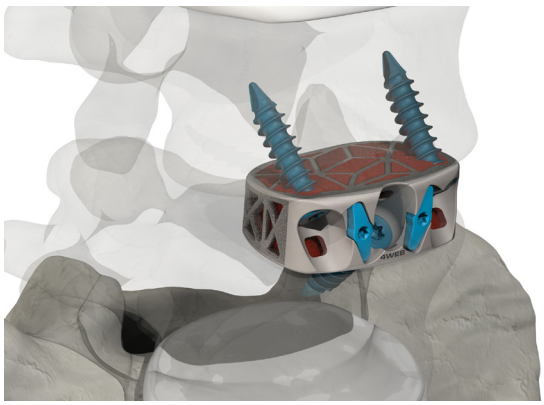


Figure 23

Locking the Anti-Backout Plates:

- Remove all instrumentation from the implant.
- Use the Anti Back Out Plate Driver to rotate the two Locking Plates approximately 90° (Fig. 24). The wings of the Locking Plate will stop against the recess on the anterior face of the implant (Fig. 25).

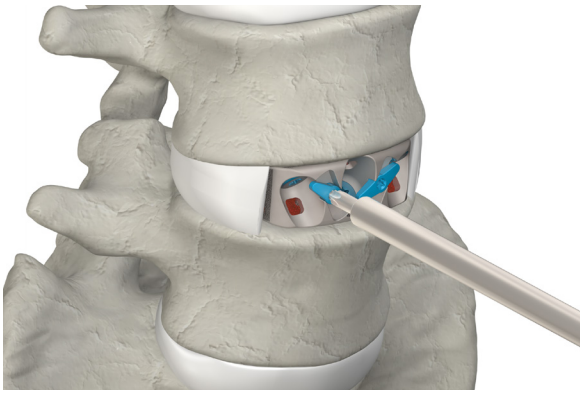


Figure 24

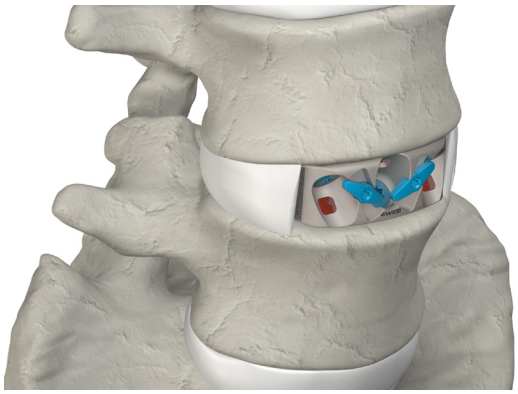


Figure 25

Final Implant Position:

- Inspect implant for correct position and assembly and confirm with fluoroscopy (Fig. 26).

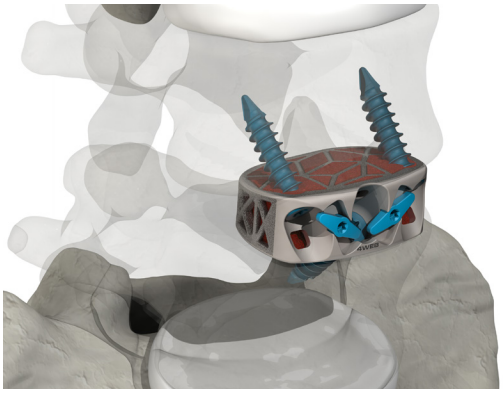


Figure 26

TECHNIQUE 3 - FREEHAND INSERTION AND GUIDED SCREW PREPARATION & INSERTION TECHNIQUE

Inserter Assembly:

- Attach the Freehand Inserter to the Quick Connect Handle (Fig. 27). To secure the Freehand Inserter to the implant turn the knob clockwise until a secure fit is achieved. If the prongs of the Freehand Inserter are open wider than the screw holes, rotate the knob counterclockwise prior to engaging with the implant.

Figure 27

Implant Insertion:

- Once the appropriate implant has been sized and selected, attach it to the inserter. For implant heights 8-12mm the Freehand Inserter engages through the screw holes. For implant heights 14-20mm the Freehand Inserter engages through the inserter cut outs.

- Pack the implant with autologous and/or allogenic bone graft (Fig. 28). 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).

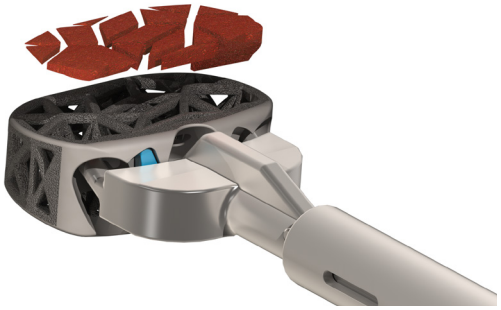


Figure 28

- Insert the implant into the disc space (Fig. 29 and 30). Use fluoroscopy to confirm proper position and placement of the implant.

- Remove the Freehand Inserter from the implant by twisting the knob counterclockwise to disengage the prongs from the implant.

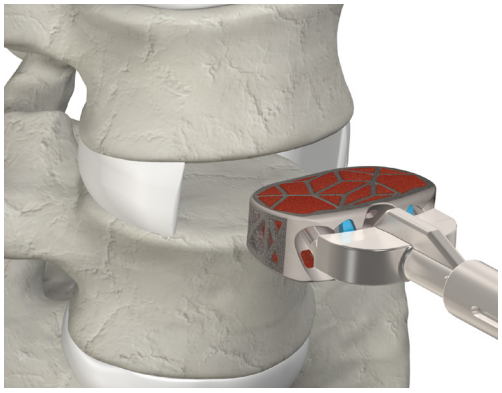


Figure 29

Implant Positioning:

- Additional implant positioning can be achieved using a tamp (Fig. 31). Two tamps are available in this system: ASTS-SA Tamp (ASTS-SA 100010) and ASTS-SA Guided Tamp (ASTS-SA100011).

