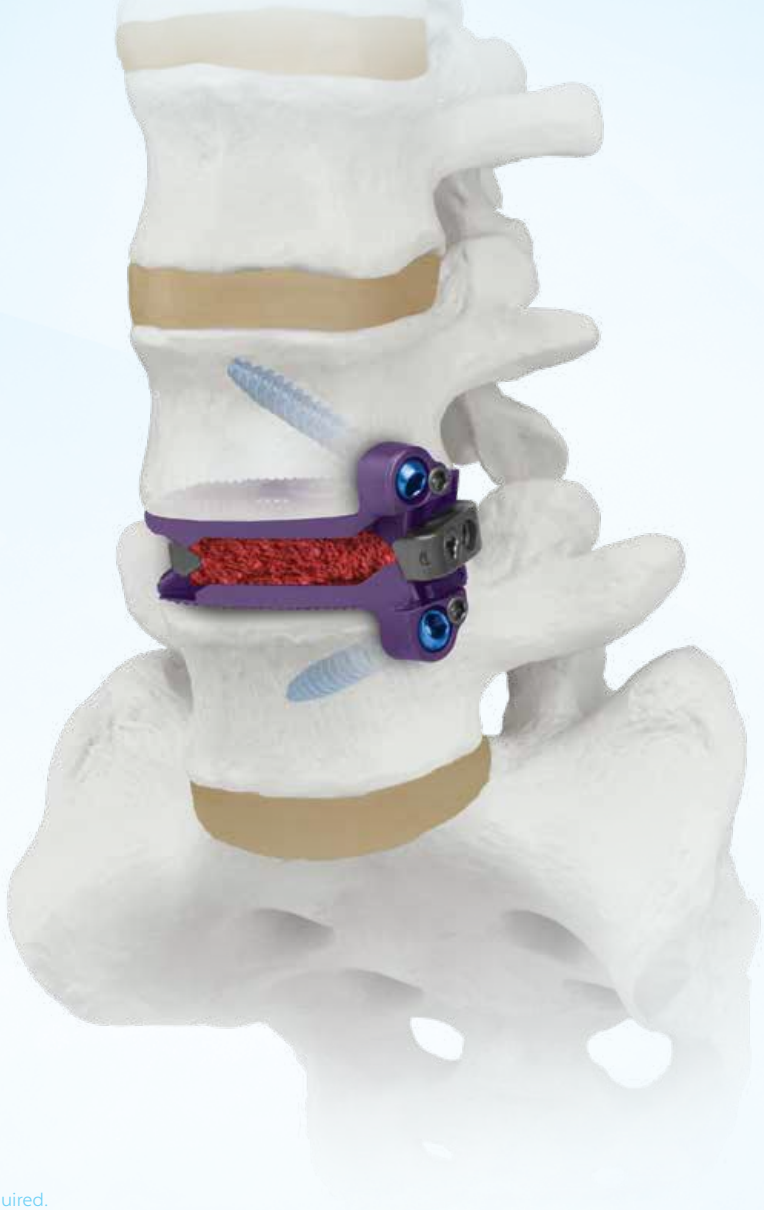
GLOBUS MEDICAL



Supplemental fixation required.

ELSA®-ATP

Anterior-to-Psoas Expandable Lumbar Interbody Spacer

SURGICAL TECHNIQUE GUIDE

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Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

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SURGICAL TECHNIQUE GUIDE

ELSA®-ATP

ELSA®-ATP

Anterior-to-Psoas Expandable Lumbar Interbody Spacer

ELSA®-ATP is an expandable lumbar interbody fusion spacer designed to ease delivery from an anterior-to-psoas lateral approach. This implant and associated instruments allow for a traditional lateral footprint while avoiding the need to dissect the psoas muscle.

MINIMIZES PSOAS RETRACTION

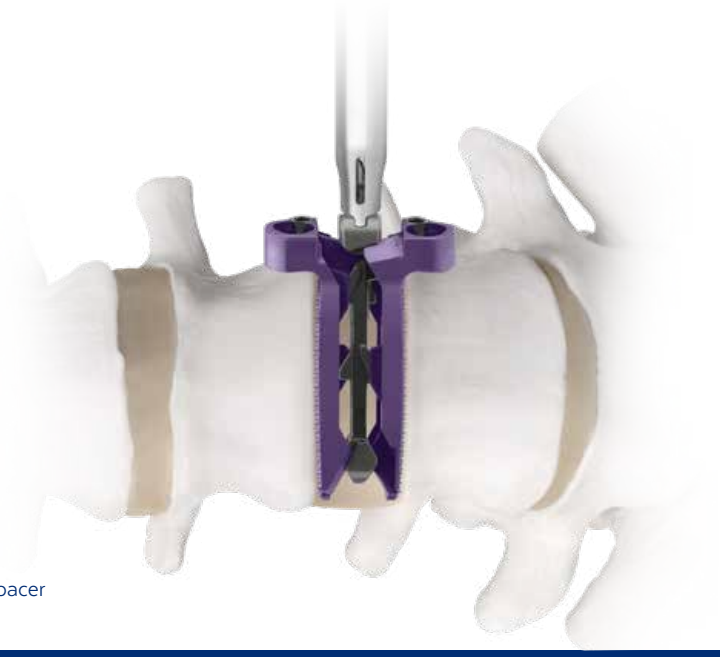
Anterolateral angled instruments allow for thorough disc preparation and direct lateral implant placement with less retraction on the psoas muscle.

FACILITATES ACCESS AT L4-L5

Anterolateral angled fixation aligns with oblique access to ease placement and avoid the iliac crest.

INTRAOPERATIVE VERSATILITY

Compatible with anchors and screws, providing multiple options for securing the spacer to the vertebral body.



LARGE GRAFT WINDOW

IN SITU BONE GRAFT DELIVERY PORT

UP TO 7MM OF EXPANSION

ROBUST TITANIUM BODY

INTEGRATED OBLIQUE ANGLED FIXATION

COMPATIBLE WITH ANCHORS AND SCREWS*

*Supplemental fixation required.

IMPLANT OVERVIEW

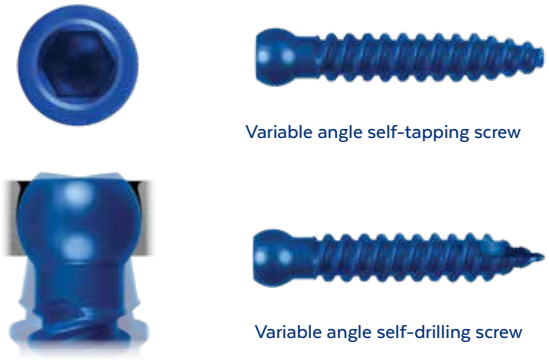
ELSA®-ATP Spacer

- Sagittal profiles: 0°, 6°, and 10°
- Expansion ranges:
  - 7–14mm, 0°
  - 8–15mm, 6° lordotic
  - 10–17mm, 0°
  - 10–17mm, 10° lordotic
- Lengths: 40–65mm, in 5mm increments
- Width: 20mm

Variable angle
Self-Drilling Screw

ELSA®-ATP Screws

- Titanium bone screws
- Variable angle screws (0°–20°)
- Lengths: 30–60mm, in 5mm increments
- Diameter: 5.5mm
- Self-tapping and self-drilling
- Hydroxyapatite (HA) coated option



Variable angle self-tapping screw

Variable angle self-drilling screw

Anchors

- Titanium anchor
- Lengths: 22, 25, 27mm
- Diameter: 5.4mm
- Variable angled anchor (0°–22°)

INSTRUMENT OVERVIEW

DISC PREPARATION INSTRUMENTS

Bayonetted Annulotomy Knife 675.405S

Penfield, Bayonetted, Pull 675.173

Penfield, Bayonetted, Pull, 190mm 675.174

Long Penfield 625.811

Cobb Elevator, Angled, Down, 10mm 6154.1110

Cobb Elevator, Angled, Up, 10mm 6154.1111

DISC PREPARATION INSTRUMENTS (CONT'D)

Cobb Elevator, Angled, Up, 20mm 6154.1121

Cobb Elevator, Angled, Up, 7°, 10mm 6154.1131

Cobb Elevator, Angled, Up, 7°, 20mm 6154.1141

Cobb Elevator, Angled, Down, 20mm 6154.1120

Cobb Elevator, Angled, Down, 7°, 10mm 6154.1130

Cobb Elevator, Angled, Down, 7°, 20mm 6154.1140

Large Cobb Elevator 675.503

DISC PREPARATION INSTRUMENTS (CONT'D)

Small Cobb Elevator 675.504

Double Rasp, Angled, Down, 12x20mm 6154.1403

Cup Curette, Angled, Down, 6.5x9.5mm, Straight 6154.1501

Cup Curette, Angled, Down, 6.5x9.5mm, 15° 6154.1520

Double Ring Curette, Angled, Down, 10mm, Straight 6154.1530

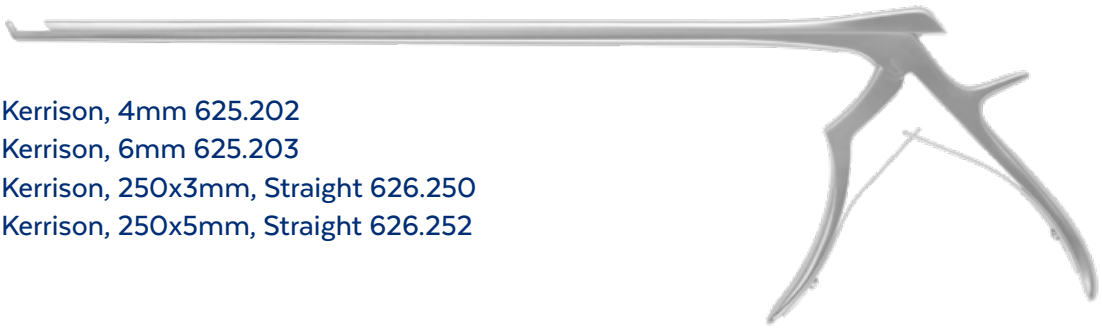
Cup Curette, Angled, Up, 6.5x9.5mm, Straight 6154.1502

Cup Curette, Angled, Up, 6.5x9.5mm, 15° 6154.1521

DISC PREPARATION INSTRUMENTS (CONT'D)

Ring Curette, Angled, Down, 10mm, 7° 6154.1533

Ring Curette, Angled, Up, 10mm, 7° 6154.1534



Kerrison, 4mm 625.202
Kerrison, 6mm 625.203
Kerrison, 250x3mm, Straight 626.250
Kerrison, 250x5mm, Straight 626.252

Disc Rongeur, 4mm 625.305
Disc Rongeur, 6mm 625.307
Disc Rongeur, 250x4mm, Straight 626.240
Disc Rongeur, 250x6mm, Straight 626.241

Disc Rongeur, Angled, Down, 4mm 6154.1240
Disc Rongeur, Angled, Down, 6mm 6154.1241
Disc Rongeur, Angled, Down, 250x4mm 6154.1260
Disc Rongeur, Angled, Down, 250x6mm 6154.1261

TRIALS

Trial, Angled Down

18mm Wide Trials		
Height	0° Lordotic	6° Lordotic
5mm	6154.2105	6154.2125
7mm	6154.2107	6154.2127
9mm	6154.2109	6154.2129
11mm	6154.2111	6154.2131
13mm	6154.2113	6154.2133
15mm	6154.2115	6154.2135
17mm	6154.2117	6154.2137

20mm Wide Trials			
Height	0° Lordotic	6° Lordotic	10° Lordotic
5mm	6154.2005	6154.2025	-
7mm	6154.2007	6154.2027	-
9mm	6154.2009	6154.2029	-
11mm	6154.2011	-	6154.2331
13mm	6154.2013	-	6154.2333
15mm	6154.2015	-	6154.2335
17mm	6154.2017	-	6154.2337

22mm Wide Trials		
Height	0° Lordotic	6° Lordotic
5mm	6154.2205	6154.2225
7mm	6154.2207	6154.2227
9mm	6154.2209	6154.2229
11mm	6154.2211	6154.2231
13mm	6154.2213	6154.2233
15mm	6154.2215	6154.2235
17mm	6154.2217	6154.2237

SCRAPERS

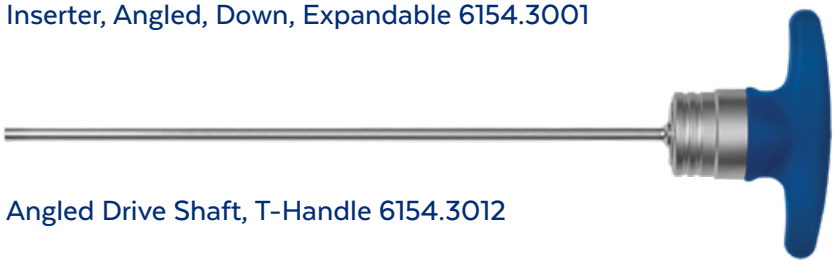
	Height	Part No.
	5mm	675.605
	7mm	675.607
	9mm	675.609
	11mm	675.611
	13mm	675.613
	15mm	675.615
	17mm	675.617

DISTRACTORS

	Height	Part No.
	5mm	675.855
	7mm	675.857
	9mm	675.859
	11mm	675.861
	13mm	675.863

IMPLANT INSERTION INSTRUMENTS

Inserter, Angled, Down, Expandable 6154.3001



Angled Drive Shaft, T-Handle 6154.3012

Counter-Torque, M6x1 6154.3003

Inserter, Angled, Down 6154.0980

Inserter, Angled, Down, Expandable 6154.3001
Angled Drive Shaft, T-Handle 6154.3012
Counter-Torque, M6x1 6154.3003
(Assembled)

Torque-Limiting Driver, 3.0Nm 693.600

Single Anchor Inserter, Lateral 6219.1000

SCREW PREPARATION INSTRUMENTS

Straight 5.5mm Drill 687.520

Straight Awl 687.524

Straight 5.5mm Tap 687.526

Straight Shaft 3.5mm Hex Driver 687.527

3.5 Expandable Hex Driver 687.603

Adjustable Awl 687.624

Adjustable Drill 687.625

SCREW PREPARATION INSTRUMENTS (CONT'D)

Adjustable Awl/Drill Sleeve 687.675

Awl/Drill Depth Adjuster 687.676

Adjustable Tap Sleeve 687.680

Tap Depth Adjuster 687.681

Adjustable Tap 687.626

Set Screw Driver, 2.5mm Hex 1.0Nm Torque 676.600

SCREW PREPARATION INSTRUMENTS (CONT'D)

Quick-Connect Swivel Handle 687.005

Ratchet Handle 687.105

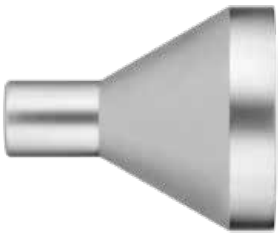
GRAFT INTRODUCTION INSTRUMENTS

Threaded Funnel Shaft 693.610

Threaded Funnel Shaft, 25° 6154.0660

Graft Plunger 693.611

Graft Plunger, 25° 6154.0611



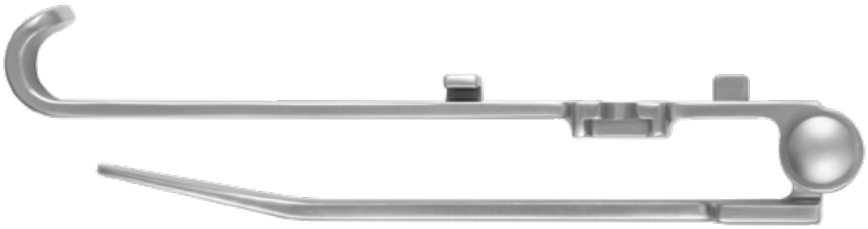
Bone Funnel 681.013

ADDITIONAL INSTRUMENTS

Removal Tool 693.613

Angled Inserter Wrench 6154.0614

Long Throw Slide Hammer 675.004



Retractor Assembly, 20x120mm 698.117
Retractor Assembly, 20x150mm 698.118

MARS™3VL INTEGRATED BONE PIN (IBP) COMPONENTS

IBP, 3.3mm, 80–110mm, Sterile 6133.0442S
IBP, 3.3mm, 120–150mm, Sterile 6133.0443S
IBP, 3.3mm, 160–200mm, Sterile 6133.0444S

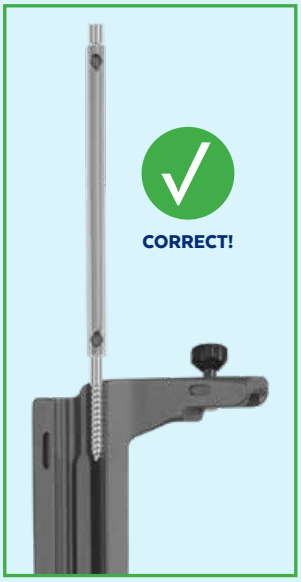
Sleeve, IBP, 80–110mm, Sterile 6133.0542S
Sleeve, IBP, 120–150mm, Sterile 6133.0543S
Sleeve, IBP, 160–200mm, Sterile 6133.0544S

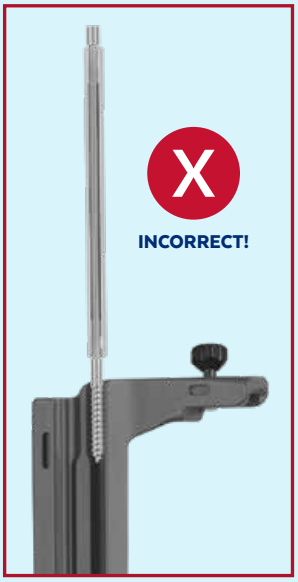
MARS™3VL IBP ASSEMBLY

Select the appropriate length IBP and sleeve based on the blade length mounted to the MARS™3VL Retractor. Snap the IBP into the corresponding sleeve. Place the assembly down the MARS™3VL ATP Blade. See page 24 for more information on the MARS™3VL retractor and ATP blades.

IBP

Sleeve





MARS™3VL Blades			
			
Length	**Posterior**	**IBP, Right**	**IBP, Left**
40mm	6133.1040	6133.2041	6133.3041
50mm	6133.1050	6133.2051	6133.3051
60mm	6133.1060	6133.2061	6133.3061
70mm	6133.1070	6133.2071	6133.3071
80mm	6133.1080	6133.2081	6133.3081
90mm	6133.1090	6133.2091	6133.3091
100mm	6133.1100	6133.2101	6133.3101
110mm	6133.1110	6133.2111	6133.3111
120mm	6133.1120	6133.2121	6133.3121
130mm	6133.1130	6133.2131	6133.3131
140mm	6133.1140	6133.2141	6133.3141
150mm	6133.1150	6133.2151	6133.3151
160mm	6133.1160	6133.2161	6133.3161
170mm	6133.1170	6133.2171	6133.3171
180mm	6133.1180	6133.2181	6133.3181
190mm	6133.1190	6133.2191	6133.3191
200mm	6133.1200	6133.2201	6133.3201

SURGICAL TECHNIQUE

ELSA®-ATP

Refer to the package insert at the back of this guide for important information on the intended use/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

ELSA®-ATP Spacers are to be used with supplemental fixation. Refer to the selected supplemental fixation system's surgical technique guide for specific instructions.

STEP 1 PATIENT PREPARATION

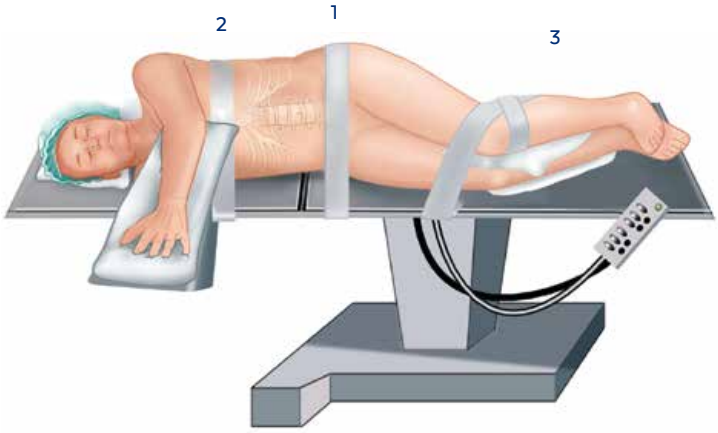
Use an oblique lateral (anterior-to-psoas) approach from the patient's left or right side.

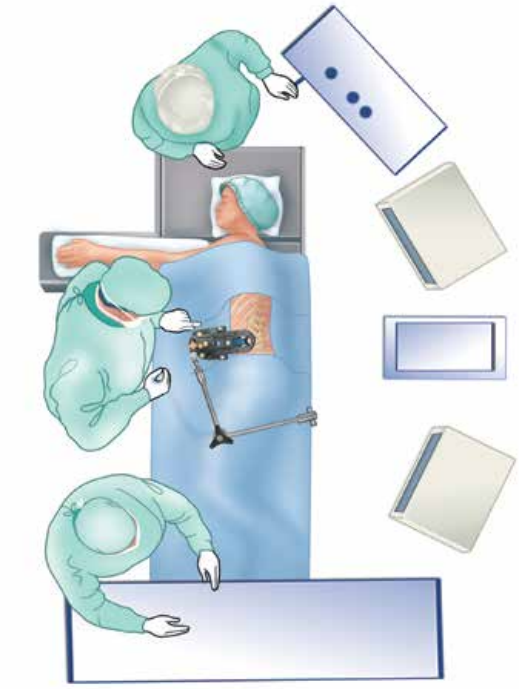
Place the patient on a flexible surgical table in a straight 90° lateral decubitus position. The legs of the patient may be slightly flexed. Breaking of the surgical table is not required.

Secure the patient at the following locations:

- Just beneath the iliac crest
- Over the thoracic region, just under the shoulder
- From the back of the table, over the ankle, and past the knee to the front of the table

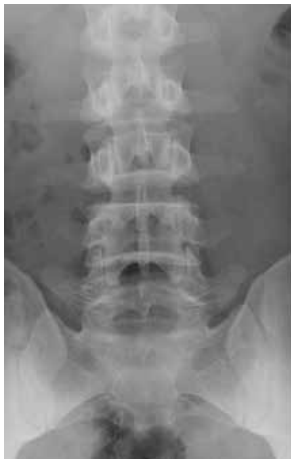
Position the C-arm posterior to the patient. Access the patient from the abdominal side.



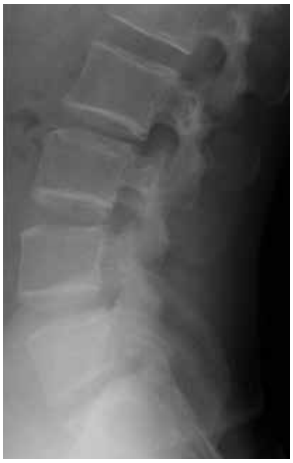


Fluoroscopic Confirmation

Use fluoroscopy to ensure the spine is oriented in a straight lateral position. Adjust the table so the C-arm provides straight AP images when at 0° and straight lateral images at 90°.



