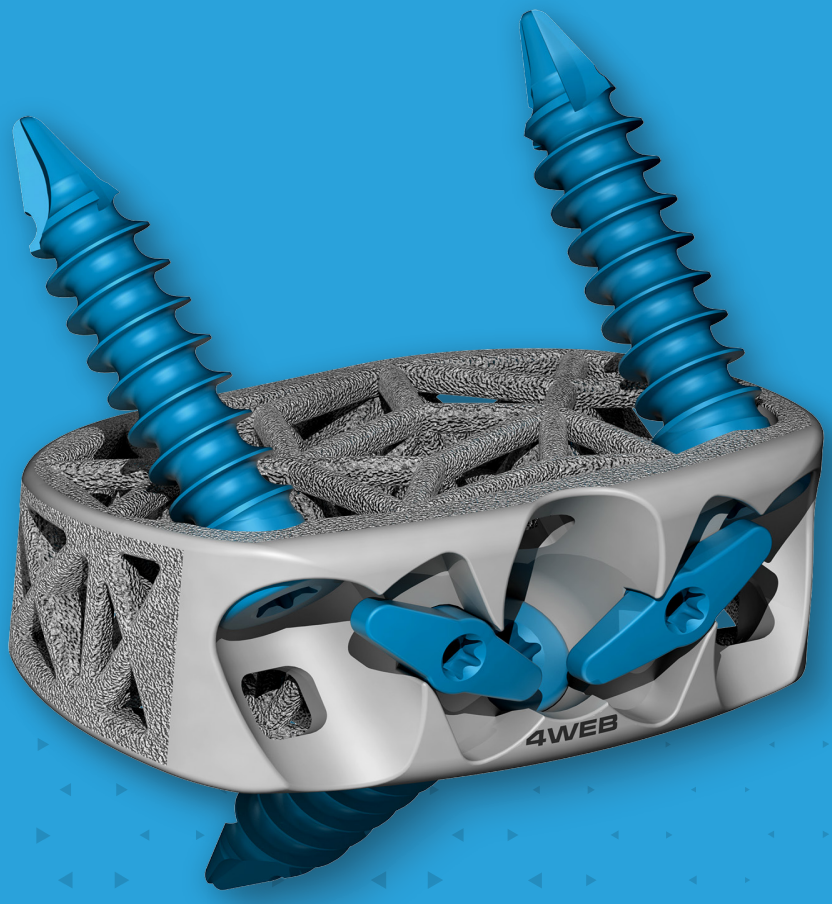
SURGICAL TECHNIQUE GUIDE

STAND ALONE ANTERIOR SPINE TRUSS SYSTEM



4WEB®

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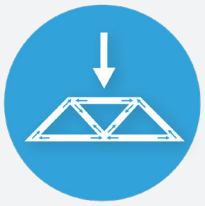
Federal law (USA) restricts these devices to sales by or on the order of a physician. Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedure based on his or her medical training and experience. Prior to use of the system, the surgeon should refer to the product's Instructions For Use (IFU) for complete warnings, precautions, indications, contraindications and adverse effects. IFUs are available by contacting 4WEB® at +1(800) 285-7090.

TRUSS IMPLANT TECHNOLOGY™

Novel Truss Implant Technology™ provides a Snow Shoe Interface that distributes load across the endplate which minimizes point loading and reduces the risk of subsidence.[1]

Hierarchical surface roughness spans from the macro to nano scale. These surface features have been shown to stimulate increased gene expression of certain osteogenic markers when compared to other interbody surfaces and materials.[2, 3]

Open architecture design allows for greater graft volume and bone growth throughout the entire construct.[1]



Distribution of load through the implant struts delivers strain to adjacent cellular material which stimulates a mechanobiologic response.[2]

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

[1] Data on file
[2] Lee et al., ORS, 2023 Annual Meeting, Dallas, TX
[3] Rowe et al., SMISS, Annual Forum '19, p.52

ASTS-SA OVERVIEW

The Anterior Spine Truss System – Stand Alone (ASTS-SA) Interbody Fusion Device 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.

INDICATIONS

The 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

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

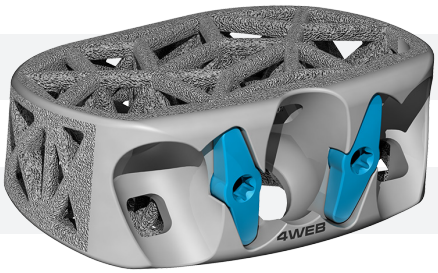
- Instruments have maintained design integrity; and,
- Proper size configurations are available.

For Instructions for Cleaning, Sterilization, Inspection and Maintenance, refer to IFU-ASTS-SA-05 or OUS-IFU-ASTS-SA-13.

* Data on file

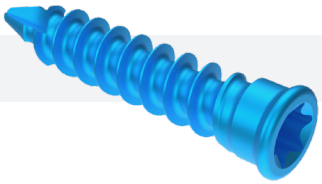
IMPLANT SPECIFICATIONS

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



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.

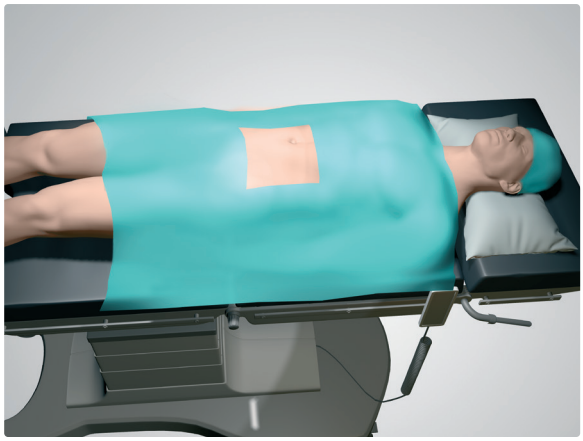


Figure 1

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).

