INNOVASIS

Ax™

Stand-Alone ALIF System

Ax™ STAND-ALONE ALIF SYSTEM

INDICATIONS FOR USE

The Innovasis® Ax™ Stand-Alone ALIF System is an intervertebral body fusion device for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbar spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to a Grade 1 spondylolisthesis or retrolisthesis at the involved levels(s). These implants are used to facilitate fusion in the lumbar spine and are placed via an anterior (ALIF) approach. Hyperlordotic implants (those with a lordotic angle greater than or equal to 20°) are indicated for use with a supplemental spinal fixation system such as the Innovasis® Excella® Spinal System. The Ax Stand-Alone interbody implants with a lordotic angle less than 20°, when used with the internal fixation screws, do not require use of supplemental fixation.

For additional product information including warnings, precautions and adverse effects concerning spinal fixation implants refer to the product insert.

CONTRAINDICATIONS (EXCLUSION CRITERIA):

Use of this system is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.

Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.

Conditions that may place excessive stress on the bone and implant, such as severe obesity or degenerative diseases are relative contraindications. The decision whether to use these devices under these conditions must be made by the physician taking into account the risks versus the benefits to the patient.

Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bone healing and may be at a higher risk of implant failure.

⚠ WARNING:

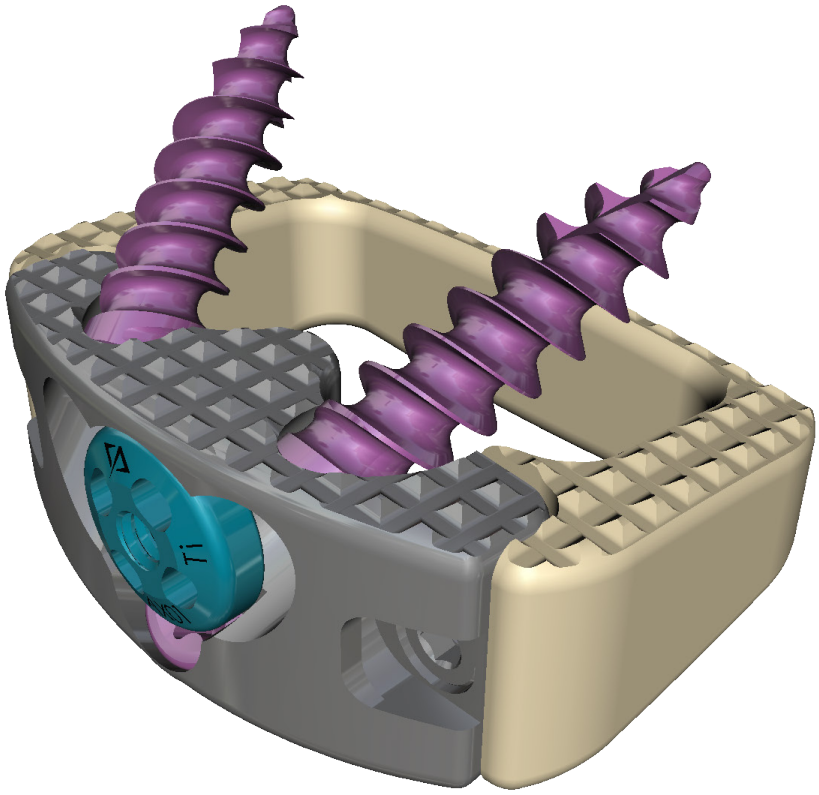
- Correct selection of the implant is EXTREMELY Important. The potential for satisfactory anterior column support is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

- Implants can break when subjected to the increased loading associated with delayed union. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree of success of union, loads produced by weight bearing, and activity levels will among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

Ax™ STAND-ALONE ALIF SYSTEM

PRODUCT OVERVIEW

The Ax™ system is for Anterior Lumbar Interbody Fusion (ALIF). The Ax implant consists of a titanium faceplate with an Invibio® PEEK-OPTIMA® HA Enhanced body. HA enhanced PEEK is integrated with osteoconductive hydroxyapatite (HA). The implant is available in multiple size options to facilitate a more precise anatomical fit. The implants have a tapered leading edge which aids in implant insertion due to limited anatomical space, and features a bi-convex profile to match the anatomy and anti-migration features to ensure implant stability during the fusion process. The large graft cavity provides increased volume for autograft loading.

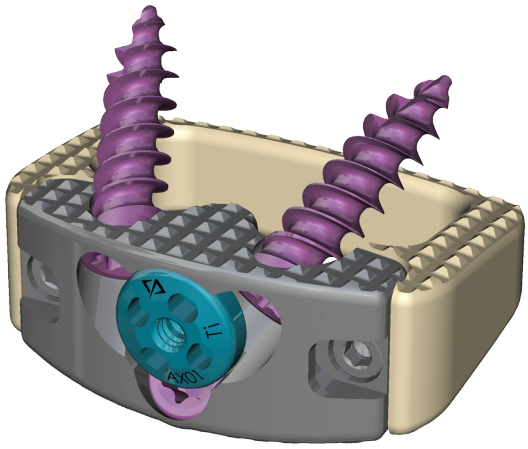


IMPLANT OVERVIEW

Ax™ IMPLANT

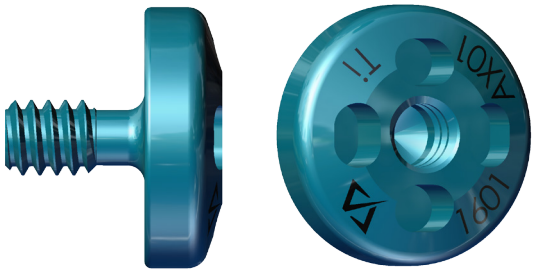
IMPLANT BODY

- Bi-convex HA PEEK body.
- Titanium faceplate.
- Pyramidal anti-expulsion teeth.
- 22˚ Lateral diverging screws.
- 35˚ Crainial caudal screw angle.
- 10˚ Conical screw variability.
- Simple anti-backout cover plate.
- 8˚, 14˚, 20˚ and 30˚ Lordotic angles.
- 6 heights, 10-20mm at 2mm increments.
- 3 Footprints
  - 30 x 24mm
  - 36 x 28mm
  - 40 x 30mm

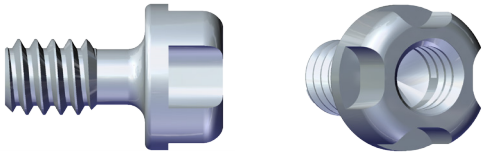


COVER PLATE

- Simple, one step cover plate.
- Color coded for size identification.
- Torque limiting driver ensures consistent locking.
- Self-retaining driver provides secure attachment during insertion.
- Small plate for 10 & 12mm tall implants.
- Large plate for 14mm to 20mm tall implants.
- Visual confirmation of screw blocking.



Large Plate

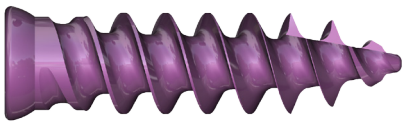


Small Plate

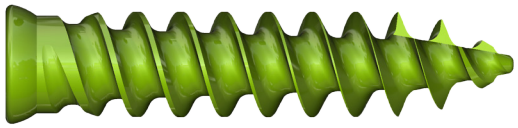
Ax™ IMPLANT (cont)

SCREWS

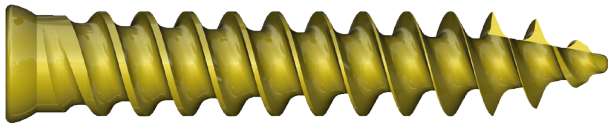
- 5.5mm diameter bone screws.
- Tapered self-tapping thread design.
- Self-retaining hexalobe drive feature.
- 20, 25 and 30mm lengths.
- Color coded for easy identification.