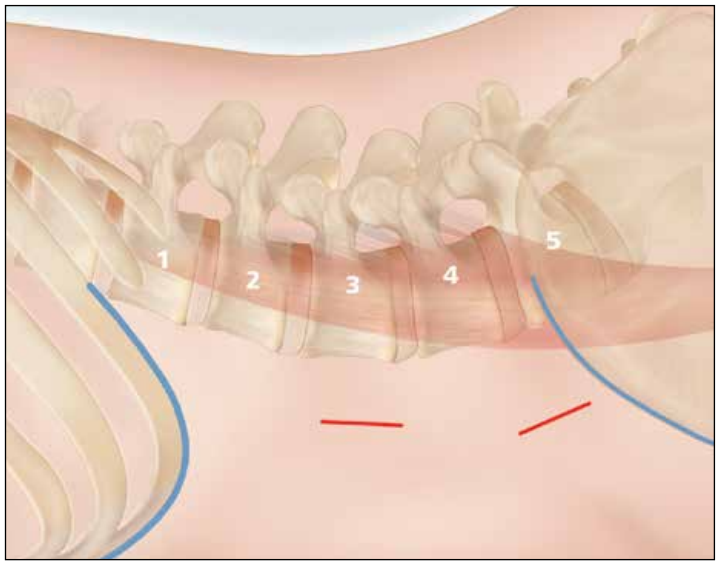
AP



Lateral

Incision Location

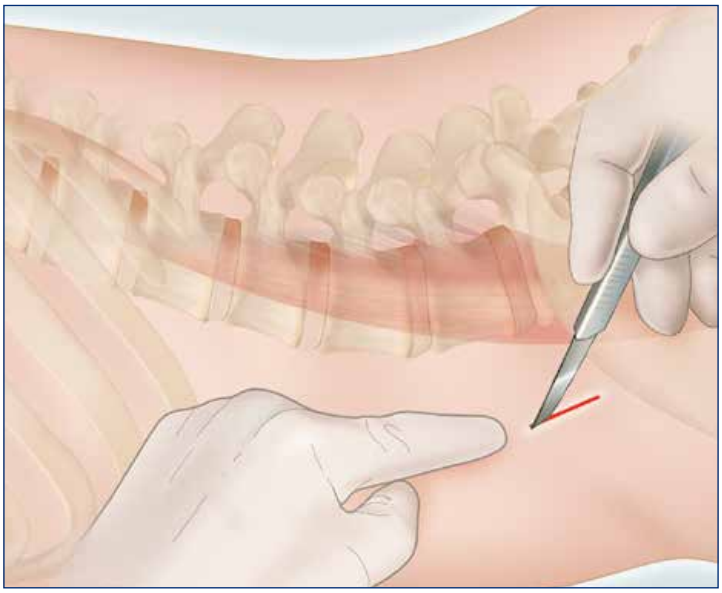
Carefully clean the operative area. Use fluoroscopy to identify the target segment. Mark the skin to further identify the iliac crest and the midline of the targeted disc space. Trace an access incision mark 4–10cm anteriorly to the midline of the target disc to indicate the position and insertion site for the retractor.



STEP 2 INCISION AND DISSECTION

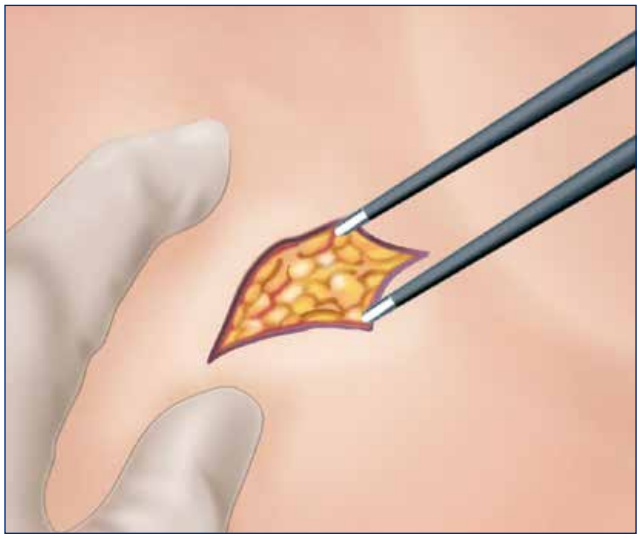
Incision

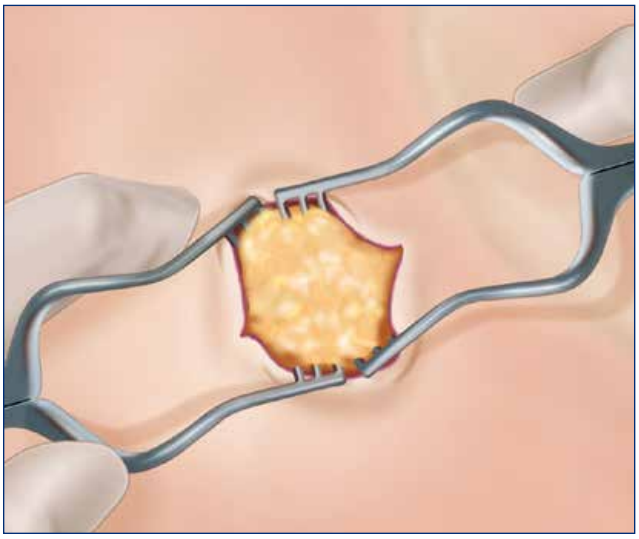
Make a small oblique incision over top of the access incision mark, anterior to the targeted disc space. If treating multiple levels, a single incision may be made anterior to the vertebral body in between each operative level.



Dissection

Dissect through adipose tissue using **Bipolar Forceps**. Position the **Weitlaner Retractor** to hold the initial dissected tissue.

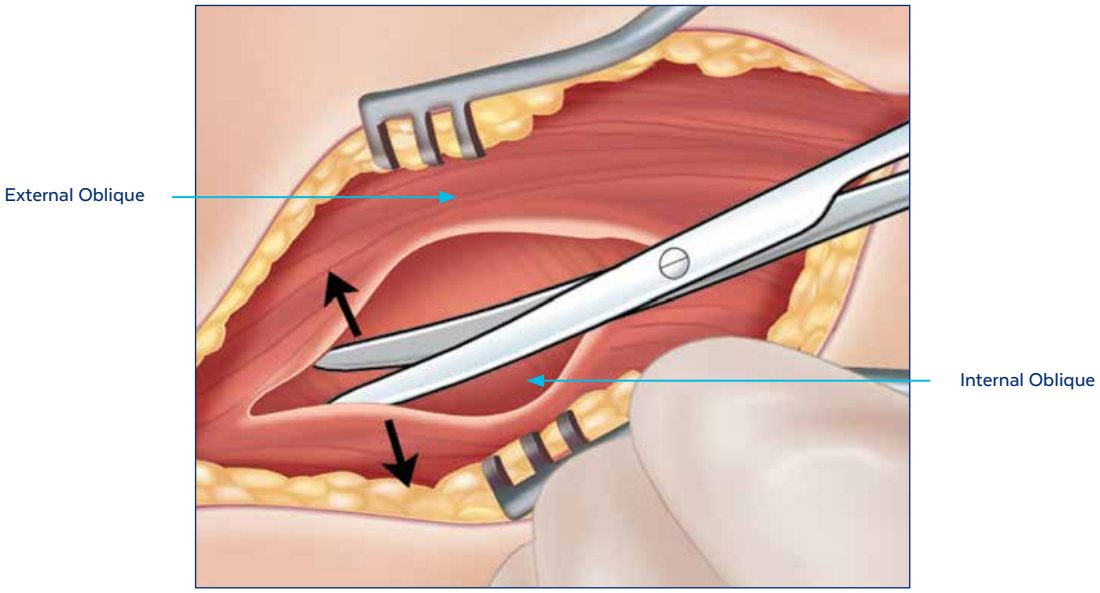




STEP 3 SPLIT ABDOMINIS MUSCLES

Open the External and Internal Oblique Muscles

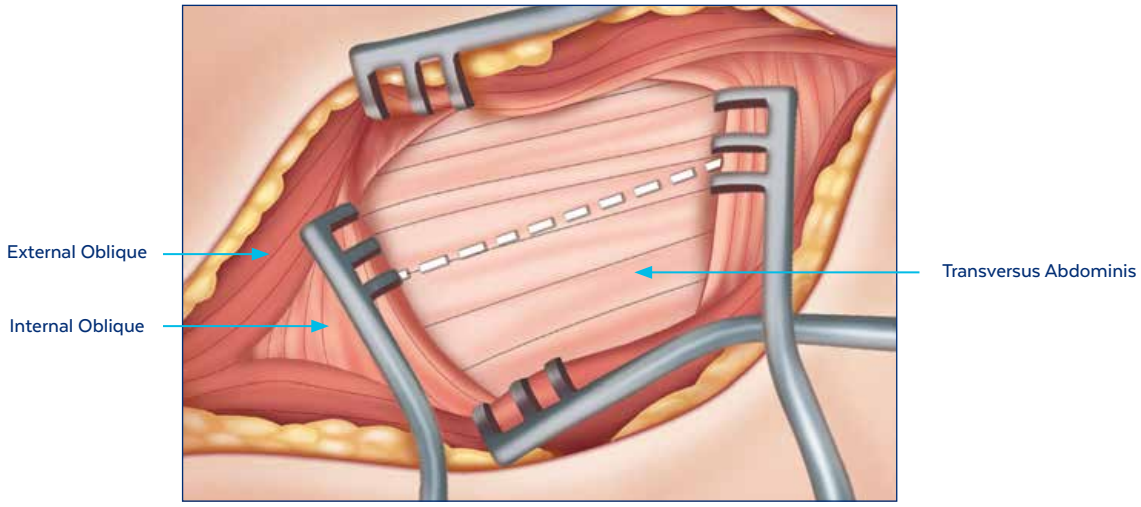
Using a combination of the **Metzenbaum Scissors** and Bipolar Forceps, split each layer in line with its respective fibers. Use hand-over-hand Weitlaner retraction on each successive muscular layer. Be aware of cutaneous nerves while moving between muscle layers.



Incising the Transversus Abdominis

Identify the transversus abdominis and incise sharply with scissors approximately 2–3cm, cautiously splitting each layer in line with its fibers.

The transversus abdominis must be closed at the end of the procedure to prevent abdominal hernia.



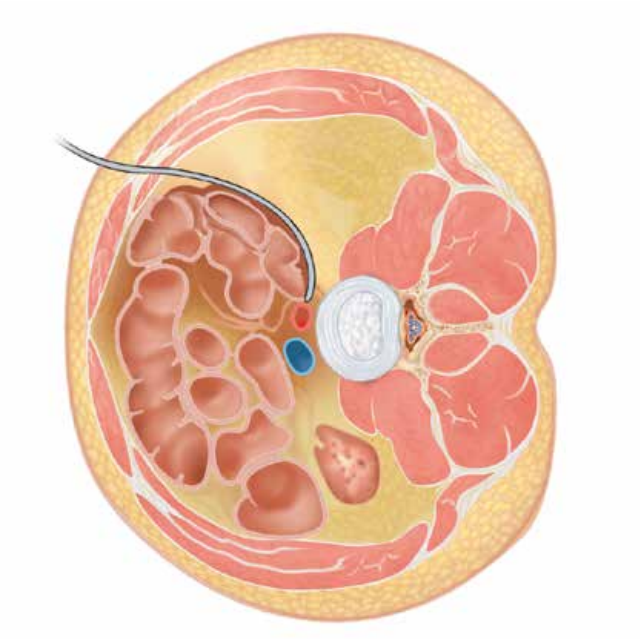
STEP 4 NAVIGATING THE RETROPERITONEAL SPACE

Retract the Peritoneum

Once the external oblique, internal oblique, and transversus abdominis have been split, retract the peritoneum.

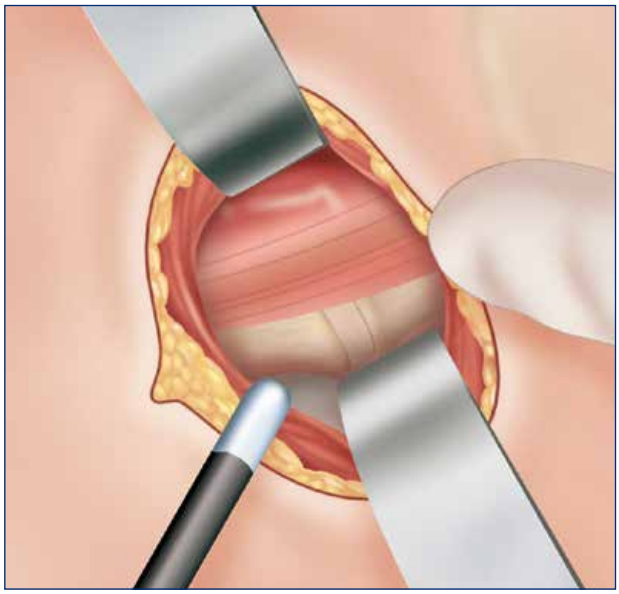
Insert the **Deaver Retractor** in an anterior position superficial to the psoas. Use a wet mini lap to protect the peritoneum.

Using the Deaver on the anterior of the disc space, dissect the fat plane from the peritoneum and retract anteriorly, past the anterior of the psoas.



Expose the Psoas Muscle

Use the **Endoscopic Dissector Sticks** and a wet mini lap to dissect and softly separate the retroperitoneal space, enabling a direct look at the anterior of the psoas and potentially the anterior of the disc space.

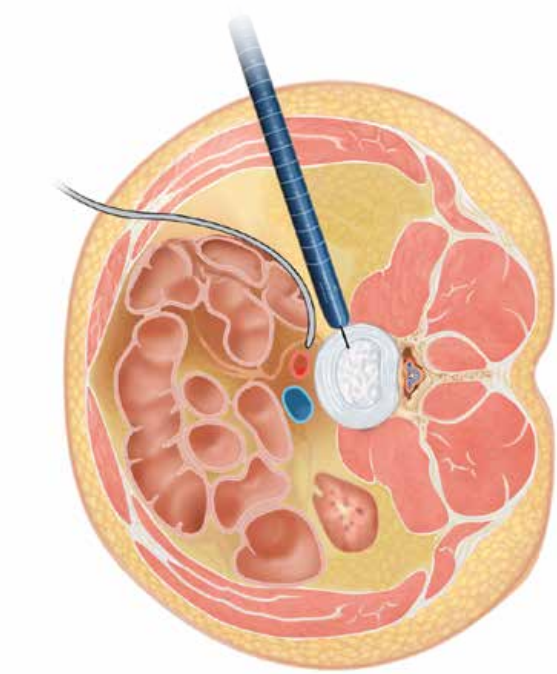


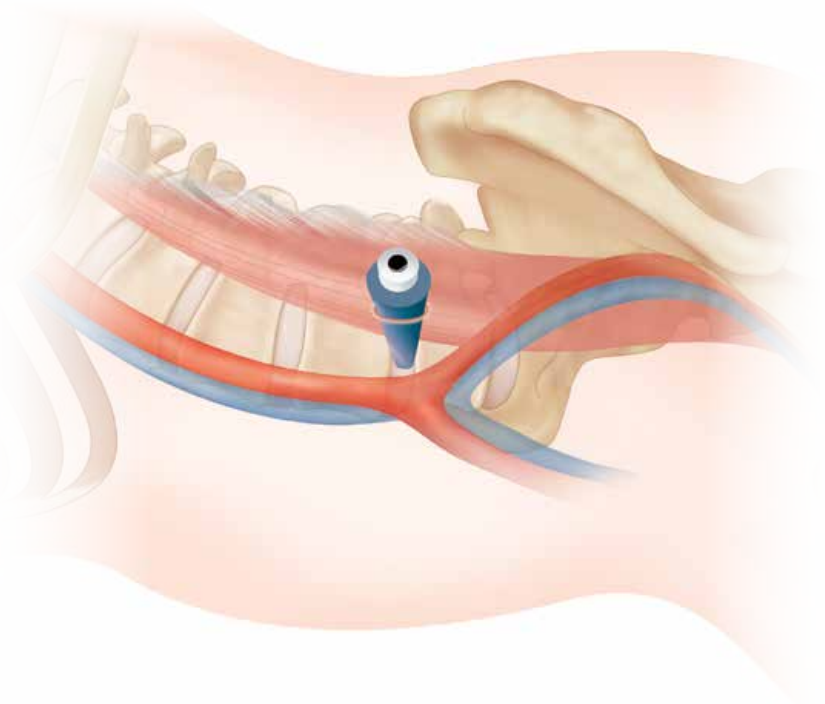
STEP 5 DILATION

Dilator Insertion

If the disc space is not visible, gently retract the psoas muscle posteriorly. After a safe retroperitoneal pathway is established under direct visualization, insert **Cannula A** and place on the disc space anterior to psoas. Verify location using fluoroscopy. Advance the K-wire through Cannula A and into the disc at the desired location. Sequentially dilate using **Cannula B**.

Depth markings on Cannulas A and B determine the proper MARS™3VL blade length. When the cannulas are fully seated on the disc space, note the depth markings that are flush with the patient's skin. Add 10mm to the measurement to determine blade length.

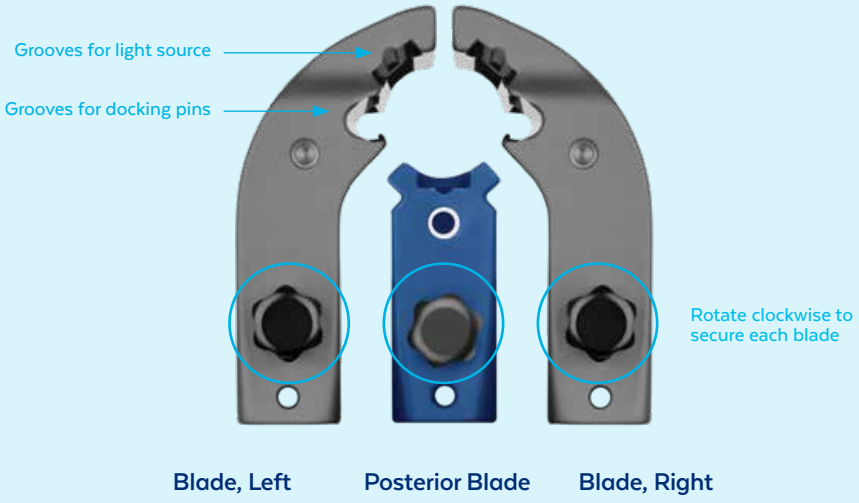




STEP 6 RETRACTOR INSERTION

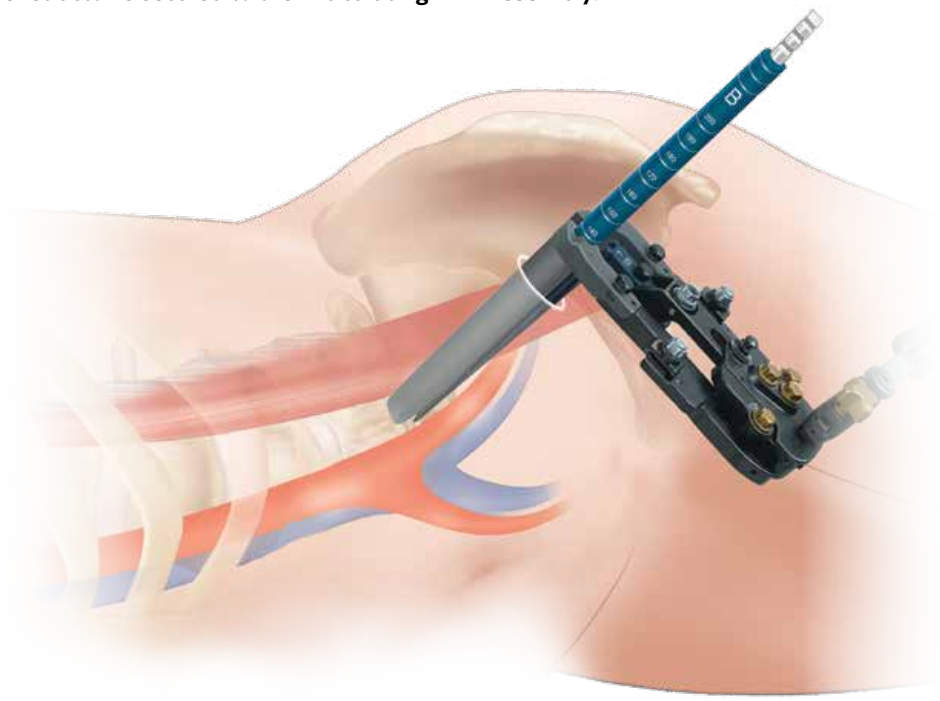
MARS™3VL RETRACTOR ASSEMBLY

Select the appropriate length blade and attach to the corresponding blade mount on the **MARS™3VL Retractor**. Rotate the thumbscrew clockwise until finger tight. Place the **Socket Driver 8mm/10mm** on top of the thumbscrew and rotate clockwise to fully secure the blade. Repeat for all blades.



MARS™3VL Retractor Insertion

With the retractor fully closed, insert it over Cannula B. To minimize tissue creep, apply gentle downward pressure on the frame until the retractor is secured to the **Articulating Arm Assembly**.

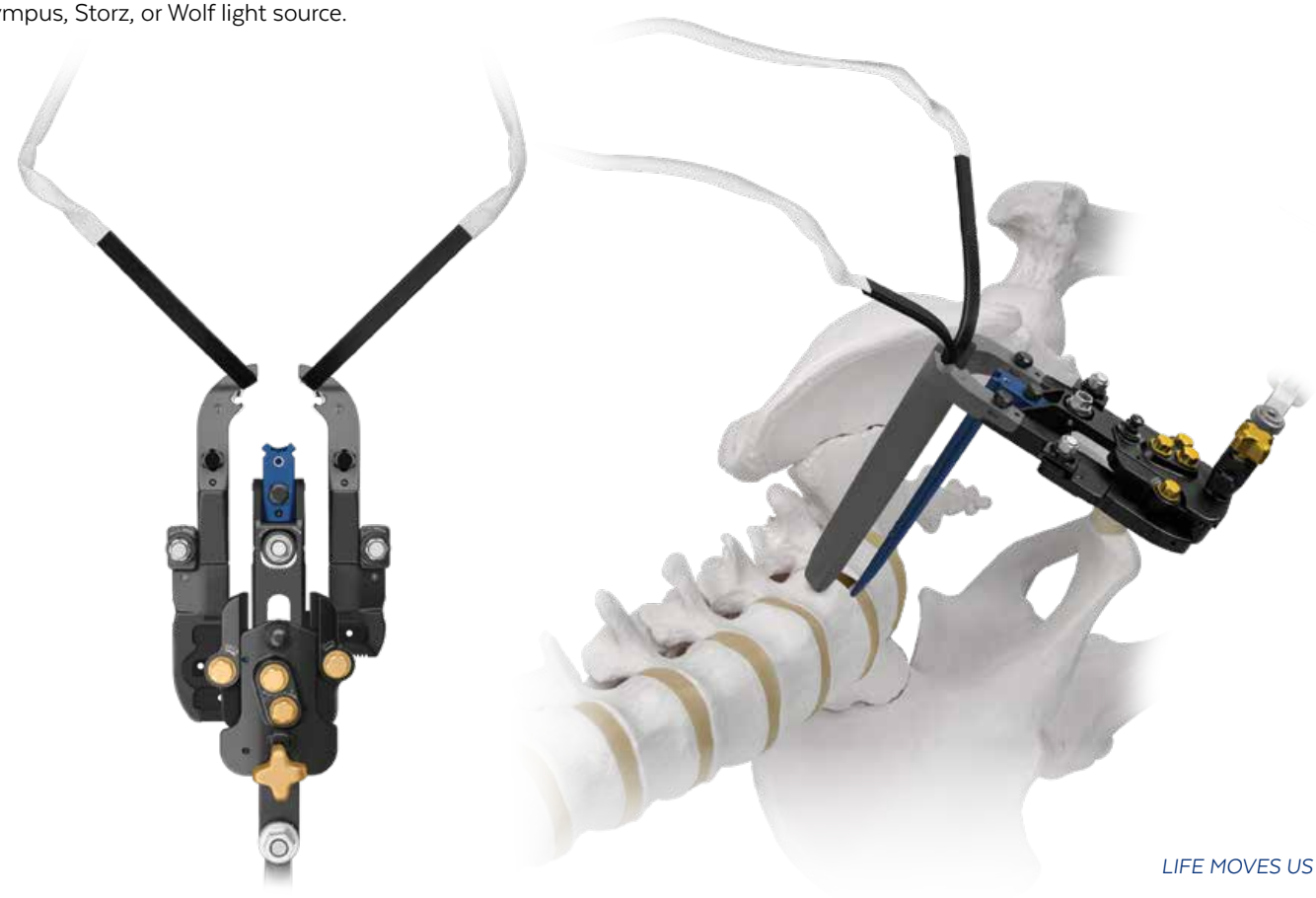


Use fluoroscopy to ensure the retractor is in a desired position above the disc space. Once positioning is achieved, remove Cannulas A and B to expose the working corridor. For added fixation, docking pins may be inserted along the designated grooves in the blades.