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.

Figure 3

Carefully impact the sizer into the disc space (Fig. 4). Check the correct fit of the sizer with the aid of fluoroscopy and palpation.

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.

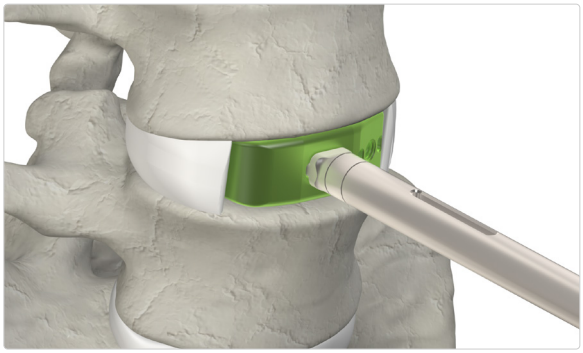


Figure 4

IMPLANT INSERTION, SCREW PREPARATION, AND SCREW INSERTION

There are four 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 9-12). 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 13-16).

Technique 3 - Midline Freehand Technique

The Midline Freehand Technique uses a Midline Inserter to insert the implant and freehand instruments to prepare and insert the screws (pages 17-20).

Technique 4 - 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 21-25), 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.

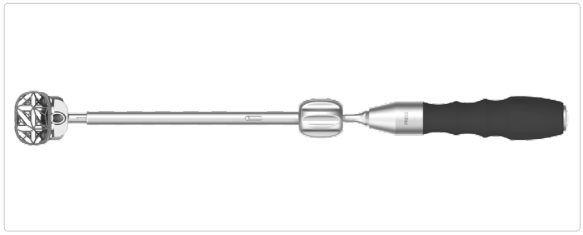


Figure 5

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.

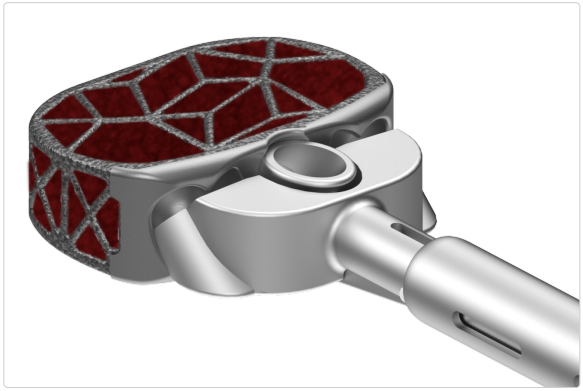


Figure 6

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).

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

Figure 7

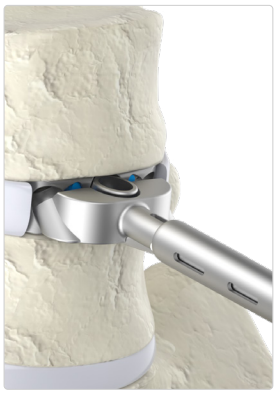


Figure 8

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).

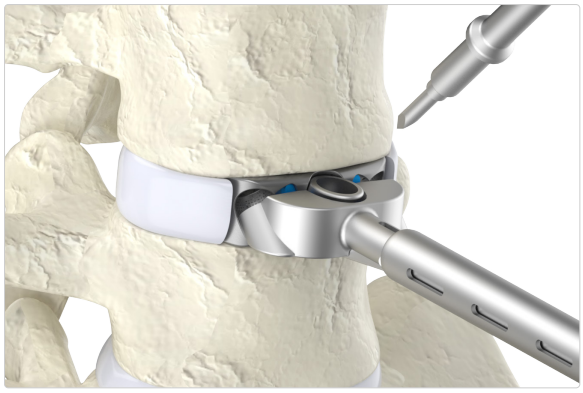


Figure 9

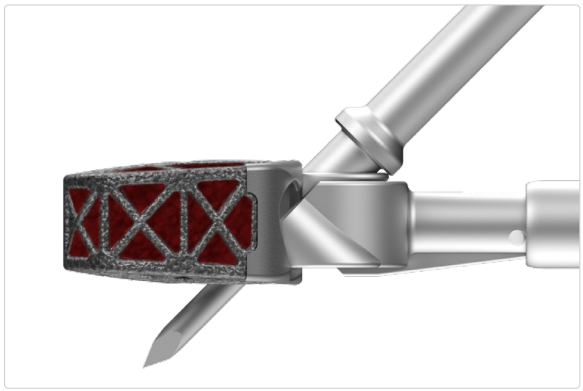


Figure 10

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.

Note: For angled screw trajectories, use the Fixed or Variable Angled Driver to ensure proper screw engagement and to prevent driver damage.

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).

Locking the Anti-Backout Plates:

Remove the Guided Inserter from the implant by twisting the knob counterclockwise to release the outer shaft.

Connect the Anti Back Out Plate Driver to the Torque Limiting Handle. 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).