ASTS-SA Tamp (ASTS-SA 10010)

ASTS-SA Guided Tamp (ASTS-SA 100011)

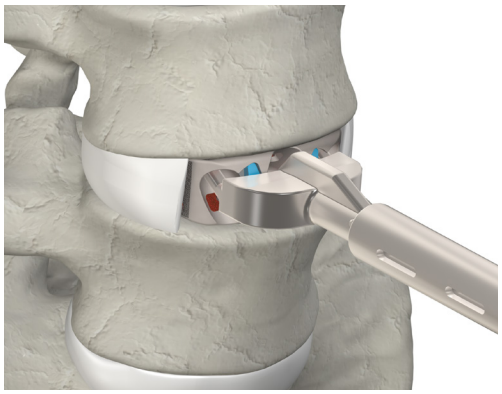


Figure 30

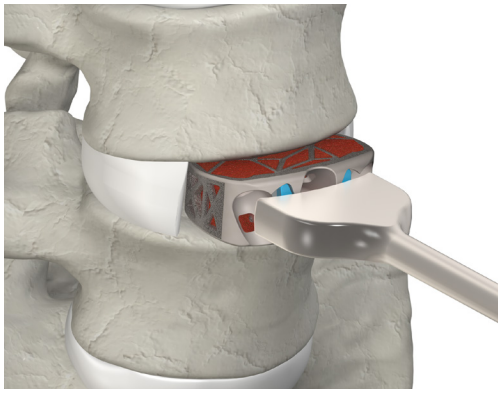


Figure 31

Screw Hole Preparation - Guided:

- The ASTS-SA System offers two free hand guides: Freehand Guide (ASTS-SA-100008) and Freehand Awl Guide (ASTS-SA-100009). The Freehand Guide allows for guidance of both the static awls and screws, whereas, the Freehand Awl Guide only allows for guidance of the static awls. Select the desired Freehand Guide and attach the Handle at the end of the instrument.

- It is recommended to use either the Straight Awl (ASTS-SA-100004) or Fixed Angle Awl (ASTS-SA-100005) with the Freehand Guides. The Straight Punch Awl (ASTS-SA-100006) and Angled Punch Awl (ASTS-SA-100007) are designed to be used independent of the guides. Select the desired awl and attach the Quick Connect Handle at the end of the instrument.

- Insert the desired Freehand Guide into the screw hole of the implant. Insert the distal end of the awl through the Freehand Guide and apply axial force to the handle to puncture the cortical bone of the vertebral body (Fig. 32).

- Repeat this step through all three screw holes.

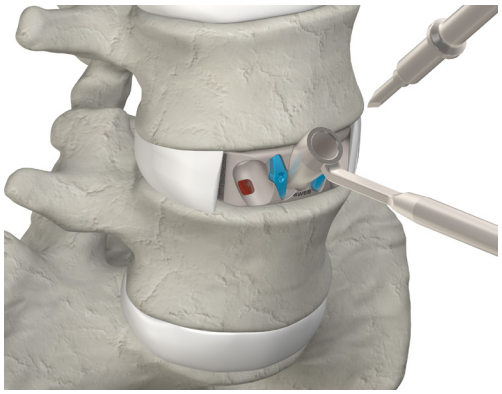


Figure 32

Note: The static awls provide a maximum of 11.6mm of bone penetration when the awl is fully deployed through the Freehand Guide (Fig. 33).

Figure 33

Screw Insertion - Guided:

- The ASTS-SA System offers three drivers: ASTS-SA Straight Driver, Variable Angle Driver, Short Variable Angle Driver. The Straight Driver and Variable Angle Driver are designed to be used with the Freehand Guide and the Short Variable Angle Driver is designed to be used independent of any guides. All drivers have a self-retaining screw feature.

- Depending on the angle and position of the implant, select the desired driver and attach the Ratcheting Handle or Quick Connect Handle to the proximal end of the instrument.

- Select the desired length screw and fix it to the distal end of the driver. Insert the screw through the Freehand Guide into the screw hole of the implant (Fig. 34). Drive the screw until it is fully seated in the implant. Repeat this step for all three screws (Fig. 35).

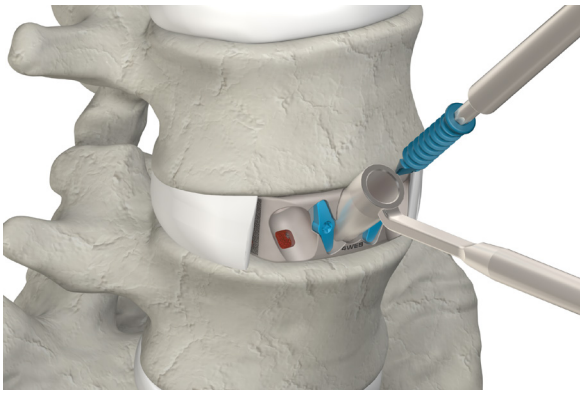


Figure 34

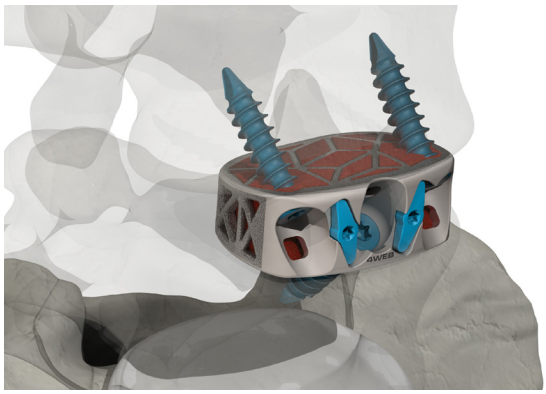


Figure 35

Note: The Freehand Awl Guide does not allow for guided placement of the screw. If using the Freehand Awl Guide, it will have to be removed from the implant for screw placement.

Locking the Anti-Backout Plates:

- Remove all instrumentation from the implant.
- Use the Anti Back Out Plate Driver to rotate the two Locking Plates approximately 90° (Fig. 36). The wings of the Locking Plate will stop against the recess on the anterior face of the implant (Fig. 37).