Illumination System Insertion

Insert the **Illumination System** along the designated grooves in the retractor blades. Deploy the light to the bottom of the blade and adjust upwards as needed. Bend the malleable away from the surgical field.

The Fiber-Optic Cord attaches to the light source used for head lamps or endoscopes. The adaptors accommodate an ACMI, Olympus, Storz, or Wolf light source.



STEP 7 DISC PREPARATION

Annulotomy

Use the **Bayonetted Annulotomy Knife** to create a window centered in the anterior half of the annulus, large enough for graft insertion.

Contralateral Annulus Release

Pass the **Angled Cobb Elevator** along both endplates to release the contralateral annulus, allowing for height restoration upon implant insertion.

Using Angled Cobb Elevator

Using Angled Disc Rongeur

Disc Space Preparation

Leaving the posterior annulus intact, remove the intervertebral disc and osteophytes as needed. Angled instruments including the **Disc Box Cutter, Disc Rongeurs, Kerrisons, Curettes, Scrapers,** and **Rasps** are available for disc removal and endplate preparation.

Preserve the posterior and anterior walls of the annulus to provide peripheral support for the implant and bone graft material.

Endplate Preparation

Remove the superficial layers of the cartilaginous endplates to expose bleeding bone.

STEP 8 DISTRACTION AND IMPLANT SIZING

To determine the appropriate implant size, insert the smallest **Trial** into the disc space, moving to larger trials as needed.

For correct orientation, insert the trial into the disc space with the side etched “ANTERIOR” facing the patient’s anterior side. Determine which trial best fits the prepared disc space. A secure fit is desirable to maintain disc height and to stabilize the segment.

Ensure the tapered end of the trial overhangs the contralateral edge to account for implant endplate contact.

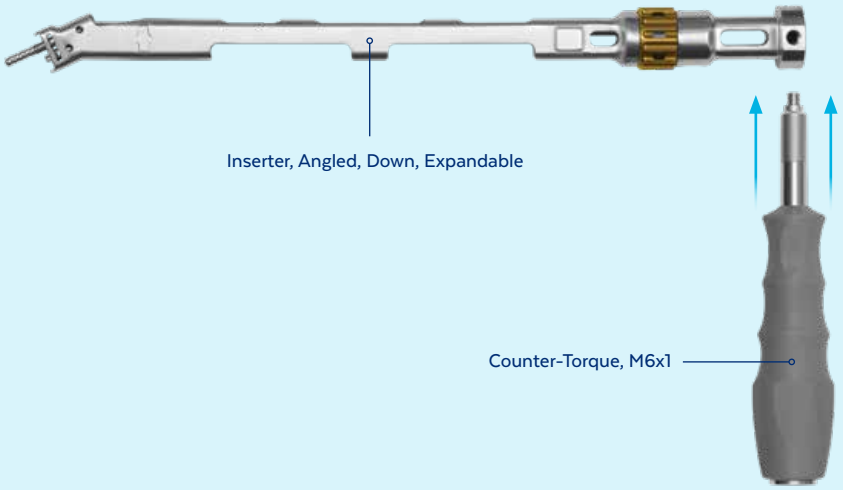
Implant sizing

STEP 9 IMPLANT INSERTION

Select the appropriate implant length and height range based on trial size.

ASSEMBLING THE INSERTER

Thread the **Counter-Torque, M6x1** into the **Inserter, Angled, Down, Expandable,** until finger tight. Avoid overtightening. Four attachment options are available for preferred orientation.

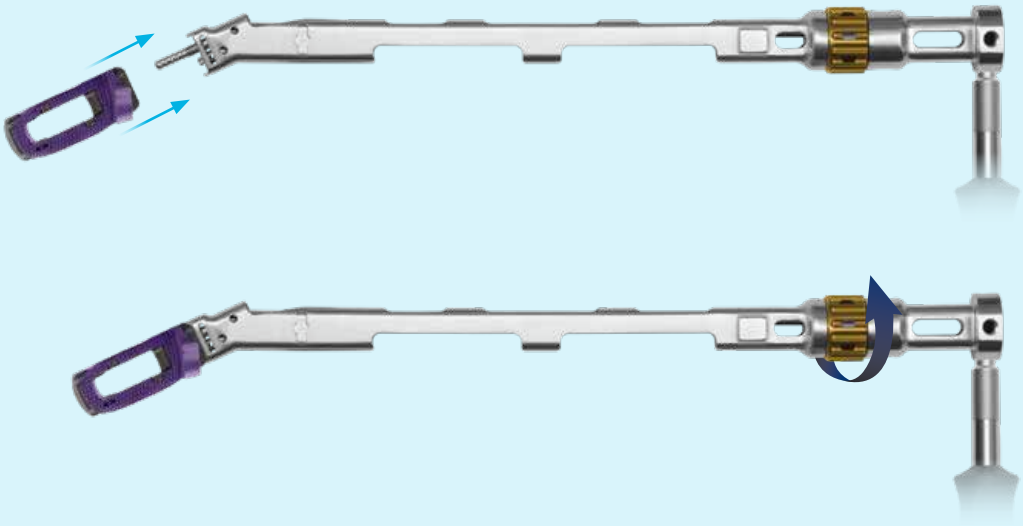


ATTACHING THE IMPLANT

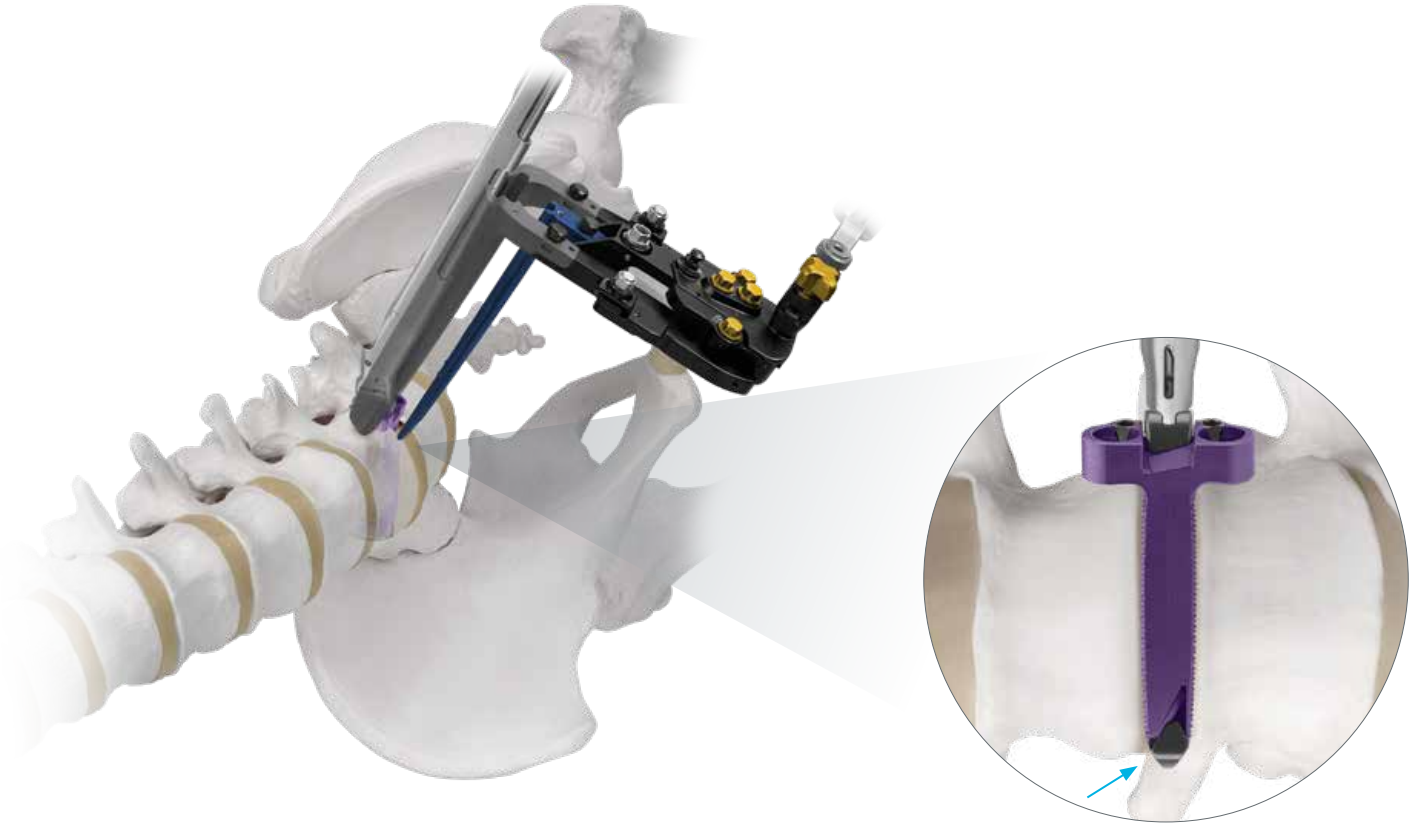
Select the appropriately sized implant and pack allogenic or autogenous bone graft material into the graft chamber.

Place the inserter into the threaded hole of the implant and orient the inserter's tabs into the implant's slots. To thread the implant on the inserter, rotate the gold thumbwheel clockwise until it stops.

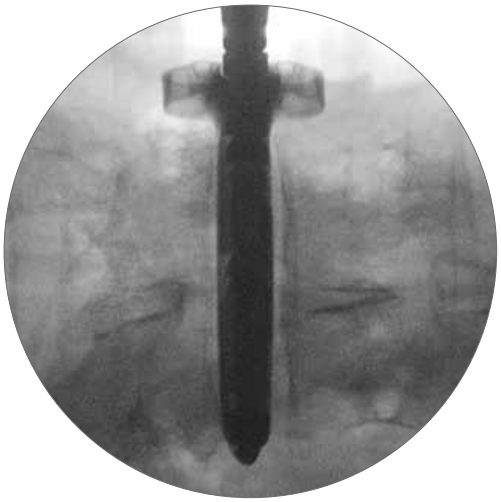
*Note: Do not use the **Angled Inserter Wrench** to tighten the implant.*



Insert the implant obliquely into the disc space in the collapsed state, using the Implant Inserter Assembly. Once the implant is inserted a few millimeters, adjust the distal implant tip anteriorly to orient the implant laterally and insert further into the disc space. Ensure the tapered end of the implant overhangs the contralateral apophyseal ring of the vertebrae. If necessary, impact the end of the inserter.



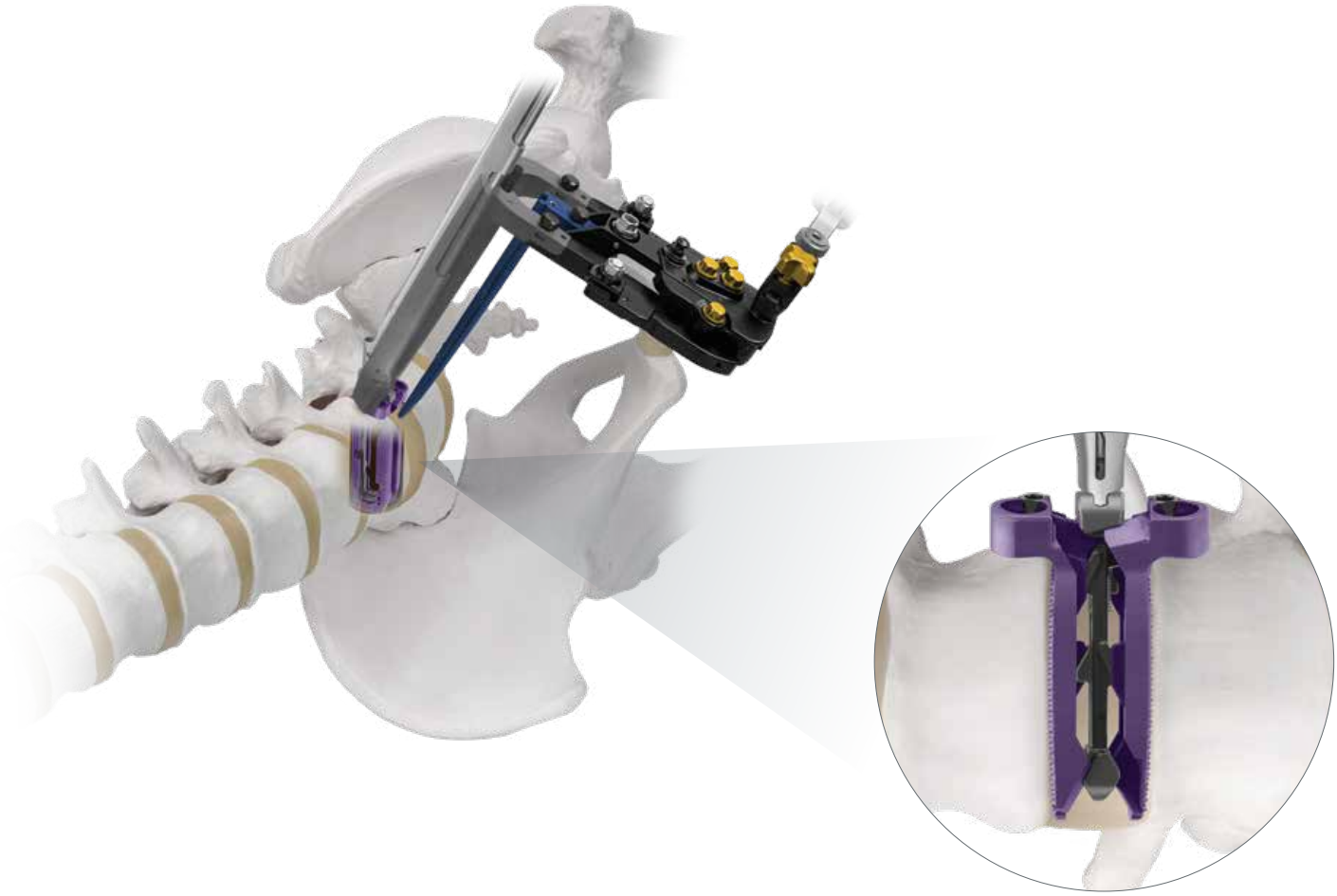
Tapered end of implant overhanging contralateral edge



Implant inserted into disc space (AP view)

STEP 10 IMPLANT EXPANSION

Insert the **Angled Drive Shaft, T-Handle, 5.0Nm** into the Implant Inserter Assembly. Rotate clockwise to expand the implant to the desired height.



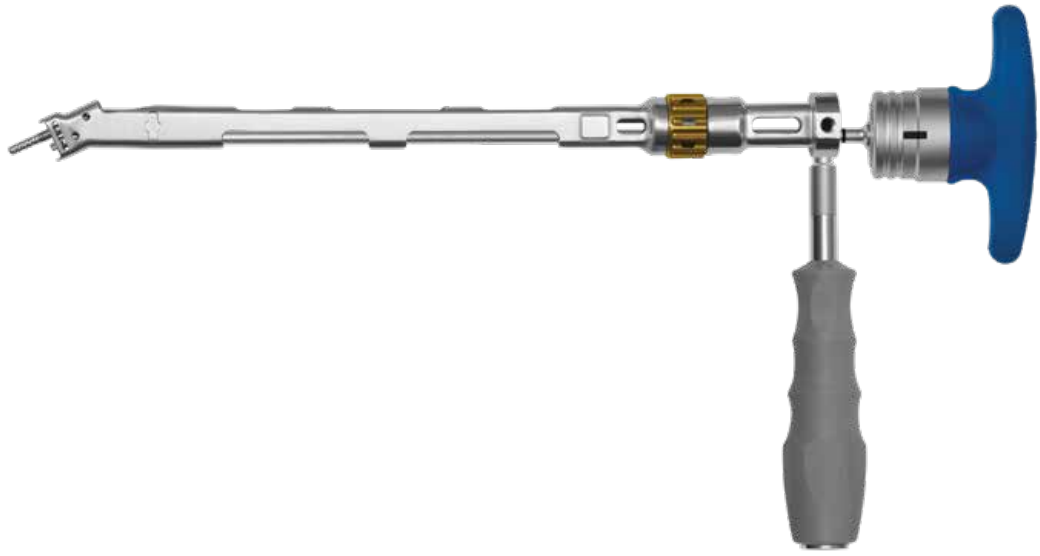
Implant expansion using Implant Inserter Assembly

Determining Implant Height

Determine implant expansion using fluoroscopy and tactile feel of the implant in the disc space. Gently toggle the implant in the AP direction until the desired fit is achieved. Refer to healthy levels above and below the operative level to further aid in determining final disc height.

Make minor height adjustments before the implant is detached from the inserter by rotating the driver clockwise to expand or counterclockwise to collapse.

Determine the overall height by counting the number of revolutions of the driver. One revolution equals 0.5mm of expansion. Use the etching on the side of the driver to help count the number of revolutions.



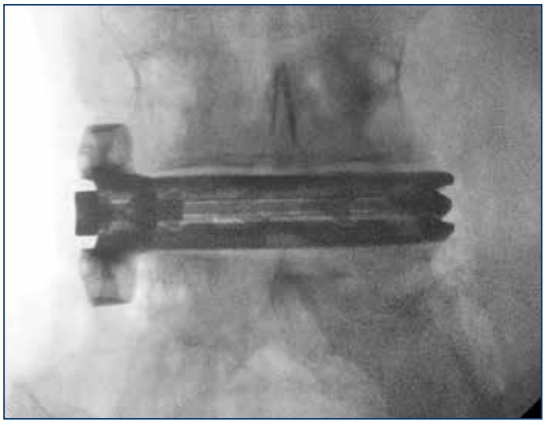
The torque-limiting Angled Drive Shaft, T-Handle, 5.0Nm helps to identify when the implant has reached its maximum expansion height or when it has exerted the 5.0Nm maximum distraction force allowed.

Note: Use caution while expanding the implant to avoid excessive distraction and damage to the endplates.

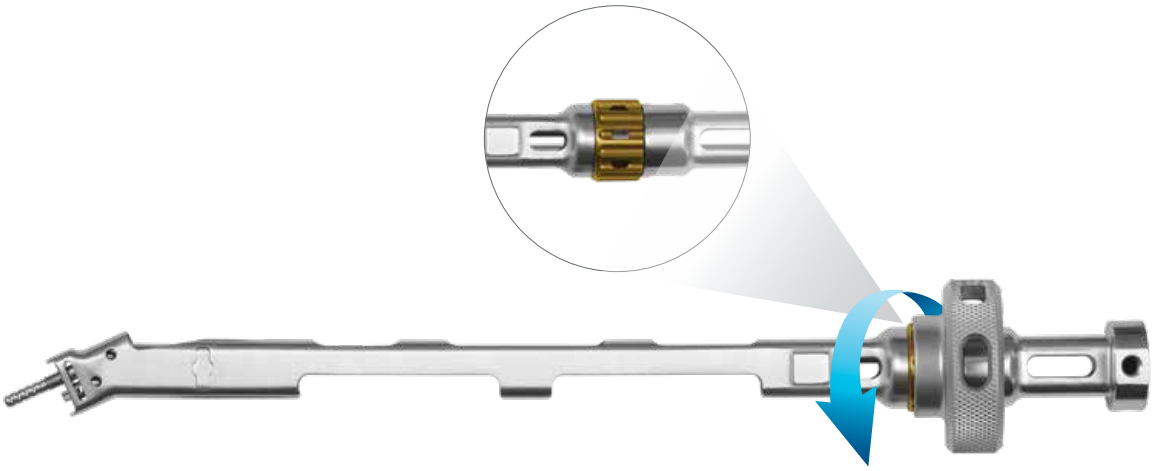
Revolutions Required											
Implant Size	Final Height (mm)										
	7	8	9	10	11	12	13	14	15	16	17
7-14mm	0	2	4	6	8	10	12	14	-	-	-
8-15mm	-	0	2	4	6	8	10	12	14	-	-
10-17mm	-	-	-	0	2	4	6	8	10	12	14

STEP 11 RADIOGRAPHIC CONFIRMATION

Use fluoroscopy to verify the final position of the implant before disengaging the Implant Inserter Assembly.



Once the desired position is achieved, disengage the Implant Inserter Assembly by removing the Angled Drive Shaft, T-Handle. Rotate the gold thumbwheel counterclockwise and gently release the inserter from the implant. If necessary, use the **Angled Inserter Wrench** to loosen the gold thumbwheel.



Using Angled Inserter Wrench to loosen gold thumb wheel

Repositioning the Implant

Once the implant is released from the inserter, it may be necessary to reposition the implant. To reattach the inserter to the implant, place the inserter into the proximal end of the implant and orient the tabs of the inserter tabs into the lateral slots on the implant. Rotate the gold thumbwheel clockwise to tighten the inserter onto the implant. Once the inserter is reattached, insert the torque-limiting Angled Drive Shaft, 5.0Nm and reduce the implant height. Contract the implant counterclockwise until two finger tight.

ELSA®-ATP may be used with two screws, two anchors, or a combination of both screws and anchors.

Screw Fixation: Follow steps 12-14 on pages 33-37.

