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Supplemental fixation required

ELSA®

Expandable Integrated Lateral 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®

ELSA®

EXPANDABLE INTEGRATED LATERAL LUMBAR INTERBODY SPACER

ELSA® is an expandable lateral lumbar interbody fusion spacer with integrated fixation that is inserted at a minimized profile and expanded to help restore segmental lordosis. ELSA® allows for sagittal balance correction while minimizing disruption to patient anatomy.

Sagittal Alignment

ELSA® allows for sagittal balance correction from the anterior column.

Adjustable Lordosis

Hyperlordotic implants with adjustability from 5° to 20° or 15° to 30° allow for insertion at a smaller starting height for a more precise fit.

Integrated Fixation

Integrated fixation can be delivered through a smaller access window compared to traditional lateral fixation, while fixation eyelets maintain ideal placement during implant expansion.

Intraoperative Versatility

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

INSTRUMENT OVERVIEW

DISC PREPARATION INSTRUMENTS

Bayonetted Annulotomy Knife 675.405S

Penfield, Bayonetted, Pull 675.173

Penfield #4, Pull, 190mm 675.174

Cobb Elevator, Straight, 20mm 675.503

Cobb Elevator, Straight, 10mm 675.504

Thin Rasp, 12x20mm 675.510

DISC PREPARATION INSTRUMENTS (CONT'D)

Cobb, 10mm, 7° Up-Angled 675.515

Cobb, 20mm, 7° Up-Angled 675.516

Ring Curette, 10mm Straight 675.518

Ring Curette, 10mm 7°, Up-Angle 675.519

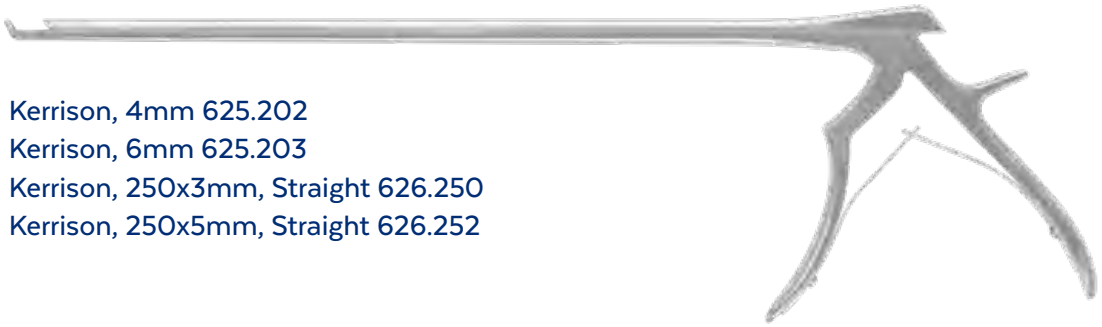
Double Rasp 675.520

Cup Curette, 6.5x9.5mm, Straight 675.525

Cup Curette, 6.5x9.5mm, 15°, Up-Angle 675.526

Cup Curette, 6.5x9.5mm, 90°, Down-Angle 675.527

DISC PREP INSTRUMENTS (CONT'D)



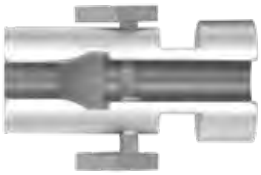
Kerrison, 4mm 625.202
Kerrison, 6mm 625.203
Kerrison, 250x3mm, Straight 626.250
Kerrison, 250x5mm, Straight 626.252

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

Osteophyte Removal Tool 6105.2016

ADDITIONAL DISC PREPARATION INSTRUMENTS

T-Handle with Impaction Cap 675.005



Slap Hammer Adapter 675.002

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

PADDLE DISTRACTORS

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

BOX CUTTERS

	Height	Part No.
	5mm	675.533
	7mm	675.534
	9mm	675.535

TRIALS

Trial, 0° Lordotic

Trial, 6° Lordotic

Trial, 15° Lordotic 6122.0015

Trials			
Height	**0° Lordotic**	**6° Lordotic**	**15° Lordotic**
5mm	687.004	687.055	-
7mm	687.007	687.057	-
9mm	687.009	687.059	-
11mm	-	-	6122.0015

Note: Trials marked with a green ring on the shaft are 0° lordotic. Trials marked with a purple ring are 6° lordotic.

Adjustable Trial, Parallel

Adjustable Trials		
Sagittal Profile	**Height**	**Part No.**
Parallel	7-15mm	6122.0200
Lordotic	8-16mm	6122.0210

MIS Handle 673.003

Adjustable Trial Handle 694.418

IMPLANT INSERTION INSTRUMENTS

Lateral Torque-Limiting Driver, 3.0N 693.600

Lateral Inserter 693.601

MIS Handle 673.003

Lateral Inserter 693.601
Lateral Torque-Limiting Driver 3.0N 693.600
MIS Handle 673.003
(Assembled)

Lateral Angled Inserter 693.602

SCREW PREPARATION

Straight Awl 687.524

Angled Awl 10° 6122.0511

Sleeveless Awl 10° 6122.0512

Straight 5.5mm Drill 687.520

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

SCREW PREPARATION (CONT'D)

Adjustable Drill 687.625

Adjustable Awl/Drill Sleeve 687.675

Awl/Drill Depth Adjuster 687.676

Adjustable Tap 687.626

Adjustable Tap Sleeve 687.680

Tap Depth Adjuster 687.681

SCREW PREPARATION (CONT'D)

3.5 Angled Hex Driver 10° 6122.0504

Angled Holder Sleeve 10° 6122.0505

Angled Holder Shaft 10° 6122.0506

3.5 Hex Driver Tip 10° 6122.0024

5.5 Drill Tip 10° 6122.0521

5.5 Tap Tip 10° 6122.0721

SCREW PREPARATION (CONT'D)

Quick-Connect Swivel Handle 687.005

Ratchet Handle 687.105

Anti-Torque Holder 687.906

Angled Holder Nut 687.507

Spanner Wrench 687.509

SCREW PREPARATION (CONT'D)

3.5 Angled Hex Driver 10° 6122.0504
Quick-Connect Swivel Handle 687.005
Anti-Torque Holder 687.906
(Assembled)

Angled Holder Sleeve 10° 6122.0505
Angled Holder Shaft 10° 6122.0506
3.5 Hex Driver Tip 10° 6122.0024
Quick-Connect Swivel Handle 687.005
Angled Holder Nut 687.507
Anti-Torque Holder 687.906
(Assembled)

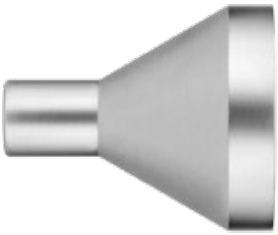
Single Anchor Inserter, Lateral 6219.1000

Set Screw Driver, 2.5mm Hex (1.0Nm Torque) 676.600

GRAFT INTRODUCTION

Threaded Funnel Shaft 693.610

Graft Plunger 693.611



Bone Funnel 681.013

ADDITIONAL INSTRUMENTS

Removal Tool 693.613

Inserter Wrench 693.614

Slide Hammer 694.018

SURGICAL TECHNIQUE

ELSA®

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

ELSA® Spacers are to be used with supplemental fixation. Please refer to the technique guide for the selected supplemental fixation system.

STEP 1 PATIENT PREPARATION

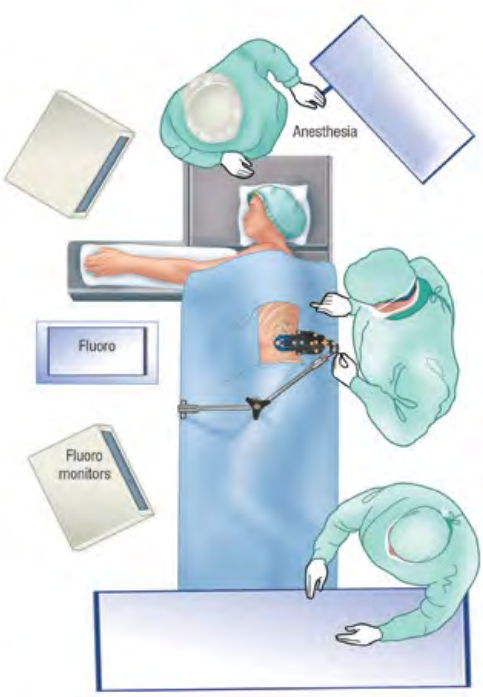
Patient Positioning

A direct lateral approach from the patient's left or right side is used.

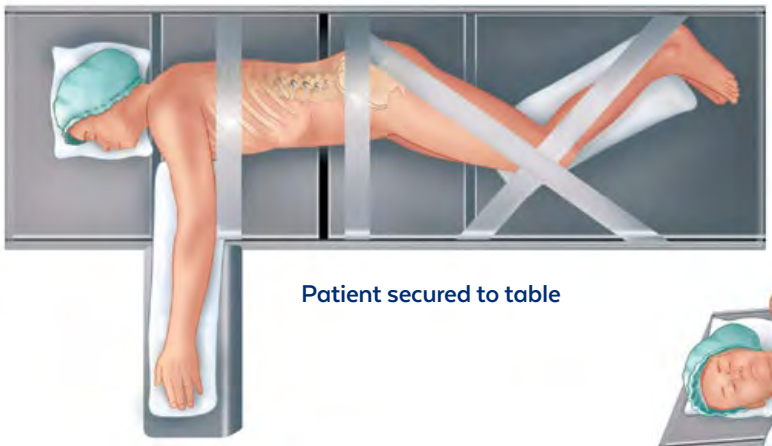
The patient is placed on a flexible surgical table in a straight 90° right lateral decubitus position so the iliac crest is just over the table break, as shown below.

The patient is then secured to the table at the following locations: (1) just beneath the iliac crest; (2) over the thoracic region, just under the shoulder; and (3) from the back of the table, over the ankle, and past the knee to the front of the table.

The table should be flexed to open the interval between the 12th rib and iliac crest, and provide direct access to the disc space as shown below.



Patient positioning



Patient secured to table

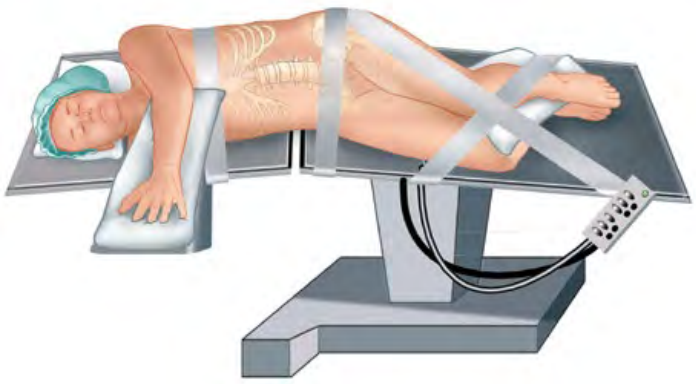
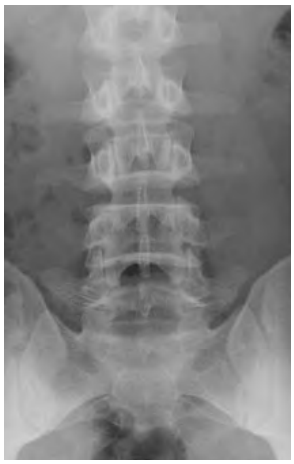


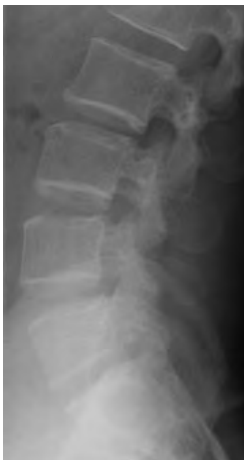
Table flexed

X-Ray Confirmation

Fluoroscopy is used to ensure that the spine is oriented in a straight lateral position. The table should be adjusted so that the C-arm provides straight AP images when at 0° and straight lateral images at 90°.



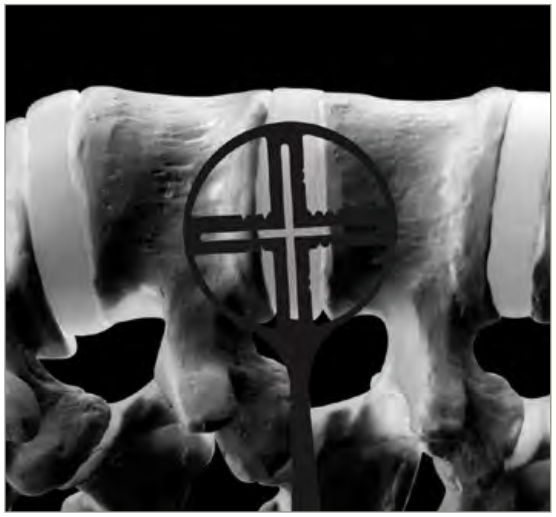
AP image



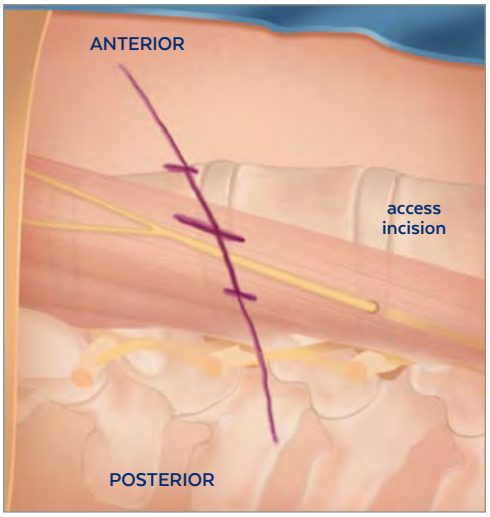
Lateral image

Incision Location

The operative area is carefully cleaned and the **Incision Locator** is used under fluoroscopy to identify the middle of the disc space to be fused. An access incision mark is then traced on the patient's skin to indicate the position and insertion site for the retractor. Position the desired retractor.