20mm



25mm

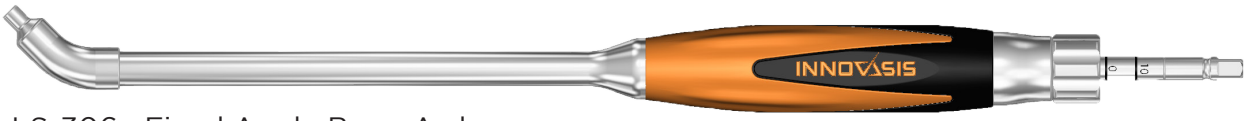


30mm

INSTRUMENTS OVERVIEW

INSTRUMENTS

LA-184 Universal Ratchet Handle



LS-306 Fixed Angle Bone Awl

LS-307 Straight Bone Awl

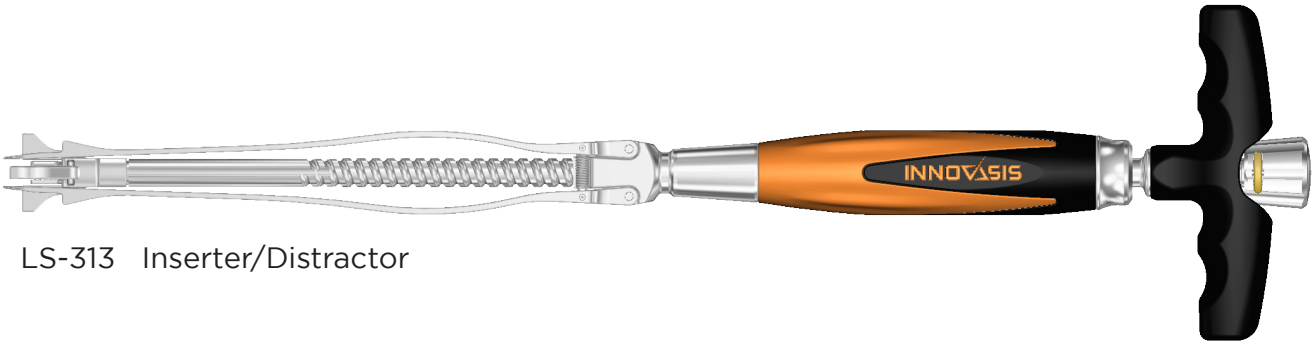
LS-308 Fixed Angle Driver

LS-309 Straight Driver

LS-310 Variable Angle Driver

INSTRUMENTS (CONT.)

LS-312 Inserter



LS-313 Inserter/Distractor

LS-314 Disc Spreader

LS-316 Trial Inserter

LS-317 Cover Plate Inserter

INSTRUMENTS (CONT.)

LS-318 Small Footprint Trial

LS-319 Medium Footprint Trial

LS-320 Large Footprint Trial

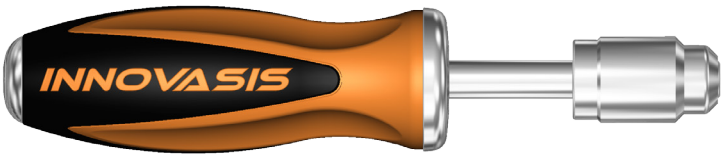
LS-321 Slide Hammer

LS-322 2 LB Mallet

INSTRUMENTS (CONT.)

LS-327 Insertion Tamp

LS-328 Palm Handle



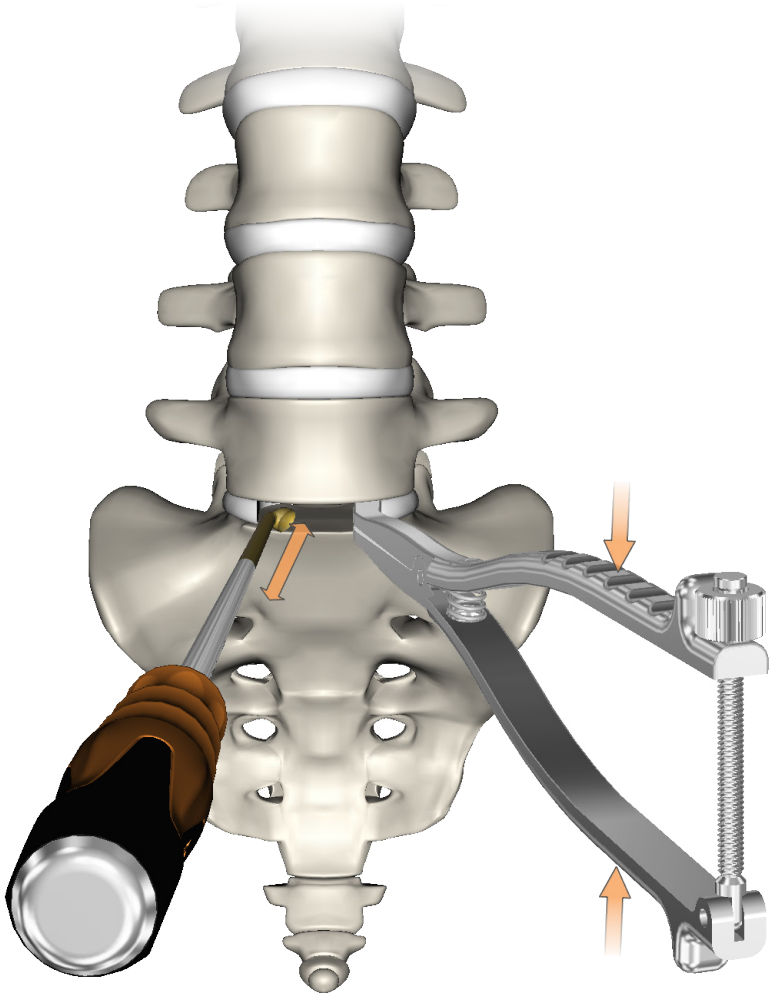
LS-345 Torque Limiting Handle

APPROACH

Position the patient in the supine position.

Per surgeon preference perform a standard anterior approach.

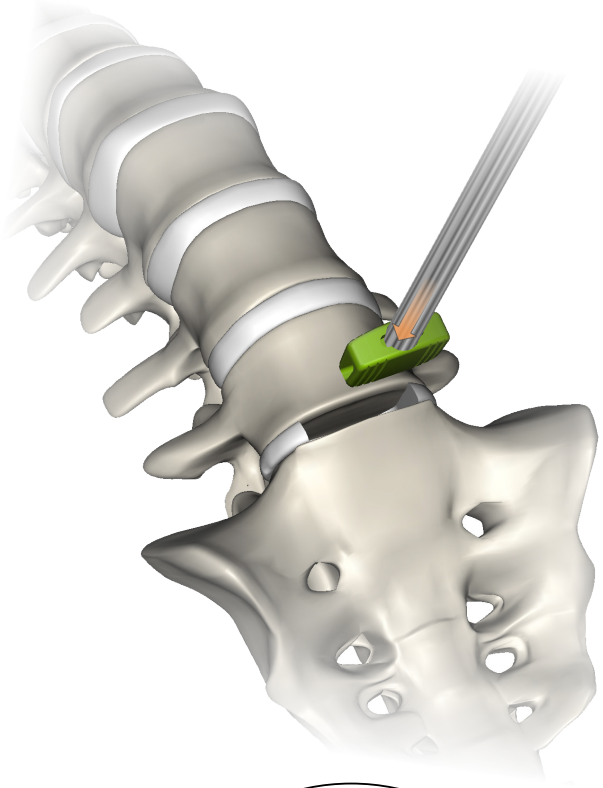
The Anterior Disc Preparation Set can be used to expose the disc and remove the disc material. Prepare the vertebral endplates by removing the superficial cartilaginous layers. Preserve the posterior and lateral walls of the annulus for peripheral support.