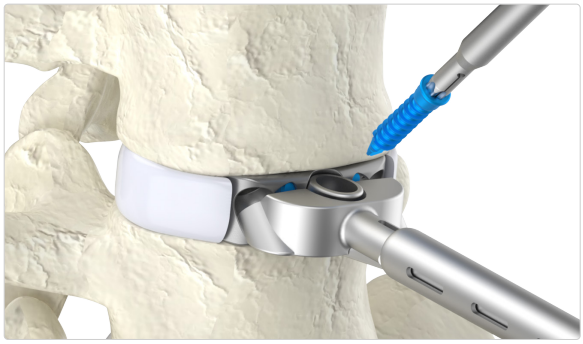


Figure 11

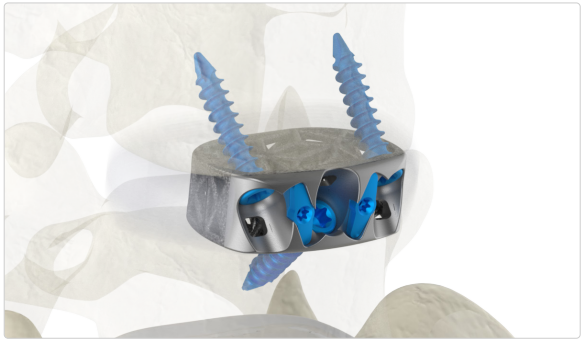


Figure 12

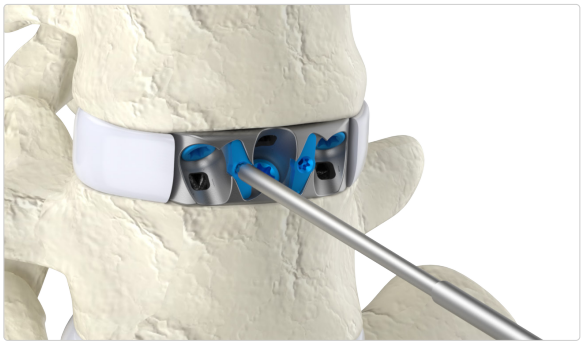


Figure 13

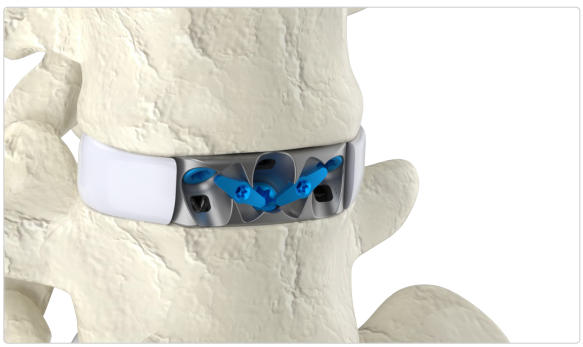


Figure 14

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.

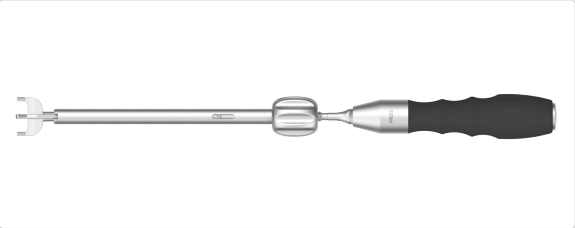


Figure 16

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).

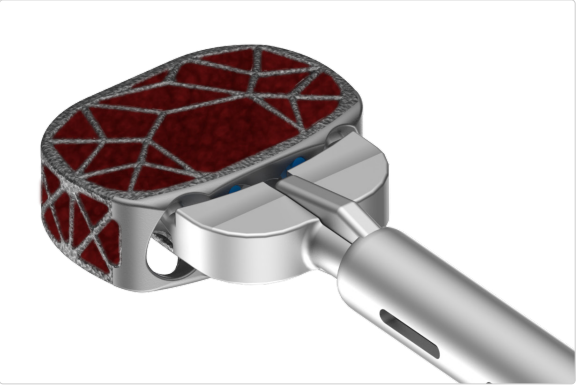


Figure 17

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.

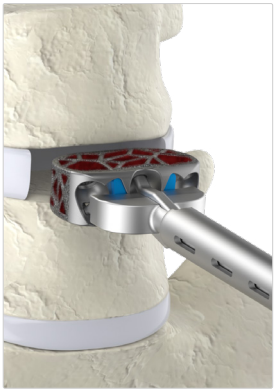


Figure 18

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)

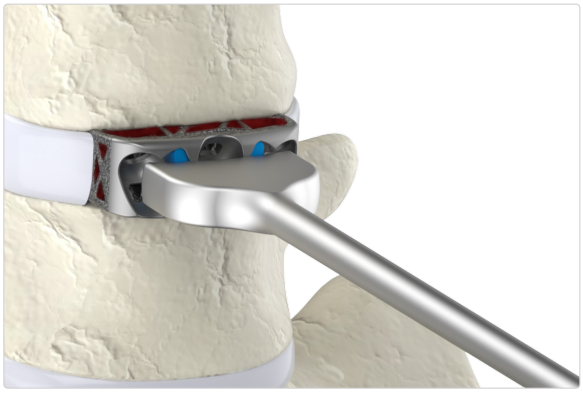


Figure 20

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.

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.

Figure 21

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.

Connect the Anti Back Out Plate Driver to the Torque Limiting Handle. 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).