Using Incision Locator



Marking incision locations

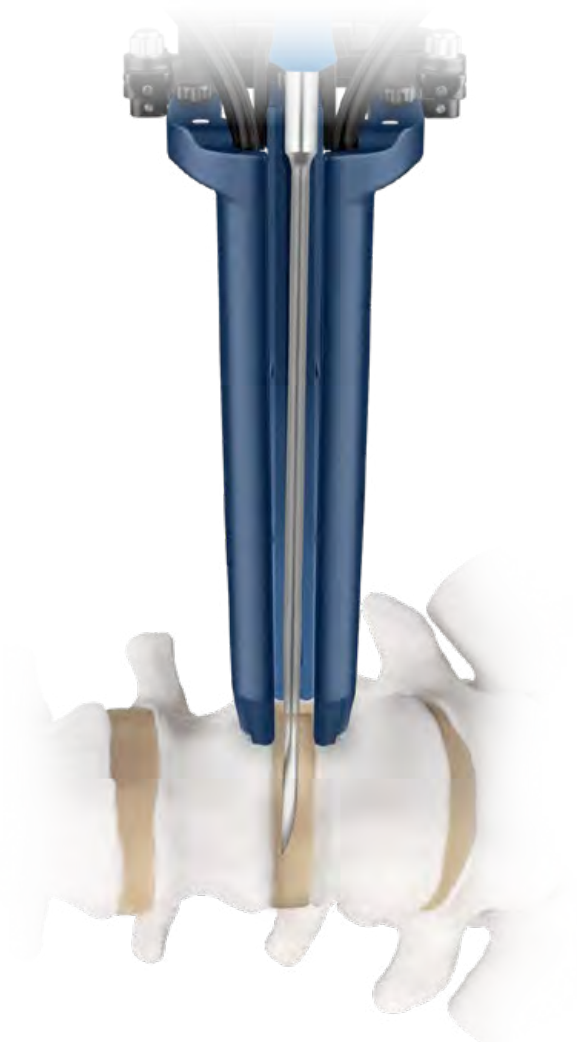
STEP 2 DISC PREPARATION

Annulotomy

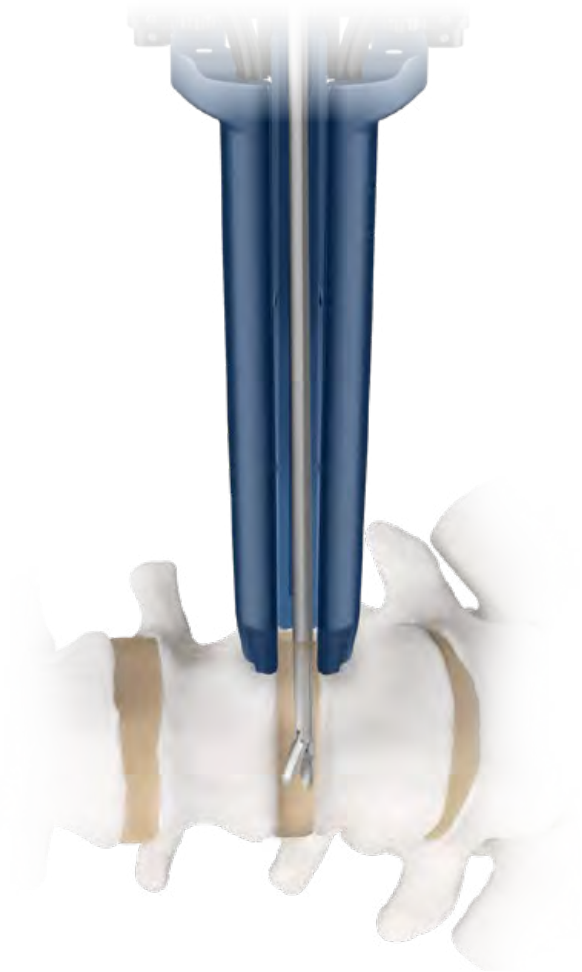
The **Bayonneted Annulotomy Knife** may be used to create a window centered in the anterior half of the annulus, large enough for graft insertion.

Contralateral Annulus Release

The **Cobb Elevator** may be passed along both endplates through the disc space, far enough to provide release of the contralateral annulus. This allows for height restoration upon implant insertion.



Using Cobb Elevator



Using Disc Rongeur

Disc Space Preparation

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

The posterior and anterior walls of the annulus should be preserved 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 3 DISTRACTION AND IMPLANT SIZING

Static InterContinental® trials should be used to determine implant length. Insert the smallest **Static 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 stabilize the segment, and can be confirmed using fluoroscopy and tactile feel.

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

Resection of the anterior longitudinal ligament (ALL) may be performed if desired using rongeurs, scalpels, curettes, and/or other suitable instruments. Trialing should be confirmed following ALL resection.

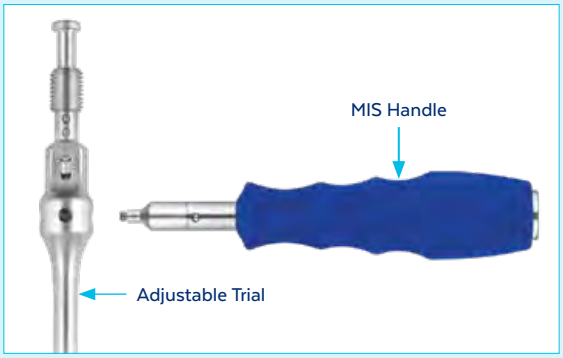
Implant sizing

DISTRACTION AND IMPLANT SIZING (CONT'D)

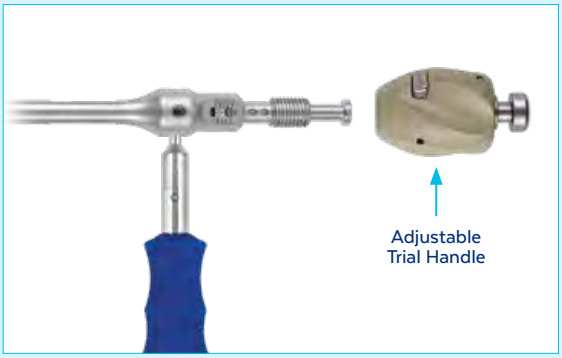
Implant Sizing with the Adjustable Trial

ASSEMBLING THE ADJUSTABLE TRIAL

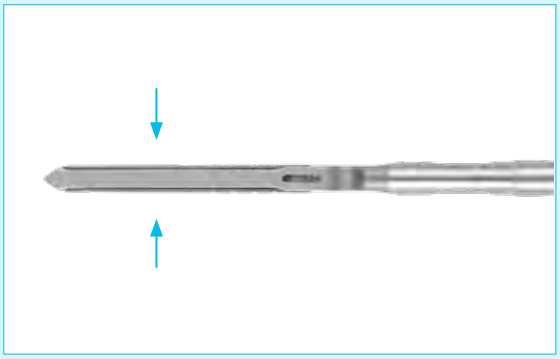
1. Thread the **MIS Handle** into the **Adjustable Trial**, finger tight. Do not overtighten. Four attachment options are available for preferred orientation.



2. Thread the **Adjustable Trial Handle** onto the proximal end of the Adjustable Trial until it is fully seated.



3. Contract the Adjustable Trial back to its starting height by rotating the trial handle counterclockwise until it stops.



Insert the Adjustable Trial Assembly into the disc space at its minimized height until the tapered end of the trial overhangs the contralateral edge.

Expand the trial gradually to the desired height by rotating the trial handle clockwise. Use caution while expanding the trial to avoid excessive distraction and damage to the endplates.

Determine which height best fits the prepared disc space. A secure fit is desirable to maintain disc height and stabilize the segment. The final implant height may be confirmed using fluoroscopy.

Implant Selection (Height)

After the disc height is measured, select an implant with a height range that spans the measured height. For example, if a height between 9mm and 10mm is measured using the trial, then either a 7-14mm parallel implant or an 8-15mm lordotic implant may be used.

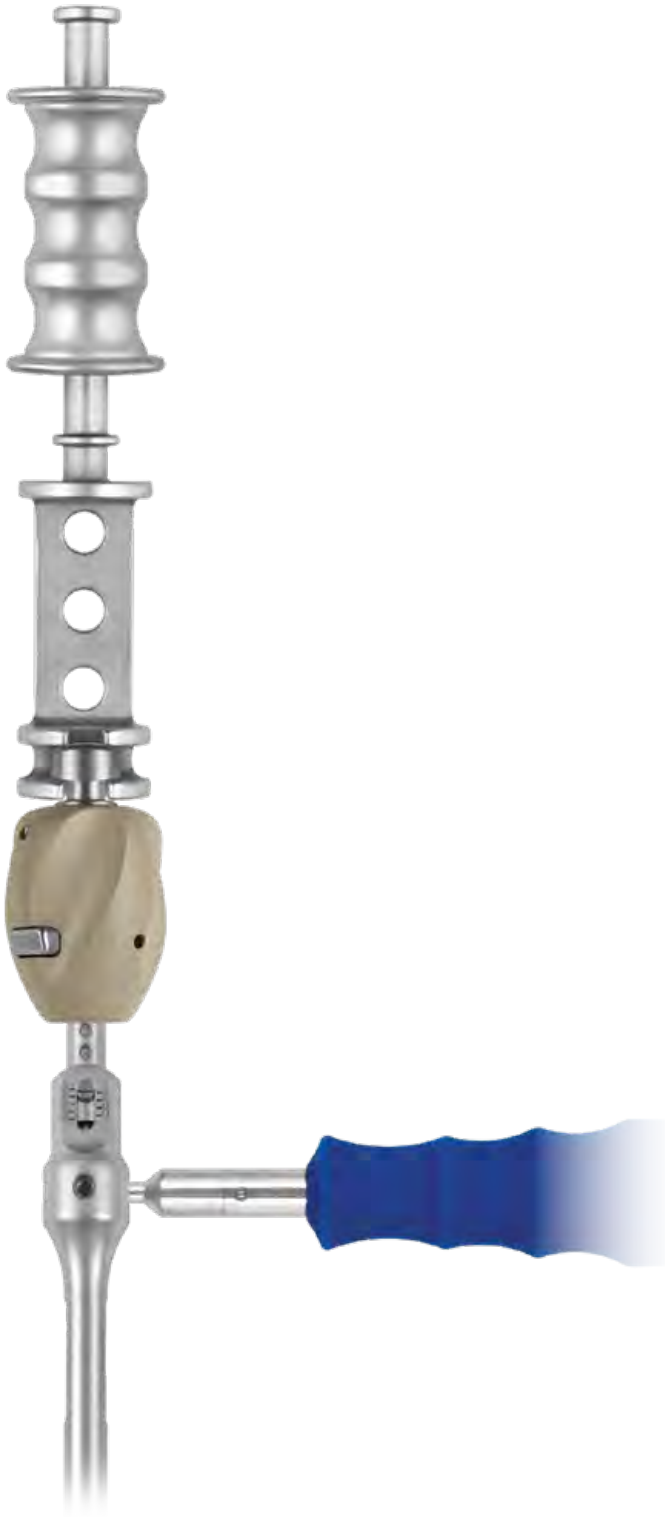
Indicator on Adjustable Trial Assembly shows disc height between 9mm and 10mm

Removing the Adjustable Trial

When removing the Adjustable Trial Assembly, contract the trial height completely by rotating the trial handle counterclockwise until it stops. The **Slide Hammer** may be attached to the Adjustable Trial Handle, if needed, to remove from the disc space.

Disassembling the Adjustable Trial Assembly

To remove the Adjustable Trial Handle, rotate the handle counterclockwise until it tightens. Then slightly loosen the handle by rotating it clockwise a quarter turn. Press the silver button on the Adjustable Trial Handle and hold while rotating counterclockwise one turn. Release the silver button and continue to unthread the handle to fully disengage the instrument.