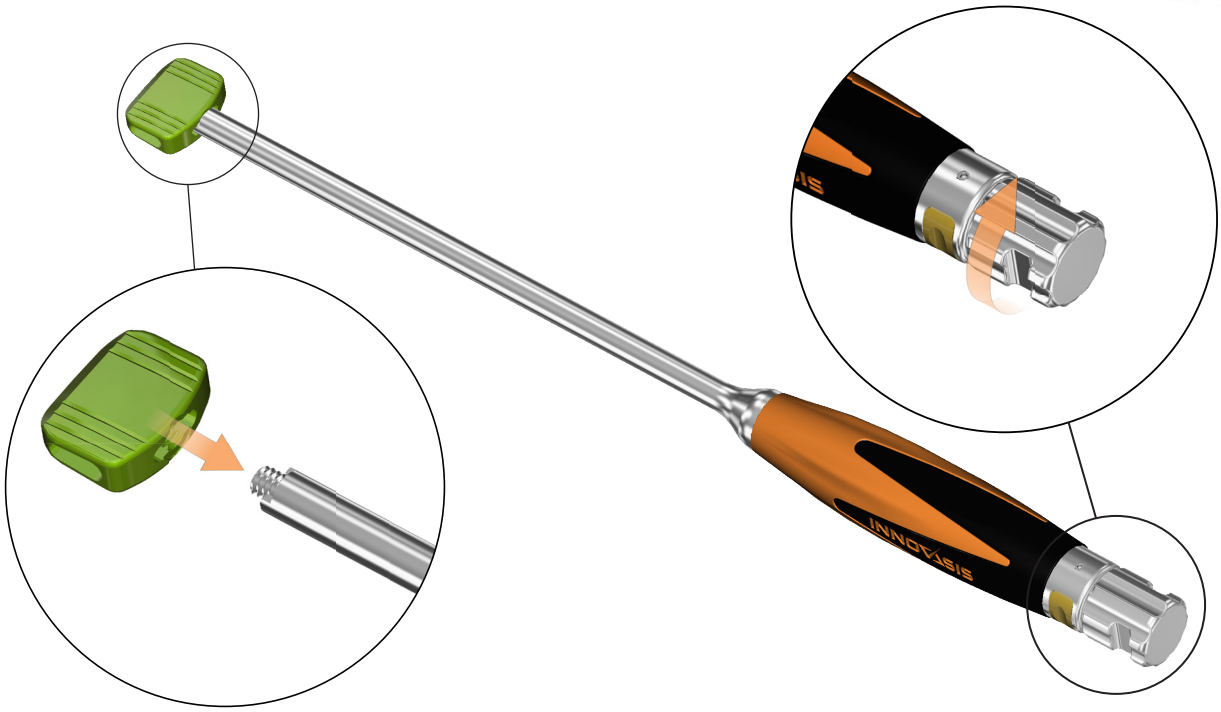


TRIALING

Select the appropriate Trial and attach it to the Trial Inserter. Insert the Trial into the disc space. In order to maintain disc height and ensure segment stabilization select a Trial height that provides a secure fit. Start with the smallest height, progressing to taller heights until the desired fit is acheived.

⚠ *Note: The Ax™ trials are sized to the root of the pyramidal teeth for the hybrid implant and the overall height of the titanium implant. The pyramidal teeth are .5mm tall ie. a 12mm implant would measure 13mm to the tip of the pyramidal teeth.*



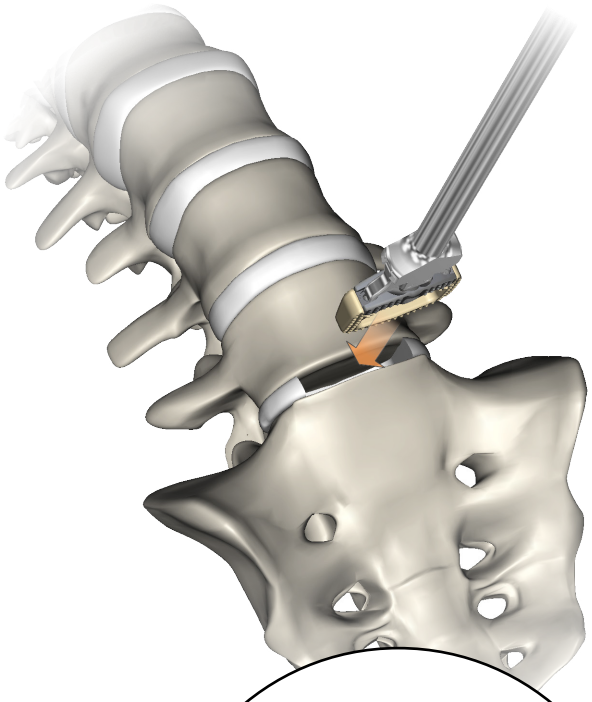


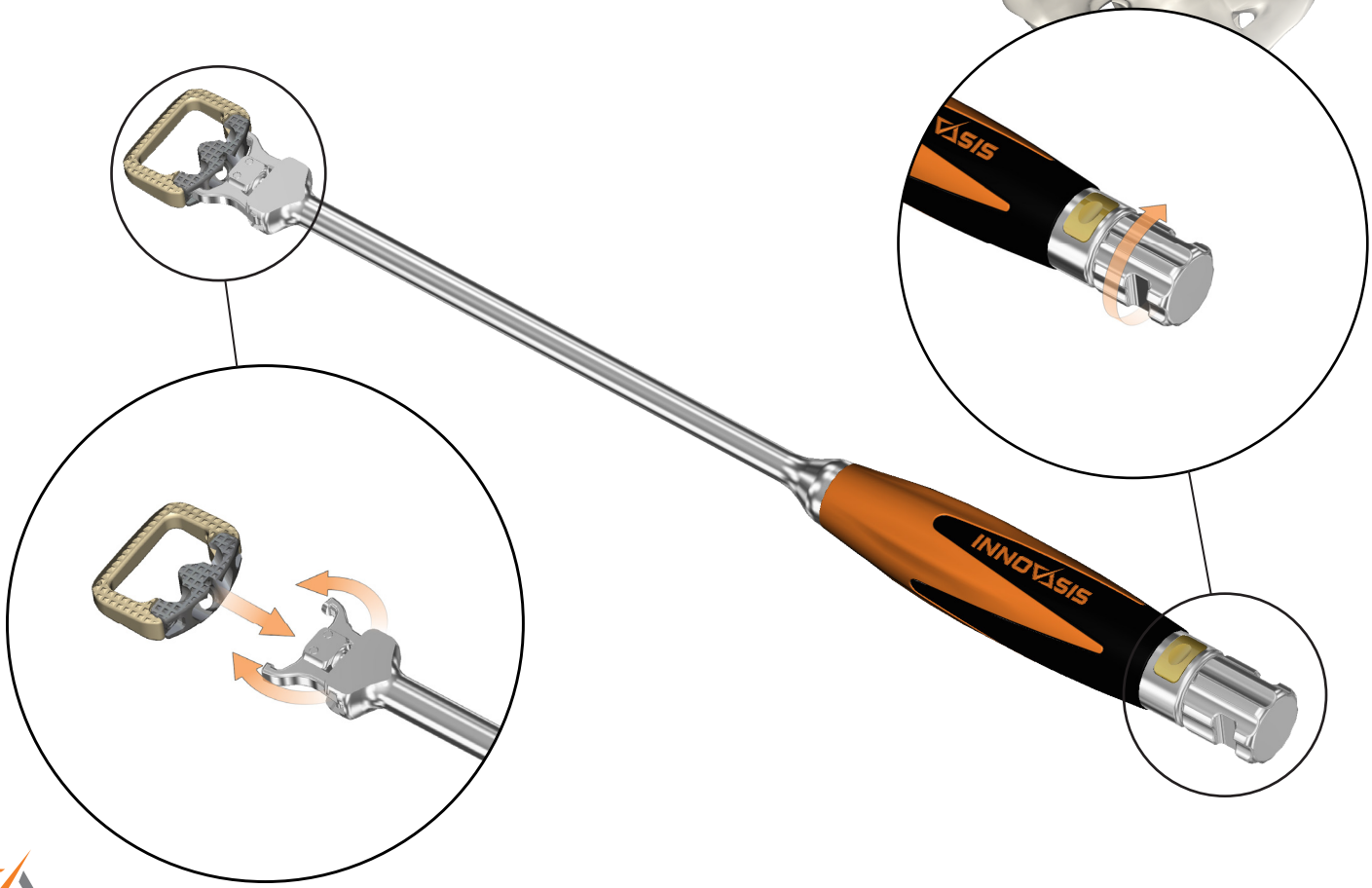
IMPLANT INSERTION

Once the appropriate implant has been sized and selected, attach it to the Inserter. Tighten the thumb wheel on the proximal end of the Inserter to assure a secure fit. Insert the implant into the disc space. Using flouroscopy, confirm the position and placement of the implant.

Optional fine-tuning of the implant position can be acheived using the Tamp and Mallet.