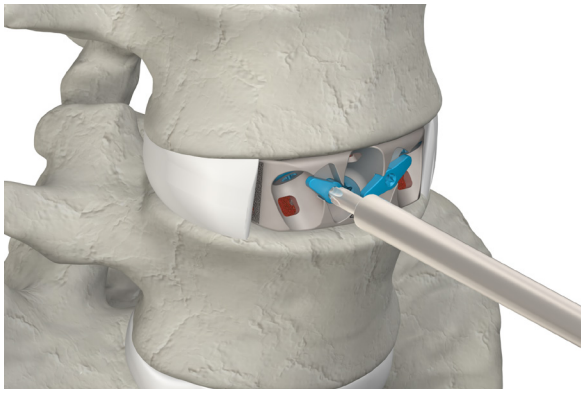


Figure 36

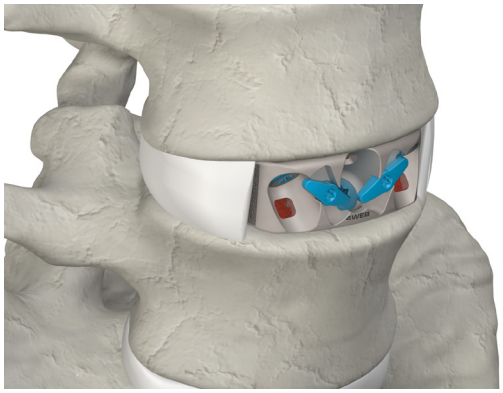


Figure 37

Final Implant Position:

- Inspect implant for correct position and assembly and confirm with fluoroscopy (Fig. 38).

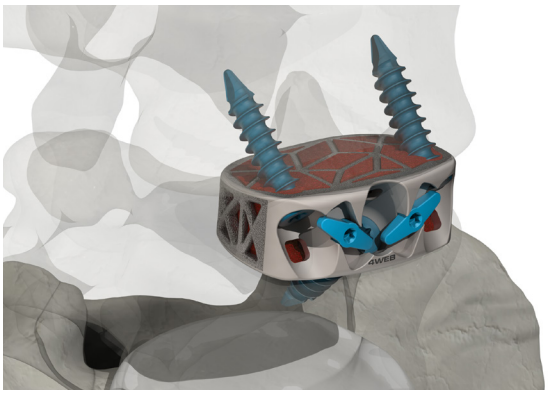


Figure 38

Implant Removal/Revision:

- If implant removal is necessary, rotate the Locking Plates to an unlocked position until the screws are no longer retained (Fig. 39). Remove the screws using the screw driver.

- If implant removal is required, the intervertebral space should be distracted in the same manner as for implant placement. The implant should be disengaged from the superior and inferior endplates with the surgeon's preferred technique.

- Once distracted the implant may be removed by using either the inserter (Fig. 40). If necessary, the Slap Hammer can be attached to the inserter for additional removal force.

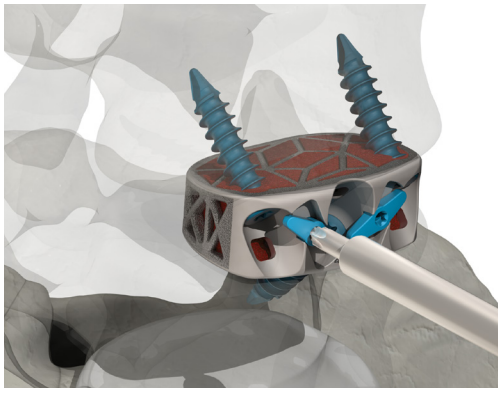


Figure 39

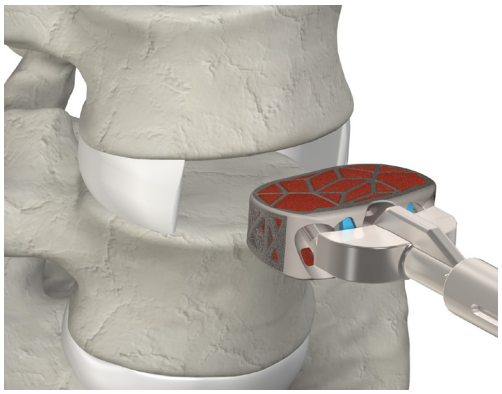


Figure 40

INSTRUMENT CATALOG

PART NUMBER	DESCRIPTION
ASTS-SA-100001	ASTS-SA STRAIGHT DRIVER

ASTS-SA-100002	ASTS-SA VARIABLE ANGLE DRIVER

ASTS-SA-100003	ASTS-SA SHORT VARIABLE ANGLE DRIVER

ASTS-SA-100020	ASTS-SA ANTI BACK OUT PLATE DRIVER

ASTS-SA-100004	ASTS-SA STRAIGHT AWL

PART NUMBER	DESCRIPTION
ASTS-SA-100005	ASTS-SA FIXED ANGLE AWL

ASTS-SA-100006	ASTS-SA STRAIGHT PUNCH AWL

ASTS-SA-100007	ASTS-SA ANGLED PUNCH AWL

ASTS-SA-100008	ASTS-SA FREEHAND GUIDE

ASTS-SA-100009	ASTS-SA FREEHAND AWL GUIDE

PART NUMBER	DESCRIPTION
ASTS-SA-100010	ASTS-SA TAMP

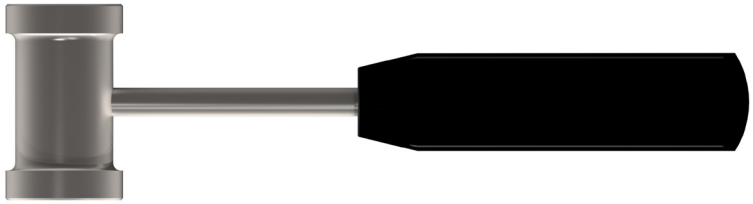
ASTS-SA-100011	ASTS-SA GUIDED TAMP

ASTS-SA-100012	ASTS-SA 10-12MM GUIDED INSERTER

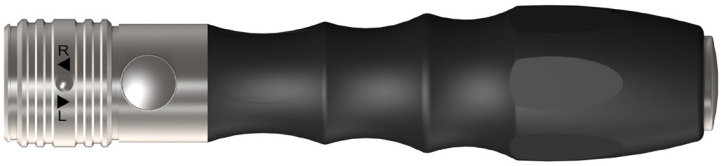
ASTS-SA-100013	ASTS-SA 14-20MM GUIDED INSERTER