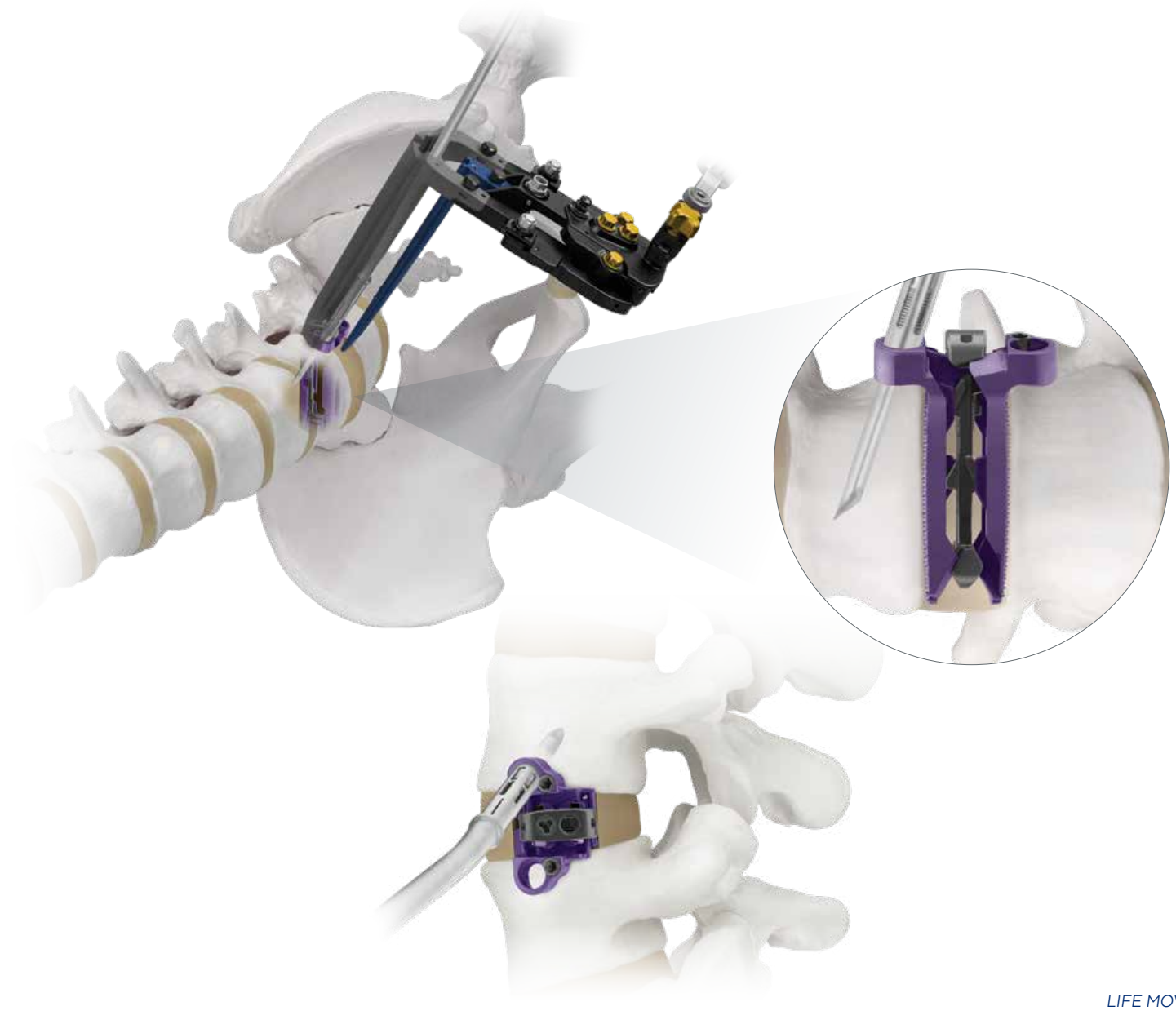
Anchor Fixation: Follow steps 12-14 on pages 38-41.

Hybrid Screw/Anchor Fixation: For screw fixation, follow steps 12-14 on pages 33-37. For anchor fixation, follow steps 12-14 on pages 38-41.

SCREW FIXATION

STEP 12 SCREW HOLE PREPARATION

Insert the desired awl through the screw hole to perforate the cortex. While inserting the awl, ensure that the flat on the upper shaft faces the most proximal endplate. Use the appropriate **Drill** and **Tap** to further prepare the screw hole. Remove any tissue in the screw hole. Refer to screw insertion (step 13) before preparing the second screw hole.

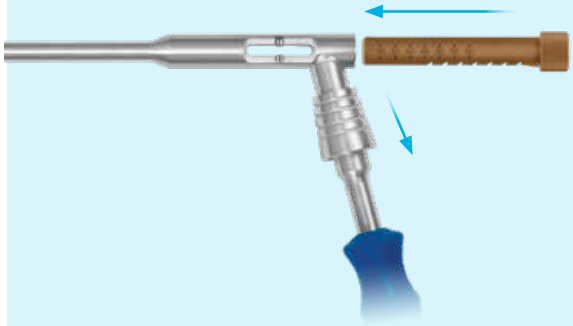


SCREW HOLE PREPARATION (CONT'D)

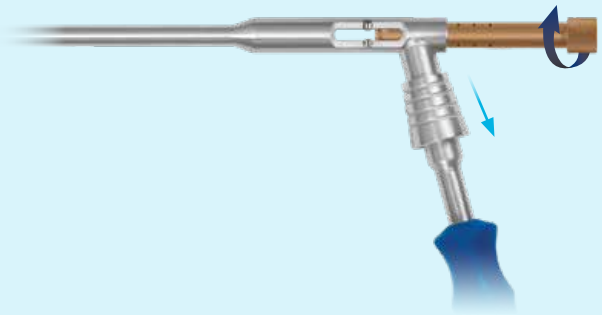
ADJUSTABLE AWL AND ADJUSTABLE DRILL ASSEMBLY

With one hand, hold the **Adjustable Awl/Drill Sleeve** and pull down on the retractable collar.

With the other hand, insert the **Tap Depth Adjuster** into the proximal end of the Adjustable Awl/Drill Sleeve until it stops.



Continue to pull down on the retractable collar. Rotate the Tap Depth Adjuster clockwise until the sleeve catches and sits in the groove. The depth adjuster should slide in and out of the sleeve freely.

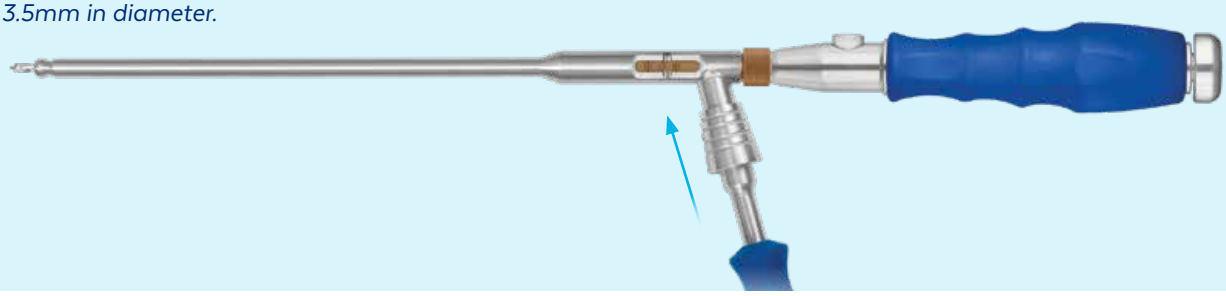


Continue to pull down on the collar and set the depth adjuster to the desired depth, indicated by the Depth Gauge. Release the collar and pull the depth adjuster until it seats firmly.

55mm depth

Select the **Adjustable Awl** or the **Adjustable Drill** and attach the **Quick-Connect Swivel Handle**.

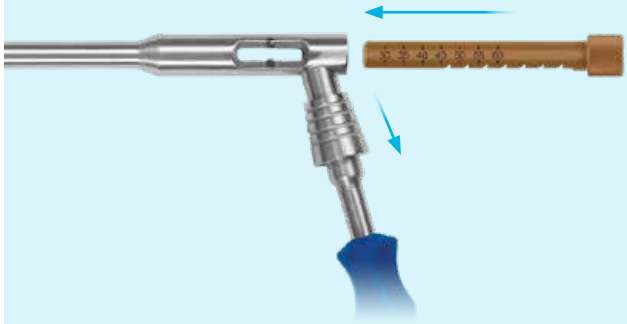
Insert the Adjustable Awl or Adjustable Drill into the proximal end of the assembly. *Note: The awl and drill are 3.5mm in diameter.*



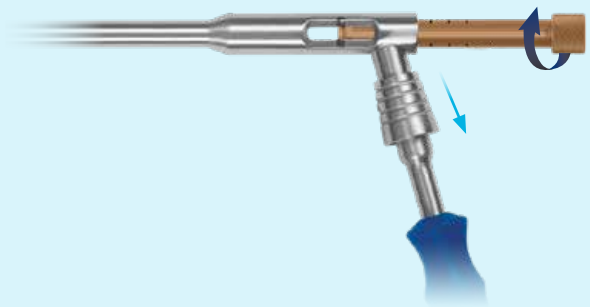
ADJUSTABLE TAP ASSEMBLY

With one hand, hold the **Adjustable Tap Sleeve** and pull down on the retractable collar.

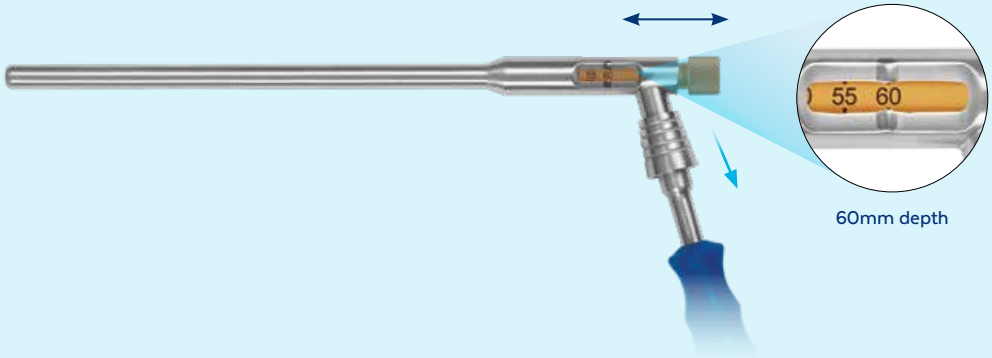
With the other hand, insert the Tap Depth Adjuster into the proximal end of the **Adjustable Tap Sleeve** until it stops.



Continue to pull down on the collar. Rotate the Tap Depth Adjuster clockwise until the sleeve catches and sits in the groove. The depth adjuster should slide in and out of the sleeve freely.

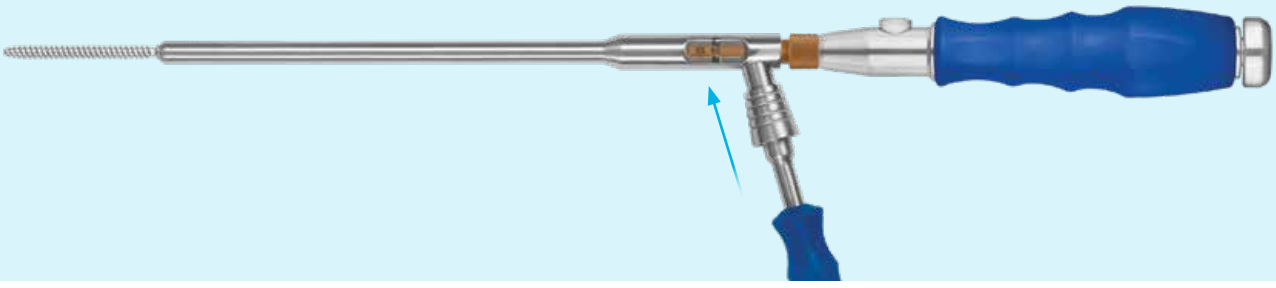


Continue to pull down on the collar and set the depth adjuster to the desired depth, indicated by the Depth Gauge. Release the collar and pull the depth adjuster until it seats firmly.



Select the Adjustable Tap, attach the Quick-Connect Swivel Handle, and insert into the proximal end of the assembly.

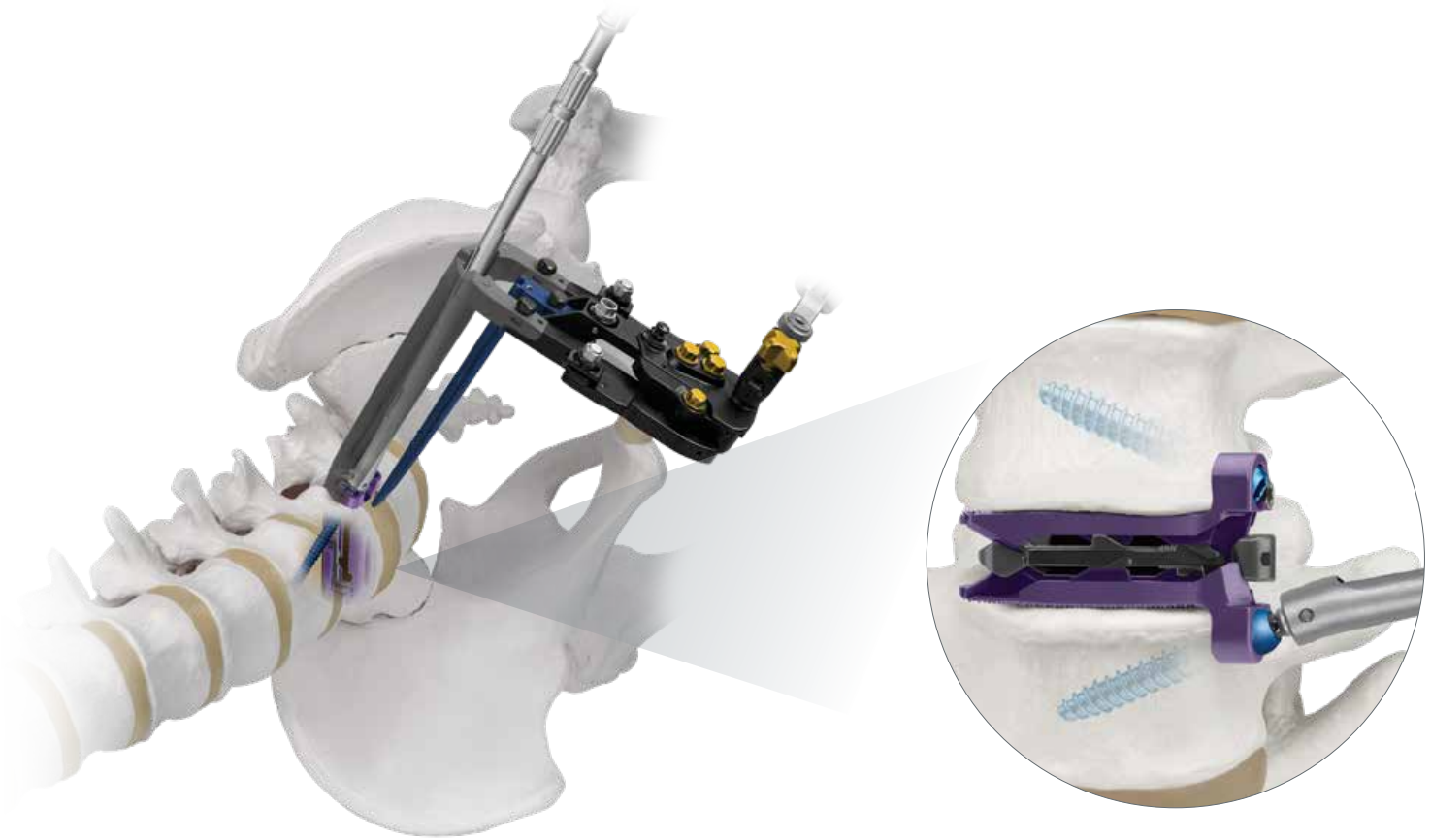
Insert the Adjustable Tap into the proximal end of the assembly. *Note: The awl and drill are 3.5mm in diameter.*



STEP 13 SCREW INSERTION

Select the desired bone screw length and insert with the **Angled Driver Assembly**. Insert the screw until the screw head contacts the plate. Confirm the screw is oriented at the same angle as the awl. Ensure the screws do not disrupt any adjacent structures outside the vertebrae. Do not final tighten. Repeat screw hole preparation (step 12) and screw insertion (step 13) for the second screw hole.

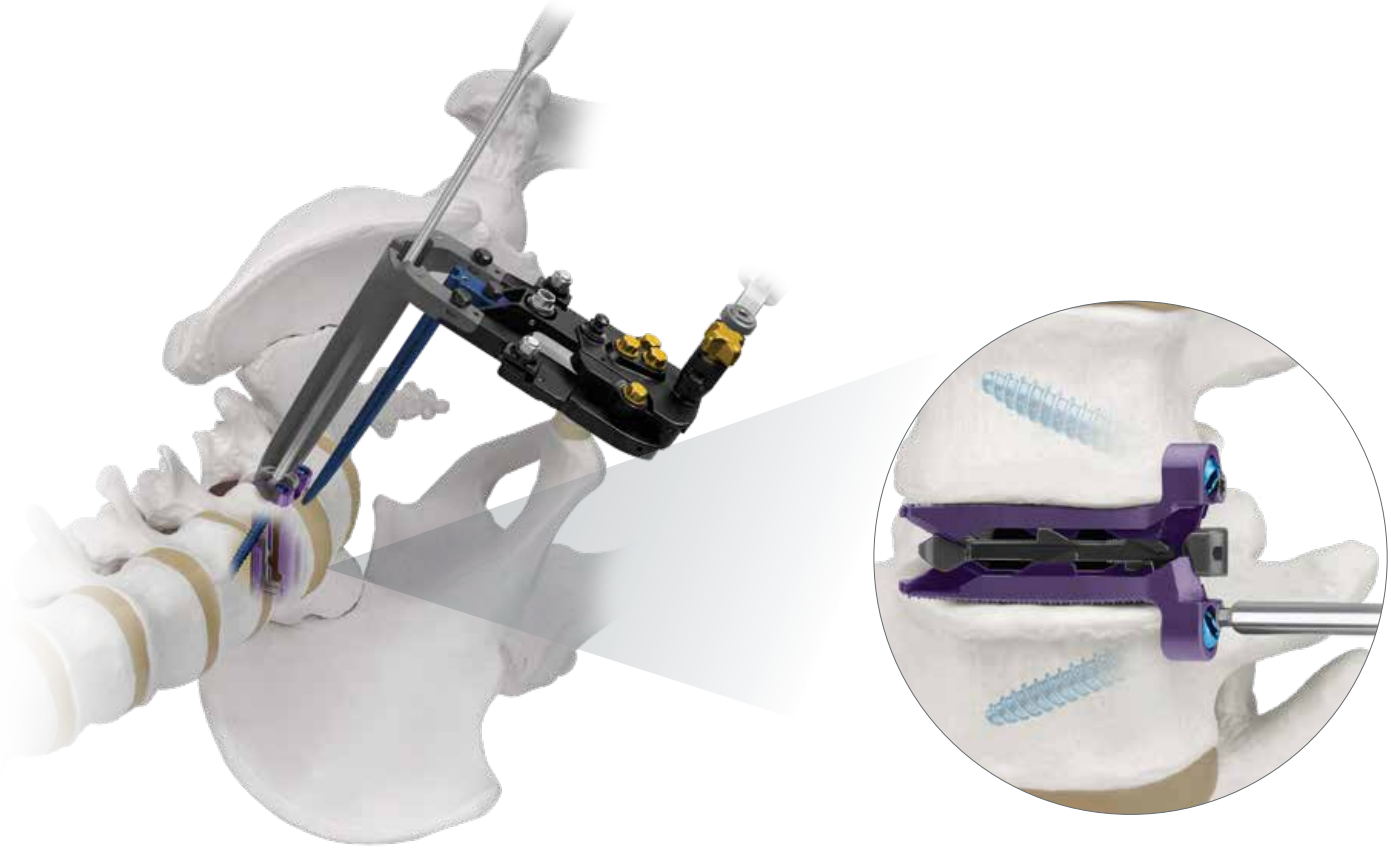
Once both screws are inserted and positioned, final tighten the screws using the Angled Driver Assembly until fully seated within the plate.



Screw insertion with the Angled Driver Assembly

STEP 14 POSITIONING THE BLOCKING SET SCREW

Use the **2.5mm Hex Set Screw Driver** to engage the blocking set screw and rotate it clockwise. An audible and tactile click occurs when the blocking set screw reaches its final position. Supplemental fixation is required. See page 46 for details.



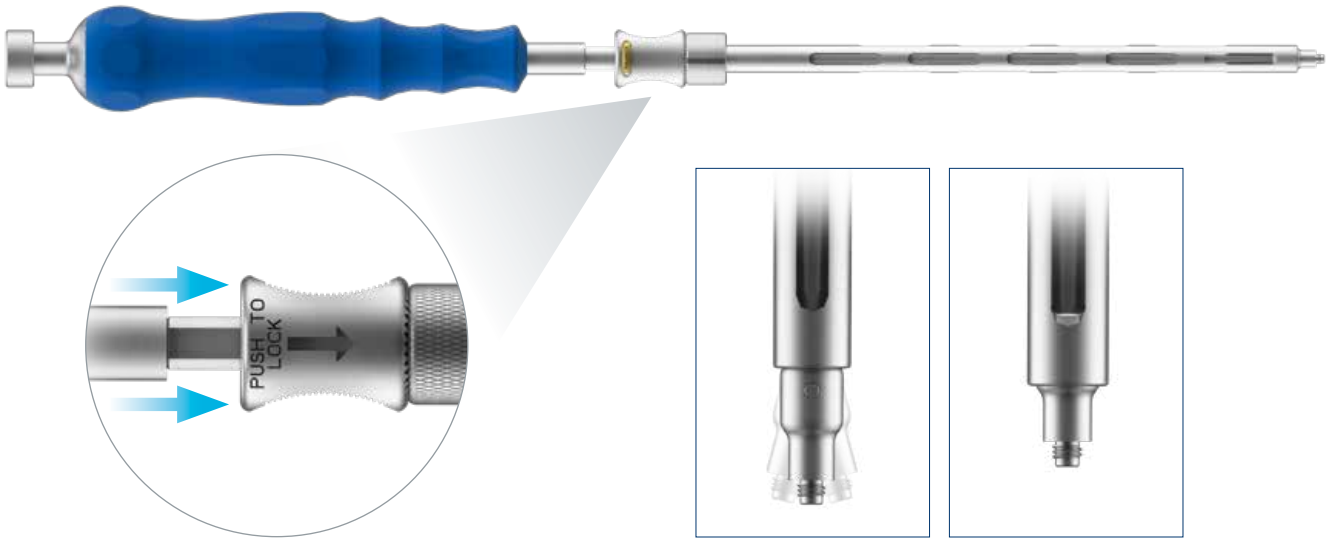
Unblocked

Blocked

ANCHOR FIXATION

STEP 12 ANCHOR INSERTION

Place the **Single Anchor Inserter, Lateral** in the locked position by sliding the lock assembly towards the distal end. To confirm that the inserter is locked, ensure that the outer sleeve is pushed forward and the tip does not angulate.



Placing instrument in locked position

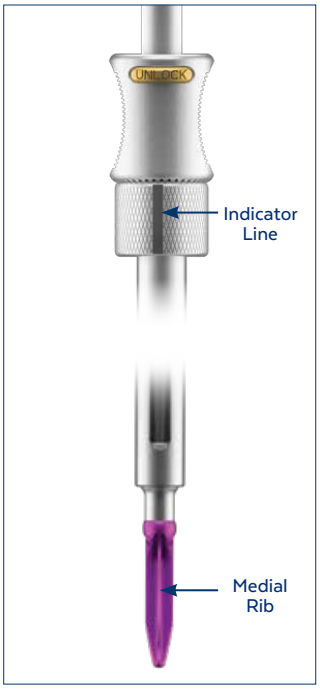
Unlocked

Locked

Confirm the implant is flush with the vertebral body, then select the appropriate anchor length. Thread the anchor onto the inserter by rotating the handle clockwise. Ensure the anchor is flush against the inserter. Do not over-tighten the anchor, as this may damage the threads or make removal challenging. Use care when handling the anchor as the tip is sharp.