⚠ *Note: The implant should be recessed a few millimiters into the disc space.*



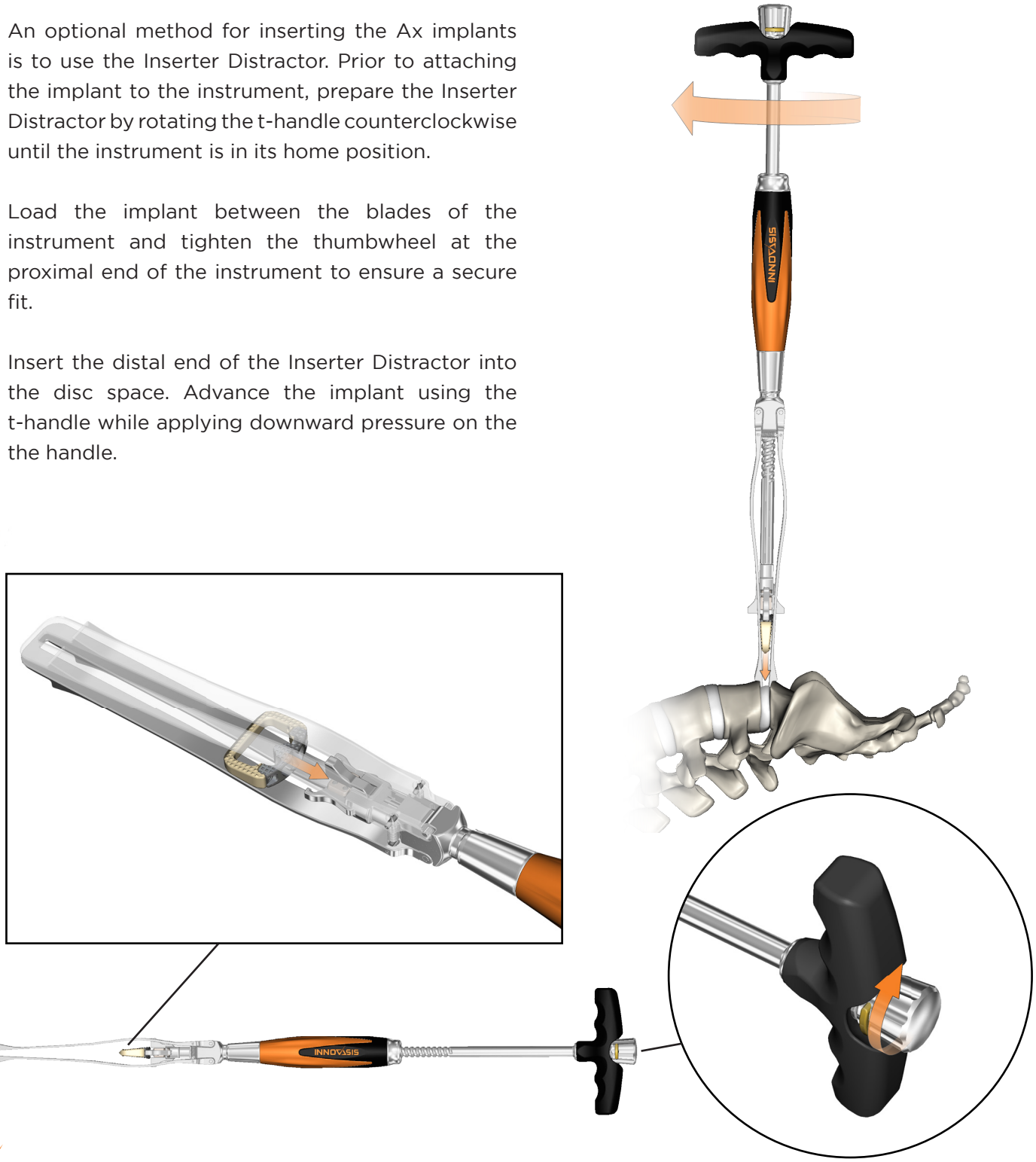


IMPLANT INSERTION (OPTIONAL)

An optional method for inserting the Ax implants is to use the Inserter Distractor. Prior to attaching the implant to the instrument, prepare the Inserter Distractor by rotating the t-handle counterclockwise until the instrument is in its home position.

Load the implant between the blades of the instrument and tighten the thumbwheel at the proximal end of the instrument to ensure a secure fit.

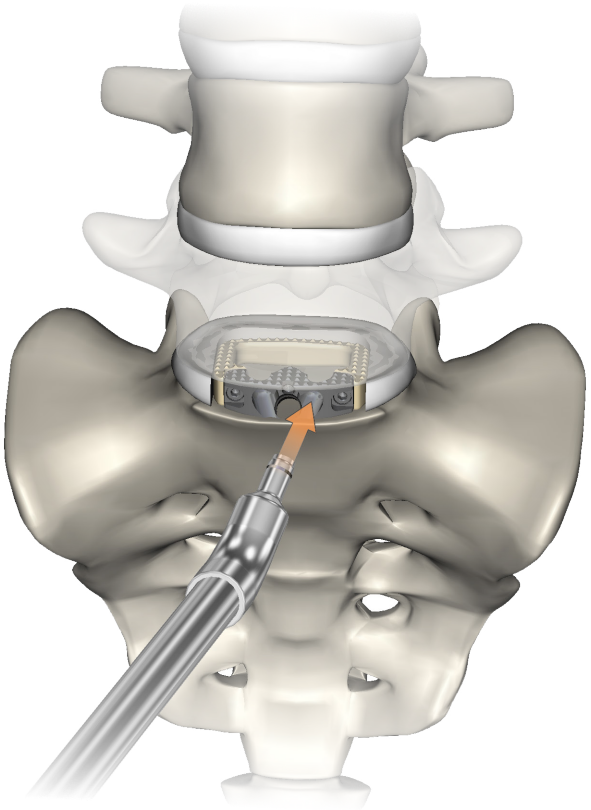
Insert the distal end of the Inserter Distractor into the disc space. Advance the implant using the t-handle while applying downward pressure on the the handle.

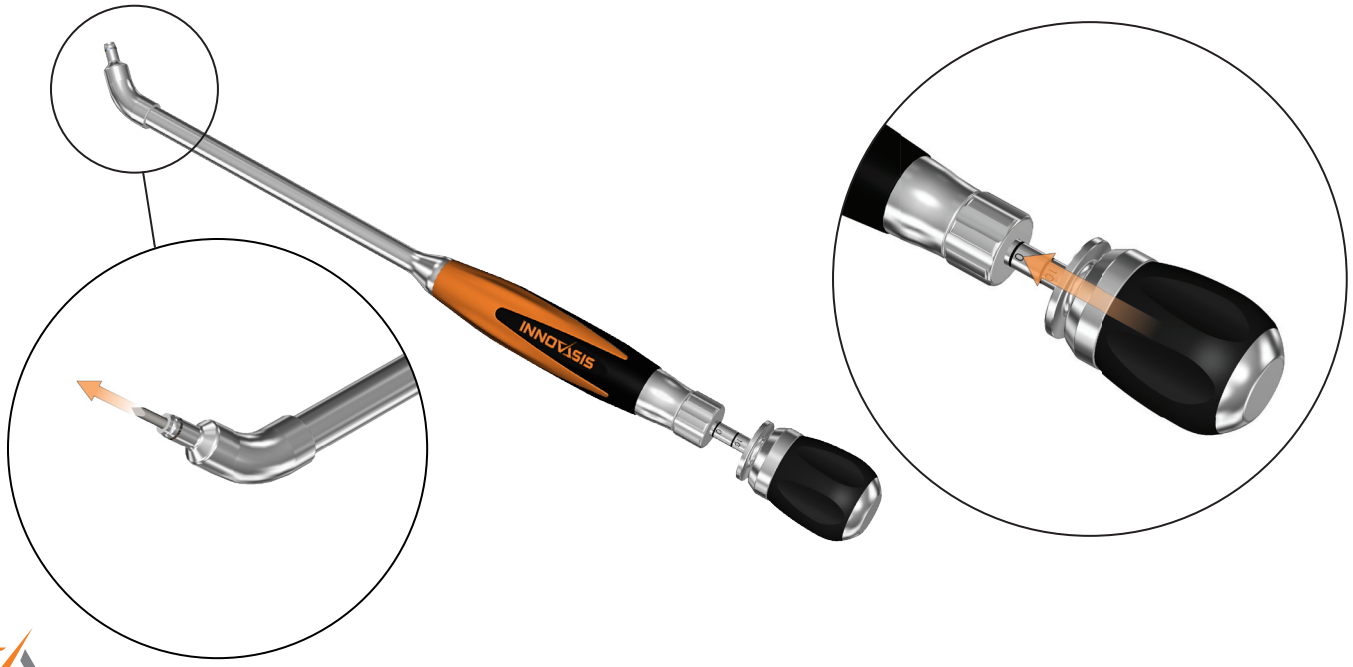


SCREW HOLE PREPARATION

The Ax Stand-Alone ALIF System offers a straight and fixed angle bone awl for screw hole preparation. Select the desired Awl and attach the Palm Handle to the proximal end of the instrument. Insert the distal end of the Awl through a screw bore hole in the implant. The Awl tip is recessed inside the instrument and requires actuation in order to puncture bone. Actuate the instrument by applying axial force on the Palm Handle until the Awl tip pierces the bone.