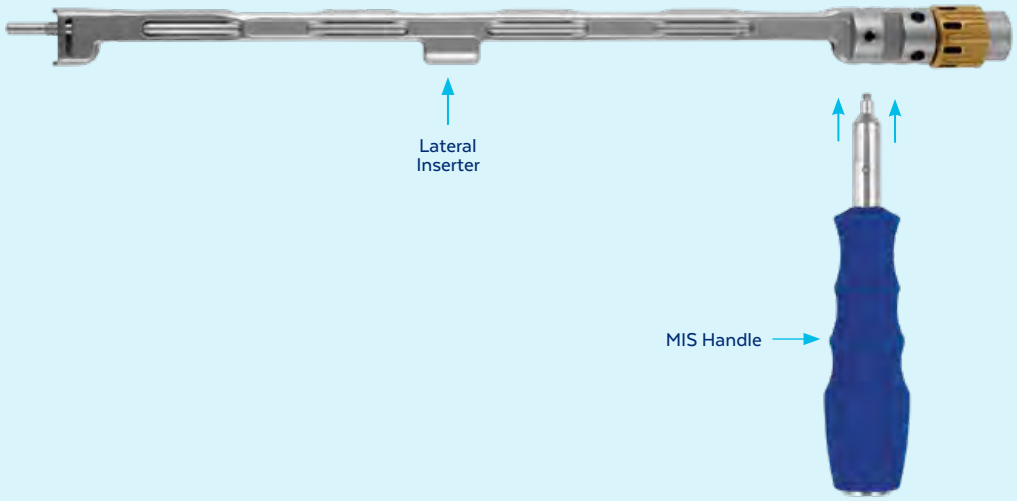


Using Slide Hammer

STEP 4 IMPLANT INSERTION

ASSEMBLING THE INSERTER

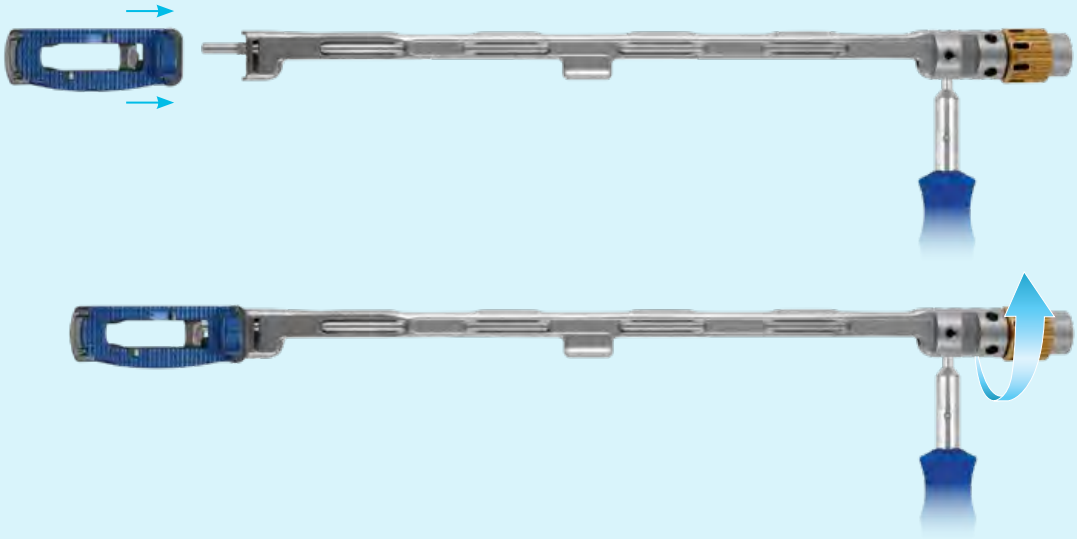
Thread the MIS Handle into the **Lateral Inserter**, finger tight. Do not overtighten. Four attachment options are available for preferred orientation.



IMPLANT ATTACHMENT

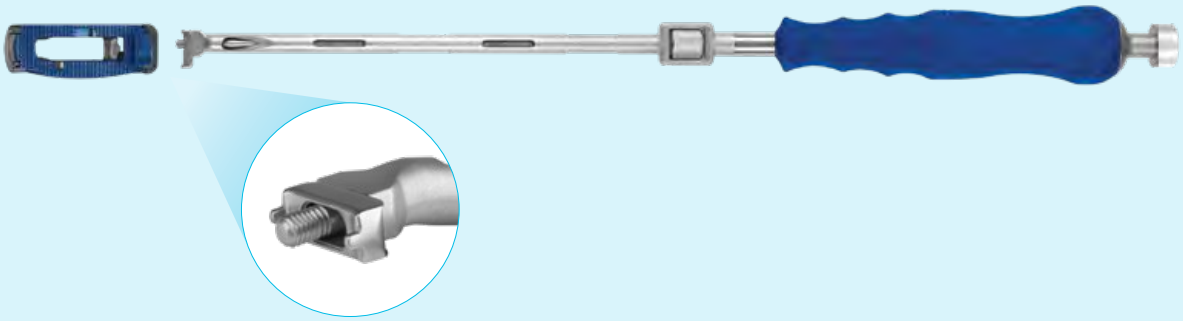
Select the appropriately sized implant and pack allogenic or autogenous bone graft material into the graft chamber of the implant.

Place the inserter into the threaded hole of the implant and orient the tabs of the inserter into the slots on the side of the implant. Rotate the gold thumbwheel on the inserter clockwise until it stops to thread the implant onto the inserter. Do not use the **Inserter Wrench** to tighten the implant.

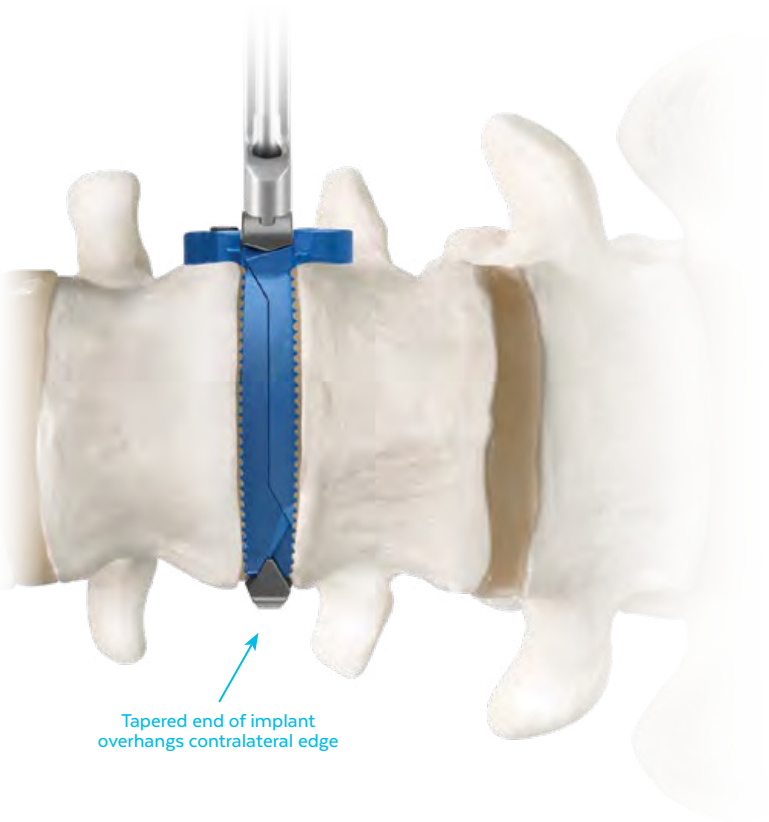


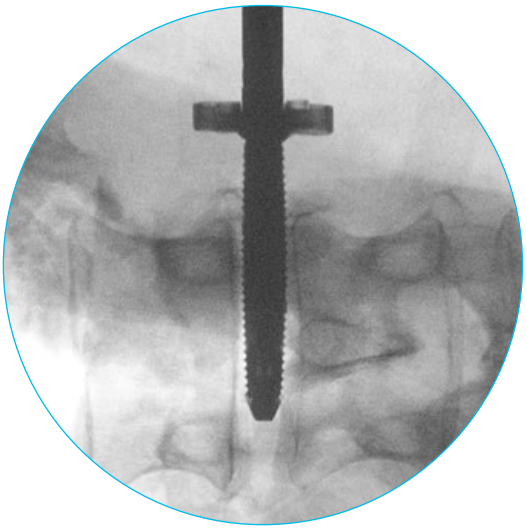
USING THE ANGLED INSERTER

The **Angled Inserter** is available for difficult levels such as L4-L5. Adjust the tip of the inserter to the left or right side to accommodate surgeon approach. Attach the inserter into the threaded portion of the implant and rotate the thumbwheel clockwise to tighten. Ensure that the anterior side of the implant is on the appropriate side of the inserter, oriented to the patient's anterior side.



Insert the implant into the disc space, in the collapsed state, using the implant inserter assembly until the tapered end of the implant overhangs the contralateral apophyseal ring of the vertebrae. If necessary, impact the end of the inserter.

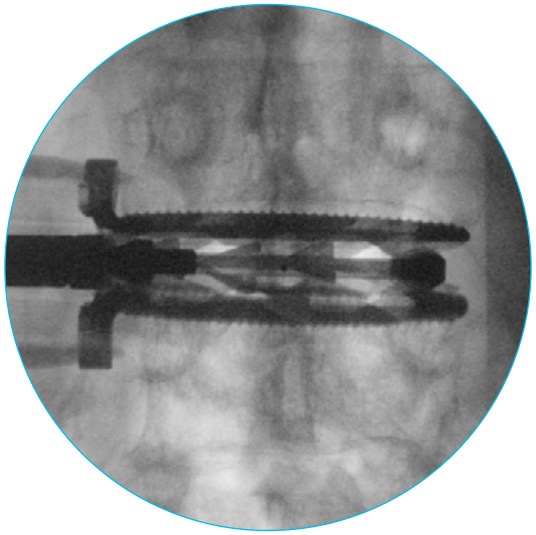




Implant inserted AP into disc space

STEP 5 IMPLANT EXPANSION

Insert the **Lateral Torque-Limiting Driver, 3.0Nm** into the implant inserter assembly and rotate clockwise to expand the implant to the desired height.



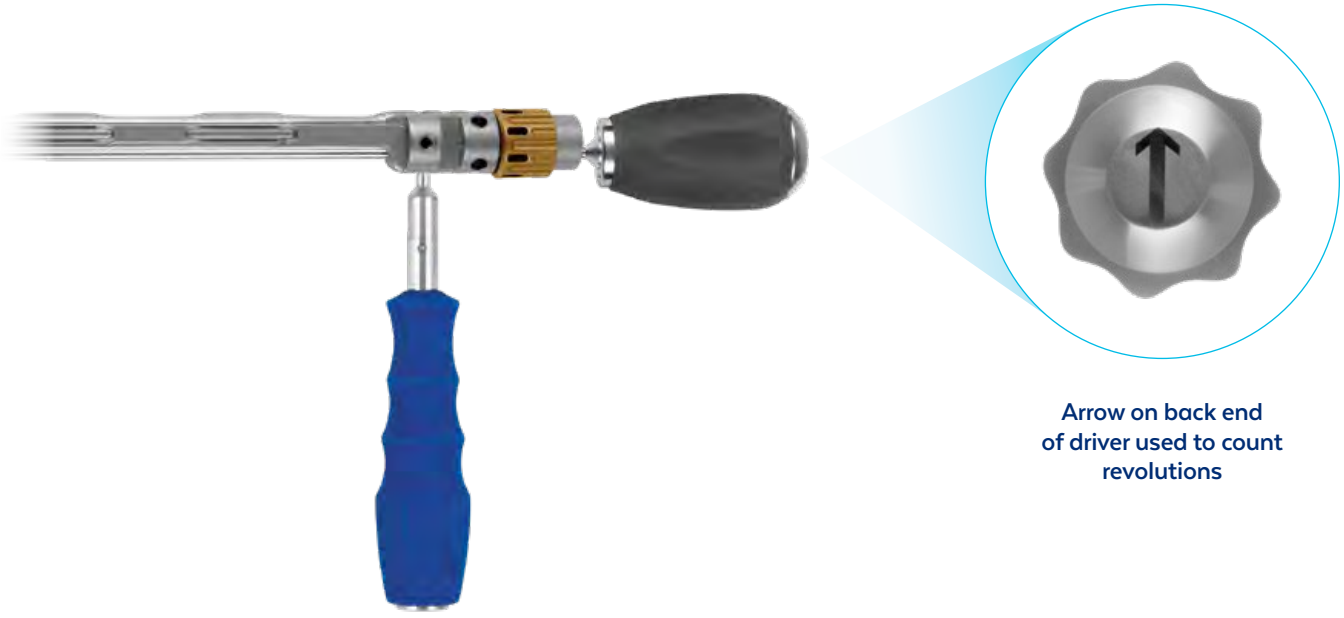
Implant expanded within disc space

Determining Implant Height

Implant expansion is determined by fluoroscopy and the 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.

Minor height adjustments can be made before the implant is detached from the inserters by rotating the driver clockwise to expand or counterclockwise to collapse.

The overall height can be determined by counting the number of revolutions of the driver. One revolution equals 0.5mm of expansion. The etched arrow at the back of the driver may be used to help count the number of revolutions.



Arrow on back end of driver used to count revolutions

The torque-limiting driver helps to identify when the implant has reached its maximum height expansion or when the implant is exerting the maximum distraction force that the implant allows.