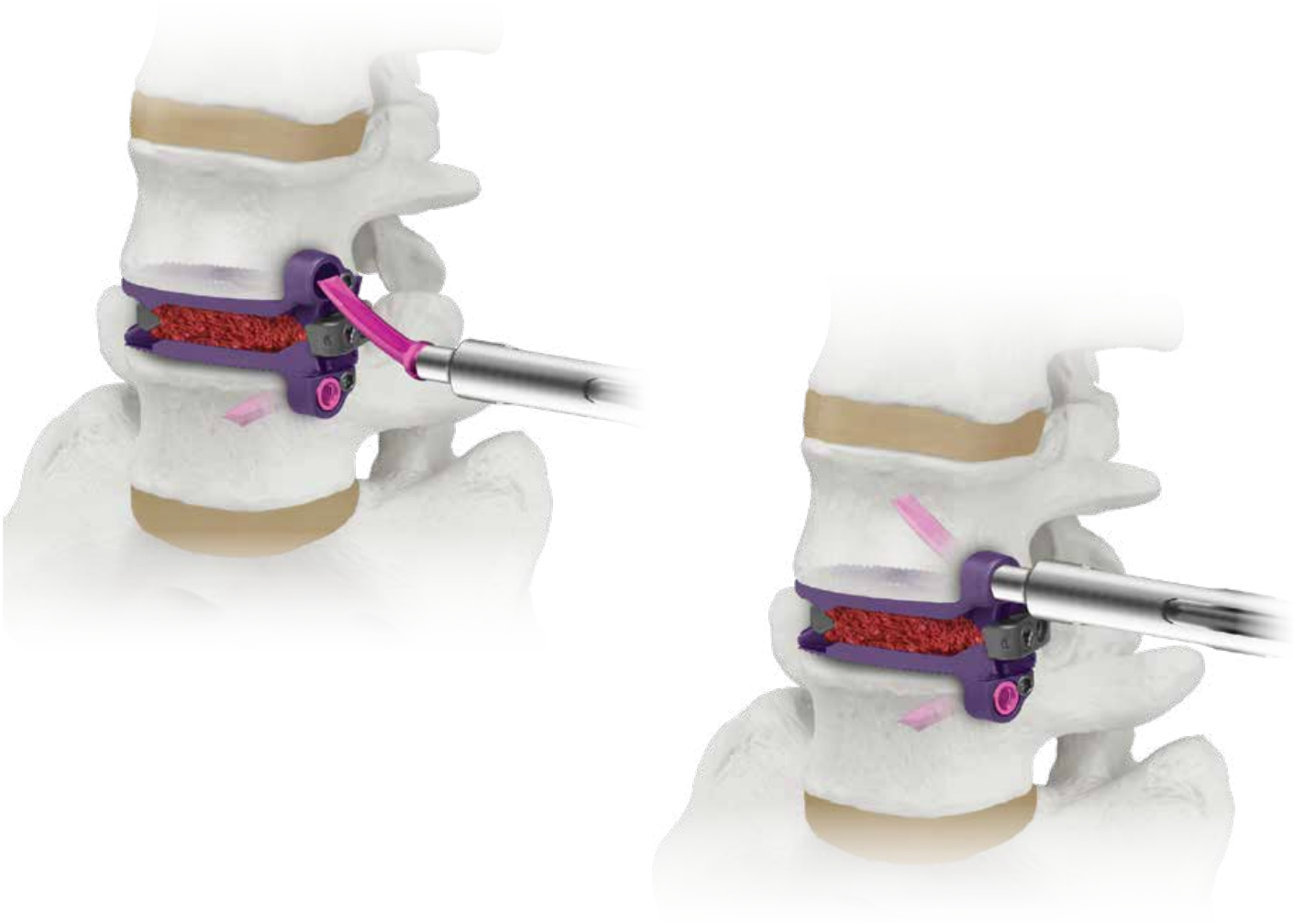
The directional indicator can be used to track the direction of the anchor after being introduced into the surgical corridor. To adjust the indicator, pull down distally and rotate to align the indicator line with the medial rib of the anchor.

Threading anchor onto inserter



Directional indicator

Carefully insert the anchor into the surgical corridor to seat the anchor tip into a fixation hole in the plate. Check the desired trajectory. Using a mallet, gently tamp the inserter to advance the anchor under AP fluoroscopy.



Inserting anchors using Anchor Inserter

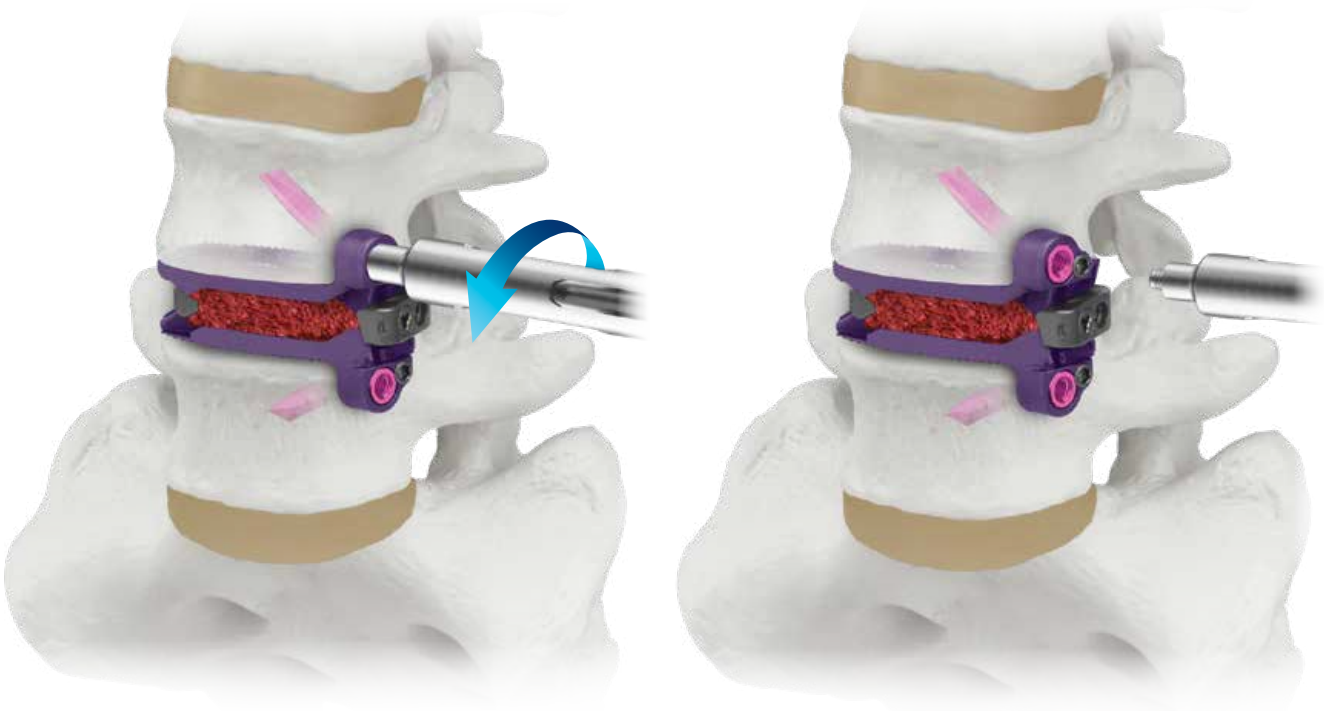
ANCHOR INSERTION (CONT'D)

ANCHOR ANGULATION

The tip on the Anchor Inserter is designed to angulate for difficult trajectories. After placing the anchor into the fixation hole, begin impacting the inserter. If needed, press the gold button to release the slider to allow angulation. The anchor may be impacted while in the unlocked position.

STEP 13 INSERTER REMOVAL

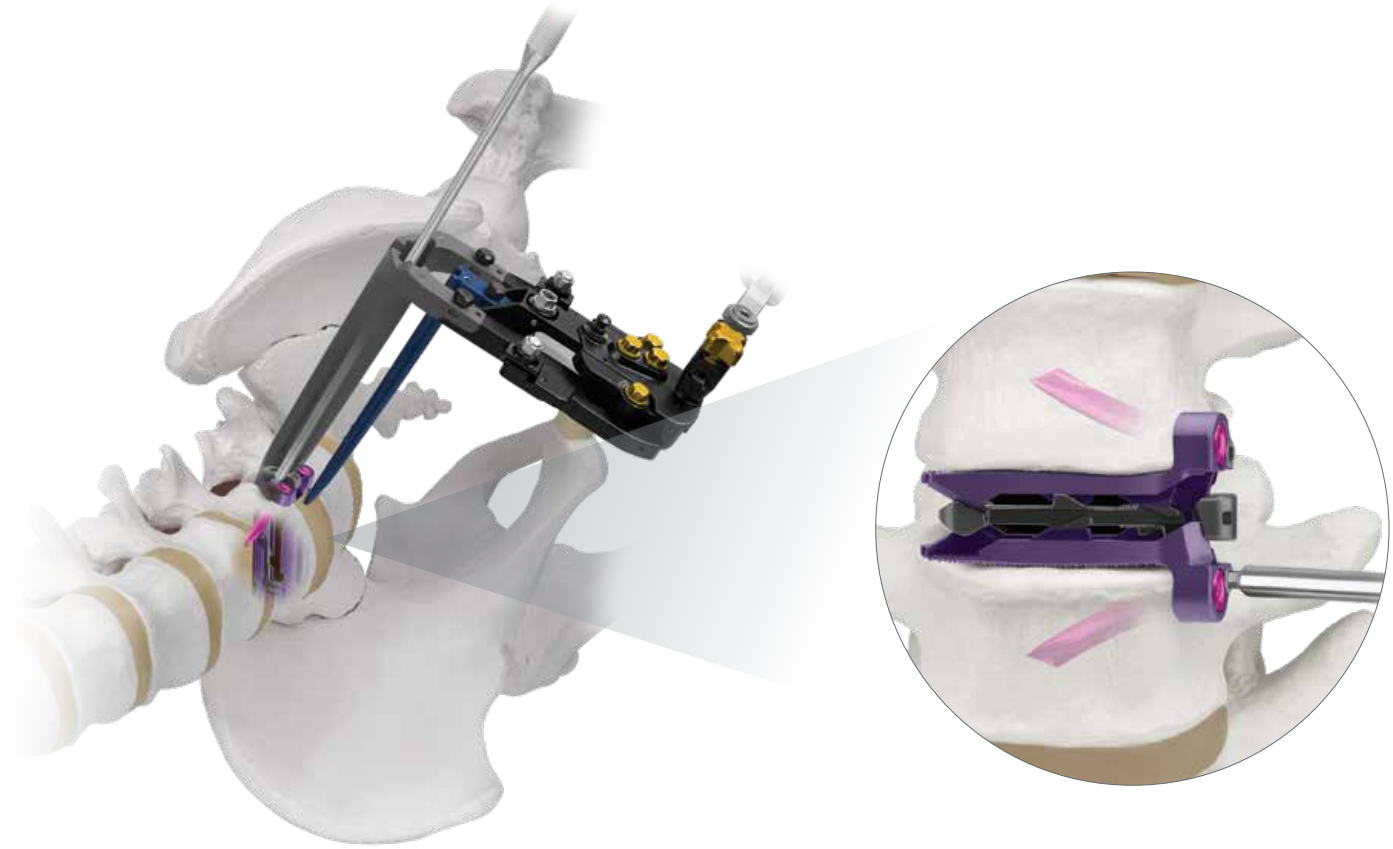
Once the anchor is fully seated in the fixation hole, rotate the inserter counterclockwise to disengage the anchor. When the inserter is disconnected, it may be removed. Repeat steps 12 and 13 for the second anchor.



Disconnecting and removing inserter

STEP 14 POSITIONING THE BLOCKING SET SCREW

Use the **2.5mm Hex Set Screw Driver** to engage the blocking set screw and rotate it clockwise. An audible and tactile click occurs when the blocking set screw reaches its final position. Supplemental fixation is required. See page 46 for details.



Unblocked

Blocked

HYBRID SCREW/ANCHOR FIXATION

If a hybrid screw/anchor construct is desired, follow steps 1-11 for disc prep and implant sizing.

For screw fixation, follow steps 12-14 on pages 33-37.

For anchor fixation, follow steps 12-14 on pages 38-41.

HYBRID FIXATION FINAL POSITION

Supplemental fixation is required. See page 46 for details.

Hybrid final construct

STEP 15 GRAFT PACKING

Additional allogenic or autogenous bone graft material may be packed into the implant's graft chamber after expansion through the inserter attachment hole.

The **Threaded Funnel Shaft** holds 2.4cc of autograft and can be pre-loaded. Morselize bone graft material and advance through the shaft to confirm that the graft particulate size easily pushes through. After the inserter is removed from the implant, insert the conical tip of the funnel shaft into the proximal end of the implant until mated.

Insert the **Graft Plunger** through the shaft to advance bone graft material into the implant.

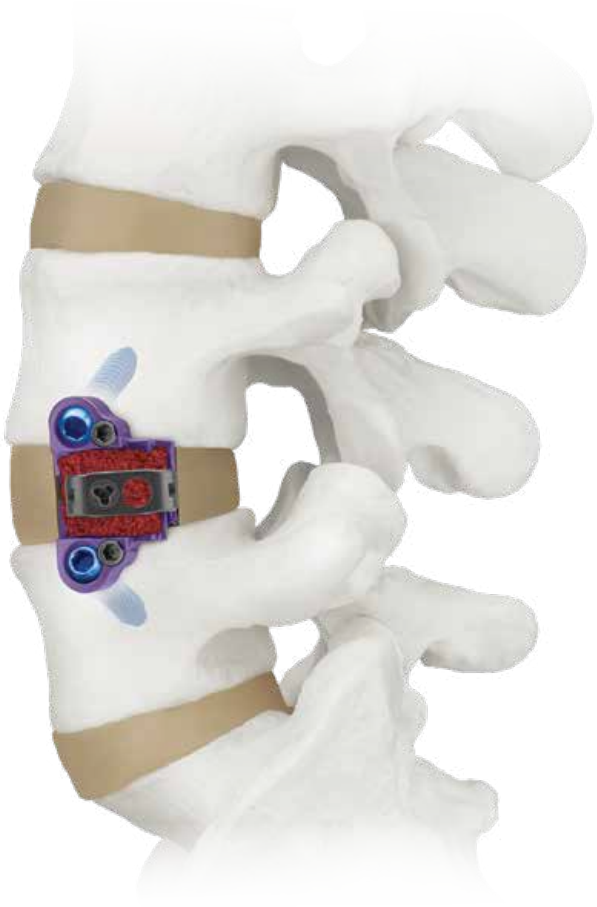
The volume of graft required to fill an ELSA®-ATP spacer depends on the selected implant size and expansion. Monitor the volume used to determine when the implant is filled.

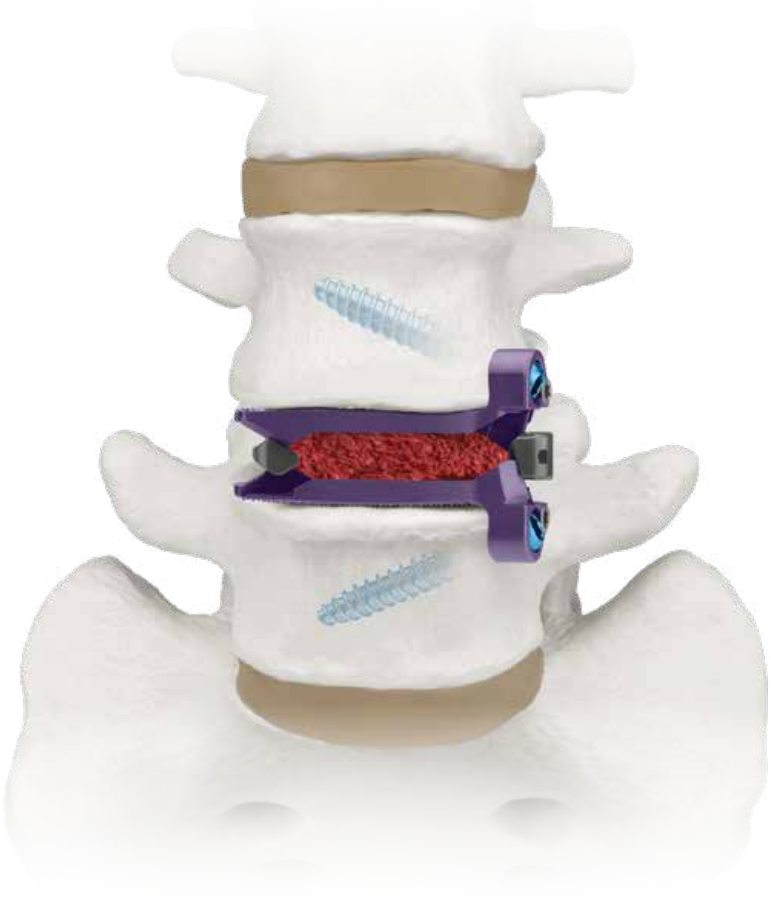
Refer to the table on page 47 for approximate graft volume.

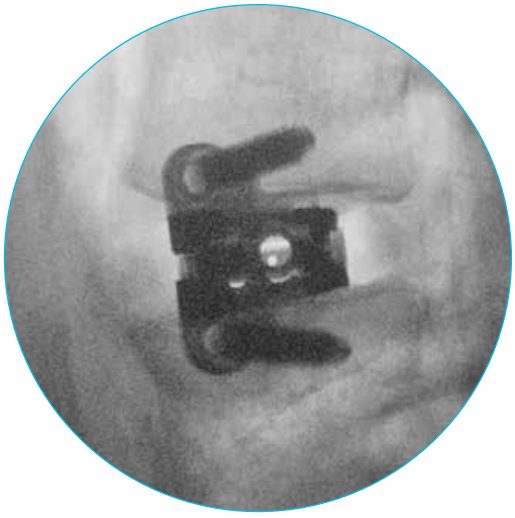
Using Graft Plunger with Threaded Funnel Shaft

FINAL POSITION

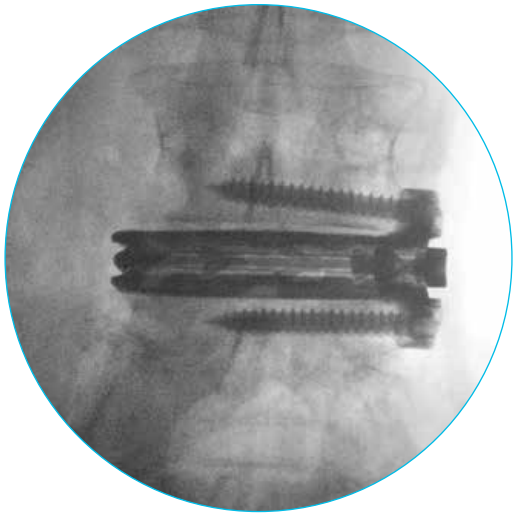
Supplemental fixation is required. See page 46 for details.







Screws final position - lateral view

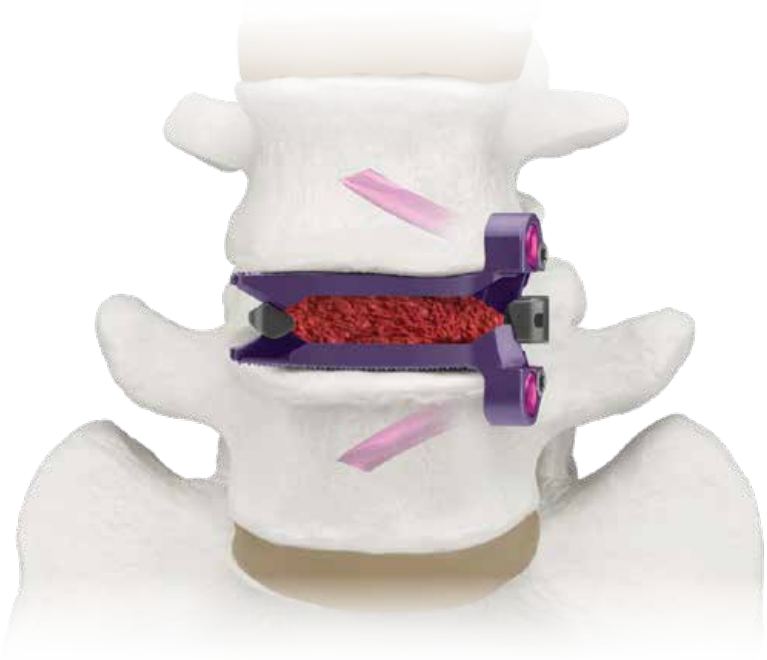


Screws final position - AP view

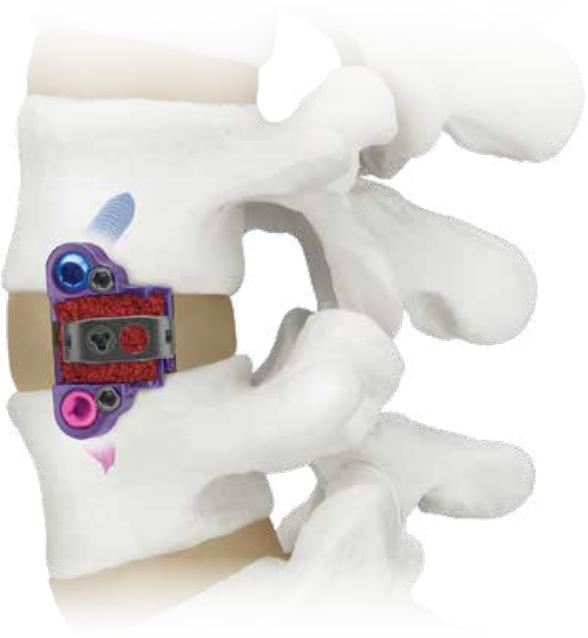
FINAL POSITION

Supplemental fixation is required. See page 46 for details.

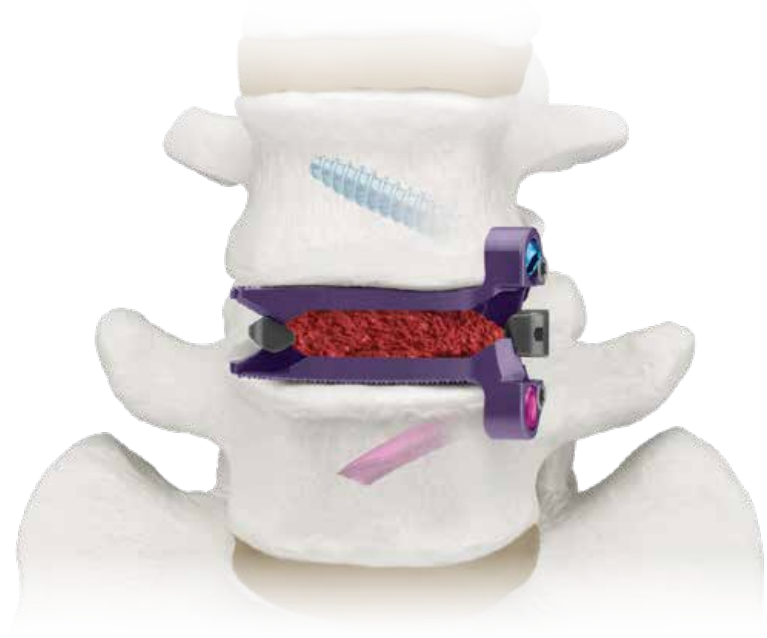
Anchor final position - lateral view



Anchor final position - AP view



Hybrid final position - lateral view



Hybrid final position - AP view

SUPPLEMENTAL FIXATION

ELSA®-ATP is intended for use with supplemental fixation with or without two integrated screws or anchors. Refer to the selected supplemental fixation system's surgical technique guide for specific instructions.

OPTIONAL: IMPLANT REMOVAL

For implant removal, use a Hex Set Screw Driver to unlock the blocking screw. Remove bone screws using a screwdriver. Remove anchors by reattaching the inserter and using a Slap Hammer.