⚠ *Note: The bone awl provides a maximum of 10mm of awl depth.*

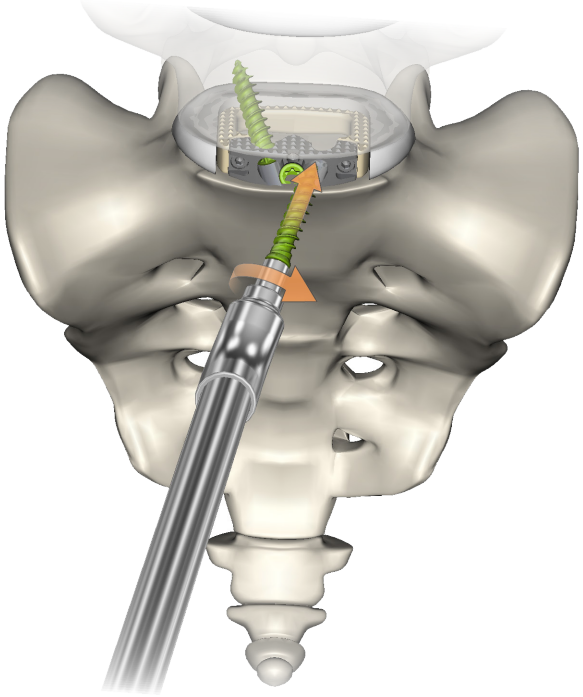




SCREW INSERTION

The Ax Stand-Alone ALIF System offers straight, fixed and variable angle drivers for screw insertion. Depending on the angle and position of the implant, select the desired driver and attach the ratcheting handle to the proximal end of the instrument.

Select the desired length screw and fix it to the distal end of the self-retaining Driver. Insert the screw throught the bore hole in the implant. Drive the screw until it is fully seated inside the implant.



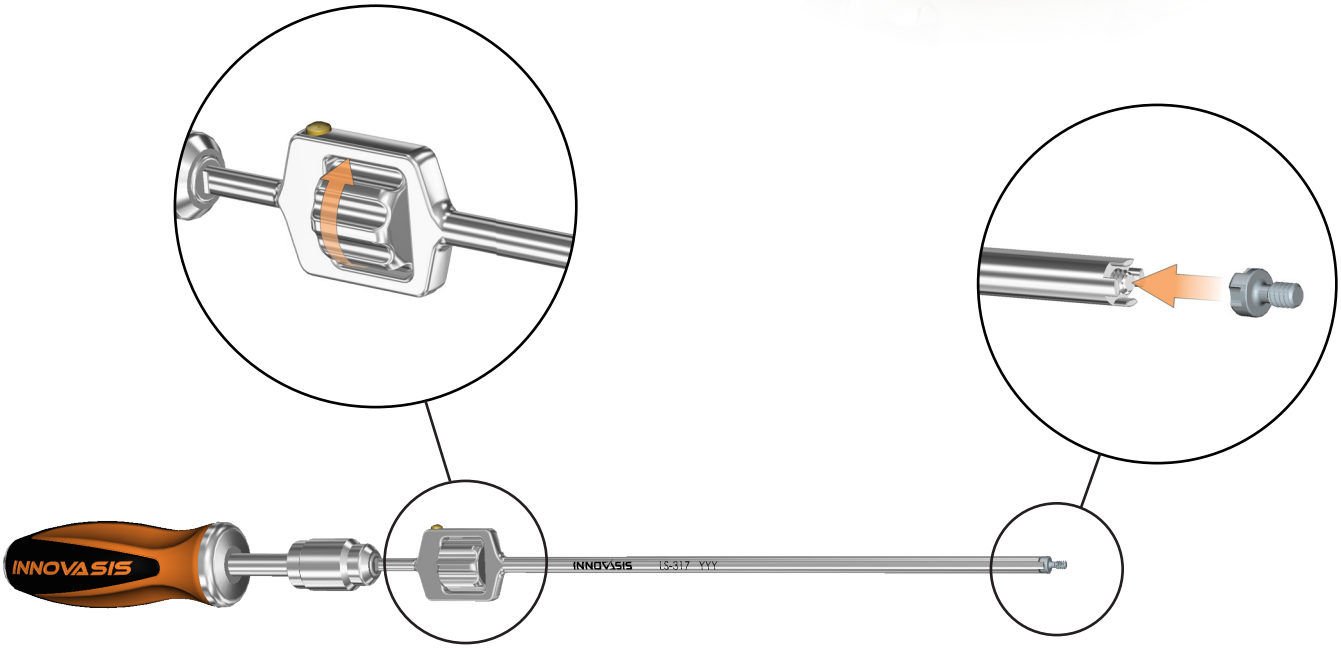
COVER PLATE INSERTION

Select the cover plate that corresponds with the implanted size.

⚠ *Note: The small cover plate is used with the 10mm and 12mm implant heights only. The large cover plate is used with all other sizes.*

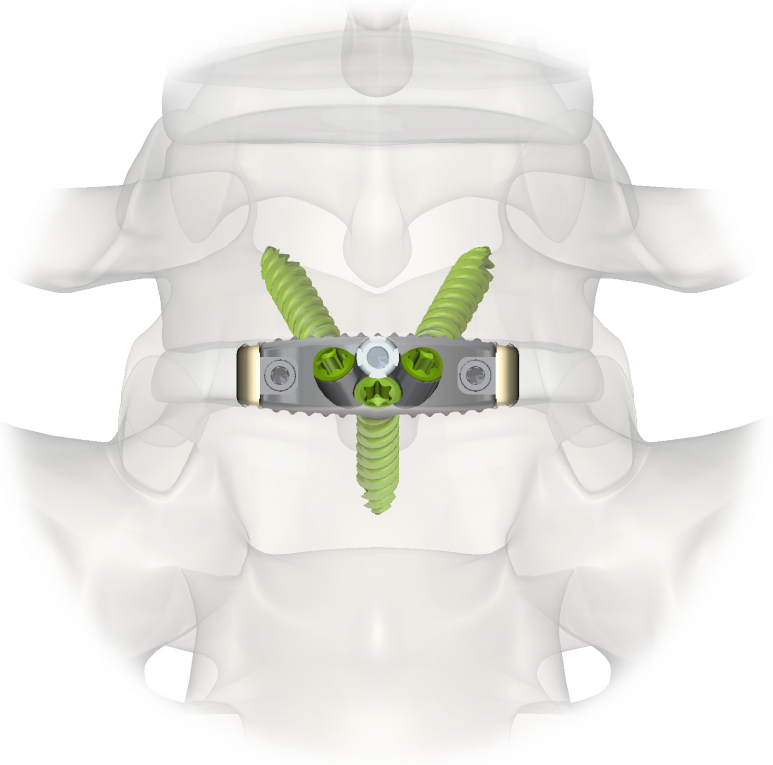
Assemble the Cover Plate Driver to the Torque Limiting handle. Load the Cover Plate onto the Cover Plate Driver by tightening the thumbwheel to secure the Cover Plate to the Driver.

Insert the Cover Plate into the implant and tighten to the limit of the Torque Limiting Handle (6 in-lb.) The Torque Limiting Handle will click when the appropriate torque has been achieved.