ASTS-SA-100014	ASTS-SA FREEHAND INSERTER

PART NUMBER	DESCRIPTION
761-9028-0	ASTS-SA MALLET



ASTS-SA-100018	ASTS-SA RATCHETING HANDLE



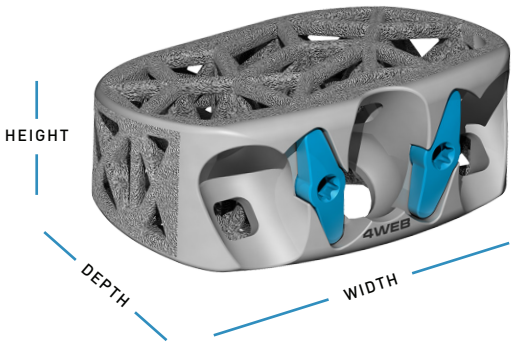
PSTS-000008	STRAIGHT INSERTER

4WEB-000003	SLAP HAMMER

PSTS-000013	SILICONE STRAIGHT HANDLE WITH IMPACTOR

IMPLANT CATALOG

INTERBODY DEVICES



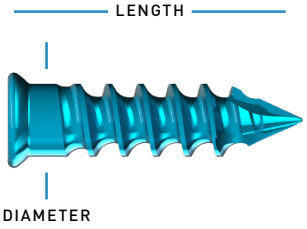
CATALOG NUMBER	FOOTPRINT W x D x H	LORDOSIS	GRAFT VOLUME (CC)	ANTERIOR HEIGHT (MM)	POSTERIOR HEIGHT (MM)
ASTS-SA-SM0608-SP	21 x 34 x 8mm	6°	1.67	8.0	6.4
ASTS-SA-SM0610-SP	21 x 34 x 10mm	6°	2.42	10.0	8.4
ASTS-SA-SM0612-SP	21 x 34 x 12mm	6°	3.23	12.0	10.4
ASTS-SA-SM0614-SP	21 x 34 x 14mm	6°	4.08	14.0	12.4
ASTS-SA-SM0616-SP	21 x 34 x 16mm	6°	4.94	16.0	14.4
ASTS-SA-MD0608-SP	24 x 36 x 8mm	6°	2.43	8.0	6.0
ASTS-SA-MD0610-SP	24 x 36 x 10mm	6°	3.42	10.0	8.0
ASTS-SA-MD0612-SP	24 x 36 x 12mm	6°	4.46	12.0	10.0
ASTS-SA-MD0614-SP	24 x 36 x 14mm	6°	5.59	14.0	12.0
ASTS-SA-MD0616-SP	24 x 36 x 16mm	6°	6.70	16.0	14.0
ASTS-SA-LG0608-SP	27 x 40 x 8mm	6°	3.55	8.0	5.5
ASTS-SA-LG0610-SP	27 x 40 x 10mm	6°	4.96	10.0	7.5
ASTS-SA-LG0612-SP	27 x 40 x 12mm	6°	6.39	12.0	9.5
ASTS-SA-LG0614-SP	27 x 40 x 14mm	6°	8.01	14.0	11.5
ASTS-SA-LG0616-SP	27 x 40 x 16mm	6°	9.58	16.0	13.5
ASTS-SA-SM1208-SP	21 x 34 x 8mm	12°	1.28	8.0	4.6
ASTS-SA-SM1210-SP	21 x 34 x 10mm	12°	2.03	10.0	6.6
ASTS-SA-SM1212-SP	21 x 34 x 12mm	12°	2.82	12.0	8.6

CATALOG NUMBER	FOOTPRINT W x D x H	LORDOSIS	GRAFT VOLUME (CC)	ANTERIOR HEIGHT (MM)	POSTERIOR HEIGHT (MM)
ASTS-SA-SM1214-SP	21 x 34 x 14mm	12°	3.67	14.0	10.6
ASTS-SA-SM1216-SP	21 x 34 x 16mm	12°	4.52	16.0	12.6
ASTS-SA-MD1208-SP	24 x 36 x 8mm	12°	1.76	8.0	3.9
ASTS-SA-MD1210-SP	24 x 36 x 10mm	12°	2.81	10.0	5.9
ASTS-SA-MD1212-SP	24 x 36 x 12mm	12°	3.81	12.0	7.9
ASTS-SA-MD1214-SP	24 x 36 x 14mm	12°	4.95	14.0	9.9
ASTS-SA-MD1216-SP	24 x 36 x 16mm	12°	6.06	16.0	11.9
ASTS-SA-LG1208-SP	27 x 40 x 8mm	12°	2.44	8.0	3.0
ASTS-SA-LG1210-SP	27 x 40 x 10mm	12°	3.94	10.0	5.0
ASTS-SA-LG1212-SP	27 x 40 x 12mm	12°	5.38	12.0	7.0
ASTS-SA-LG1214-SP	27 x 40 x 14mm	12°	6.93	14.0	9.0
ASTS-SA-LG1216-SP	27 x 40 x 16mm	12°	8.50	16.0	11.0
ASTS-SA-SM1610-SP	21 x 34 x 10mm	16°	1.79	10.0	5.5
ASTS-SA-SM1612-SP	21 x 34 x 12mm	16°	2.56	12.0	7.5
ASTS-SA-SM1614-SP	21 x 34 x 14mm	16°	3.42	14.0	9.5
ASTS-SA-SM1616-SP	21 x 34 x 16mm	16°	4.27	16.0	11.5
ASTS-SA-MD1610-SP	24 x 36 x 10mm	16°	2.41	10.0	4.6
ASTS-SA-MD1612-SP	24 x 36 x 12mm	16°	3.46	12.0	6.6
ASTS-SA-MD1614-SP	24 x 36 x 14mm	16°	4.55	14.0	8.6
ASTS-SA-MD1616-SP	24 x 36 x 16mm	16°	5.66	16.0	10.6
ASTS-SA-LG1610-SP	27 x 40 x 10mm	16°	3.29	10.0	3.4
ASTS-SA-LG1612-SP	27 x 40 x 12mm	16°	4.75	12.0	5.4
ASTS-SA-LG1614-SP	27 x 40 x 14mm	16°	6.28	14.0	7.4
ASTS-SA-LG1616-SP	27 x 40 x 16mm	16°	7.84	16.0	9.4