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

IMPLANT EXPANSION (CONT'D)

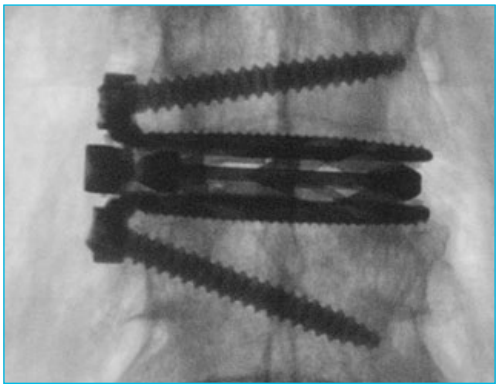
Implant Size	ELSA® Standard Final Height (mm)											
	7	8	9	10	11	12	13	14	15	16	17	
7-14mm	0	2	4	6	8	10	12	14	-	-	-	Rotations
8-15mm	-	0	2	4	6	8	10	12	14	-	-	
10-17mm	-	-	-	0	2	4	6	8	10	12	14	

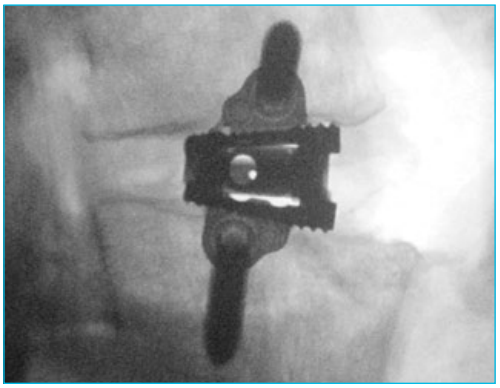
ELSA® 5°-20° Adjustable Lordosis										
Rotations	0	2	4	6	8	10	12	14	16	17.5
Anterior Height (mm)	8.3	9.4	10.5	11.5	12.6	13.6	14.7	15.7	16.7	17.4
Posterior Height (mm)	6.7	7.2	7.7	8.2	8.6	9.1	9.6	10	10.5	10.8
Lordotic Angle (°)	5	6.7	8.4	10.2	11.9	13.6	15.3	17.0	18.7	19.9

ELSA® 15°-30° Adjustable Lordosis										
Rotations	0	2	4	6	8	10	12	14	16	17.5
Anterior Height (mm)	11.2	12.7	13.7	14.7	15.8	16.8	17.8	18.8	19.8	20.4
Posterior Height (mm)	6.8	7.2	7.7	8.2	8.6	9.1	9.6	10.0	10.5	10.8
Lordotic Angle (°)	15	16.7	18.4	20.1	21.7	23.4	25.8	26.8	28.4	29.5

STEP 6 RADIOGRAPHIC CONFIRMATION

Use fluoroscopy to verify the final position of the implant before disengaging the implant insertion assembly.





Once the desired position is achieved, disengage the assembly from the implant by first removing the torque-limiting driver. Rotate the gold thumbwheel on the inserter counterclockwise and gently release the inserter from the implant. If necessary, the Inserter Wrench may be used to loosen the thumbwheel.

Using Inserter Wrench

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 into the lateral slots of the implant. Rotate the gold thumbwheel clockwise to tighten the inserter onto the implant. Once the inserter is reattached to the implant, reduce the implant height. Contract the implant until two finger tight in the counterclockwise direction. The implant may be repositioned as necessary.

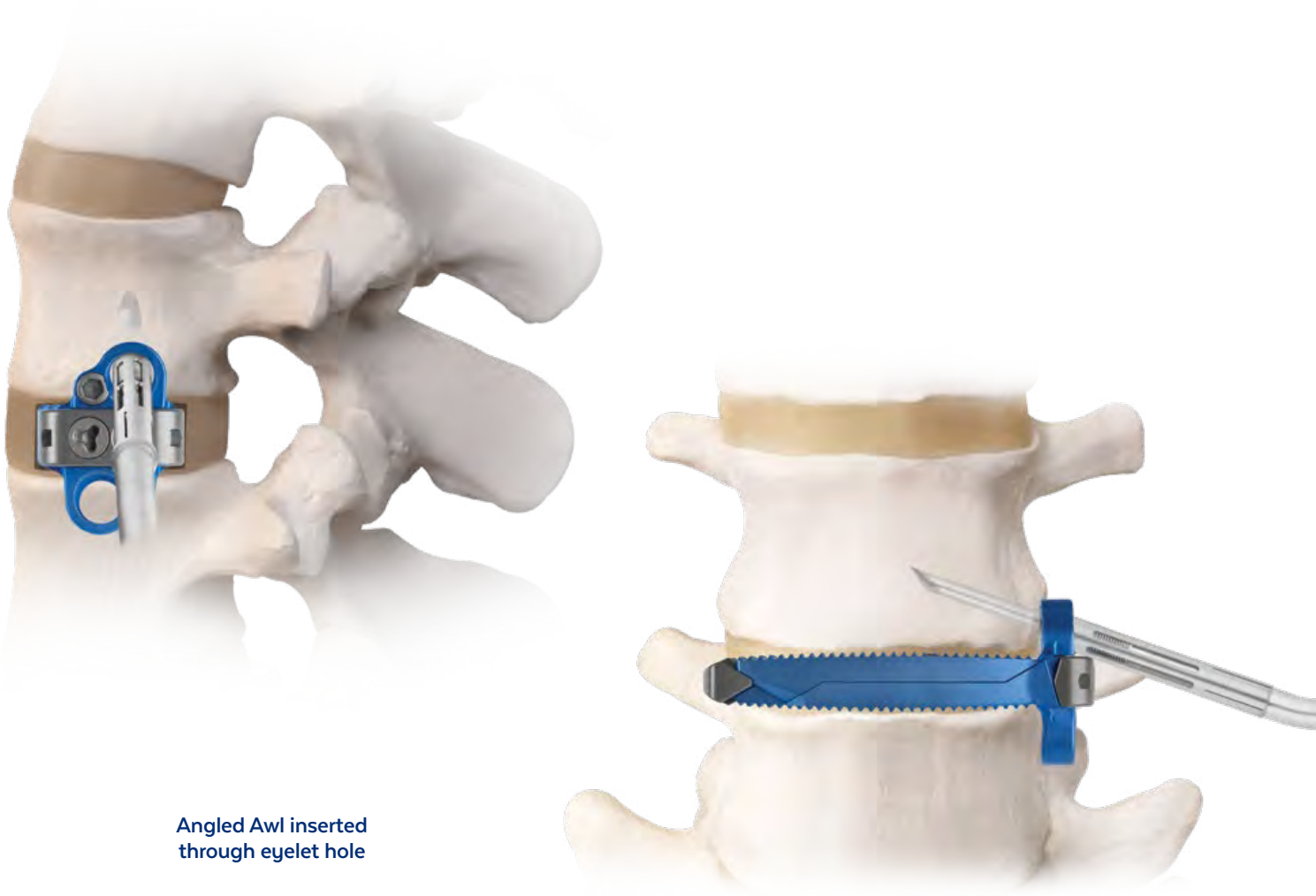
ELSA® may be used with two screws, two anchors, or a combination of both screws and anchors.

- **Screw Fixation:** Follow steps 7-9 on pages 30-37.
- **Anchor Fixation:** Follow steps 7-9 on pages 38-41.
- **Hybrid Screw/Anchor Fixation:** For screw fixation follow steps 7-9 on pages 30-37. For anchor fixation follow steps 7-9 on pages 38-41.

SCREW FIXATION

STEP 7 SCREW HOLE PREPARATION

Insert an awl through the eyelet hole in the implant to perforate the cortex. While inserting the awl, ensure that the flat on the upper shaft faces the most proximal endplate. Remove the awl and clear any tissue in the bone eyelet hole. A drill and tap may also be used to further prepare the screw hole. Refer to the Instrument Overview (pages 6–17) for a list of available straight, angled, and adjustable instrument options. After one of the screw holes is prepared, move to screw insertion (step 8) before preparing the second screw hole.

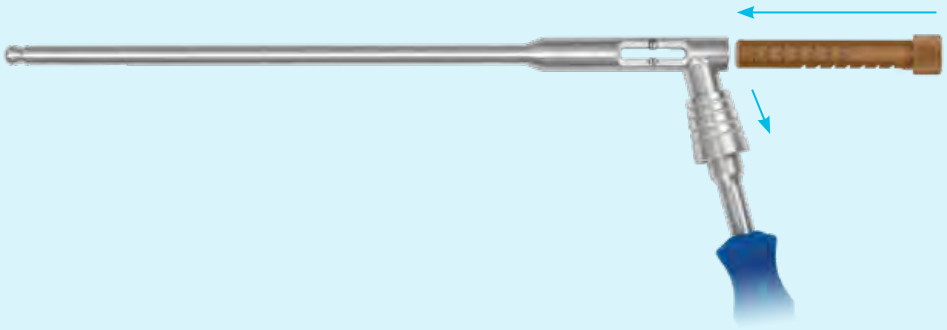


Angled Awl inserted through eyelet hole

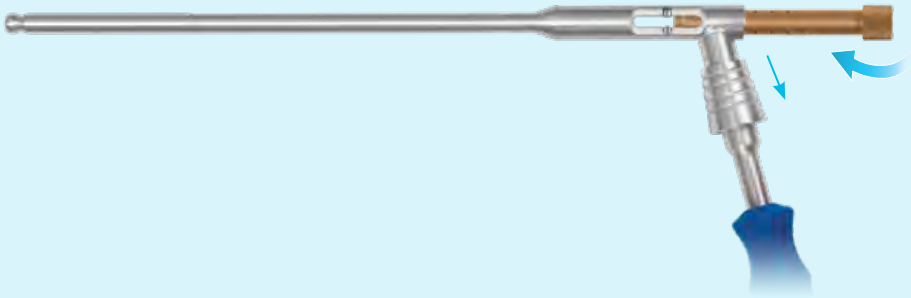
ADJUSTABLE AWL AND ADJUSTABLE DRILL ASSEMBLY

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

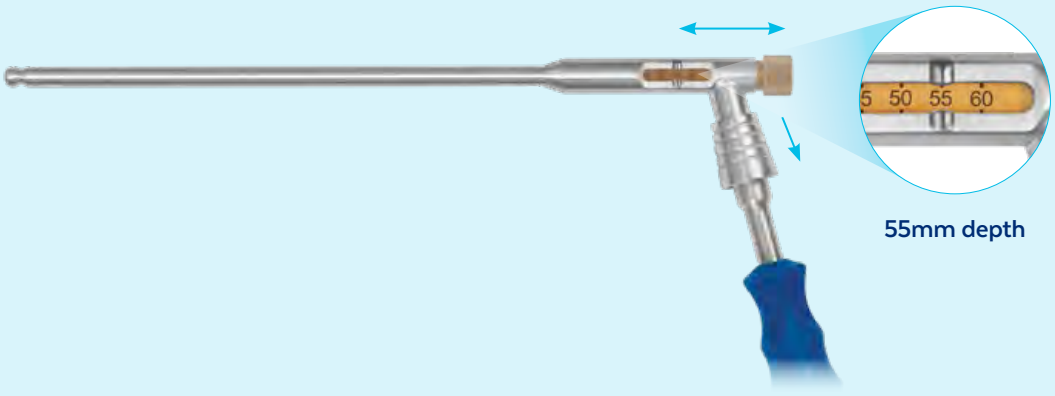
With the other hand, insert the **Tap Depth Adjuster** into the proximal end of the Adjustable Awl/Drill Sleeve until it stops.



Continue to pull down on the collar and rotate the Tap Depth Adjuster clockwise until the sleeve catches and sits in the groove on the Tap Depth Adjuster. The depth adjuster then slides 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, as shown below. Release the collar and pull the depth adjuster until it seats firmly.

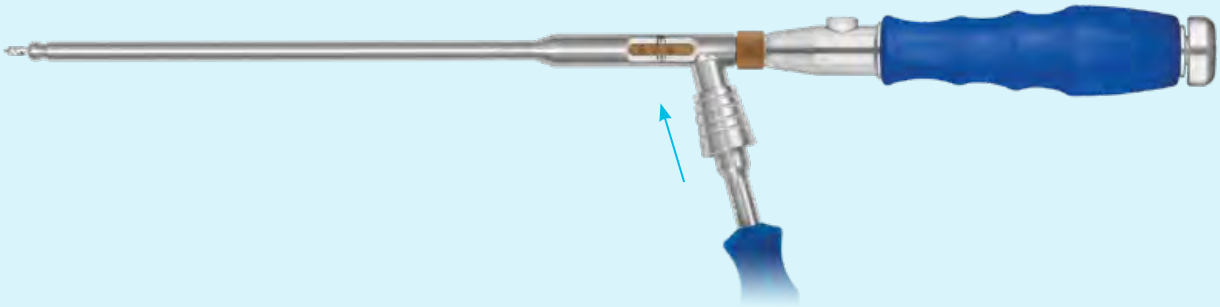


55mm depth

SCREW HOLE PREPARATION (CONT'D)

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

Insert the Adjustable Awl or Drill into the proximal end of the assembly.



ADJUSTABLE TAP ASSEMBLY

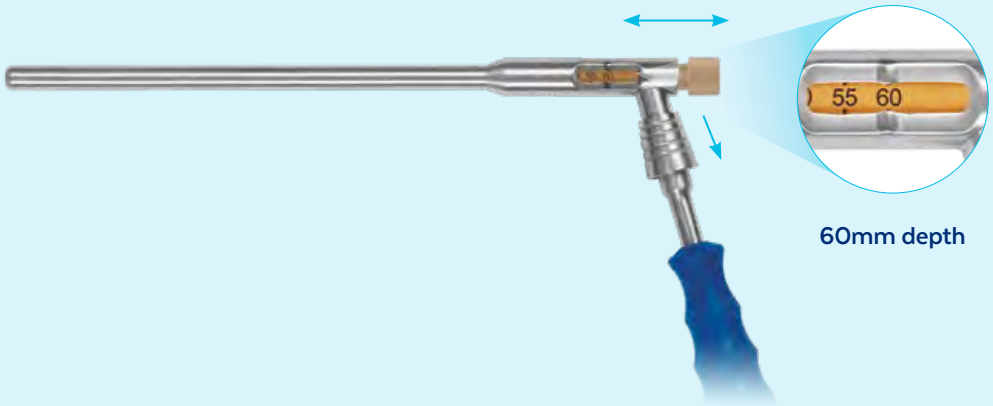
With one hand, hold the **Adjustable Tap Sleeve** and pull down on the retractable collar.