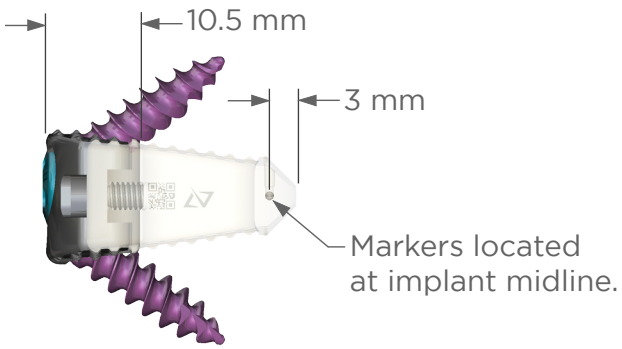


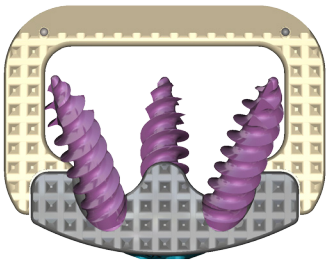
FINAL IMPLANT POSITION

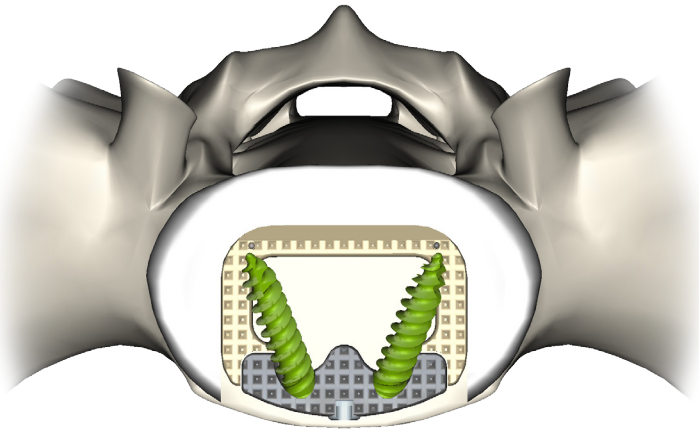
Inspect implant for correct position and assembly.



RADIOGRAPHIC MARKERS







IMPLANT REMOVAL/REVISION

Should it become necessary to remove the Ax System, the following steps should be followed:

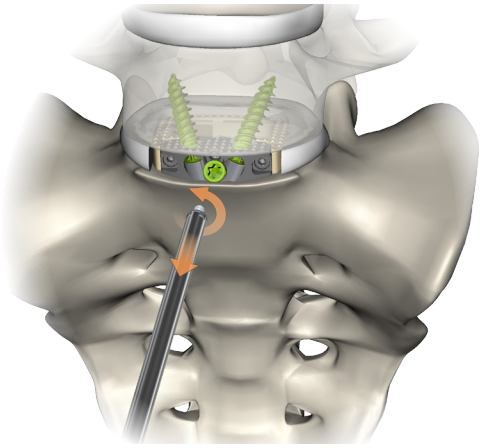
Soft tissue on the anterior portion of the implant should be removed for sufficient implant visualization.

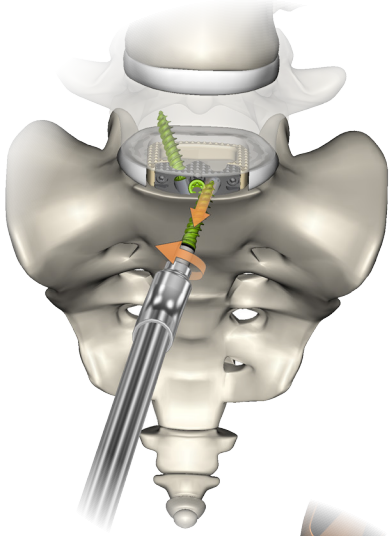
The Cover Plate is removed by attaching the Cover Plate Driver and turning counter clockwise.

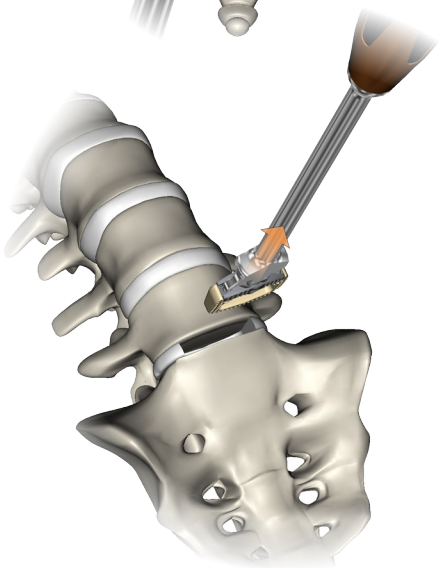
The Straight, Fixed Angled or Variable Angled screw driver with a T20 hexalobe is used to remove the Bone Screws by turning counter clockwise.

Once the Bone Screws are removed the cage can be removed by re-attaching the Inserter .

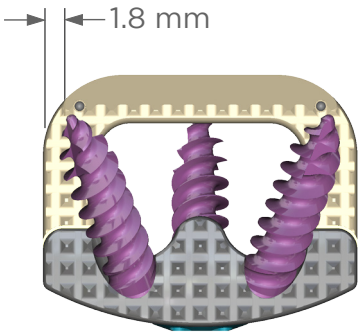
If necessary the Slide Hammer can be attached to the Inserter for additional removal force.

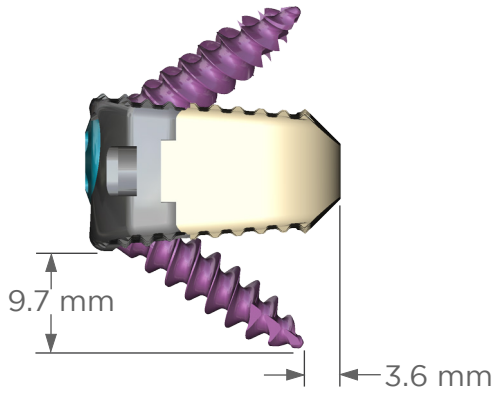


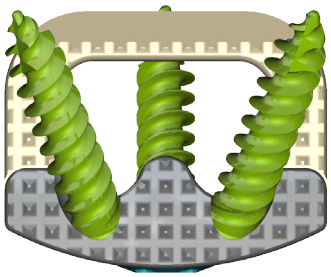


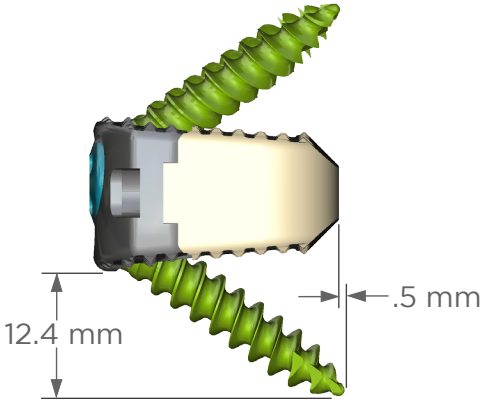


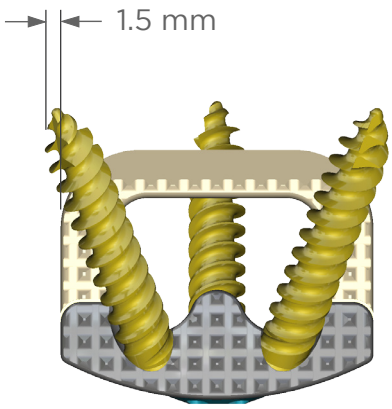
SCREW LENGTH DIAGRAMS, 30 x 24mm FOOTPRINT