CATALOG NUMBER	FOOTPRINT W x D x H	LORDOSIS	GRAFT VOLUME (CC)	ANTERIOR HEIGHT (MM)	POSTERIOR HEIGHT (MM)
ASTS-SA-SM2012-SP	21 x 34 x 12mm	20°	3.21	12.0	8.5
ASTS-SA-SM2014-SP	21 x 34 x 14mm	20°	4.06	14.0	10.5
ASTS-SA-SM2016-SP	21 x 34 x 16mm	20°	4.91	16.0	12.5
ASTS-SA-SM2018-SP	21 x 34 x 18mm	20°	5.79	18.0	14.5
ASTS-SA-MD2012-SP	24 x 36 x 12mm	20°	3.11	12.0	5.3
ASTS-SA-MD2014-SP	24 x 36 x 14mm	20°	4.21	14.0	7.3
ASTS-SA-MD2016-SP	24 x 36 x 16mm	20°	5.29	16.0	9.3
ASTS-SA-MD2018-SP	24 x 36 x 18mm	20°	6.42	18.0	11.3
ASTS-SA-LG2012-SP	27 x 40 x 12mm	20°	4.15	12.0	3.8
ASTS-SA-LG2014-SP	27 x 40 x 14mm	20°	5.70	14.0	5.8
ASTS-SA-LG2016-SP	27 x 40 x 16mm	20°	7.24	16.0	7.8
ASTS-SA-LG2018-SP	27 x 40 x 18mm	20°	8.83	18.0	9.8
ASTS-SA-SM2414-SP	21 x 34 x 14mm	24°	3.00	14.0	7.4
ASTS-SA-SM2416-SP	21 x 34 x 16mm	24°	3.65	16.0	9.4
ASTS-SA-SM2418-SP	21 x 34 x 18mm	24°	4.30	18.0	11.4
ASTS-SA-SM2420-SP	21 x 34 x 20mm	24°	4.97	20.0	13.4
ASTS-SA-MD2414-SP	24 x 36 x 14mm	24°	3.87	14.0	6.0
ASTS-SA-MD2416-SP	24 x 36 x 16mm	24°	4.75	16.0	8.0
ASTS-SA-MD2418-SP	24 x 36 x 18mm	24°	5.64	18.0	10.0
ASTS-SA-MD2420-SP	24 x 36 x 20mm	24°	6.54	20.0	12.0
ASTS-SA-LG2414-SP	27 x 40 x 14mm	24°	5.28	14.0	4.1
ASTS-SA-LG2416-SP	27 x 40 x 16mm	24°	6.55	16.0	6.1
ASTS-SA-LG2418-SP	27 x 40 x 18mm	24°	7.82	18.0	8.1
ASTS-SA-LG2420-SP	27 x 40 x 20mm	24°	9.12	20.0	10.1

IMPLANT CATALOG

SCREWS

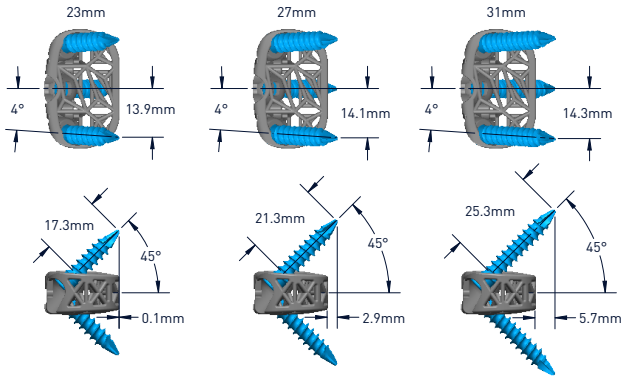


CATALOG NUMBER	DIAMETER, LENGTH
ASCR-5023-SD-SP	ø5.0mm, L 23mm
ASCR-5027-SD-SP	ø5.0mm, L 27mm
ASCR-5031-SD-SP	ø5.0mm, L 31mm
ASCR-5523-SD-SP	ø5.5mm, L 23mm
ASCR-5527-SD-SP	ø5.5mm, L 27mm
ASCR-5531-SD-SP	ø5.5mm, L 31mm