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 and rotate the Tap Depth Adjuster clockwise until the sleeve catches and sits in the groove on the Tap Depth Adjuster. The depth adjuster then slides in and out of the sleeve freely.

ADJUSTABLE TAP ASSEMBLY (CONT'D)

Continue to pull down on the collar and set the Tap Depth Adjuster to the desired depth, indicated by the depth gauge as shown below. Release the collar and pull the depth adjuster until it seats firmly.

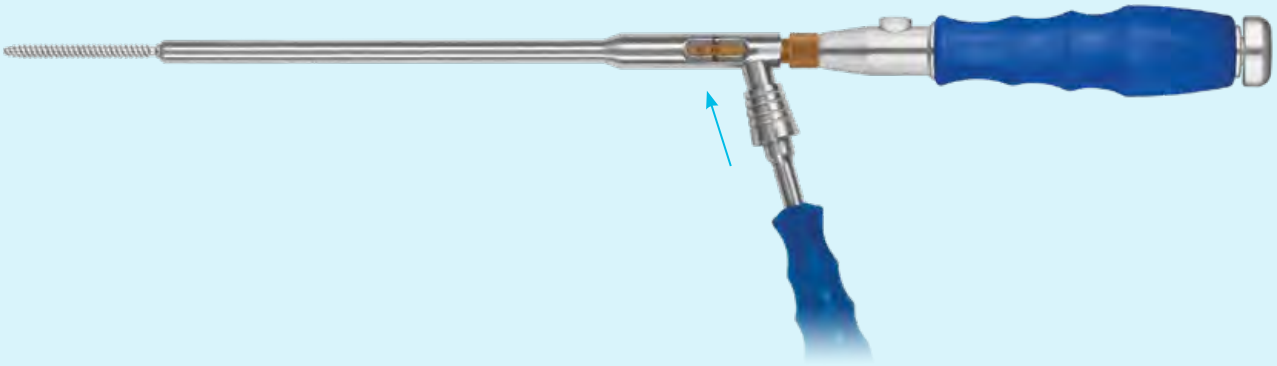


60mm depth

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.

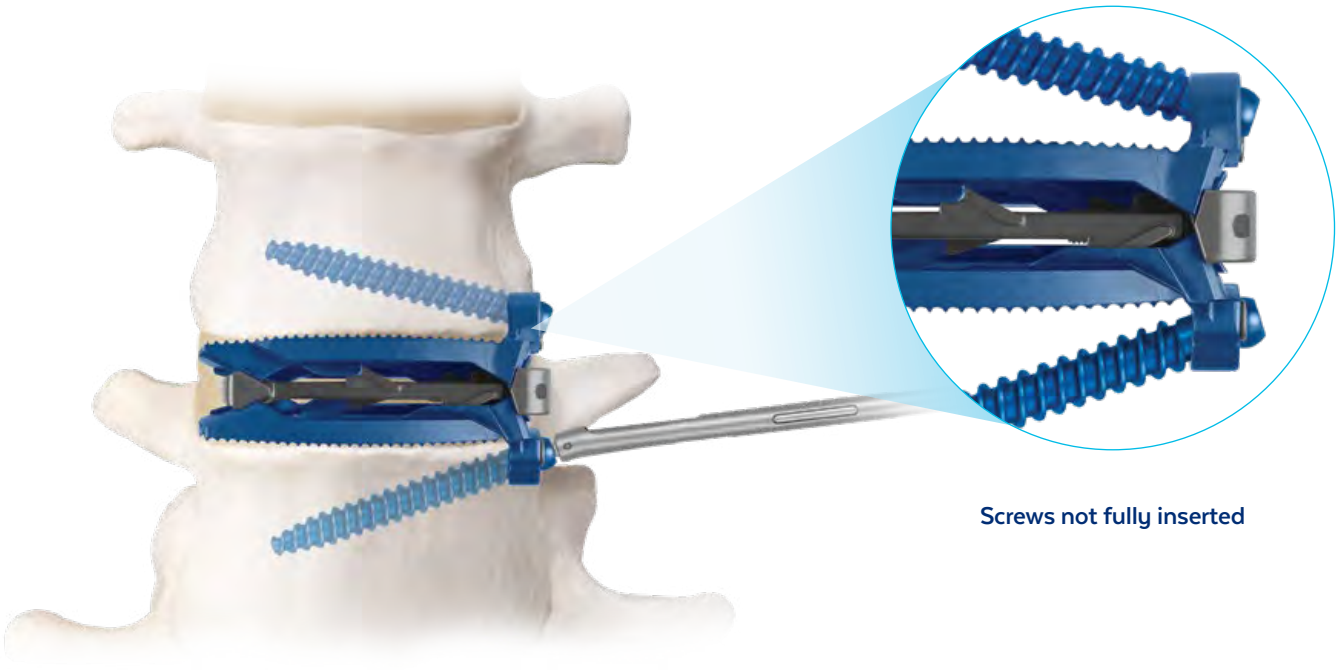
Note: The awl and drill both have a 3.5mm diameter.



STEP 8 SCREW INSERTION

Insert the desired length screw with the Angled Driver Assembly until the screw head contacts the plate. Confirm that the bone screw is the same angle as the awl. Ensure that the screws do not disrupt any adjacent structures outside the vertebrae.

Note: Do not final tighten at this time. Repeat screw hole preparation (step 7) and screw insertion (step 8) for the second screw hole.

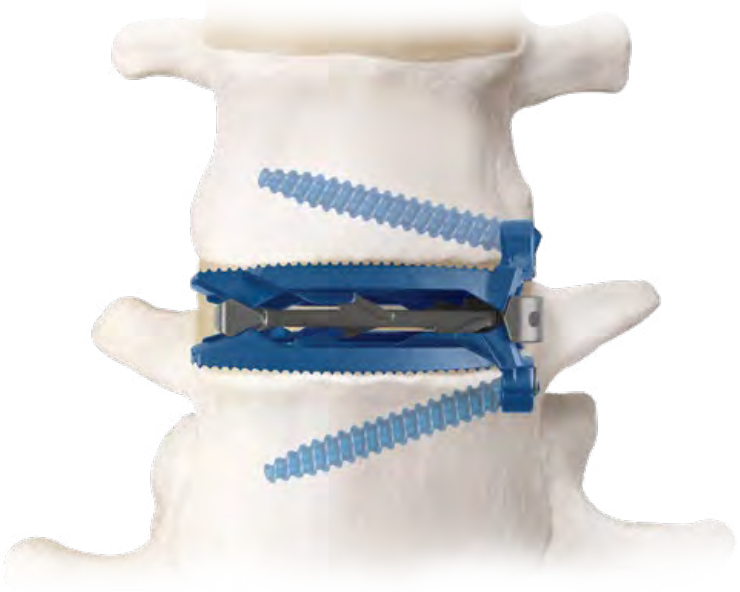


Screws not fully inserted

Inserting screws using Angled Driver Assembly

Final Screw Positioning

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

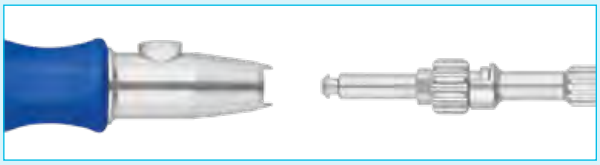


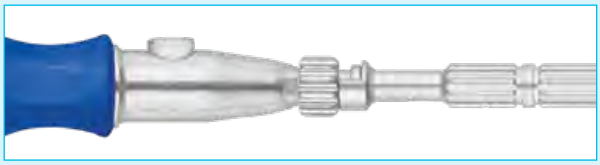
Final screw positioning

ANGLED DRIVER ASSEMBLY USING 3.5MM ANGLED HEX DRIVER 10°

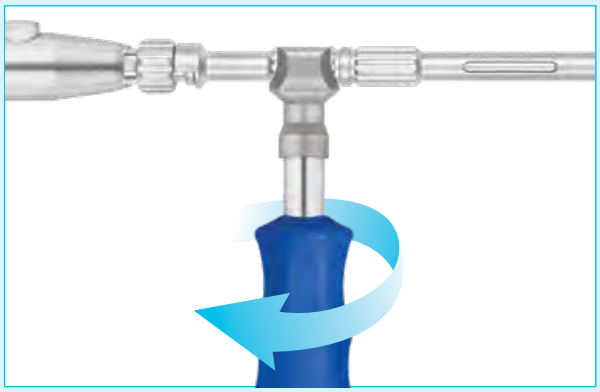
Select the **3.5mm Angled Hex Driver 10°**.

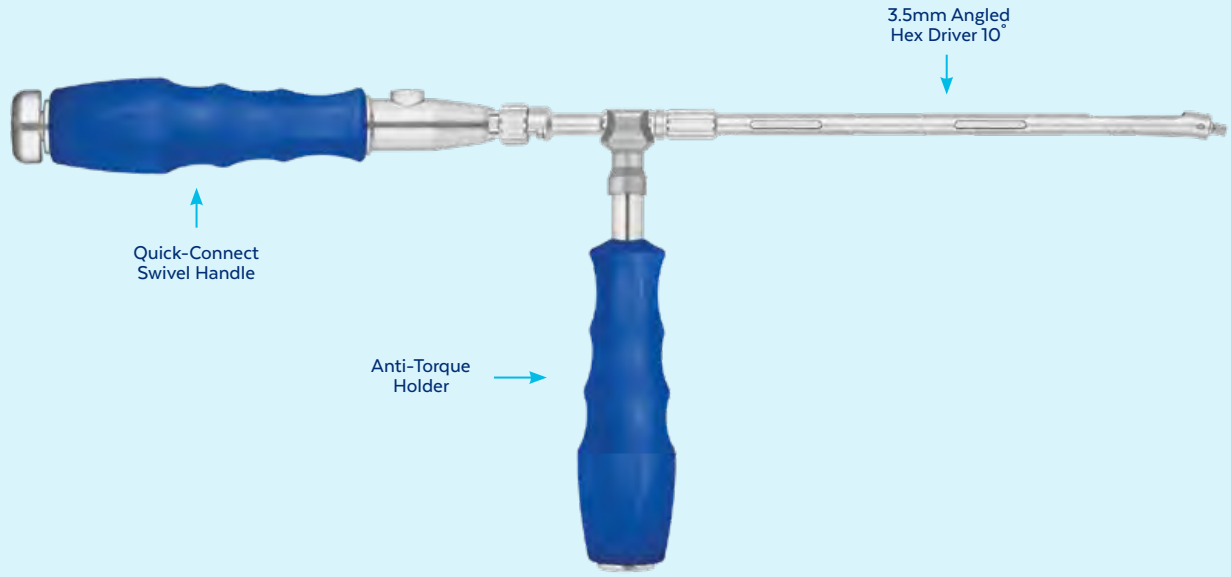
Connect the **Quick-Connect Swivel Handle** to the 3.5mm Angled Hex Driver.





Slide the **Anti-Torque Holder** from the smooth portion of the angled hex driver to the knurled portion.Rotate the Anti-Torque Holder clockwise to tighten the Quick-Connect Swivel Handle.



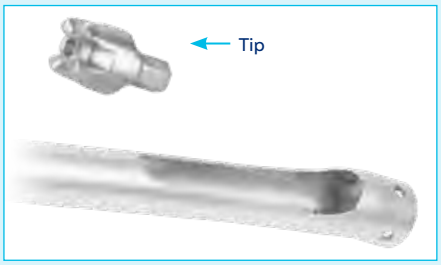


SCREW INSERTION (CONT'D)

ANGLED DRIVER ASSEMBLY USING COMPONENTS

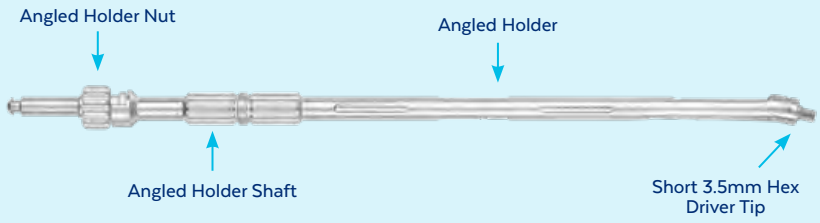
Select the appropriate tip.

Hold the **Angled Holder Sleeve 10°** downward with the cutout facing up, as shown below. Insert the tip in the distal end of the sleeve.