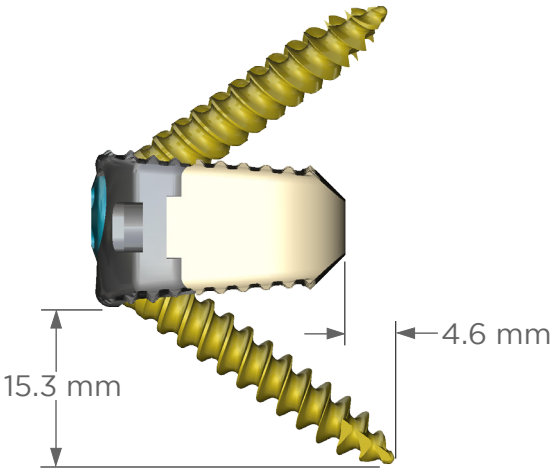




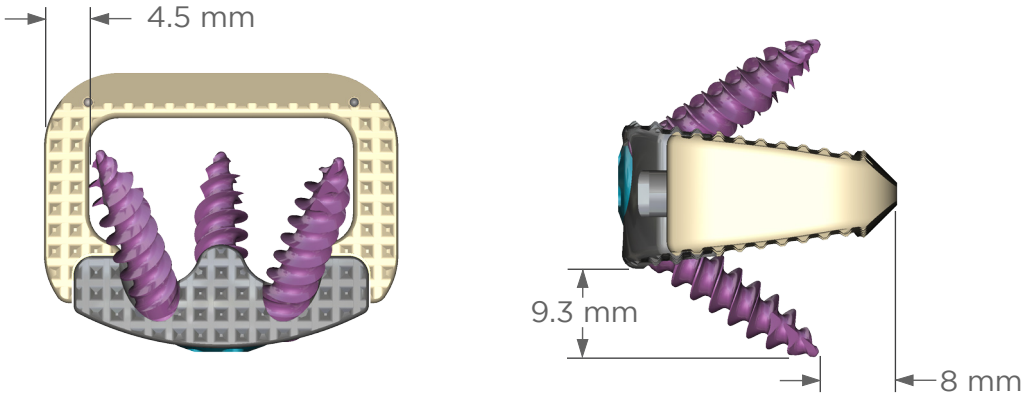


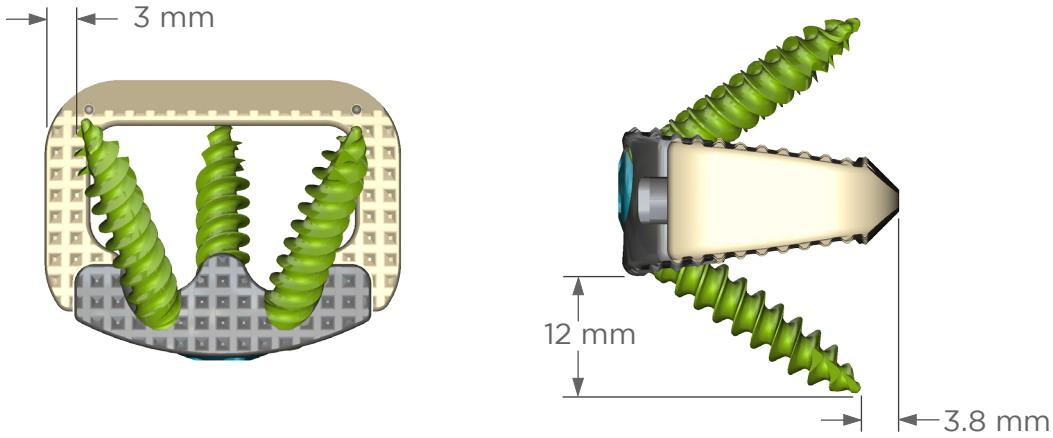


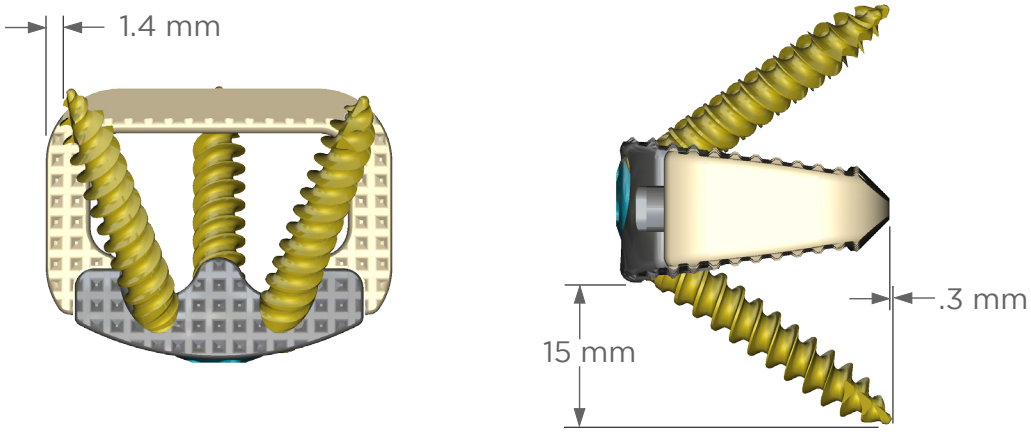




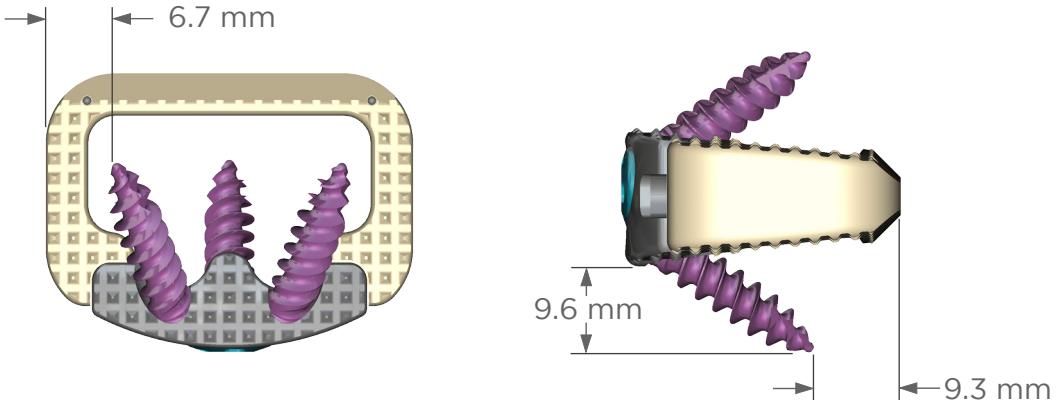
SCREW LENGTH DIAGRAMS, 36 x 28mm FOOTPRINT