Reposition the inserter on the implant and reduce the implant height by inserting the Angled Drive Shaft, T-Handle and rotating counterclockwise. Contract the implant until two finger tight. If necessary, attach the **Slide Hammer** to the inserter and gently remove the implant.

Use the **Removal Tool** if the Implant Inserter Assembly cannot be reattached to the implant. Thread the Removal Tool into the proximal end of the implant. Use the Lateral Torque-Limiting Driver, 3.0Nm to reduce the implant height by inserting and rotating counterclockwise. If necessary, use the Slide Hammer to gently remove the implant.

Use forceps or other manual surgical instruments to grasp and extract the implant. Supplemental fixation may be removed before the implant is removed; refer to the corresponding surgical technique for removal instructions

Removal Tool

Implant removal using Slide Hammer

Implant removal using Slap Hammer

GRAFT VOLUME

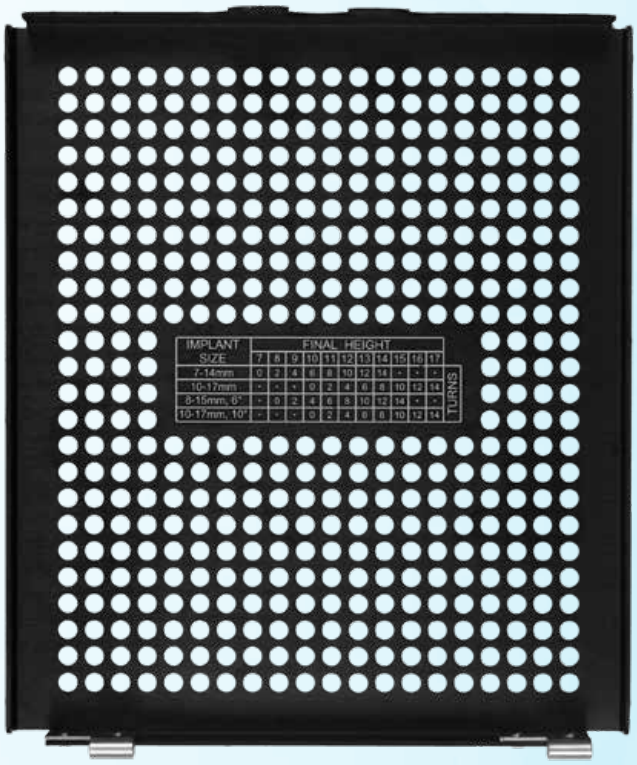
Graft Volume by Implant Size					
Part No.	**Description**	**Length (mm)**	**Height (mm)**	**Full Expansion Volume (cc)**	**No Expansion Volume (cc)**
1154.0040	ELSA®-ATP Spacer 20x40mm, 7-14mm	40	7-14	4.0	1.6
1154.0045	ELSA®-ATP Spacer 20x45mm, 7-14mm	45	7-14	4.7	1.9
1154.0050	ELSA®-ATP Spacer 20x50mm, 7-14mm	50	7-14	5.4	2.3
1154.0055	ELSA®-ATP Spacer 20x55mm, 7-14mm	55	7-14	6.1	2.6
1154.0060	ELSA®-ATP Spacer 20x60mm, 7-14mm	60	7-14	6.9	2.9
1154.0065	ELSA®-ATP Spacer 20x65mm, 7-14mm	65	7-14	7.6	3.2
1154.0140	ELSA®-ATP Spacer 20x40mm, 8-15mm, 6°	40	8-15	4.1	1.8
1154.0145	ELSA®-ATP Spacer 20x45mm, 8-15mm, 6°	45	8-15	4.9	2.1
1154.0150	ELSA®-ATP Spacer 20x50mm, 8-15mm, 6°	50	8-15	5.7	2.5
1154.0155	ELSA®-ATP Spacer 20x55mm, 8-15mm, 6°	55	8-15	6.4	2.8
1154.0160	ELSA®-ATP Spacer 20x60mm, 8-15mm, 6°	60	8-15	7.2	3.2
1154.0165	ELSA®-ATP Spacer 20x65mm, 8-15mm, 6°	65	8-15	7.9	3.5
1154.0440	ELSA®-ATP Spacer 20x40mm, 10-17mm	40	10-17	4.7	2.4
1154.0445	ELSA®-ATP Spacer 20x45mm, 10-17mm	45	10-17	5.6	2.8
1154.0450	ELSA®-ATP Spacer 20x50mm, 10-17mm	50	10-17	6.5	3.4
1154.0455	ELSA®-ATP Spacer 20x55mm, 10-17mm	55	10-17	7.4	3.8
1154.0460	ELSA®-ATP Spacer 20x60mm, 10-17mm	60	10-17	8.3	4.3
1154.0465	ELSA®-ATP Spacer 20x65mm, 10-17mm	65	10-17	9.2	4.8
1154.0540	ELSA®-ATP Spacer 20x40mm, 10-17mm, 10°	40	10-17	4.4	2.1
1154.0545	ELSA®-ATP Spacer 20x45mm, 10-17mm, 10°	45	10-17	5.3	2.5
1154.0550	ELSA®-ATP Spacer 20x50mm, 10-17mm, 10°	50	10-17	6.1	2.9
1154.0555	ELSA®-ATP Spacer 20x55mm, 10-17mm, 10°	55	10-17	6.9	3.3
1154.0560	ELSA®-ATP Spacer 20x60mm, 10-17mm, 10°	60	10-17	7.7	3.8
1154.0565	ELSA®-ATP Spacer 20x65mm, 10-17mm, 10°	65	10-17	8.6	4.2

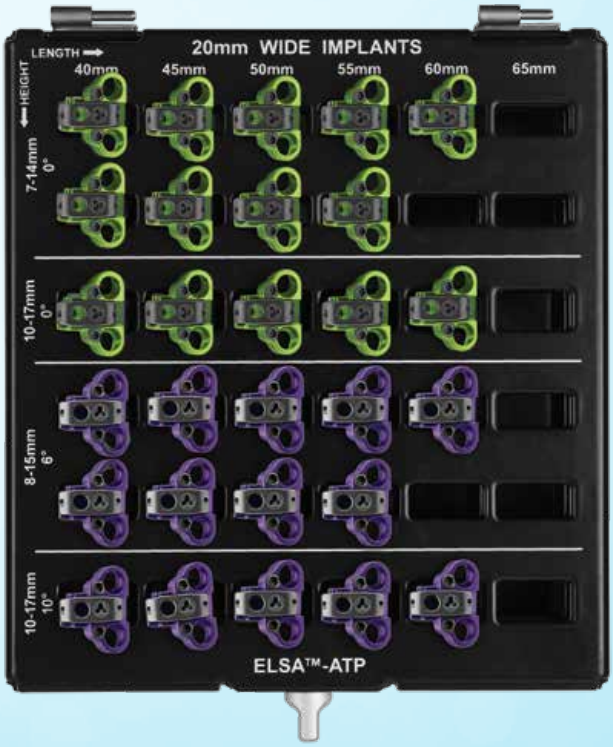
ELSA®-ATP
IMPLANT SET 9154.9011

Part No.	Description	Qty
1154.0040	ELSA®-ATP Spacer 20x40mm, 7-14mm	2
1154.0045	ELSA®-ATP Spacer 20x45mm, 7-14mm	2
1154.0050	ELSA®-ATP Spacer 20x50mm, 7-14mm	2
1154.0055	ELSA®-ATP Spacer 20x55mm, 7-14mm	2
1154.0060	ELSA®-ATP Spacer 20x60mm, 7-14mm	1
1154.0065	ELSA®-ATP Spacer 20x65mm, 7-14mm	
1154.0140	ELSA®-ATP Spacer 20x40mm, 8-15mm, 6°	2
1154.0145	ELSA®-ATP Spacer 20x45mm, 8-15mm, 6°	2
1154.0150	ELSA®-ATP Spacer 20x50mm, 8-15mm, 6°	2
1154.0155	ELSA®-ATP Spacer 20x55mm, 8-15mm, 6°	2
1154.0160	ELSA®-ATP Spacer 20x60mm, 8-15mm, 6°	1
1154.0165	ELSA®-ATP Spacer 20x65mm, 8-15mm, 6°	
1154.0440	ELSA®-ATP Spacer 20x40mm, 10-17mm	1
1154.0445	ELSA®-ATP Spacer 20x45mm, 10-17mm	1
1154.0450	ELSA®-ATP Spacer 20x50mm, 10-17mm	1
1154.0455	ELSA®-ATP Spacer 20x55mm, 10-17mm	1
1154.0460	ELSA®-ATP Spacer 20x60mm, 10-17mm	1
1154.0465	ELSA®-ATP Spacer 20x65mm, 10-17mm	
1154.0540	ELSA®-ATP Spacer 20x40mm, 10-17mm, 10°	1
1154.0545	ELSA®-ATP Spacer 20x45mm, 10-17mm, 10°	1
1154.0550	ELSA®-ATP Spacer 20x50mm, 10-17mm, 10°	1
1154.0555	ELSA®-ATP Spacer 20x55mm, 10-17mm, 10°	1
1154.0560	ELSA®-ATP Spacer 20x60mm, 10-17mm, 10°	1
1154.0565	ELSA®-ATP Spacer 20x65mm, 10-17mm, 10°	
9154.0011	ELSA®-ATP Implant Module	

*Additionally available

ELSA®-ATP
IMPLANT SET 9154.9011

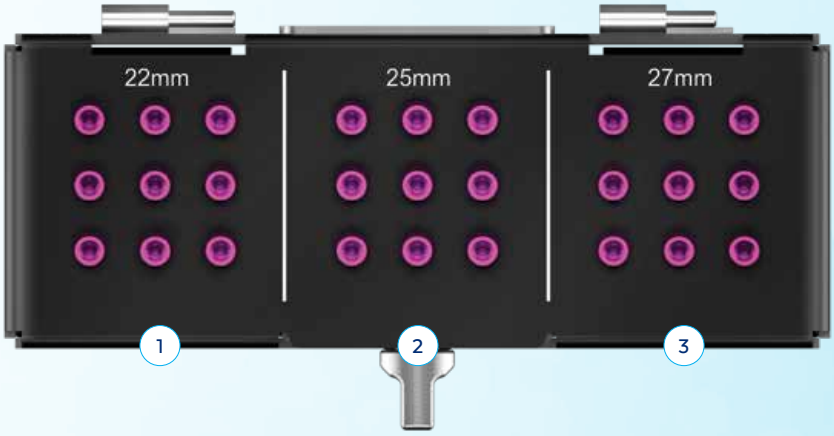


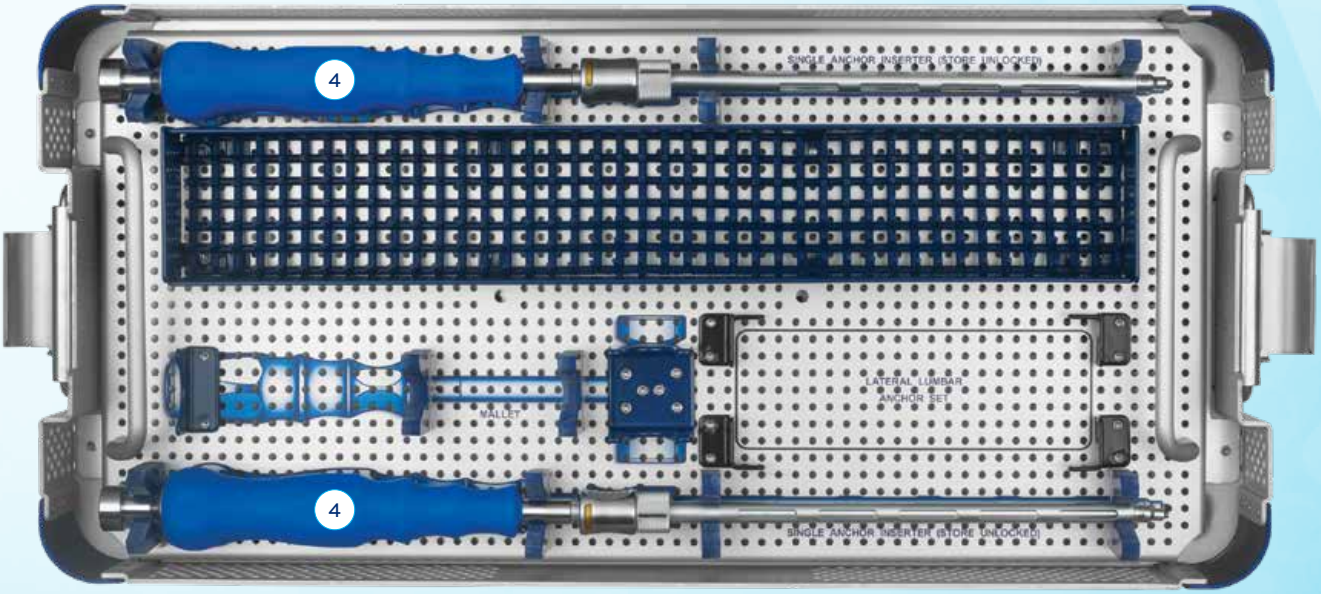


LATERAL MIS
IMPLANT AND INSTRUMENT SET 9219.0001

	Part No.	Description	Qty
	675.004	Long Throw Slide Hammer	1
1	1219.0022	Lateral Anchor 22mm	6
2	1219.0025	Lateral Anchor 25mm	6
3	1219.0027	Lateral Anchor 27mm	6
4	6219.1000	Single Anchor Inserter, Lateral	2
	9219.0001	Lateral MIS Anchor Module	
	9219.0002	Lateral MIS Graphic Case	

LATERAL MIS
IMPLANT AND INSTRUMENT SET 9219.0001

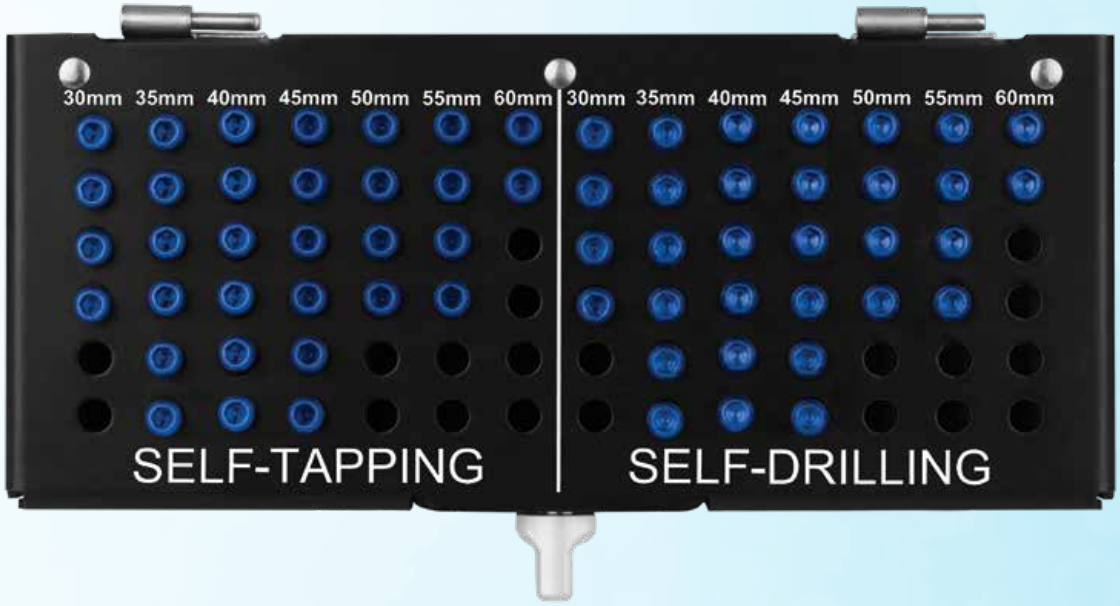




ELSA®
SCREW SET 9122.9003

Part No.	Description	Qty
176.230	Bone Screw, Variable Angle 5.5mm, 30mm	4
176.235	Bone Screw, Variable Angle 5.5mm, 35mm	6
176.240	Bone Screw, Variable Angle 5.5mm, 40mm	6
176.245	Bone Screw, Variable Angle 5.5mm, 45mm	6
176.250	Bone Screw, Variable Angle 5.5mm, 50mm	4
176.255	Bone Screw, Variable Angle 5.5mm, 55mm	4
176.260	Bone Screw, Variable Angle 5.5mm, 60mm	2
176.730	Self Drilling Screw, Variable Angle 5.5mm, 30mm	4
176.735	Self Drilling Screw, Variable Angle 5.5mm, 35mm	6
176.740	Self Drilling Screw, Variable Angle 5.5mm, 40mm	6
176.745	Self Drilling Screw, Variable Angle 5.5mm, 45mm	6
176.750	Self Drilling Screw, Variable Angle 5.5mm, 50mm	4
176.755	Self Drilling Screw, Variable Angle 5.5mm, 55mm	4
176.760	Self Drilling Screw, Variable Angle 5.5mm, 60mm	2
9122.0003	ELSA® Screws Graphic Case	

ELSA®
SCREW SET 9122.9003

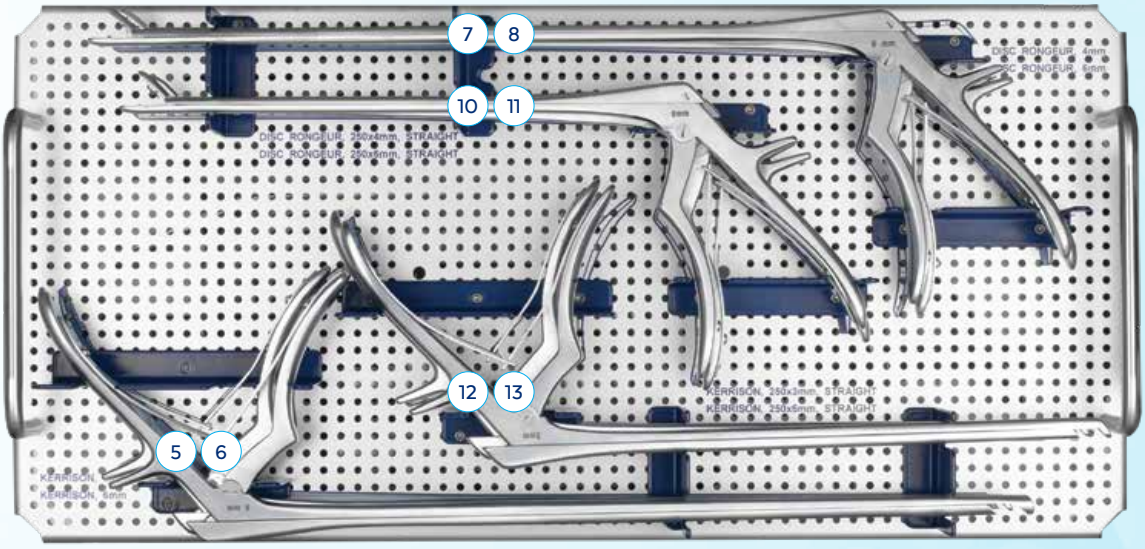


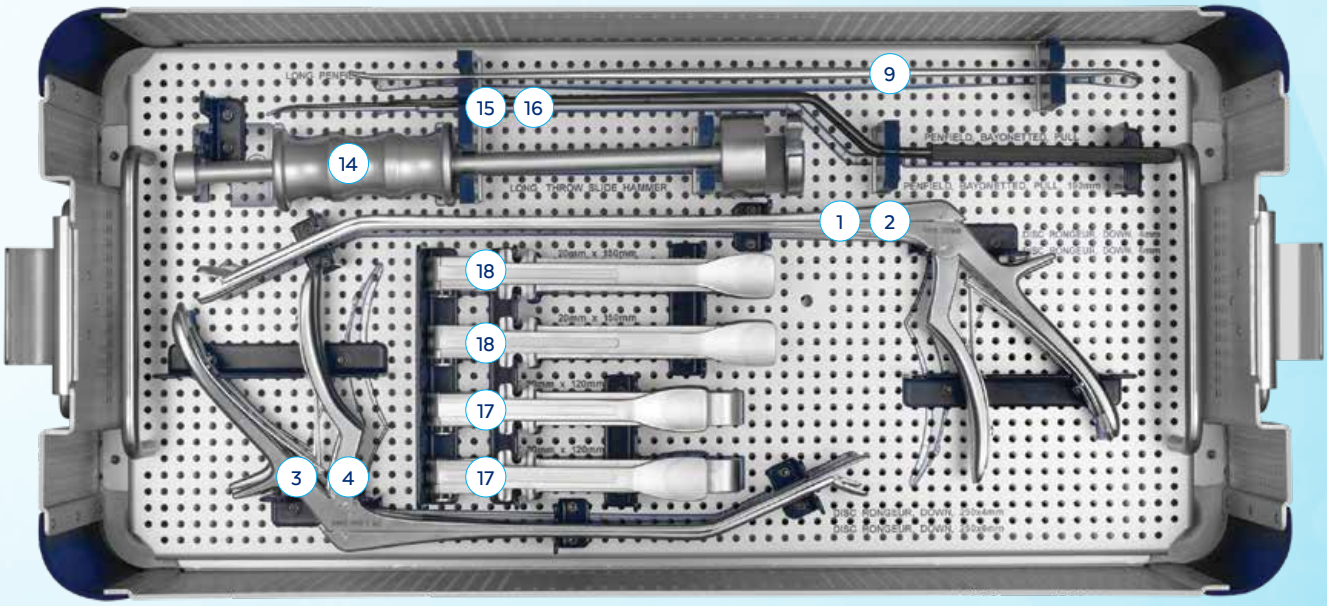
ANTEROLATERAL DISC PREP
INSTRUMENT I SET 9154.9061

	Part No.	Description	Qty
1	6154.1240	Disc Rongeur, Angled, Down, 4mm	1
2	6154.1241	Disc Rongeur, Angled, Down, 6mm	1
3	6154.1260	Disc Rongeur, Angled, Down, 250x4mm	1
4	6154.1261	Disc Rongeur, Angled, Down, 250x6mm	1
5	625.202	Kerrison, 4mm	1
6	625.203	Kerrison, 6mm	1
7	625.305	Disc Rongeur, 4mm	1
8	625.307	Disc Rongeur, 6mm	1
9	625.811	Long Penfield	1
10	626.240	Disc Rongeur, 250x4mm, Straight	1
11	626.241	Disc Rongeur, 250x6mm, Straight	1
12	626.250	Kerrison, 250x3mm, Straight	1
13	626.252	Kerrison, 250x5mm, Straight	1
14	675.004	Long Throw Slide Hammer	1
15	675.173	Penfield, Bayonetted, Pull	1
16	675.174	Penfield, Bayonetted, Pull, 190mm	1
	675.405S	Bayonetted Annulotomy Knife	
17	698.117	Retractor Assembly, 20mmx120mm	2
18	698.118	Retractor Assembly, 20mmx150mm	2
	9154.0061	Anterolateral Disc Prep Instruments I Graphic Case	