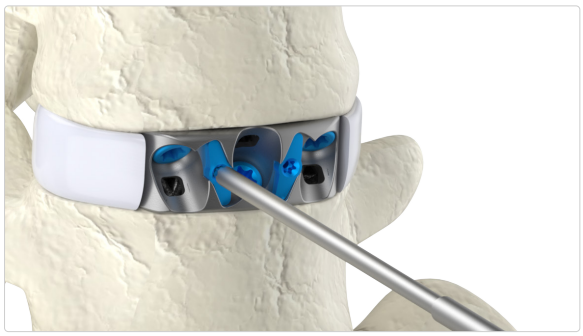


Figure 24

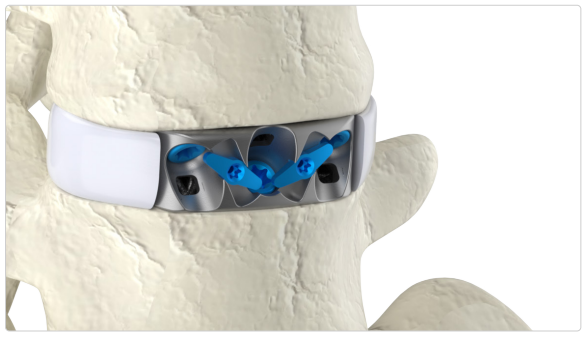


Figure 25

Final Implant Position:

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

Figure 26

TECHNIQUE 3 – MIDLINE FREEHAND TECHNIQUE

Inserter Assembly:

Attach the Midline Inserter to the Quick Connect Handle (Fig. 27). To secure the Midline Inserter to the implant, insert into the middle hole on the implant and turn the knob clockwise until a secure fit is achieved.

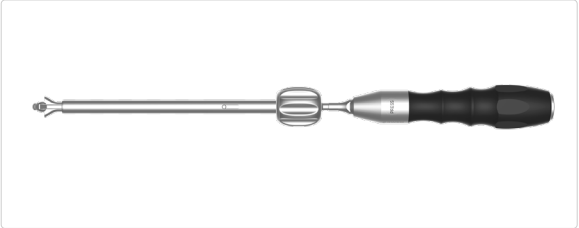


Figure 27

Implant Insertion:

Once the appropriate implant has been sized and selected, attach it to the inserter.

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).

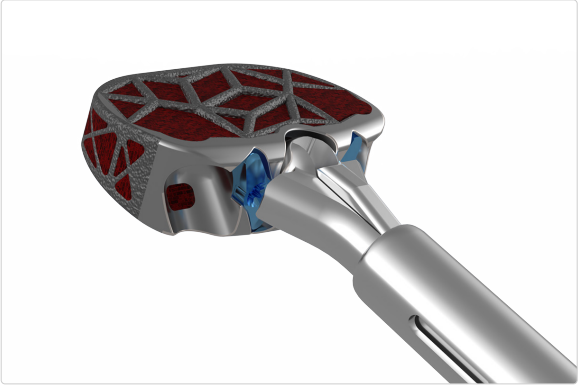


Figure 28

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

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

Figure 29

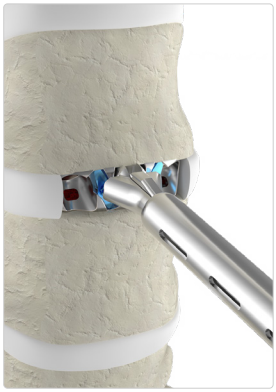


Figure 30

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)

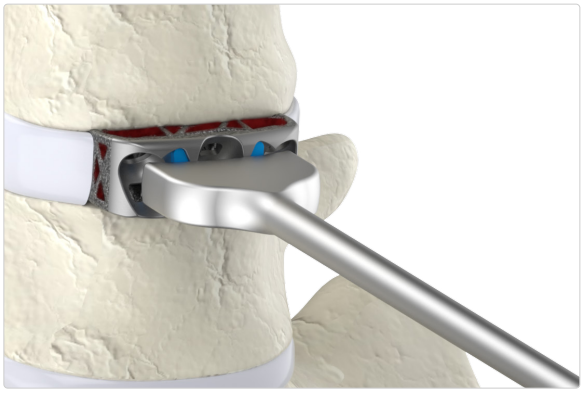


Figure 31

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. 32).

Repeat this step through all three screw holes.

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.

Figure 32

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. 33). Drive the screw until it is fully seated in the implant. Repeat this step for all three screws (Fig. 34).

Figure 33

Figure 34

Locking the Anti-Backout Plates:

Remove all instrumentation from the implant.

Connect the Anti Back Out Plate Driver to the Torque Limiting Handle. Use the Anti Back Out Plate Driver to rotate the two Locking Plates approximately 90° (Fig. 35). The wings of the Locking Plate will stop against the recess on the anterior face of the implant (Fig. 36).

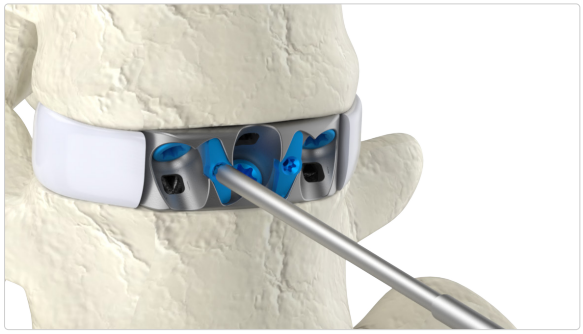


Figure 35

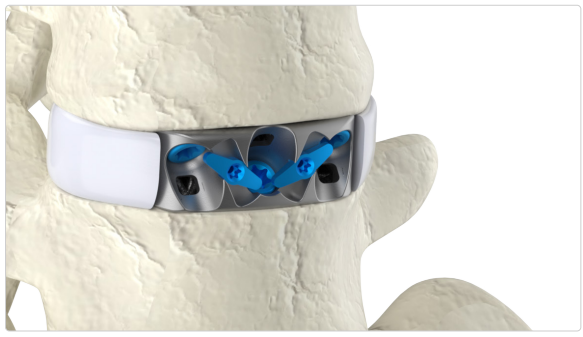


Figure 36

Final Implant Position:

Inspect implant for correct position and assembly and confirm with fluoroscopy (Fig. 37).