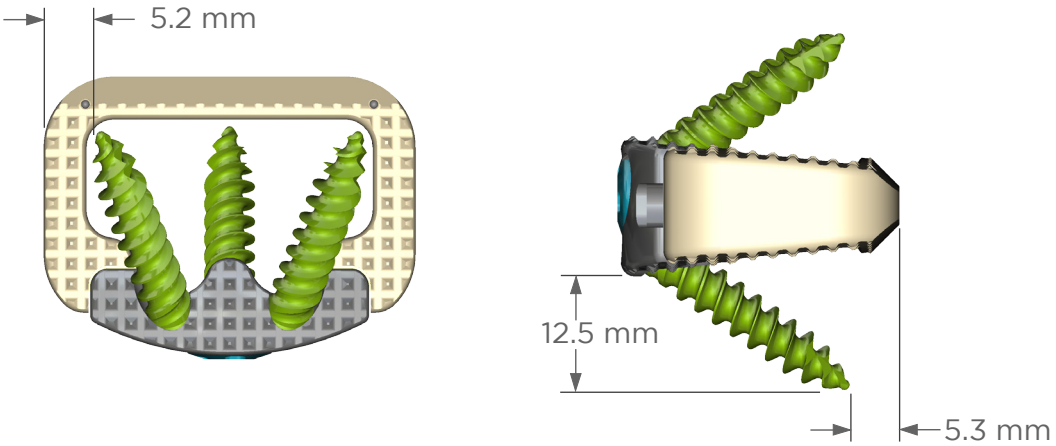


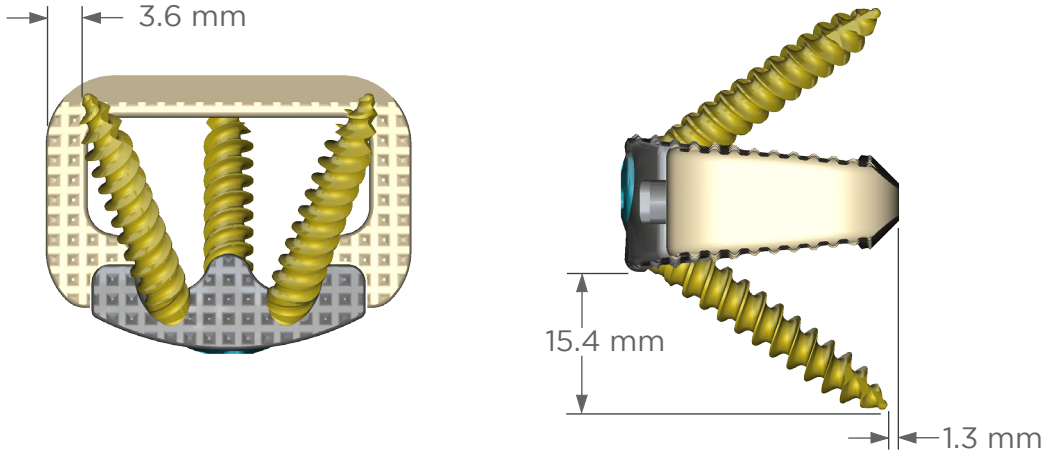




SCREW LENGTH DIAGRAMS, 40 x 30mm FOOTPRINT







SURGICAL TECHNIQUE

HYBRID IMPLANTS

SMALL FOOTPRINT			MEDIUM FOOTPRINT			LARGE FOOTPRINT		
Part No.	**Size**	**Graft Vol.**	**Part No.**	**Size**	**Graft Vol.**	**Part No.**	**Size**	**Graft Vol.**
AX103008	10H x 30W x 8°	1.8cc	AX103608	10H x 36W x 8°	3.1cc	AX104008	10H x 40W x 8°	3.7cc
AX123008	12H x 30W x 8°	2.3cc	AX123608	12H x 36W x 8°	3.8cc	AX124008	12H x 40W x 8°	4.7cc
AX143008	14H x 30W x 8°	2.7cc	AX143608	14H x 36W x 8°	4.6cc	AX144008	14H x 40W x 8°	5.6cc
AX163008	16H x 30W x 8°	3.2cc	AX163608	16H x 36W x 8°	5.4cc	AX164008	16H x 40W x 8°	6.6cc
AX183008	18H x 30W x 8°	3.6cc	AX183608	18H x 36W x 8°	6.2cc	AX184008	18H x 40W x 8°	7.6cc
AX203008	20H x 30W x 8°	4.0cc	AX203608	20H x 36W x 8°	6.9cc	AX204008	20H x 40W x 8°	8.5cc
AX103014	10H x 30W x 14°	1.7cc	AX103614	10H x 36W x 14°	2.7cc			
AX123014	12H x 30W x 14°	2.1cc	AX123614	12H x 36W x 14°	3.5cc	AX124014	12H x 40W x 14°	4.2cc
AX143014	14H x 30W x 14°	2.6cc	AX143614	14H x 36W x 14°	4.3cc	AX144014	14H x 40W x 14°	5.1cc
AX163014	16H x 30W x 14°	3.0cc	AX163614	16H x 36W x 14°	5.0cc	AX164014	16H x 40W x 14°	6.1cc
AX183014	18H x 30W x 14°	3.4cc	AX183614	18H x 36W x 14°	5.8cc	AX184014	18H x 40W x 14°	7.0cc
AX203014	20H x 30W x 14°	3.9cc	AX203614	20H x 36W x 14°	6.6cc	AX204014	20H x 40W x 14°	8.0cc
AX123020	12H x 30W x 20°	2.0cc						
AX143020	14H x 30W x 20°	2.4cc	AX143620	14H x 36W x 20°	3.9cc			
AX163020	16H x 30W x 20°	2.8cc	AX163620	16H x 36W x 20°	4.7cc	AX164020	16H x 40W x 20°	5.6cc
AX183020	18H x 30W x 20°	3.3cc	AX183620	18H x 36W x 20°	5.4cc	AX184020	18H x 40W x 20°	7.0cc
AX203020	20H x 30W x 20°	3.7cc	AX203620	20H x 36W x 20°	6.2cc	AX204020	20H x 40W x 20°	7.5cc
AX163030	16H x 30W x 30°	2.6cc						
AX183030	18H x 30W x 30°	3.0cc	AX183630	18H x 36W x 30°	4.8cc			
AX203030	20H x 30W x 30°	3.5cc	AX203630	20H x 36W x 30°	5.6cc	AX204030	20H x 40W x 20°	6.7cc

BONE SCREWS

Part No.	Size
AX5520	5.5mm X 20mm
AX5525	5.5mm X 25mm
AX5530	5.5mm X 30mm

COVER PLATES

Part No.	Size
AX01	Large
AX02	Small

SURGICAL TECHNIQUE

INSTRUMENTS

Part No.	Description
LS-306	ANGLED AWL
LS-307	STRAIGHT AWL
LS-308	ANGLE DRIVER
LS-309	STRAIGHT DRIVER
LS-310	VARIABLE ANGLE DRIVER
LS-312	INSERTER
LS-313	INSERTER/DISTRACTOR
LS-314	DISC SPREADER
LS-316	TRIAL INSERTER
LS-317	COVER PLATE DRIVER
LS-318	24 X 30mm TRIALS (SEE TRIALS TABLE FOR PART NO.'S)
LS-319	28 X 36mm TRIALS (SEE TRIALS TABLE FOR PART NO.'S)
LS-320	30 X 40mm TRIALS (SEE TRIALS TABLE FOR PART NO.'S)
LS-321	SLIDE HAMMER
LS-322	MALLET, 2LB
LS-327	INSERTION TAMP
LS-328	PALM HANDLE, 1/4" SQ DRIVE
LS-345	TORQUE LIMITING DRIVER
LA-184	RATCHETING HANDLE

IMPLANT TRIALS

SMALL FOOTPRINT		MEDIUM FOOTPRINT		LARGE FOOTPRINT	
Part No.	**Size**	**Part No.**	**Size**	**Part No.**	**Size**
LS-318-1008	10H x 30W x 8°	LS-319-1008	10H x 36W x 8°	LS-320-1008	10H x 40W x 8°
LS-318-1208	12H x 30W x 8°	LS-319-1208	12H x 36W x 8°	LS-320-1208	12H x 40W x 8°
LS-318-1408	14H x 30W x 8°	LS-319-1408	14H x 36W x 8°	LS-320-1408	14H x 40W x 8°
LS-318-1608	16H x 30W x 8°	LS-319-1608	16H x 36W x 8°	LS-320-1608	16H x 40W x 8°
LS-318-1808	18H x 30W x 8°	LS-319-1808	18H x 36W x 8°	LS-320-1808	18H x 40W x 8°
LS-318-2008	20H x 30W x 8°	LS-319-2008	20H x 36W x 8°	LS-320-2008	20H x 40W x 8°
LS-318-1014	10H x 30W x 14°	LS-319-1014	10H x 36W x 14°		
LS-318-1214	12H x 30W x 14°	LS-319-1214	12H x 36W x 14°	LS-320-1214	12H x 40W x 14°
LS-318-1414	14H x 30W x 14°	LS-319-1414	14H x 36W x 14°	LS-320-1414	14H x 40W x 14°
LS-318-1614	16H x 30W x 14°	LS-319-1614	16H x 36W x 14°	LS-320-1614	16H x 40W x 14°
LS-318-1814	18H x 30W x 14°	LS-319-1814	18H x 36W x 14°	LS-320-1814	18H x 40W x 14°
LS-318-2014	20H x 30W x 14°	LS-319-2014	20H x 36W x 14°	LS-320-2014	20H x 40W x 14°
LS-318-1220	12H x 30W x 20°				
LS-318-1420	14H x 30W x 20°	LS-319-1420	14H x 36W x 20°		
LS-318-1620	16H x 30W x 20°	LS-319-1620	16H x 36W x 20°	LS-320-1620	16H x 40W x 20°
LS-318-1820	18H x 30W x 20°	LS-319-1820	18H x 36W x 20°	LS-320-1820	18H x 40W x 20°
LS-318-2020	20H x 30W x 20°	LS-319-2020	20H x 36W x 20°	LS-320-2020	20H x 40W x 20°
LS-318-1630	16H x 30W x 30°				
LS-318-1830	18H x 30W x 30°	LS-319-1830	18H x 36W x 30°		
LS-318-2030	20H x 30W x 30°	LS-319-2030	20H x 36W x 30°	LS-320-2030	20H x 40W x 30°

INNOVASIS

INNOVATE / INVOLVE / INVENT

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