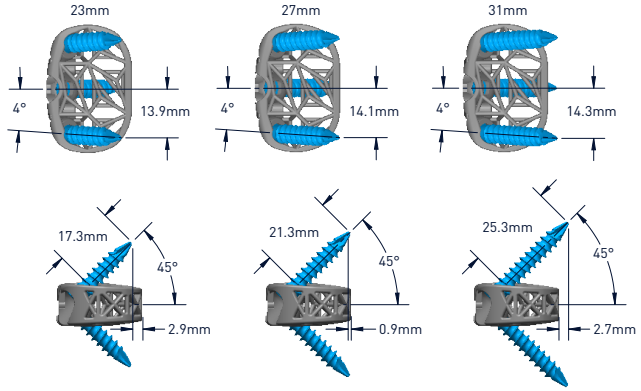
SCREW ANGULATION CHART

NOMINAL SCREW ANGULATION

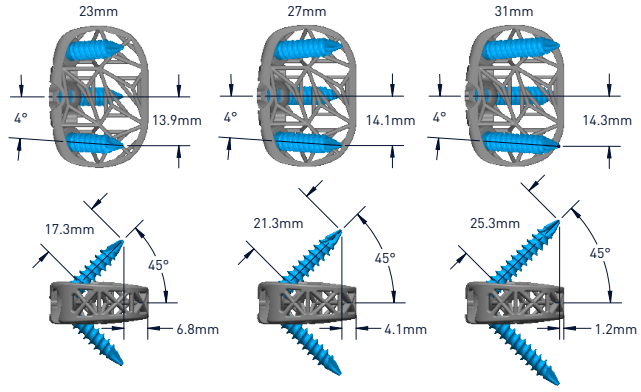
SMALL FOOTPRINT 21 x 34mm



MEDIUM FOOTPRINT 24 x 36mm

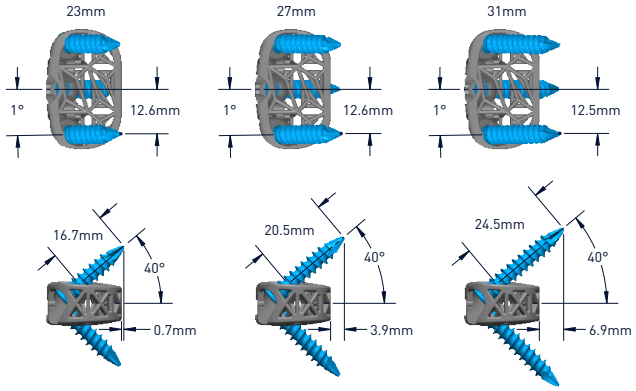


LARGE FOOTPRINT 27 x 40mm

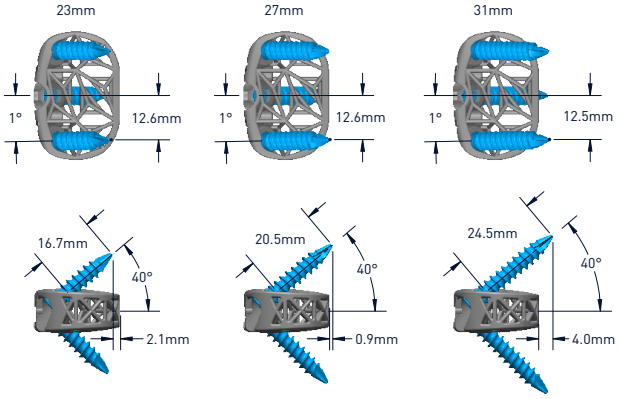


NOMINAL SCREW ANGULATION -5° SCREW VARIABILITY

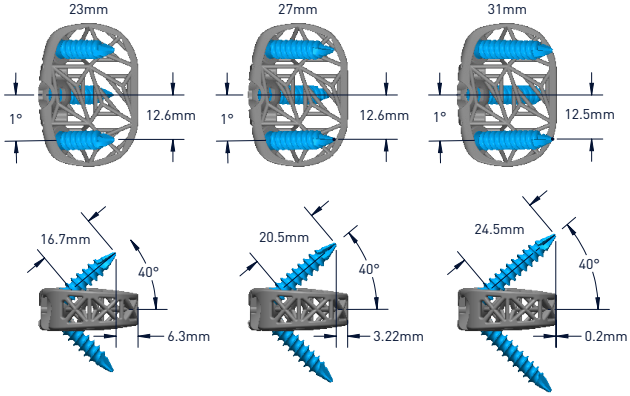
SMALL FOOTPRINT 21 x 34mm



MEDIUM FOOTPRINT 24 x 36mm

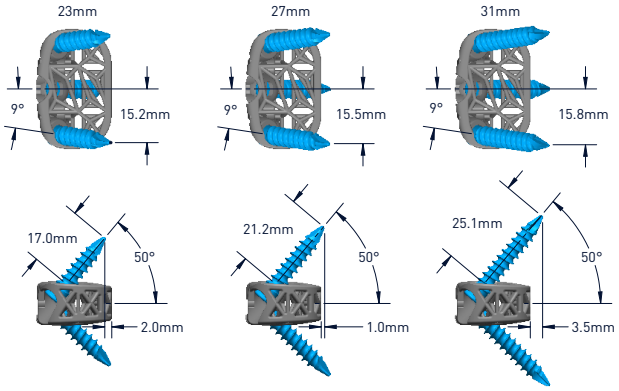


LARGE FOOTPRINT 27 x 40mm

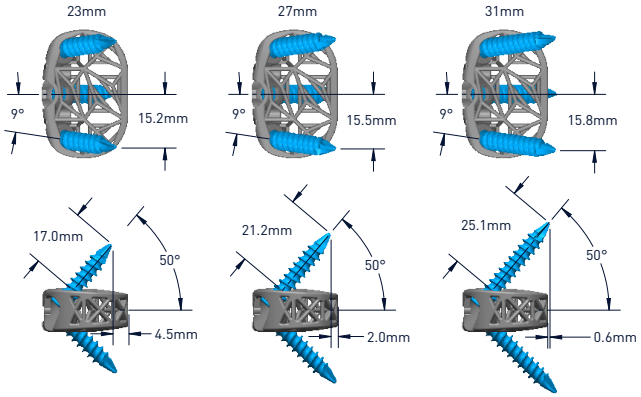


NOMINAL SCREW ANGULATION +5° SCREW VARIABILITY

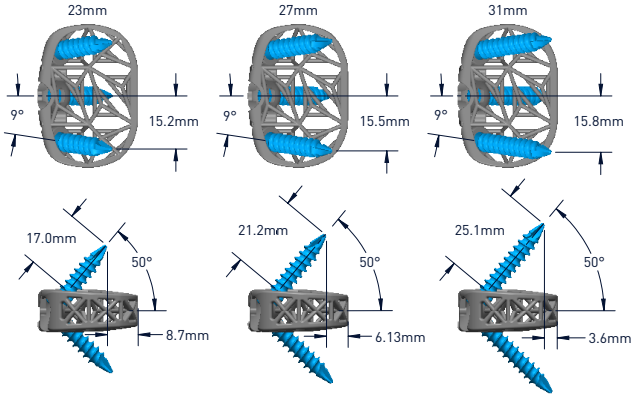
SMALL FOOTPRINT 21 x 34mm



MEDIUM FOOTPRINT 24 x 36mm



LARGE FOOTPRINT 27 x 40mm



ANTERIOR SPINE TRUSS SYSTEM - STAND ALONE (ASTS-SA) INTERBODY FUSION DEVICE

INSTRUCTIONS FOR USE

PLEASE READ CAREFULLY

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALES BY OR ON THE ORDER OF A PHYSICIAN.

INTENDED USE:
The Anterior Spine Truss System - Stand Alone (ASTS-SA) Interbody Fusion Device is designed to provide mechanical support to the lumbar spine while biologic fusion takes place.

DEVICE DESCRIPTION:
The device is an open architecture truss design mathematically formulated to provide structural support with open space throughout the implant for bone growth and fusion. The 4WEB additive manufacturing process provides a hierarchical surface roughness. The implant is made from Ti6Al4V alloy. The device is available in a variety of sizes and lordotic angles to accommodate the patient's anatomy. Screws are inserted through the anterior portion of the implant into adjacent vertebral bodies for bony fixation.