Figure 37

TECHNIQUE 4 - FREEHAND INSERTION AND GUIDED SCREW PREPARATION & INSERTION TECHNIQUE

Inserter Assembly:

Attach the Freehand Inserter to the Quick Connect Handle (Fig. 38). 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.

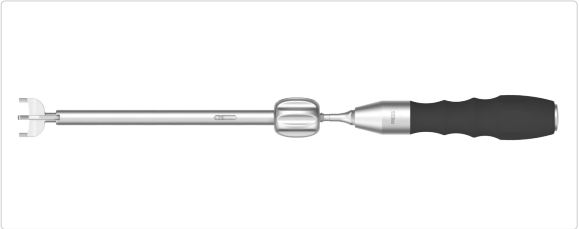


Figure 38

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. 39). 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).

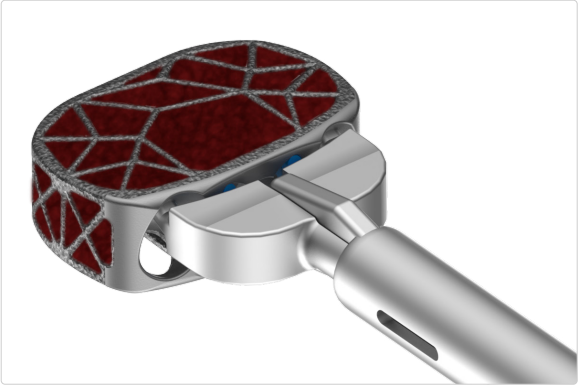


Figure 39

Insert the implant into the disc space (Fig. 40 and 41). 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.

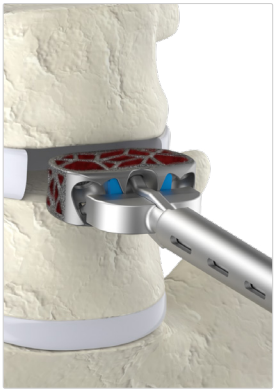


Figure 40

Figure 41

Implant Positioning:

Additional implant positioning can be achieved using a tamp (Fig. 42). 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)

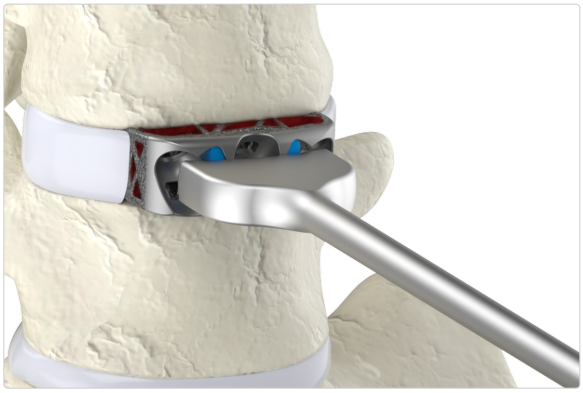


Figure 42

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. 43).

Repeat this step through all three screw holes.

Note: The static awls provide a maximum of 11.6mm of bone penetration when the awl is fully deployed through the Freehand Guide (Fig. 44).

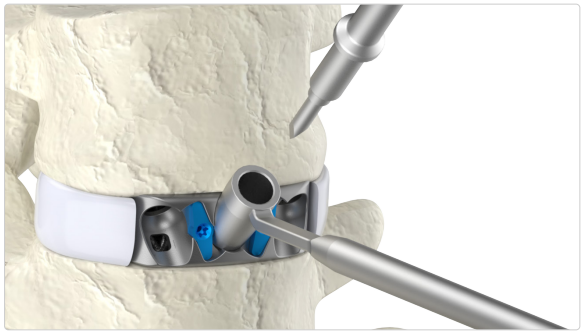


Figure 43

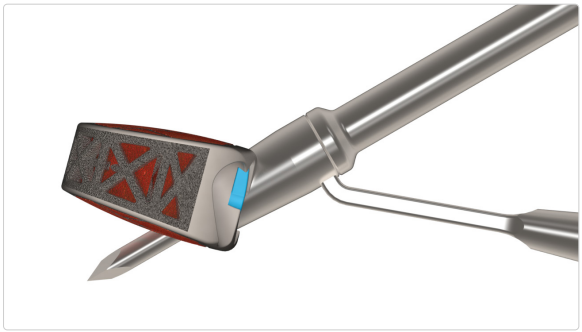


Figure 44

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. 45). Drive the screw until it is fully seated in the implant. Repeat this step for all three screws (Fig. 46).

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.

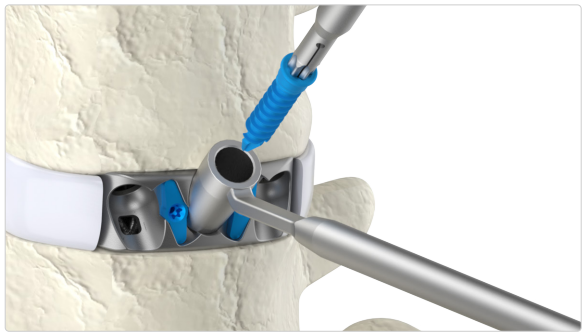


Figure 45

Figure 46

Locking the Anti-Backout Plates:

Remove all instrumentation from the implant.