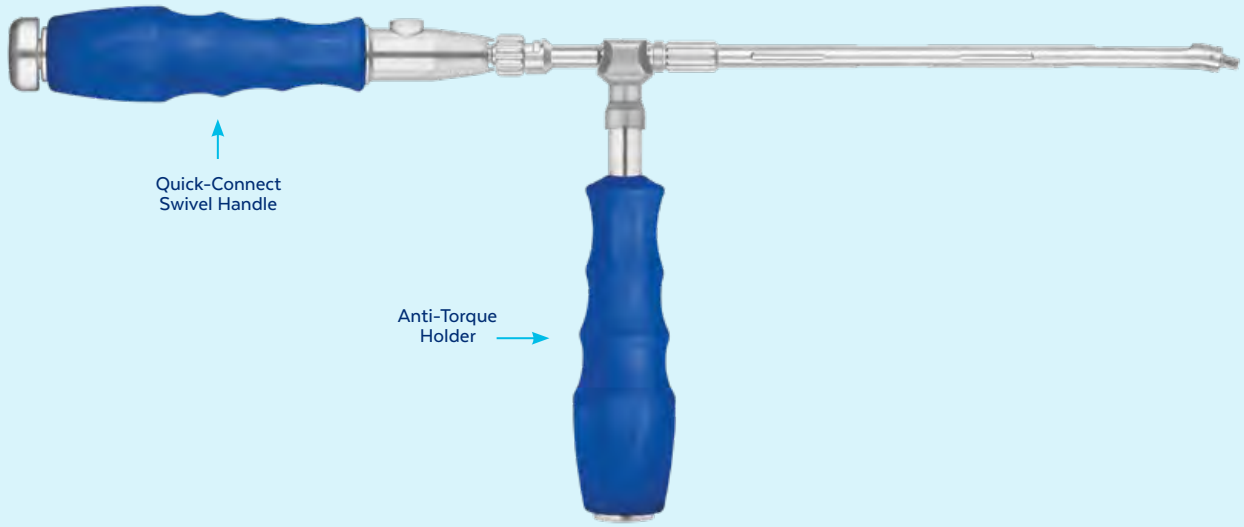


A 3.5mm Hex Driver Tip 10° is shown at left. A drill or tap tip may also be used.

Place the **Angled Holder Nut** into the notch at the proximal end of the Angled Holder Sleeve. Insert the **Angled Holder Shaft 10°** through the nut and sleeve so that the shaft gears align with the tip gears. Attach the Quick-Connect Swivel Handle to the shaft and rotate the nut counterclockwise until tight.
Use the **Spanner Wrench** to tighten the nut.



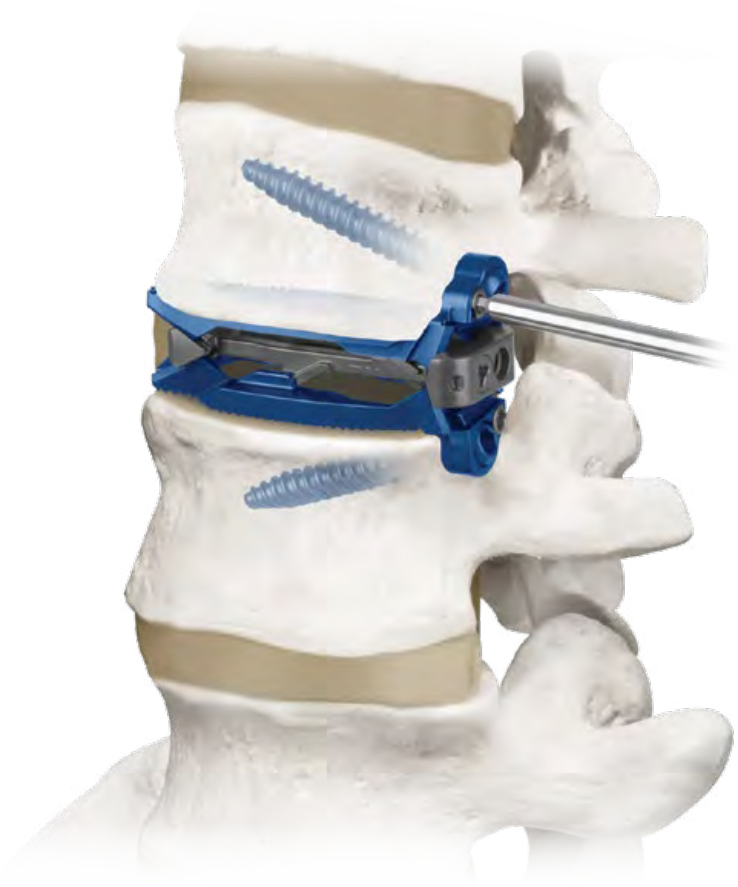
Connect the swivel handle. Slide the Anti-Torque Holder from the smooth portion of the Angled Holder to the knurled portion. Rotate the Anti-Torque Holder clockwise to tighten the swivel handle.



STEP 9 POSITIONING THE SET SCREW

Use the **2.5mm Hex Set Screw Driver** to engage the blocking set screw and rotate clockwise. An audible and tactile click occurs when the blocking set screw reaches its final position.

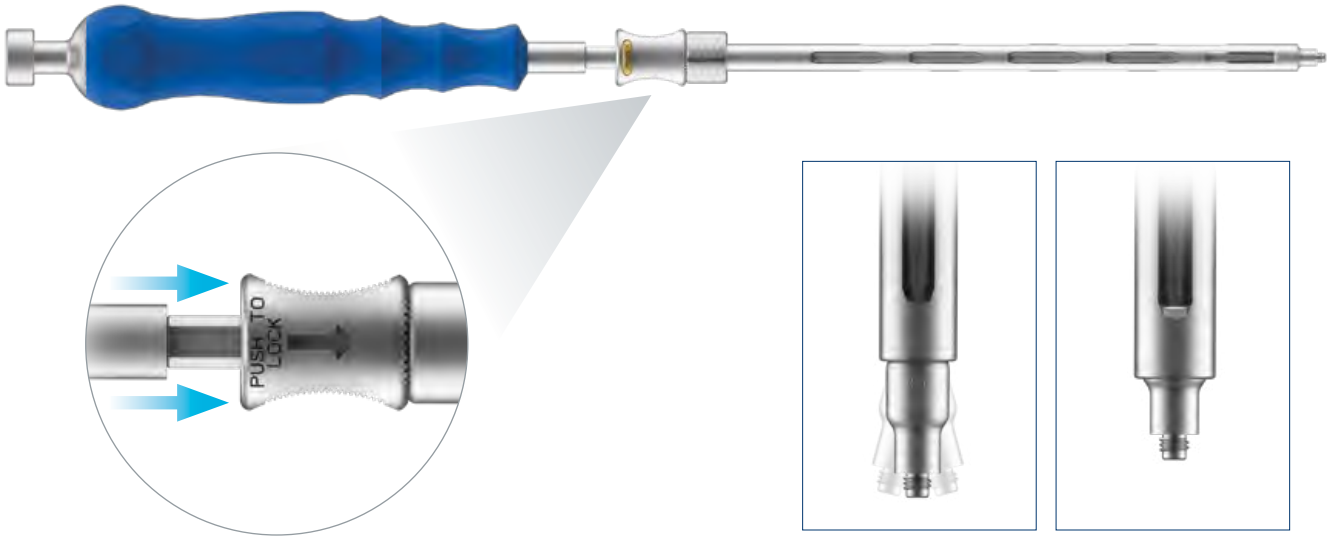
Supplemental fixation is required. See page 46 for details.



ANCHOR FIXATION

STEP 7 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

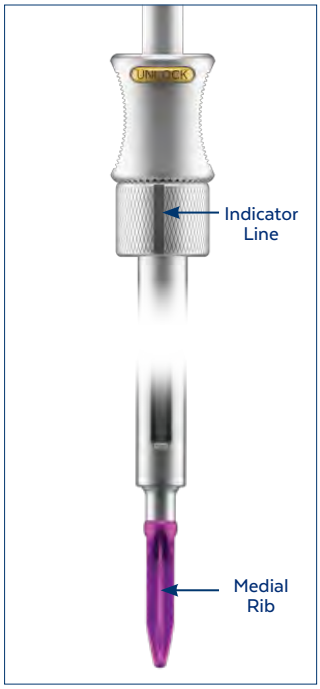
Unlocked

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.

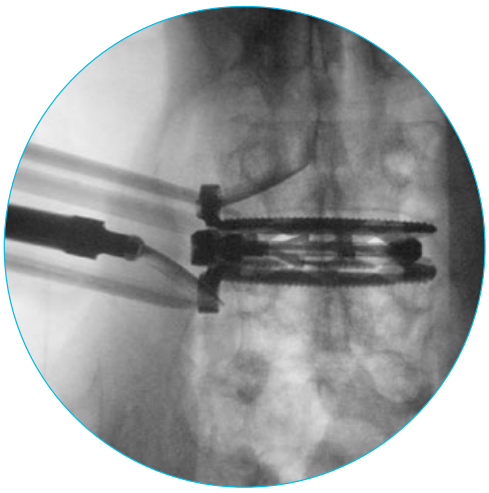
Threading anchor onto inserter



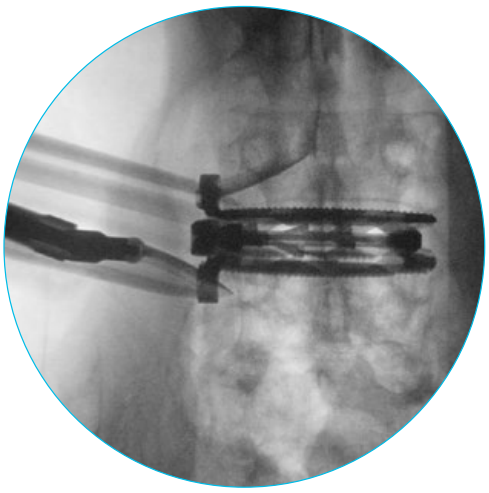
Directional indicator

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



Locked



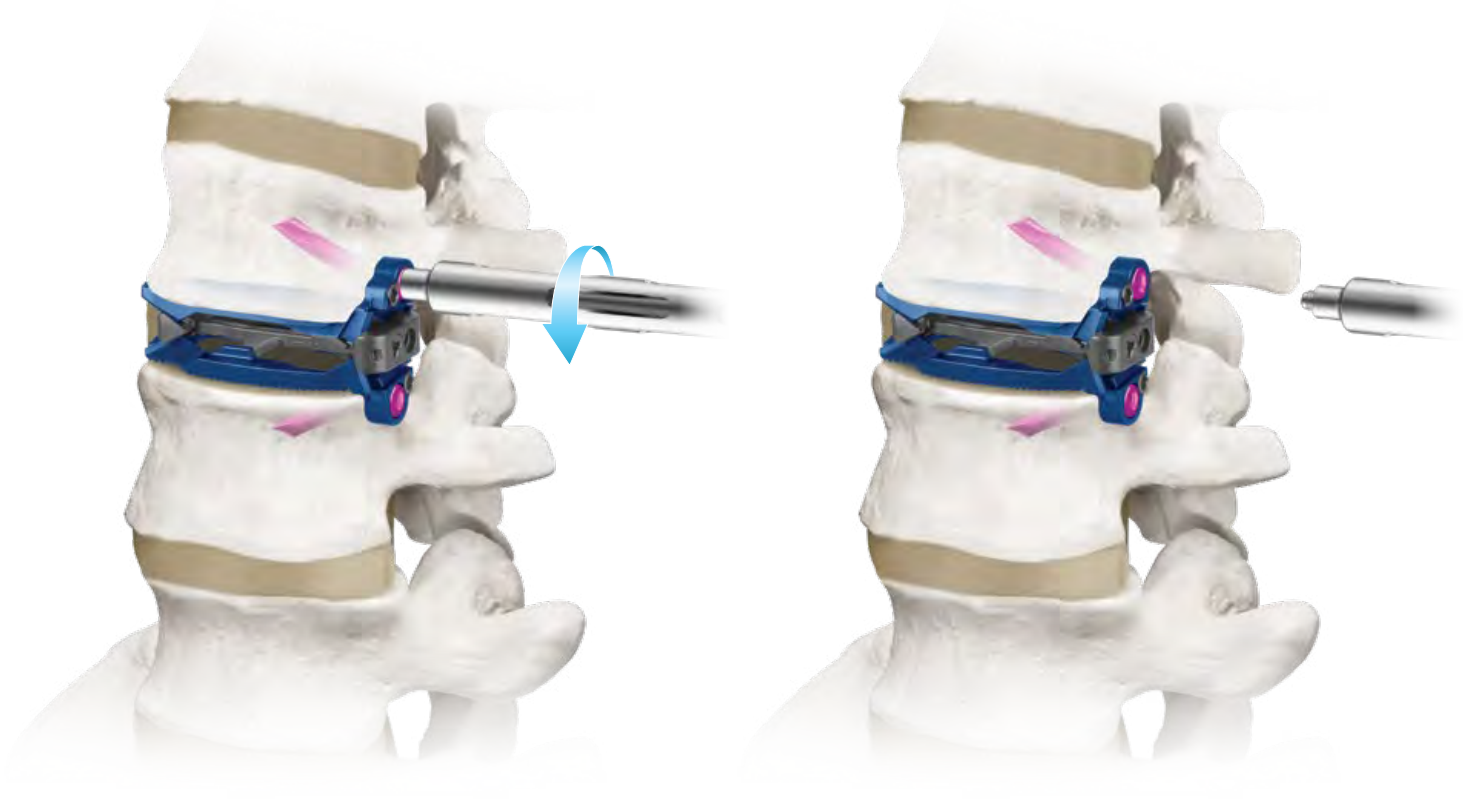
Unlocked

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 8 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 4 and 5 for the second anchor.



Disconnecting and removing inserter

STEP 9 POSITIONING THE SET SCREW

Use the **2.5mm Hex Set Screw Driver** to engage the blocking set screw and rotate 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.

HYBRID SCREW/ANCHOR FIXATION

If a hybrid screw/anchor construct is desired, follow steps 1-6 for disc prep and implant sizing.

For screw fixation, follow steps 7-9 on pages 30-37.

For anchor fixation, follow steps 7-9 on pages 38-41.

HYBRID FIXATION FINAL IMPLANT POSITION

Supplemental fixation is required. See page 46 for details.

Hybrid final implant position

STEP 10 GRAFT PACKING

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

The **Threaded Funnel Shaft** holds 2.4cc of autograft and can be pre-loaded. Bone graft material should be morselized and advanced through the shaft to confirm that the graft particulate size can be easily pushed 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 until tightly packed.