INDICATIONS FOR USE:
The Anterior Spine Truss System – Stand Alone (ASTS-SA) Interbody Fusion Device is a stand-alone interbody fusion device indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the lumbosacral spine at one or two contiguous disc levels. Each interbody fusion device is intended to be used with three titanium alloy screws which accompany the implant. Hyperlordotic implants (>20° lordosis) are intended to be used with supplemental fixation (e.g. posterior fixation). DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. ASTS-SA Interbody Fusion Devices are used as an adjunct to fusion in the lumbosacral spine and are placed via an anterior approach at the L2 to S1 disc levels using autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

CONTRAINDICATIONS:
The ASTS-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:
Safety and effectiveness have not been established in the following conditions:
- Gross obesity
- Smoking
- Three or more levels to be fused
- Symptomatic cardiac disease
- Pregnancy
- Previous fusion attempts at the involved level(s)
- Spondylolisthesis or retrolisthesis greater than Grade I
- Significant loss of bone stock as seen with osteoporosis or osteomalacia
- Conditions requiring chronic corticosteroid use
- Active drug abuse

The ASTS-SA Interbody Fusion Device is for single use only.

Bending or fracture of the implants or instruments can occur if not handled properly.

All sizers and instrumentation are provided non-sterile and must be steam sterilized prior to use.

No implant should be reused if it has come in contact with blood or other bodily fluids.

All implants, sizers and instrumentation should be inspected prior to use for possible damage or defects. Any damaged or defective component should not be used and should be returned to 4WEB.

Interbody fusion devices are intended to provide mechanical support while biologic fusion occurs. In the event of pseudoarthrosis or delayed fusion, the risk of implant migration, loosening or breakage increases. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

Only surgeons trained in lumbar spine fusion procedures should implant this device.

OPERATIVE PRECAUTIONS:
The surgeon is to be thoroughly familiar with the ASTS-SA Interbody Fusion Device, methods of application, instruments and surgical technique. The ASTS-SA Interbody Fusion Device should be implanted singly. Correct positioning of the ASTS-SA Interbody Fusion Device relative to the vertebrae should be checked intraoperatively with x-ray. The size (and more particularly the height) of the ASTS-SA Interbody Fusion Device must be chosen on the basis of the patient's anatomy and desired correction. Implantation of the ASTS-SA Interbody Fusion Device is intended to be used with three titanium alloy screws which accompany the device.

Each ASTS-SA Interbody Fusion Device is to be filled with autologous and/or allograft bone to promote bone fusion (See Surgical Technique Manual for complete details). The implants are for single-implant use only. An explanted implant must never be re-implanted. Stresses and fracture, even though not noticeable by visual inspection, may have been created during initial implantation.

Following implantation, the product number and manufacturing lot number of the device that has been implanted must be reported in the patient's surgical file.

POTENTIAL ADVERSE EVENTS:
Potential adverse events may be related to surgery in general, spine surgery specifically or the device. These may include, but are not limited to the following:
- Adverse events related to any surgery: reactions to anesthesia, the anesthetic or other medications; bleeding; infection; ileus; blood vessel damage; nerve or soft tissue damage; atelectasis; pneumonia; hematoma; seroma; wound dehiscence or incisional hernia; urologic problems; embolism; anemia; colitis; thrombophlebitis; heart attack; stroke; or death.
- Adverse events related specifically to spine surgery: dural tear and CSF leak; nerve damage leading to radiculopathy, myelopathy, paraparesis, paresthesia or paralysis; meningitis; vertebral body damage or fracture; ligament damage; fractured sacrum; or retrograde ejaculation.
- Adverse events related to the device: implant crack or fracture, failure to achieve fusion, implant migration, dislodgement, or metal sensitivity to a foreign body, including possible tumor formation. Additional surgery may be necessary for implant removal, repositioning or replacement. Additional stabilization at the implanted level or surgery at another disc level may be necessary if non-union or anatomic change at an adjacent level develops.

POSTOPERATIVE CARE:
The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
- Detailed instructions on the use and limitations of the device must be given to the patient. The patient must be warned that loosening, and / or breakage of the device(s) are complications which may occur as result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine.
- The patient must be advised not to smoke or consume alcohol during period of the bone fusion process.
- The patient must be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- It is critical that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and / or break, the devices must be revised and / or removed immediately before serious injury occurs.
- Any retrieved devices are not to be used in another surgical procedure.

MRI SAFETY INFORMATION:
Non-clinical testing has demonstrated the ASTS-SA Interbody Fusion Device is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:
- Static magnetic field of 3 T or 1.5 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤ 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, non-clinical testing results indicate the ASTS-SA Interbody Fusion Device produces a maximum temperature rise of no more than 5.0°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 28 mm from the ASTS-SA Interbody Fusion Device when imaged with a gradient echo pulse sequence and a 3 T MR system.

PACKAGING:
ASTS-SA Interbody Fusion Device is provided sterile and is clearly labeled as such in an unopened sterile package provided by 4WEB. The contents are considered sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised.

Implants supplied sterilized from 4WEB must not be re-sterilized.

ASTS-SA ancillary instrumentation is provided non-sterile and is supplied in a tray that is used for steam sterilization prior to use in the operating room. In the case of instrument restock, individual items will be sent in a plastic bag, labeled for that device.

Storage conditions must maintain the integrity of the implants, associated ancillary instruments and their respective packaging. The condition of all implants and instruments must be checked before use. Damaged products must not be used and should be returned to 4WEB.

INFORMATION FOR CLEANING AND STERILIZATION OF SURGICAL INSTRUMENTS:

CAUTION: THESE INSTRUCTIONS DO NOT APPLY TO SINGLE-USE DEVICES.

The instruments used to implant the ASTS-SA Interbody Fusion Device do not have an indefinite functional life. All reusable instruments are subjected to repeated stresses related to bone contact, impaction, routing, cleaning, and sterilization processes. Instruments should be carefully inspected before use to ensure that they are fully functional.