Connect the Anti Back Out Plate Driver to the Torque Limiting Handle. Use the Anti Back Out Plate Driver to rotate the two Locking Plates approximately 90° (Fig. 47). The wings of the Locking Plate will stop against the recess on the anterior face of the implant (Fig. 48).

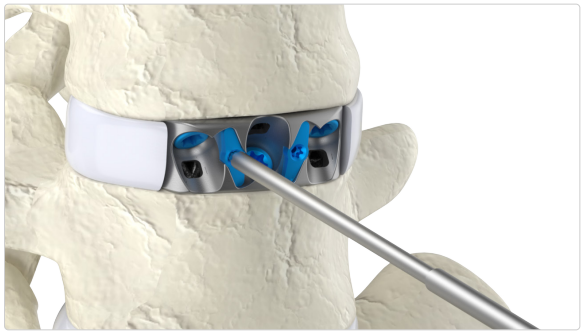


Figure 47

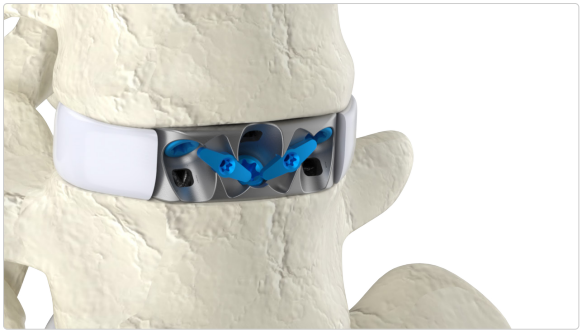


Figure 48

Final Implant Position:

Inspect implant for correct position and assembly and confirm with fluoroscopy (Fig. 49).

Figure 49

Implant Removal/Revision:

If implant removal is necessary, rotate the Locking Plates to an unlocked position until the screws are no longer retained (Fig. 50). 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. 51). If necessary, the Slap Hammer can be attached to the inserter for additional removal force.