*Additionally available

ANTEROLATERAL DISC PREP
INSTRUMENT I SET 9154.9061



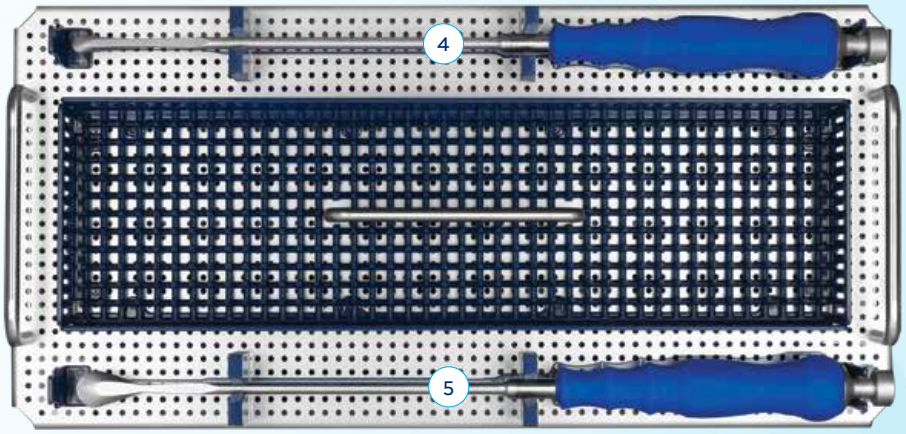


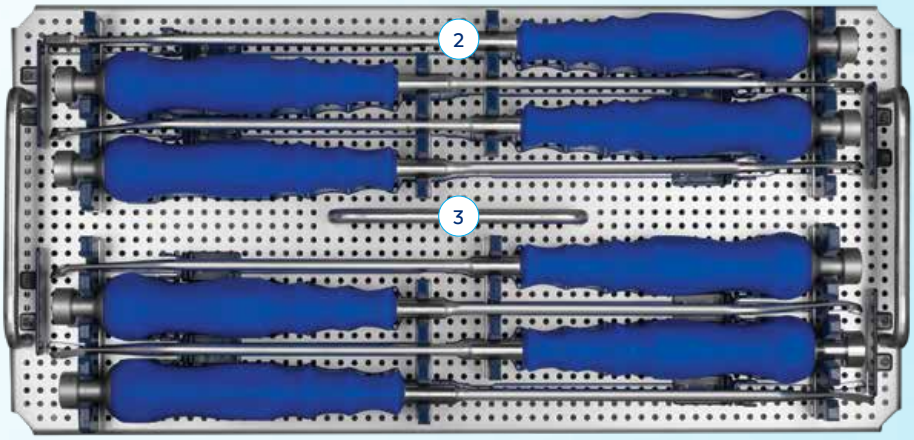
ANTEROLATERAL DISC PREP
INSTRUMENT II SET 9154.9062

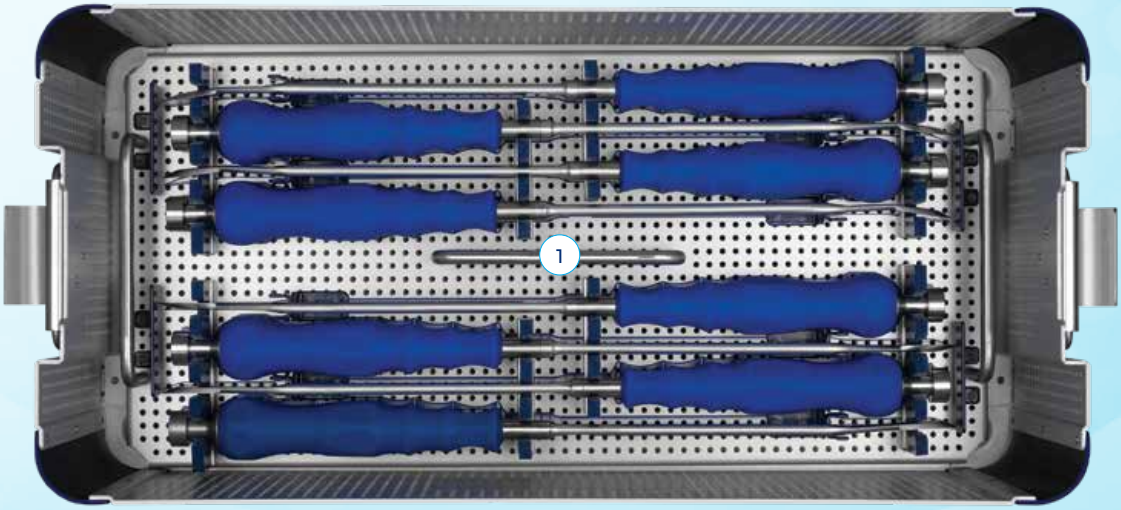
	Part No.	Description	Qty
1	6154.1110	Cobb Elevator, Angled, Down, 10mm	1
	6154.1111	Cobb Elevator, Angled, Up, 10mm	1
	6154.1120	Cobb Elevator, Angled, Down, 20mm	1
	6154.1121	Cobb Elevator, Angled, Up, 20mm	1
	6154.1130	Cobb Elevator, Angled, Down, 7°, 10mm	1
	6154.1131	Cobb Elevator, Angled, Up, 7°, 10mm	1
	6154.1140	Cobb Elevator, Angled, Down, 7°, 20mm	1
	6154.1141	Cobb Elevator, Angled, Up, 7°, 20mm	1
2	6154.1403	Double Rasp, Angled, Down, 12x20mm	1
3	6154.1501	Cup Curette, Angled, Down, 6.5x9.5mm, Straight	1
	6154.1502	Cup Curette, Angled, Up, 6.5x9.5mm, Straight	1
	6154.1520	Cup Curette, Angled, Down, 6.5x9.5mm, 15°	1
	6154.1521	Cup Curette, Angled, Up, 6.5x9.5mm, 15°	1
	6154.1530	Double Ring Curette, Angled, Down, 10mm, Straight	1
	6154.1533	Ring Curette, Angled, Down, 10mm, 7°	1
	6154.1534	Ring Curette, Angled, Up, 10mm, 7°	1
4	675.503	Large Cobb Elevator	1
3	675.504	Small Cobb Elevator	1
	9154.0062	Anterolateral Disc Prep Instruments II Graphic Case	

*Additionally available

ANTEROLATERAL DISC PREP
INSTRUMENT II SET 9154.9062







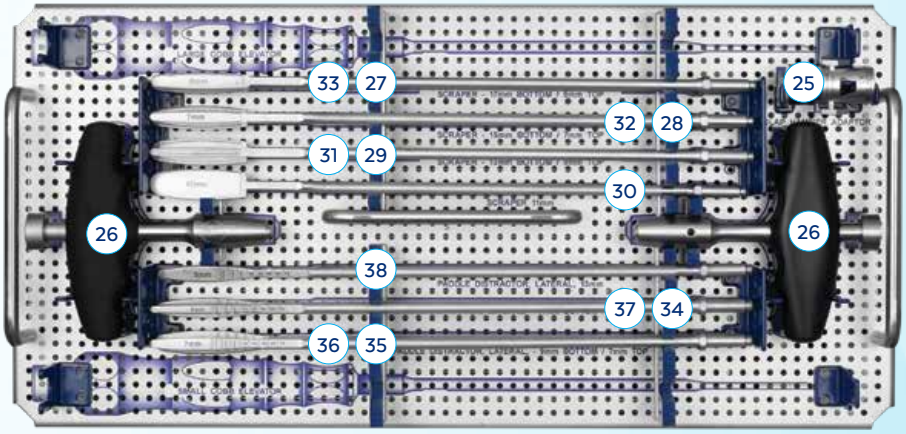
ANTEROLATERAL TRIAL
INSTRUMENT SET 9154.9063

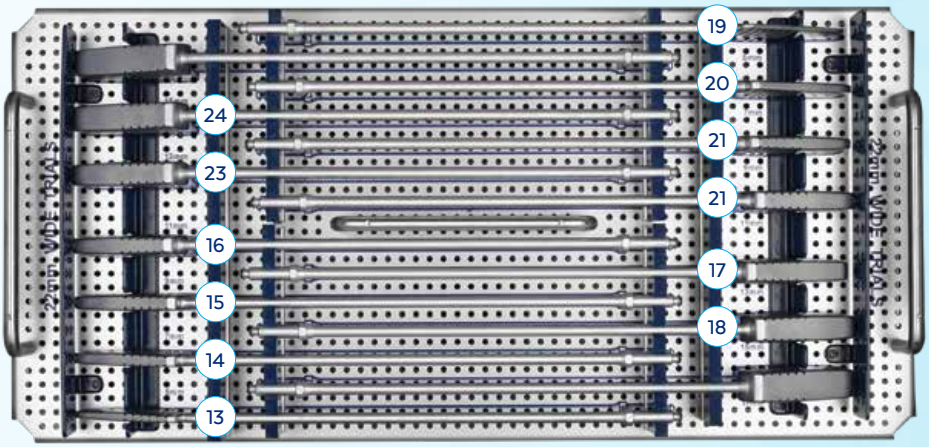
	Part No.	Description	Qty
1	6154.2105	Trial, Angled, Down, 18mm Wide, 0°, 5mm	1
2	6154.2107	Trial, Angled, Down, 18mm Wide, 0°, 7mm	1
3	6154.2109	Trial, Angled, Down, 18mm Wide, 0°, 9mm	1
4	6154.2111	Trial, Angled, Down, 18mm Wide, 0°, 11mm	1
5	6154.2113	Trial, Angled, Down, 18mm Wide, 0°, 13mm	1
6	6154.2115	Trial, Angled, Down, 18mm Wide, 0°, 15mm	1
	6154.2117	Trial, Angled, Down, 18mm Wide, 0°, 17mm	
7	6154.2125	Trial, Angled, Down, 18mm Wide, 6°, 5mm	1
8	6154.2127	Trial, Angled, Down, 18mm Wide, 6°, 7mm	1
9	6154.2129	Trial, Angled, Down, 18mm Wide, 6°, 9mm	1
10	6154.2131	Trial, Angled, Down, 18mm Wide, 6°, 11mm	1
11	6154.2133	Trial, Angled, Down, 18mm Wide, 6°, 13mm	1
12	6154.2135	Trial, Angled, Down, 18mm Wide, 6°, 15mm	1
	6154.2137	Trial, Angled, Down, 18mm Wide, 6°, 17mm	
13	6154.2205	Trial, Angled, Down, 22mm Wide, 0°, 5mm	1
14	6154.2207	Trial, Angled, Down, 22mm Wide, 0°, 7mm	1
15	6154.2209	Trial, Angled, Down, 22mm Wide, 0°, 9mm	1
16	6154.2211	Trial, Angled, Down, 22mm Wide, 0°, 11mm	1
17	6154.2213	Trial, Angled, Down, 22mm Wide, 0°, 13mm	1
18	6154.2215	Trial, Angled, Down, 22mm Wide, 0°, 15mm	1
	6154.2217	Trial, Angled, Down, 22mm Wide, 0°, 17mm	
19	6154.2225	Trial, Angled, Down, 22mm Wide, 6°, 5mm	1
20	6154.2227	Trial, Angled, Down, 22mm Wide, 6°, 7mm	1
21	6154.2229	Trial, Angled, Down, 22mm Wide, 6°, 9mm	1
22	6154.2231	Trial, Angled, Down, 22mm Wide, 6°, 11mm	1
23	6154.2233	Trial, Angled, Down, 22mm Wide, 6°, 13mm	1
24	6154.2235	Trial, Angled, Down, 22mm Wide, 6°, 15mm	1
	6154.2237	Trial, Angled, Down, 22mm Wide, 6°, 17mm	
25	675.002	Slap Hammer Adaptor	1
26	675.005	T-Handle with Impaction Cap	2
	675.170S	Bipolar Forceps Bayonetted, Straight	
	675.171S	Bipolar Forceps Bayonetted, Angled	

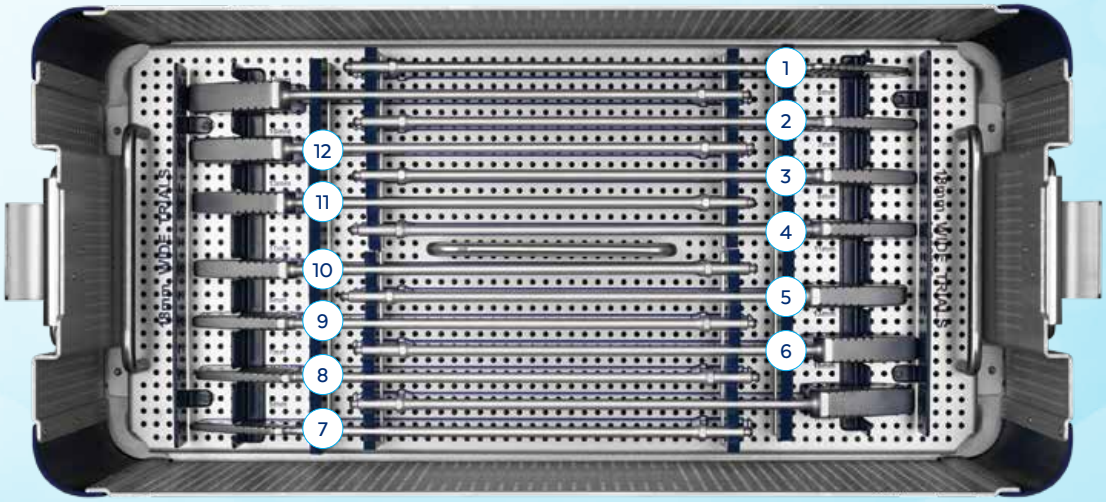
	Part No.	Description	Qty
27	675.605	Scraper, 5mm	1
28	675.607	Scraper, 7mm	1
29	675.609	Scraper, 9mm	1
30	675.611	Scraper, 11mm	1
31	675.613	Scraper, 13mm	1
32	675.615	Scraper, 15mm	1
33	675.617	Scraper, 17mm	1
34	675.855	Paddle Distractor, Lateral, 5mm	1
35	675.857	Paddle Distractor, Lateral, 7mm	1
36	675.859	Paddle Distractor, Lateral, 9mm	1
37	675.861	Paddle Distractor, Lateral, 11mm	1
38	675.863	Paddle Distractor, Lateral, 13mm	1
	9154.0063	Anterolateral Trial Instruments Graphic Case	

*Additionally available

ANTEROLATERAL TRIAL
INSTRUMENT SET 9154.9063



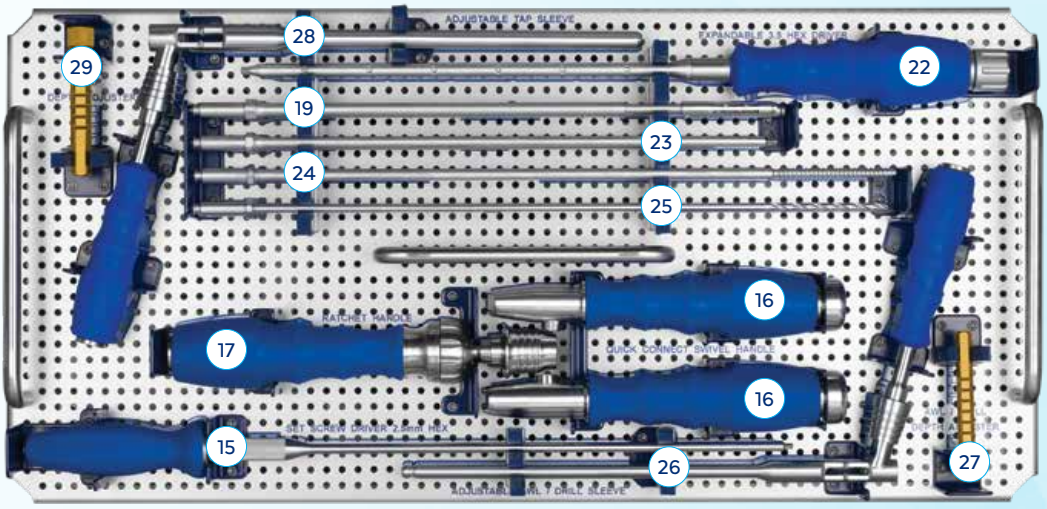


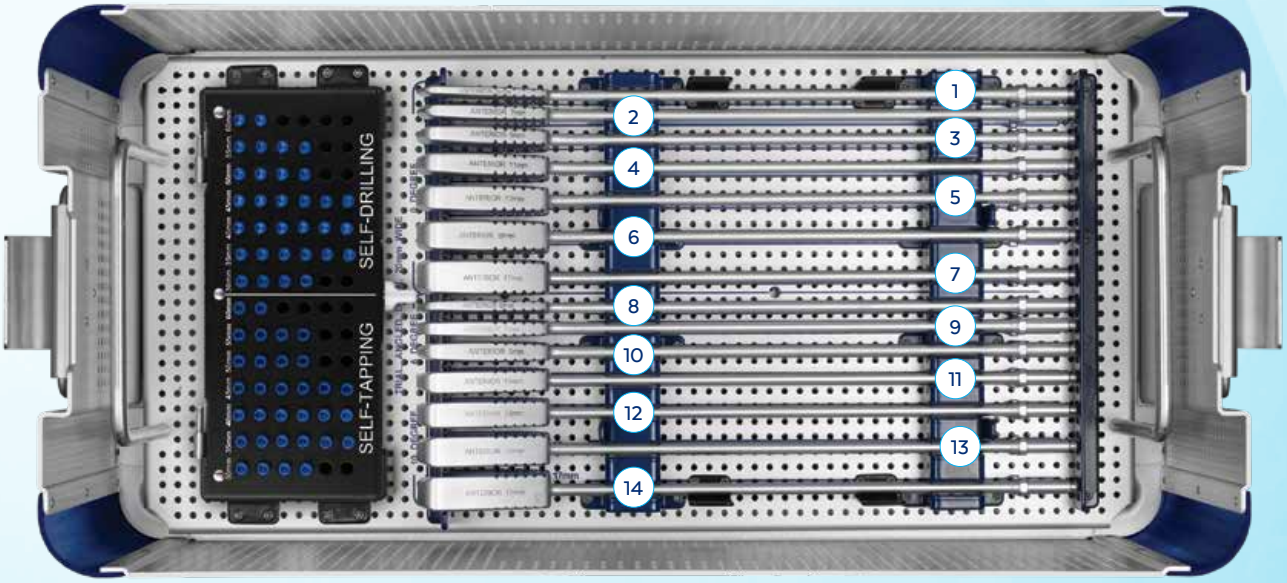


ELSA®-ATP TRIAL/SCREW PREP INSTRUMENT SET 9154.9064

	Part No.	Description	Qty
1	6154.2005	Trial, Angled, Down, 20mm Wide, 0°, 5mm	1
2	6154.2007	Trial, Angled, Down, 20mm Wide, 0°, 7mm	1
3	6154.2009	Trial, Angled, Down, 20mm Wide, 0°, 9mm	1
4	6154.2011	Trial, Angled, Down, 20mm Wide, 0°, 11mm	1
5	6154.2013	Trial, Angled, Down, 20mm Wide, 0°, 13mm	1
6	6154.2015	Trial, Angled, Down, 20mm Wide, 0°, 15mm	1
7	6154.2017	Trial, Angled, Down, 20mm Wide, 0°, 17mm	1
8	6154.2025	Trial, Angled, Down, 20mm Wide, 6°, 5mm	1
9	6154.2027	Trial, Angled, Down, 20mm Wide, 6°, 7mm	1
10	6154.2029	Trial, Angled, Down, 20mm Wide, 6°, 9mm	1
11	6154.2331	Trial, Angled, Down, 20mm Wide, 10°, 11mm	1
12	6154.2333	Trial, Angled, Down, 20mm Wide, 10°, 13mm	1
13	6154.2335	Trial, Angled, Down, 20mm Wide, 10°, 15mm	1
14	6154.2337	Trial, Angled, Down, 20mm Wide, 10°, 17mm	1
15	676.600	Set Screw Driver, 2.5mm Hex, 1.0Nm Torque	1
16	687.005	Quick-Connect Swivel Handle	2
17	687.105	Ratchet Handle	1
18	687.520	Straight Shaft 5.5mm Drill	1
19	687.524	Straight Shaft Awl	1
20	687.526	Straight Shaft 5.5mm Tap	1
21	687.527	Straight Shaft 3.5mm Hex Driver	1
22	687.603	Expandable 3.5 Hex Driver	1
23	687.624	Adjustable Awl	1
24	687.625	Adjustable Drill	1
25	687.626	Adjustable Tap	1
26	687.675	Adjustable Awl/Drill Sleeve	1
27	687.676	Awl/Drill Depth Adjuster	1
28	687.680	Adjustable Tap Sleeve	1
29	687.681	Tap Depth Adjuster	1
	9154.0064	ELSA®-ATP Trial/Screw Prep Instruments Graphic Case	

ELSA®-ATP TRIAL/SCREW PREP
INSTRUMENT SET 9154.9064

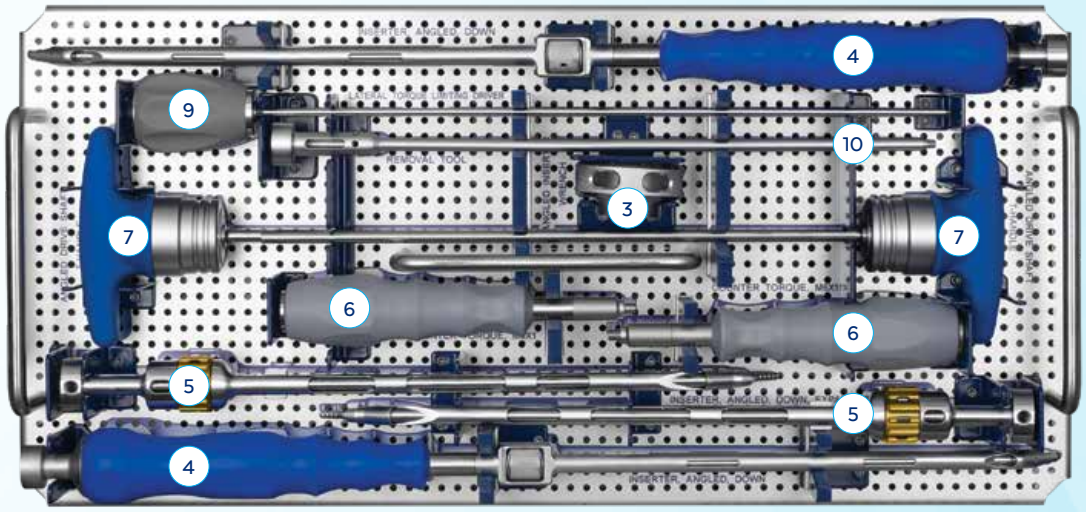


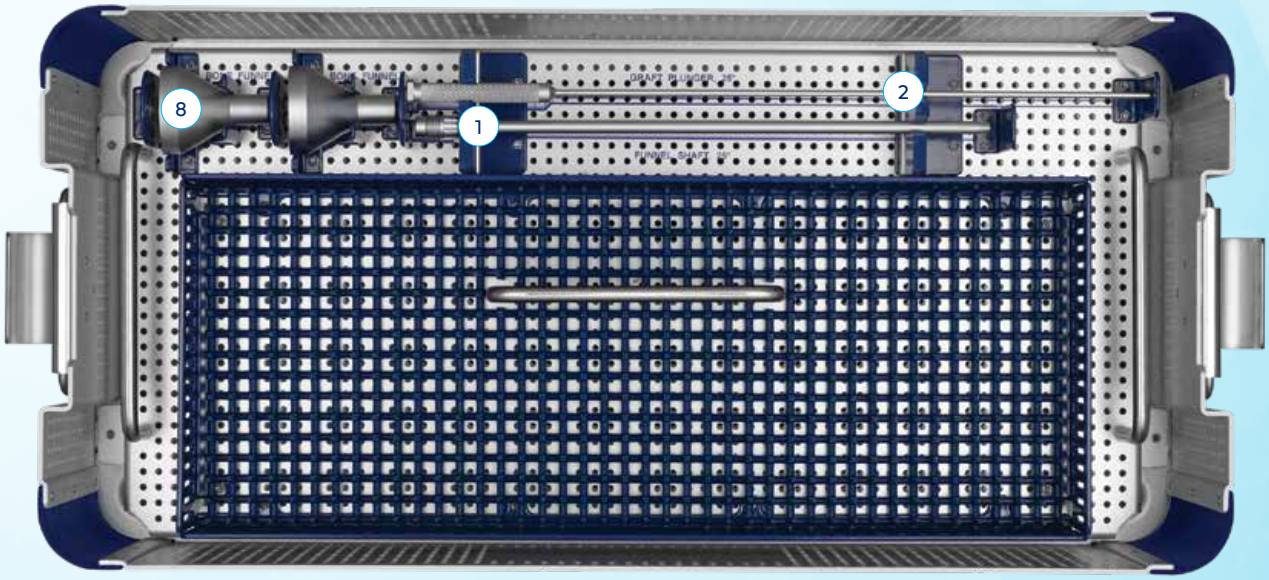


ANTEROLATERAL INSERTION
INSTRUMENT SET 9154.9065

	Part No.	Description	Qty
1	6154.0660	Threaded Funnel Shaft, 25°	2
2	6154.0611	Graft Plunger, 25°	2
3	6154.0614	Angled Inserter Wrench	1
4	6154.0980	Inserter, Angled, Down	2
5	6154.3001	Inserter, Angled, Down, Expandable	2
6	6154.3003	Counter-Torque, M6x1	2
7	6154.3012	Angled Drive Shaft, T-Handle	2
8	681.013	Bone Funnel	2
9	693.600	Lateral Torque-Limiting Driver, 3.0Nm	1
10	693.613	Removal Tool	1
	693.610	Threaded Funnel Shaft	1
	693.611	Graft Plunger	1
	9154.0065	Anterolateral Insertion Instruments Graphic Case	