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

Refer to the table at right for approximate graft volume for the selected implant.

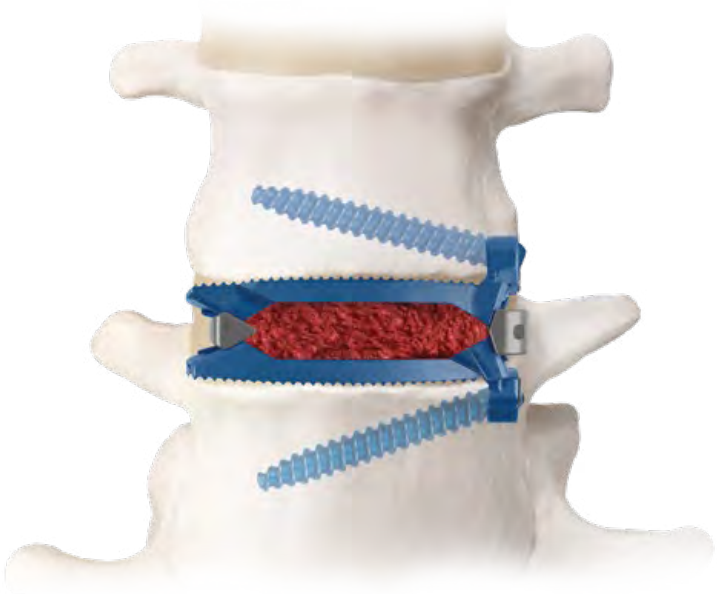
Using Graft Plunger with Threaded Funnel Shaft

Graft Volume by Implant Size

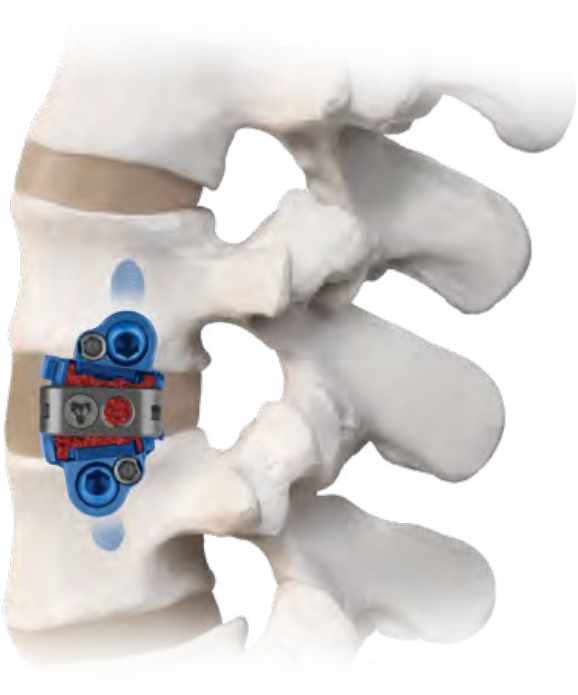
Part No.	Length (mm)	Height (mm)	Full Expansion Volume (cc)	No Expansion Volume (cc)
STANDARD				
1122.0035	35	7-14	3.2	1.3
1122.0040	40	7-14	4.0	1.6
1122.0045	45	7-14	4.7	1.9
1122.0050	50	7-14	5.4	2.3
1122.0055	55	7-14	6.1	2.6
1122.0060	60	7-14	6.9	2.9
1122.0065	65	7-14	7.6	3.2
1122.0135	35	8-15	3.3	1.4
1122.0140	40	8-15	4.1	1.8
1122.0145	45	8-15	4.9	2.1
1122.0150	50	8-15	5.7	2.5
1122.0155	55	8-15	6.4	2.8
1122.0160	60	8-15	7.2	3.2
1122.0165	65	8-15	7.9	3.5
1122.0435	35	10-17	3.8	1.9
1122.0440	40	10-17	4.7	2.4
1122.0445	45	10-17	5.6	2.8
1122.0450	50	10-17	6.5	3.4
1122.0455	55	10-17	7.4	3.8
1122.0460	60	10-17	8.2	4.3
1122.0465	65	10-17	9.2	4.8
1122.0535	35	10-17	3.6	1.7
1122.0540	40	10-17	4.4	2.1
1122.0545	45	10-17	5.3	2.5
1122.0550	50	10-17	6.1	3.0
1122.0555	55	10-17	6.9	3.4
1122.0560	60	10-17	7.8	3.8
1122.0565	65	10-17	8.6	4.2
ADJUSTABLE LORDOSIS				
1122.1035	35	8, 5°-20°	2.5	1.2
1122.1040	40	8, 5°-20°	3.5	1.5
1122.1045	45	8, 5°-20°	4.2	1.9
1122.1050	50	8, 5°-20°	5.0	2.3
1122.1055	55	8, 5°-20°	5.7	2.6
1122.1060	60	8, 5°-20°	6.4	3.0
1122.1065	65	8, 5°-20°	7.1	3.3
1122.2035	35	11, 15°-30°	2.8	1.5
1122.2040	40	11, 15°-30°	3.9	1.9
1122.2045	45	11, 15°-30°	4.7	2.3
1122.2050	50	11, 15°-30°	5.5	2.7
1122.2055	55	11, 15°-30°	6.3	3.2
1122.2060	60	11, 15°-30°	7.1	3.6
1122.2065	65	11, 15°-30°	7.9	4.0

SCREW FIXATION FINAL POSITION

Supplemental fixation is required. See page 46 for details.



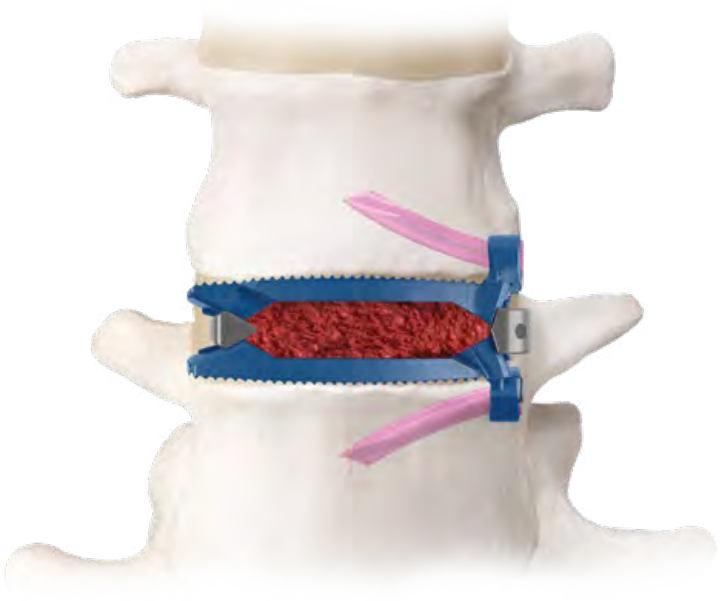
AP view



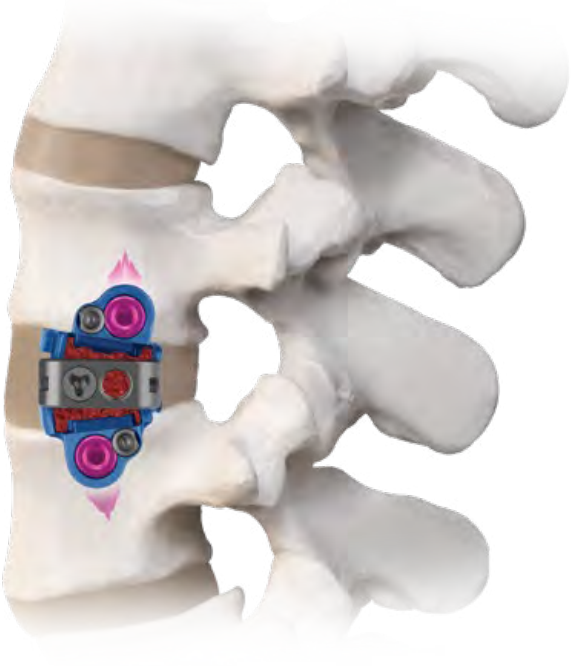
Lateral view

ANCHOR FIXATION FINAL POSITION

Supplemental fixation is required. See page 46 for details.



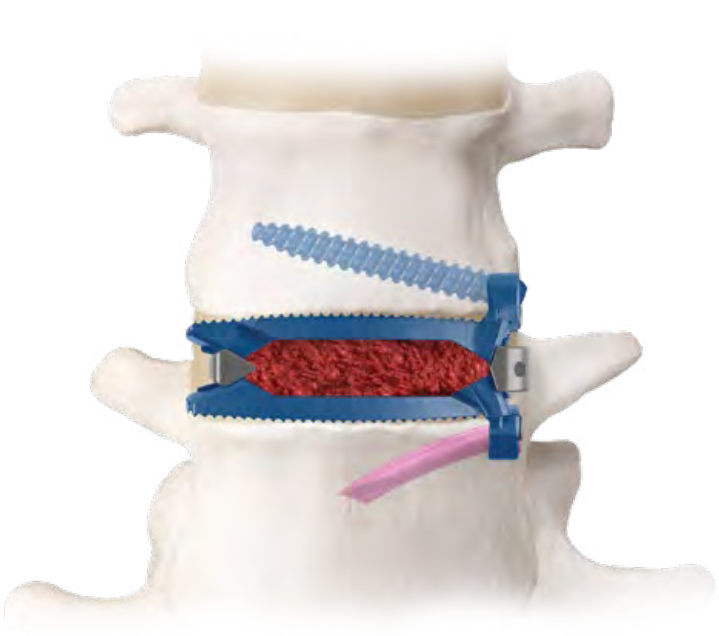
AP view



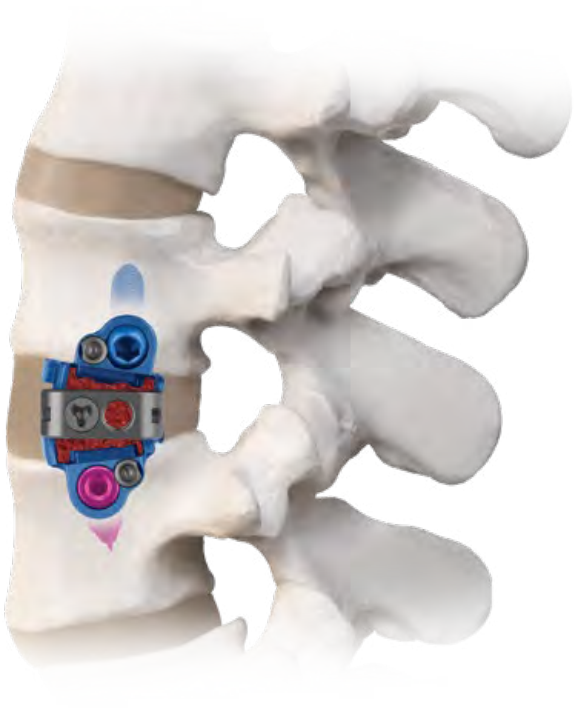
Lateral view

HYBRID FIXATION FINAL POSITION

Supplemental fixation is required. See page 46 for details.



AP view



Lateral view

SUPPLEMENTAL FIXATION

This device is intended to be used with supplemental fixation and may be used with or without two bone screws and/or anchors. Hyperlordotic (≥20°) devices must be used with two screws or anchors in addition to the supplemental fixation. Refer to the surgical technique manual for the desired supplemental fixation system 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 onto the implant and reduce implant height by inserting the torque-limiting driver and rotating counterclockwise. Contract the implant until two finger tight. If necessary, the Slide Hammer may be attached to the inserter and used to gently remove the implant.

The **Removal Tool** is also available if the Inserter Assembly cannot be reattached to the implant. Thread the Removal Tool into the proximal end of the implant. Use the torque-limiting driver to reduce implant height by inserting into the drive screw and rotating counterclockwise. Use the Slide Hammer to gently remove the implant if necessary.

Forceps or other manual surgical instruments may also be used 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.