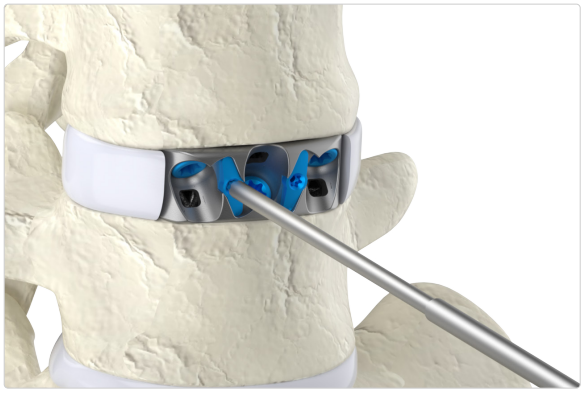


Figure 50

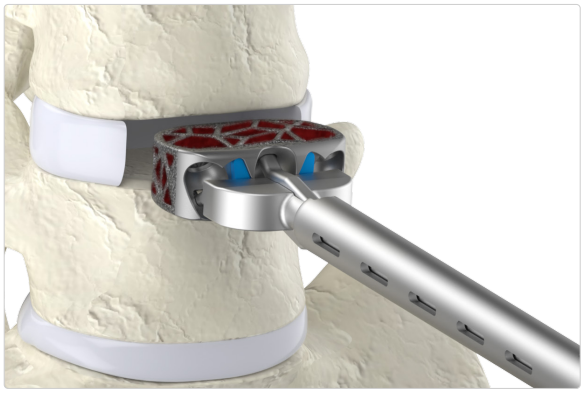


Figure 51

INSTRUMENT CATALOG

PART NUMBER	DESCRIPTION
ASTS-SA-100028	ASTS-SA STRAIGHT DRIVER, T25, SPLIT TIP

ASTS-SA-100031	ASTS-SA ANGLED DRIVER

ASTS-SA-100034	ASTS-SA SHORT VARIABLE ANGLE DRIVER, T25, SPLIT TIP

ASTS-SA-100029	ASTS-SA ANTI BACK OUT PLATE DRIVER, AO

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

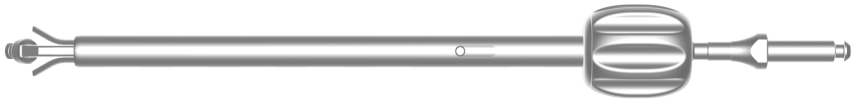
ASTS-SA-100011	ASTS-SA GUIDED TAMP

ASTS-SA-100036	ASTS-SA 10-12MM GUIDED INSERTER

ASTS-SA-100037	ASTS-SA 14-20MM GUIDED INSERTER

ASTS-SA-100044	ASTS-SA FREEHAND INSERTER

ASTS-SA-100046	ASTS-SA MIDLINE INSERTER



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

LSTS-000014	RATCHETING STRAIGHT HANDLE

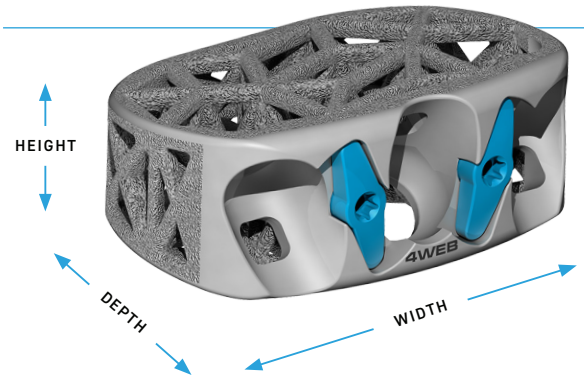
PSTS-000008/18	STRAIGHT INSERTER

4WEB-000003	SLAP HAMMER

PSTS-000013	SILICONE STRAIGHT HANDLE WITH IMPACTOR

ASTS-SA-100030	TORQUE LIMITING HANDLE, BI-DIRECTIONAL

IMPLANT CATALOG

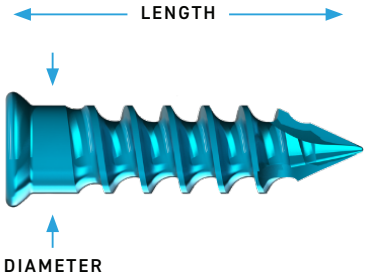


INTERBODY DEVICES

CATALOG NUMBER	FOOTPRINT D x W 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 D x W 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 D x W 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-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-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



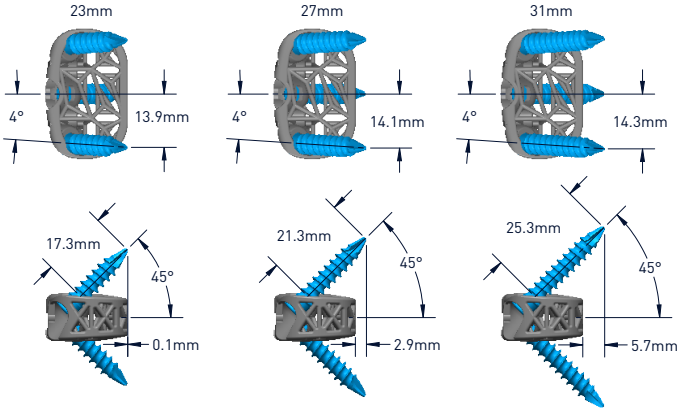
SCREWS

CATALOG NUMBER	DIAMETER, LENGTH
ASCR-5023-T25-SP	ø5.0mm, L 23mm
ASCR-5027-T25-SP	ø5.0mm, L 27mm
ASCR-5031-T25-SP	ø5.0mm, L 31mm
ASCR-5523-T25-SP	ø5.5mm, L 23mm
ASCR-5527-T25-SP	ø5.5mm, L 27mm
ASCR-5531-T25-SP	ø5.5mm, L 31mm