All ancillary instruments of the ASTS-SA Interbody Fusion Device are delivered non-sterile and therefore, must be decontaminated, cleaned and sterilized prior to surgical use. Decontamination reduces the population of microorganisms and facilitates the subsequent cleaning stage. Strict compliance with the instructions for use pertaining to decontamination and cleaning is mandatory, particularly the concentration and exposure time requirements. Thorough rinsing with water must be conducted following decontamination and cleaning.

- Decontamination: Each hospital must use their own validated decontamination procedures.
- Cleaning: Wash instruments in a LANCER type (or equivalent) washing machine with the appropriate cleaning products, rinse, and dry. Any product which may alter the material is prohibited, i.e. bleach, formalin, hypochlorite solutions, saline solution, etc.

The reprocessing instructions provided have been validated as being capable of preparing reusable 4WEB instruments. It is the responsibility of the reprocessor to ensure that the reprocessing is actually performed using appropriate equipment, materials, and personnel to achieve the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the reprocessor from these instructions should be evaluated for effectiveness and potential adverse consequences.

WARNINGS:
- Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents and equipment used.
- Do not exceed 140° C (284° F) during reprocessing steps.
- Highly alkaline conditions can damage products with aluminum parts.
- Avoid exposure to hypochlorite solutions, as these will promote corrosion.
- Scratches or dents can result in breakage.
- For instruments produced by another manufacturer, reference the manufacturer's instructions for use.
- Care should be taken to remove any debris, tissue or bone fragments that may collect on the instrument.

LIMITATIONS ON REPROCESSING:
- End of useful life is generally determined by wear or damage in surgical use.
- Carefully inspect instruments between uses to verify proper functioning and configuration.
- Damaged instruments must be replaced to prevent potential patient injury such as loss of metal fragments into the surgical site.

DECONTAMINATION CONSIDERATIONS — CREUTZFELDT-JAKOB DISEASE (CJD):
- Under certain classifications of risk, the World Health Organization (WHO) or local regulatory authorities recommend special CJD (Creutzfeldt-Jakob Disease) inactivation processing procedures. For use of this product outside the United States, consult WHO and local regulations for further information.

REPROCESSING INSTRUCTIONS
CARE AT THE POINT OF USE:
- Use purified water obtained via ultra-filtration, RO, DI and/or distilled.
- Thoroughly clean instruments as soon as possible after use. If cleaning must be delayed, immerse instruments in a compatible pH neutral detergent solution and purified water to prevent drying and encrustation of surgical soil.
- Avoid prolonged exposure to saline to minimize the chance of corrosion.
- Remove excessive soil with a low lint disposable wipe.

CLEANING:
ALL INSTRUMENTS
- No instruments provided with the ASTS-SA Interbody Fusion Device require disassembly prior to cleaning.
- Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions (1oz Enzol, or equivalent, per gallon of purified water). **Note:** the enzyme solution must be changed on a regular basis.
- Soak soiled instruments for 5 minutes in the enzymatic solution.
- Use a soft bristle brush to remove all traces of blood and debris; pay close attention to any hard- to-reach areas, textured surfaces, or crevices.
- Rinse the instrument thoroughly with purified water.
- Dry the instrument immediately after final rinse.
- Clean using the "INSTRUMENTS" cycle in a validated washer disinfector and a pH neutral cleaning agent intended for use in automated cleaning. The cleaning cycle should incorporate enzymatic pre-wash, wash, rinse, thermal rinse, and drying steps.
- Place heavier instruments on the bottom of containers. Do not place heavy instruments on top of delicate instruments.
- For instruments with concave surfaces, such as curettes, place instrument with the concave surface facing downward to facilitate draining.

CLEANING INSPECTION:
- Inspect all instruments to verify that all visible debris is removed during cleaning and prior to sterilization. If debris is still visible after cleaning, repeat the cleaning process.

MAINTENANCE INSPECTION AND FUNCTIONAL TESTING:
- Visually inspect all instruments to ensure no damage and wear.
- Ensure there are no cracked handles and shafts are secure in handles.
- Ensure long instruments are free of any bending and distortion.
- Ensure instrument tips are free of defects or burrs.
- Ensure complex instruments with moving parts function appropriately.

WRAPPING:
WRAPPING TECHNIQUE
- Use instrument trays to contain instruments that are provided in sets.
- Biological or Chemical Indicators (BIs or CIs) used for monitoring the performance of sterilization processes should be placed in the middle racks within wrapped trays. They should be tested according to the BI or CI manufacturer's directions.
- Double wrap instruments in accordance with local procedures, using standard wrapping techniques such as those described in ANSI/AAMI ST79.
- Use only FDA-cleared wraps.
- Label the contents of the wrapped tray using an indelible marker or other sterilization compatible label system.
- Allow 1 inch of free space between the instrument tray and the inside of the container lid for effective processing.

STERILIZATION:
- Use a validated, properly maintained and calibrated steam sterilizer.
- Effective steam sterilization can be achieved using the following cycle to achieve an SAL of 10^{-6}.

Cycle	Temperature	Duration	Dry Time
Gravity	121° C (250° F)	30 min	45 min
Prevacuum	132° C (270° F)	4 min	45 min

NOTE: STERILIZATION DOES NOT REPLACE DECONTAMINATION OR CLEANING. ONLY A CLEAN PRODUCT CAN BE CORRECTLY STERILIZED. ONLY STERILE IMPLANTS AND INSTRUMENTS MAY BE USED FOR SURGERY.

PRODUCT COMPLAINTS:
Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any ASTS-SA products should notify 4WEB, or, where applicable, their distributor.

SURGICAL TECHNIQUE MANUAL:
To receive additional copies of the Surgical Technique Manual, contact your local sales representative or the company at the address below.

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Standard: ISO 15223-1, Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied.

Symbol	Ref. Number	Title	Description of Symbol
	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	5.1.5	Lot number	Indicates the manufacturer's lot number so that a specific medical device can be identified.
	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42 EEC, and 98/79 EC.
	5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
	5.2.4	Sterile	Sterilized using irradiation. Indicates a medical device that has been sterilized using irradiation.
	5.2.6	Do not resterilize	Indicates a medical device that is not to be resterilized.
	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.

	ASTM F2503-13	MR Conditional	Medical device that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.
Rx Only	21 CFR 801.109	Prescription only	Requires prescription in the United States.

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