ANTEROLATERAL INSERTION
INSTRUMENT SET 9154.9065





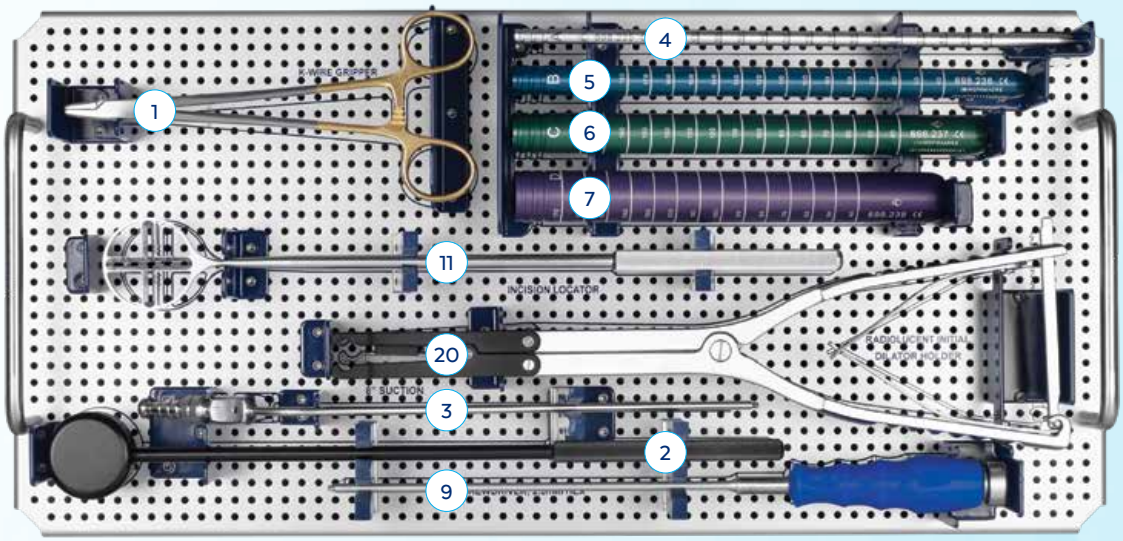
MARS™ 3VL RETRACTOR
INSTRUMENT I SET 9133.9001

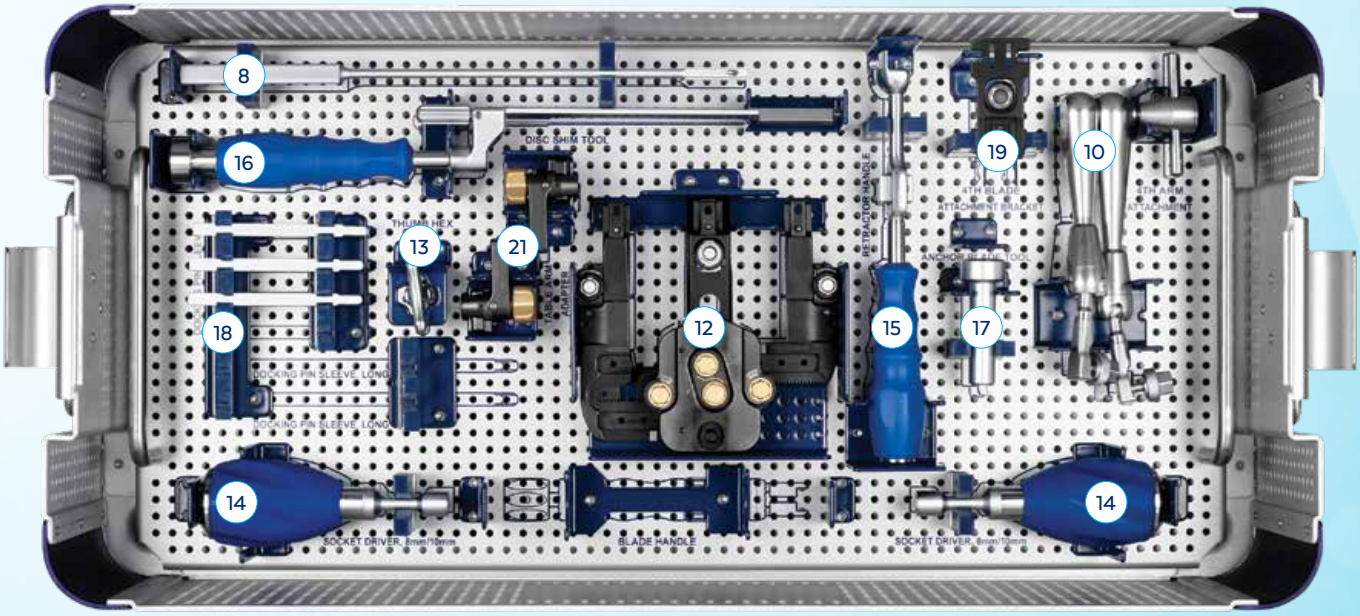
	Part No.	Description	Qty
1	623.003	K-Wire Gripper	1
2	675.403	Flouro Modulator	1
3	675.513	8” Suction	1
4	698.235	Stainless Steel Cannula A	1
5	698.236	Aluminum Cannula B	1
6	698.237	Aluminum Cannula C	1
7	698.238	Aluminum Cannula D	1
8	698.240	Shim Tool, CC	1
9	698.260	Screwdriver, 2.5mm Hex	1
10	698.355	MARS™ 3V 4th Arm Attachment	1
11	6133.0001	Incision Locator	1
12	6133.0100	MARS™ 3VL Retractor	1
13	6133.0148	Thumb Hex	1
14	6133.0150	Socket Driver, 8mm/10mm	2
15	6133.0230	Retractor Handle	1
16	6133.0330	Disc Shim Tool	1
17	6133.0332	Anchor Blade Tool	1
18	6133.0340	Docking Pin Sleeve	4
	6133.0341	Docking Pin, Sleeve, Long	
19	6133.0357	4th Blade Attachment Bracket	1
20	6133.0360	Radiolucent Initial Dilator Holder	1
21	6133.0790	Table Arm Adapter	2
	9133.0001	MARS™ 3VL Retractor Instruments I Graphic Case	

Part No.	Disposables	Qty
6133.0300S	Lengthening Shim	2
6133.0305S	Widening Shim	2
6133.0310S	Docking Pin, 3.3mm, 10mm	2
6133.0311S	Docking Pin, 3.75mm, Long, 10mm	
6133.0320S	Docking Pin, 3.3mm, 20mm	2
6133.0322S	Docking Pin, 3.75mm, Long, 20mm	
6133.0325S	Disc Shim, Aluminum	1
6133.0326S	Disc Shim, Stainless Steel	1
6133.0399S	K-Wires, Threaded, Blunt	1
675.405S	Bayonetted Annulotomy Knife	1

*Additionally available

MARS™ 3VL RETRACTOR
INSTRUMENT I SET 9133.9001

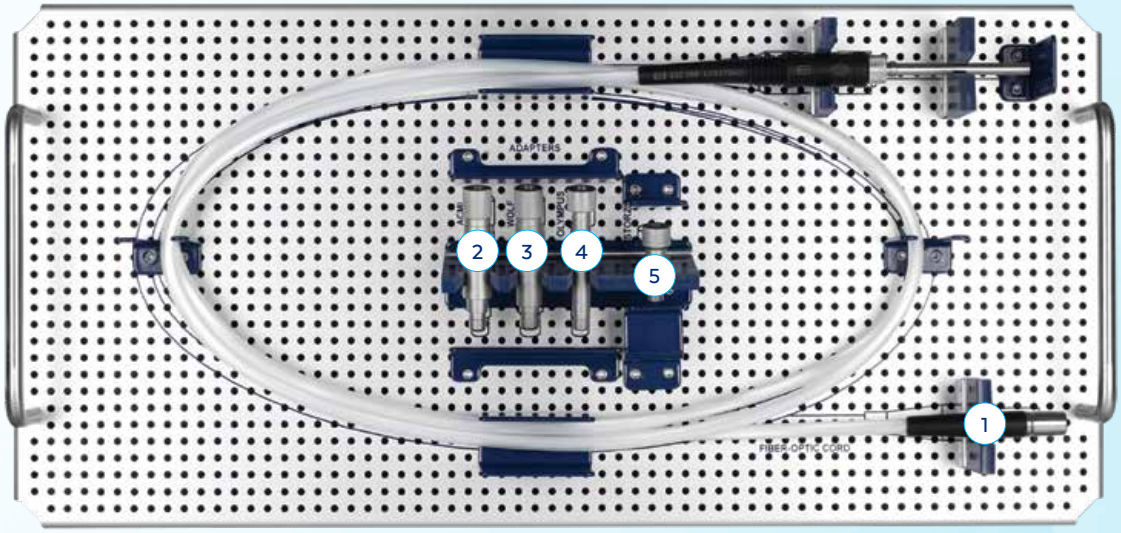




MARS™3VL
INSTRUMENT III, MOUNT SET 9133.9003

	Part No.	Description	Qty
1	632.300	Fiber-Optic Cord	1
2	632.305	Adapter, ACMI	1
3	632.306	Adapter, Wolf	1
4	632.307	Adapter, Olympus	1
5	632.308	Adapter, Storz	1
6	632.505	Table Clamp, Radial	1
7	632.785	Insulating Bushing	1
8	6133.0780	Articulating Arm Assembly	1
	698.605S	Illumination System	1
	9133.0003	MARS™3VL Retractor Instruments III Graphic Case	

MARS™ 3VL
INSTRUMENT III, MOUNT SET 9133.9003

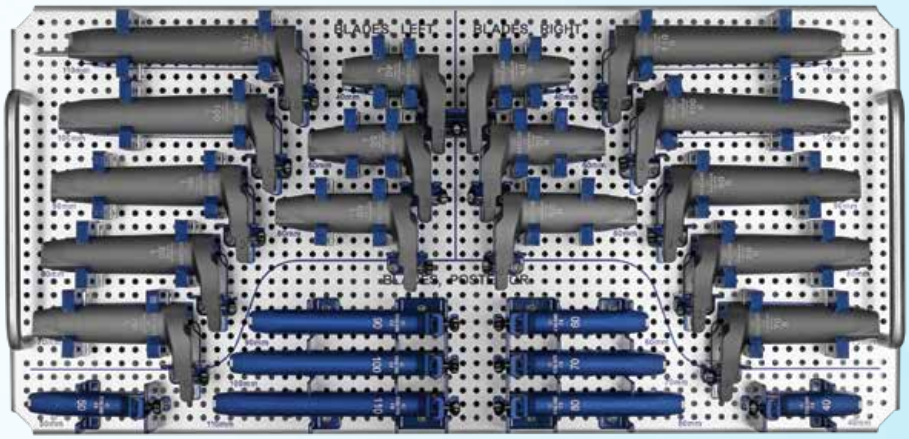


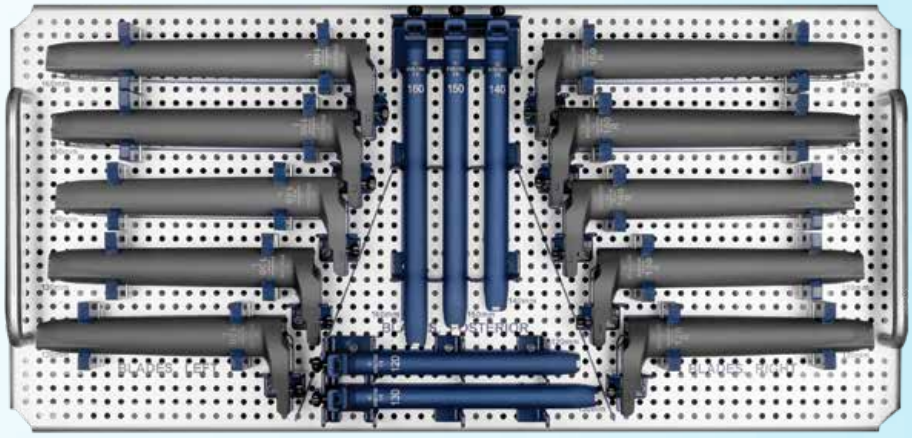
MARS™3VL RETRACTOR
INSTRUMENT V, IBP BLADE SET 9133.9005

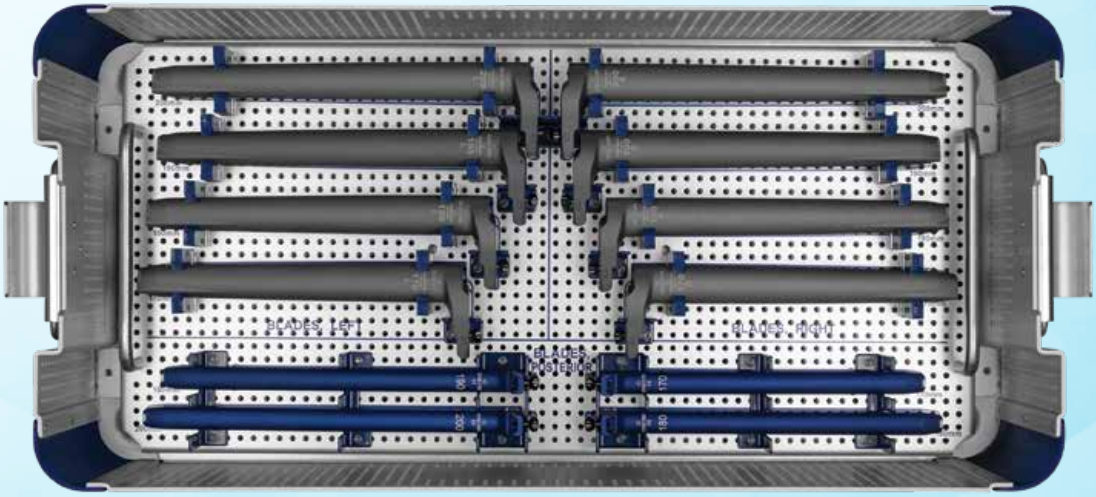
Part No	Description	Qty
6133.0442S	IBP, 3.3mm, 80-110mm, Sterile	2
6133.0443S	IBP, 3.3mm, 120-150, Sterile	2
6133.0444S	IBP, 3.3mm, 160-200, Sterile	2
6133.0542S	Sleeve, IBP, 80-110mm, Sterile	2
6133.0543S	Sleeve, IBP, 120-150, Sterile	2
6133.0544S	Sleeve, IBP, 160-200, Sterile	2
6133.0345S	Bone Pin Sleeve, Small	2
6133.0346S	Bone Pin Sleeve, Medium	2
6133.0347S	Bone Pin Sleeve, Large	2
6133.1040	Blade, Posterior, 40mm	1
6133.1050	Blade, Posterior, 50mm	1
6133.1060	Blade, Posterior, 60mm	1
6133.1070	Blade, Posterior, 70mm	1
6133.1080	Blade, Posterior, 80mm	1
6133.1090	Blade, Posterior, 90mm	1
6133.1100	Blade, Posterior, 100mm	1
6133.1110	Blade, Posterior, 110mm	1
6133.1120	Blade, Posterior, 120mm	1
6133.1130	Blade, Posterior, 130mm	1
6133.1140	Blade, Posterior, 140mm	1
6133.1150	Blade, Posterior, 150mm	1
6133.1160	Blade, Posterior, 160mm	1
6133.1170	Blade, Posterior, 170mm	1
6133.1180	Blade, Posterior, 180mm	1
6133.1190	Blade, Posterior, 190mm	1
6133.1200	Blade, Posterior, 200mm	1
6133.2041	Blade, IBP, Right, 40mm	1
6133.2051	Blade, IBP, Right, 50mm	1
6133.2061	Blade, IBP, Right, 60mm	1
6133.2071	Blade, IBP, Right, 70mm	1
6133.2081	Blade, IBP, Right, 80mm	1
6133.2091	Blade, IBP, Right, 90mm	1
6133.2101	Blade, IBP, Right, 100mm	1

Part No.	Description	Qty
6133.2111	Blade, IBP, Right, 110mm	1
6133.2121	Blade, IBP, Right, 120mm	1
6133.2131	Blade, IBP, Right, 130mm	1
6133.2141	Blade, IBP, Right, 140mm	1
6133.2151	Blade, IBP, Right, 150mm	1
6133.2161	Blade, IBP, Right, 160mm	1
6133.2171	Blade, IBP, Right, 170mm	1
6133.2181	Blade, IBP, Right, 180mm	1
6133.2191	Blade, IBP, Right, 190mm	1
6133.2201	Blade, IBP, Right, 200mm	1
6133.3041	Blade, IBP, Left, 40mm	1
6133.3051	Blade, IBP, Left, 50mm	1
6133.3061	Blade, IBP, Left, 60mm	1
6133.3071	Blade, IBP, Left, 70mm	1
6133.3081	Blade, IBP, Left, 80mm	1
6133.3091	Blade, IBP, Left, 90mm	1
6133.3101	Blade, IBP, Left, 100mm	1
6133.3111	Blade, IBP, Left, 110mm	1
6133.3121	Blade, IBP, Left, 120mm	1
6133.3131	Blade, IBP, Left, 130mm	1
6133.3141	Blade, IBP, Left, 140mm	1
6133.3151	Blade, IBP, Left, 150mm	1
6133.3161	Blade, IBP, Left, 160mm	1
6133.3171	Blade, IBP, Left, 170mm	1
6133.3181	Blade, IBP, Left, 180mm	1
6133.3191	Blade, IBP, Left, 190mm	1
6133.3201	Blade, IBP, Left, 200mm	1
9133.0005	MARS™3VL Retractor Instruments V Graphic Case	

MARS™ 3VL RETRACTOR
INSTRUMENT V, IBP BLADE SET 9133.9005







IMPORTANT INFORMATION ON ELSA®-ATP SPACERS

DESCRIPTION

ELSA® Spacers are expandable lateral lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to aid in expulsion resistance.

ELSA® Spacers are manufactured from titanium alloy, as specified in ASTM F136 and F1295, and include an internal component manufactured from radiolucent PEEK polymer, as specified in ASTM F2026. The screws and anchors used with ELSA® are manufactured from titanium alloy, as specified in ASTM F136 and F1295, and are available with hydroxyapatite

(HA) coating, as specified in ASTM F1185. Locking screws are manufactured from cobalt chromium alloy, as specified in ASTM F1537.

INDICATIONS

The ELSA® Spacer is an interbody fusion device intended for use at one or more levels of the lumbosacral spine (L1-S1),

as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). 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.

The ELSA® Spacer is intended to be used with or without two screws and/or anchors which accompany the implants. These devices are intended for use with supplemental fixation. Hyperlordotic (≥20°) implants must be used with the two screws and/or anchors and supplemental fixation in addition to the two screws and/or anchors. The ELSA® Spacer is to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.

WARNINGS

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

Interbody fusion devices for the treatment of degenerative conditions are designed to withstand both full load bearing and the loads associated with long-term use which could result from the presence of non-union or delayed union.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.

These warnings do not include all adverse effects which could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

The components of this system are manufactured from PEEK radiolucent polymer, titanium alloy, and tantalum. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

Components of this system should not be used with components of any other system or manufacturer.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

PRECAUTIONS

The implantation of intervertebral fusion devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

Surgical implants must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Based on fatigue testing, when using the ELSA® Spacer, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

MRI SAFETY INFORMATION

The ELSA® Spacer is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scan conditions defined above, the ELSA® Spacer is expected to produce a maximum temperature rise of less than or equal to 3.9°C after 15 minutes of continuous scanning.

The image artifact caused by the device is not expected to extend beyond 35mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

CONTRAINDICATIONS

Use of the ELSA® Spacer is contraindicated in patients with the following conditions:

1. 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.
2. Prior fusion at the level(s) to be treated.
3. Severe osteoporosis, which may prevent adequate fixation.
4. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
5. 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 bony healing and may be at a higher risk of implant failure.
6. Any condition not described in the indications for use.
7. Signs of local inflammation.
8. Fever or leukocytosis.
9. Morbid obesity.
10. Pregnancy.
11. Mental illness.
12. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.
13. Suspected or documented allergy or intolerance to composite materials.
14. Any case not needing a fusion.
15. Any patient not willing to cooperate with postoperative instruction.
16. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
17. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
18. Spondylolisthesis unable to be reduced to Grade 1.
19. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
20. Any case that requires the mixing of metals from two different components or systems.

IMPORTANT INFORMATION ON ELSA®-ATP SPACERS

21. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
22. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS

Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential need for additional surgery to correct these effects:

- Loosening, bending or breakage of components
- Displacement/migration of device components
- Tissue sensitivity to implant material
- Potential for skin breakdown and/or wound complications
- Non-union or delayed union or mal-union
- Infection
- Nerve damage, including loss of neurological function (sensory and/or motor), paralysis, dysesthesia, hyperesthesia, paresthesia, radiculopathy, reflex deficit, cauda equina syndrome
- Dural tears, cerebral spinal fluid leakage
- Fracture of vertebrae
- Foreign body reaction (allergic) to components or debris
- Vascular or visceral injury
- Change in spinal curvature, loss of correction, height and/or reduction
- Urinary retention or loss of bladder control or other types of disorders of the urogenital system
- Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise
- Reproductive system compromise including impotence, sterility, loss of consortium and sexual dysfunction.
- Pain or discomfort
- Bursitis
- Decrease in bone density due to stress shielding
- Loss of bone or fracture of bone above or below the level of surgery
- Bone graft donor site pain, fracture, and/or delayed wound healing
- Restriction of activities
- Lack of effective treatment of symptoms for which surgery was intended
- Need for additional surgical intervention
- Death

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING AND USE

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidently contaminated.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile. HA-coated implants are only available sterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, double foil pouch. The expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.

IMPORTANT INFORMATION ON ELSA®-ATP SPACERS

- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal Law (USA) Restricts this Device to Sale by or on the order of a Physician.

REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

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Audubon, PA 19403
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Customer Service:
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