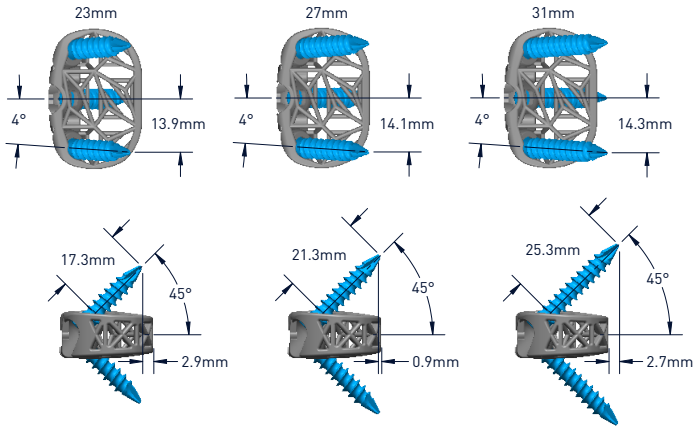
SCREW ANGULATION CHART

NOMINAL SCREW ANGULATION

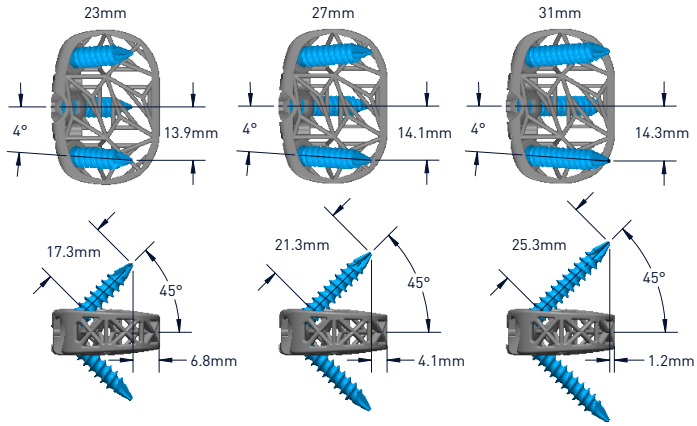
SMALL FOOTPRINT 21 x 34mm



MEDIUM FOOTPRINT 24 x 36mm

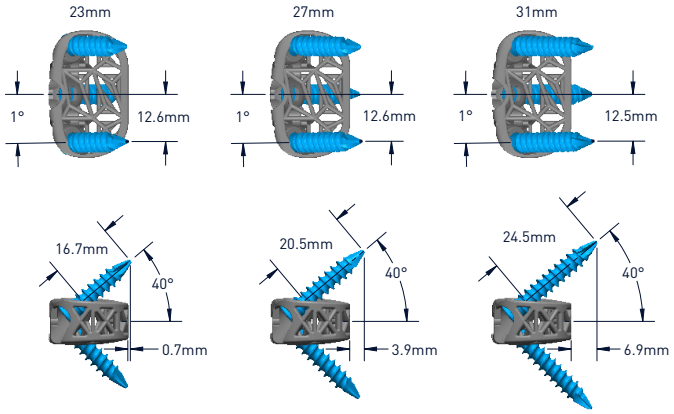


LARGE FOOTPRINT 27 x 40mm

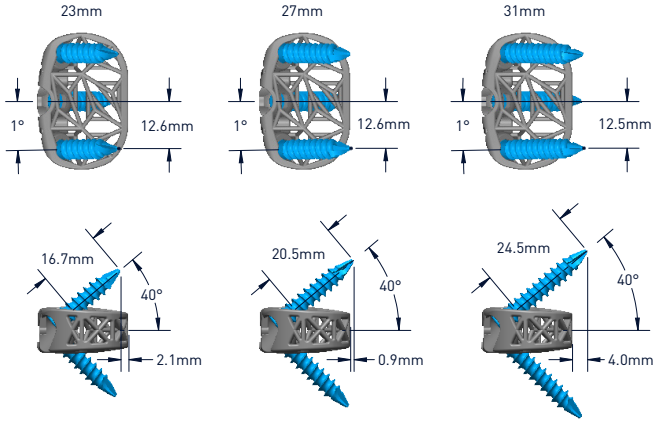


NOMINAL SCREW ANGULATION -5° SCREW VARIABILITY

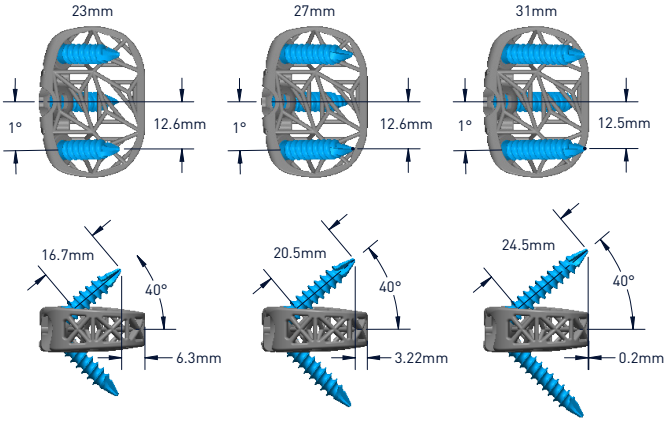
SMALL FOOTPRINT 21 x 34mm



MEDIUM FOOTPRINT 24 x 36mm

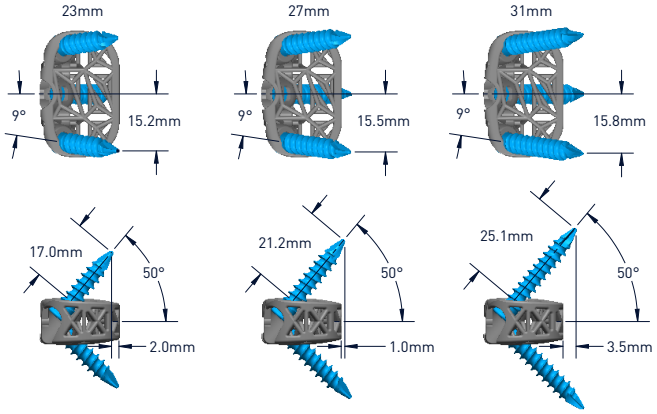


LARGE FOOTPRINT 27 x 40mm

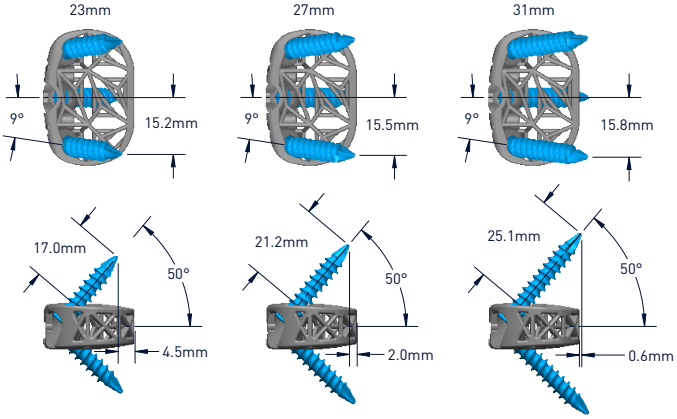


NOMINAL SCREW ANGULATION +5° SCREW VARIABILITY

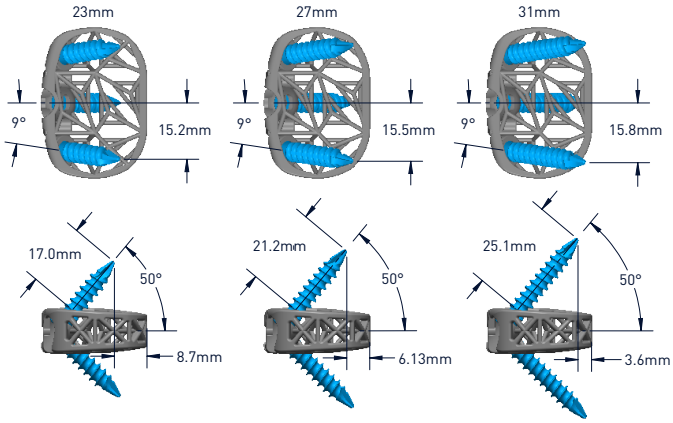
SMALL FOOTPRINT 21 x 34mm



MEDIUM FOOTPRINT 24 x 36mm



LARGE FOOTPRINT 27 x 40mm



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