Attaching the Slap Hammer

Removing the inserter

ELSA®
IMPLANT SET 9122.9002

Part No.	Description	Qty
1122.0040	ELSA® Spacer 20x40mm, 7-14mm	2
1122.0045	ELSA® Spacer 20x45mm, 7-14mm	2
1122.0050	ELSA® Spacer 20x50mm, 7-14mm	2
1122.0055	ELSA® Spacer 20x55mm, 7-14mm	2
1122.0060	ELSA® Spacer 20x60mm, 7-14mm	1
1122.0065	ELSA® Spacer 20x65mm, 7-14mm	-
1122.0140	ELSA® Spacer 20x40mm, 8-15mm, 6°	2
1122.0145	ELSA® Spacer 20x45mm, 8-15mm, 6°	2
1122.0150	ELSA® Spacer 20x50mm, 8-15mm, 6°	2
1122.0155	ELSA® Spacer 20x55mm, 8-15mm, 6°	2
1122.0160	ELSA® Spacer 20x60mm, 8-15mm, 6°	1
1122.0165	ELSA® Spacer 20x65mm, 8-15mm, 6°	-
1122.0440	ELSA® Spacer 20x40mm, 10-17mm	1
1122.0445	ELSA® Spacer 20x45mm, 10-17mm	1
1122.0450	ELSA® Spacer 20x50mm, 10-17mm	1
1122.0455	ELSA® Spacer 20x55mm, 10-17mm	1
1122.0460	ELSA® Spacer 20x60mm, 10-17mm	1
1122.0465	ELSA® Spacer 20x65mm, 10-17mm	-
1122.1040	ELSA® Spacer 20x40mm, 8-17mm, 5-20°	1
1122.1045	ELSA® Spacer 20x45mm, 8-17mm, 5-20°	1
1122.1050	ELSA® Spacer 20x50mm, 8-17mm, 5-20°	1
1122.1055	ELSA® Spacer 20x55mm, 8-17mm, 5-20°	1
1122.1060	ELSA® Spacer 20x60mm, 8-17mm, 5-20°	1
1122.1065	ELSA® Spacer 20x65mm, 8-17mm, 5-20°	-
1122.2040	ELSA® Spacer 20x40mm, 11-20mm, 15-30°	1
1122.2045	ELSA® Spacer 20x45mm, 11-20mm, 15-30°	1
1122.2050	ELSA® Spacer 20x50mm, 11-20mm, 15-30°	1
1122.2055	ELSA® Spacer 20x55mm, 11-20mm, 15-30°	1
1122.2060	ELSA® Spacer 20x60mm, 11-20mm, 15-30°	1
1122.2065	ELSA® Spacer 20x65mm, 11-20mm, 15-30°	-
9122.0012	ELSA® Parallel and 6° Implant Module	1
9122.0022	ELSA® 20° and 30° Implant Module	1
9122.0002	ELSA® Implant Graphic Case	

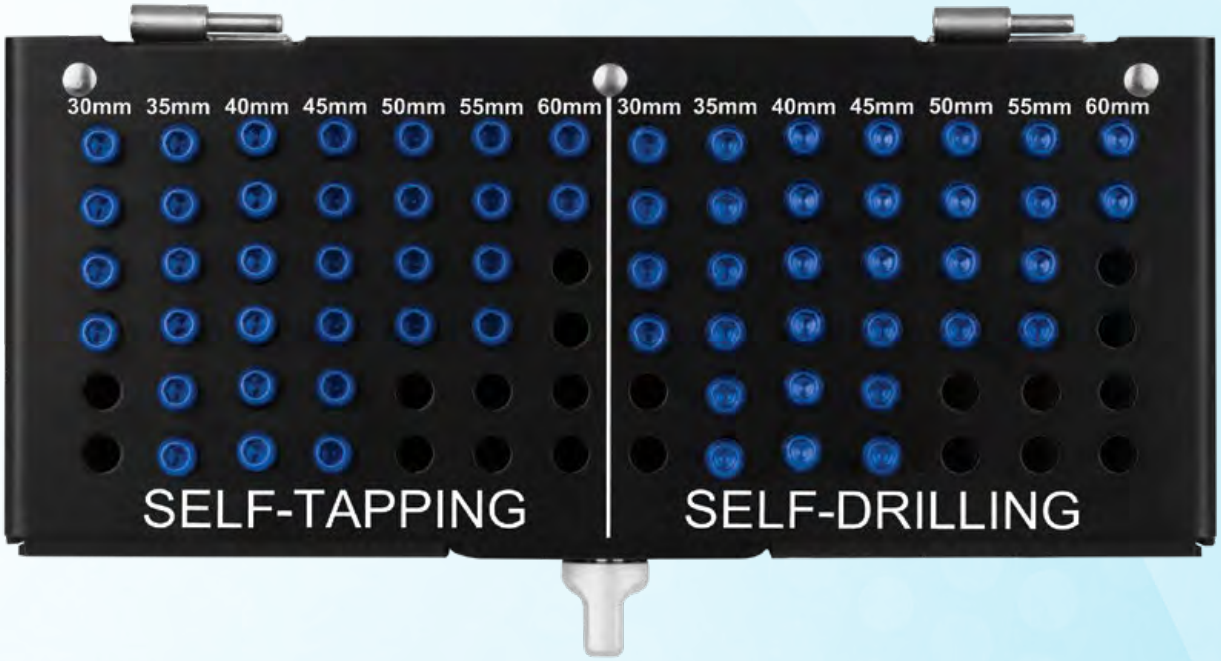
*Items in gray are additionally available.

ELSA®
IMPLANT SET 9122.9002

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	

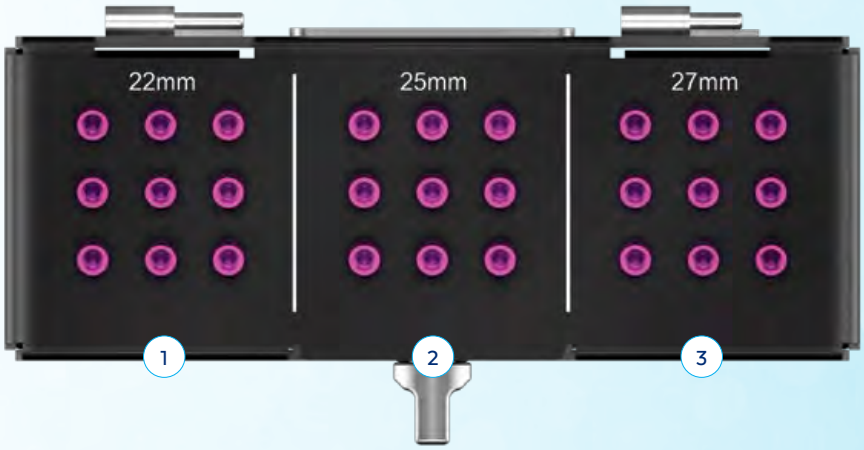
ELSA®
SCREW SET 9122.9003

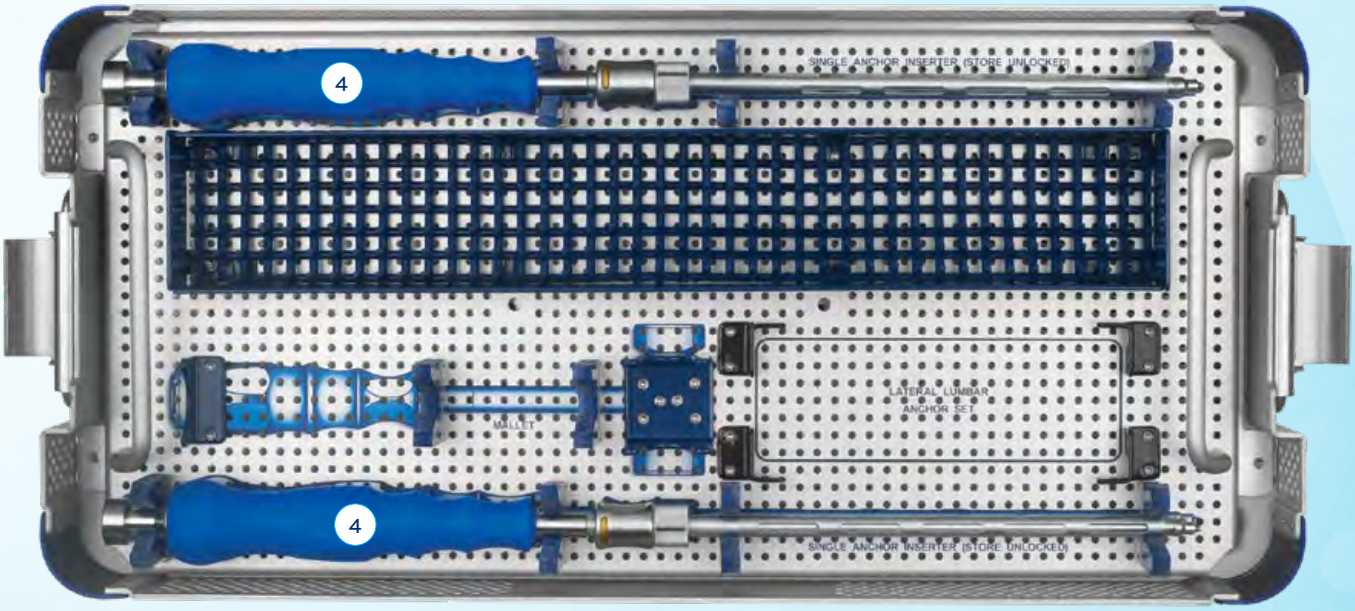


LATERAL MIS
IMPLANTS AND INSTRUMENTS SET 9219.9001

	Part No.	Description	Qty
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
IMPLANTS AND INSTRUMENTS SET 9219.9001





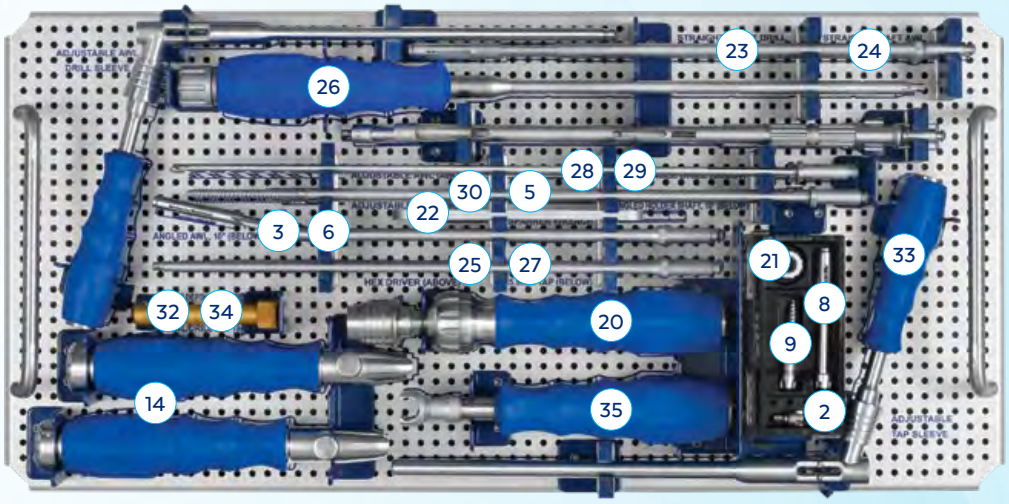
ELSA®
INSTRUMENT SET 9122.9001

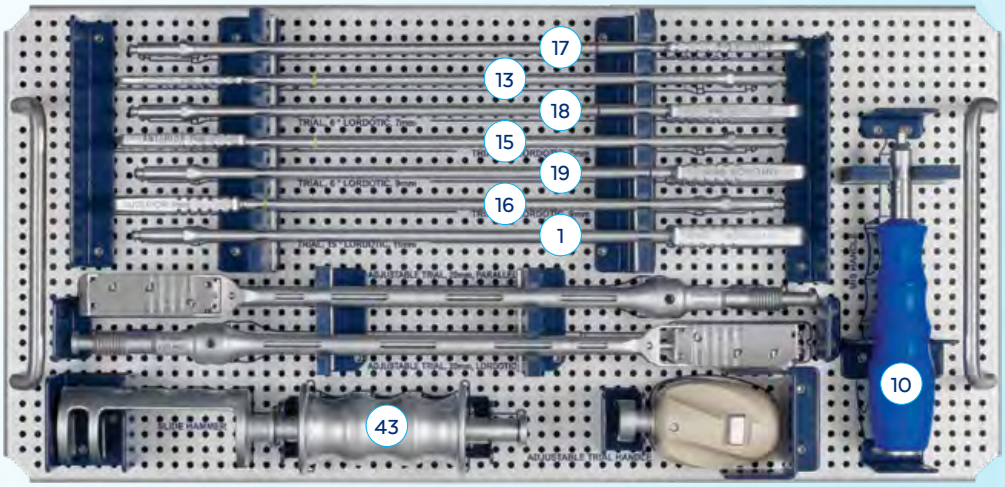
	Part No.	Description	Qty
1	6122.0015	Trial 15°, 11mm	1
2	6122.0024	3.5mm Hex Driver Tip, 10°	2
3	6122.0504	3.5mm Angled Hex Driver, 10°	1
4	6122.0505	Angled Holder Sleeve, 10°	1
5	6122.0506	Angled Holder Shaft, 10°	1
6	6122.0511	Angled Awl, 10°	1
7	6122.0512	Sleeveless Awl, 10°	1
8	6122.0521	5.5 Drill Tip, 10°	1
9	6122.0721	5.5mm Tap Tip, 10°	1
10	673.003	MIS Handle	2
11	676.600	INDEPENDENCE® Set Screw Driver, 2.5mm Hex	1
12	681.013	Bone Funnel	1
13	687.004	Trial, 0° Lordotic, 5mm	1
14	687.005	Quick-Connect Swivel Handle	2
15	687.007	Trial, 0° Lordotic, 7mm	1
16	687.009	Trial, 0° Lordotic, 9mm	1
17	687.055	Trial, 6° Lordotic, 5mm	1
18	687.057	Trial, 6° Lordotic, 7mm	1
19	687.059	Trial, 6° Lordotic, 9mm	1
20	687.105	Ratchet Handle	1
21	687.507	InterContinental® Angled Holder - Nut	1
22	687.509	Spanner Wrench	1
23	687.520	InterContinental® Straight Shaft 5.5mm Drill	1
24	687.524	InterContinental® Straight Shaft Awl	1
25	687.526	InterContinental® Straight Shaft 5.5mm Tap	1
26	687.527	InterContinental® Straight Shaft 3.5mm Hex Driver	1
27	687.603	3.5 Expandable Hex Driver	1
28	687.624	Adjustable Awl	1
29	687.625	Adjustable Drill	1
30	687.626	Adjustable Tap	1

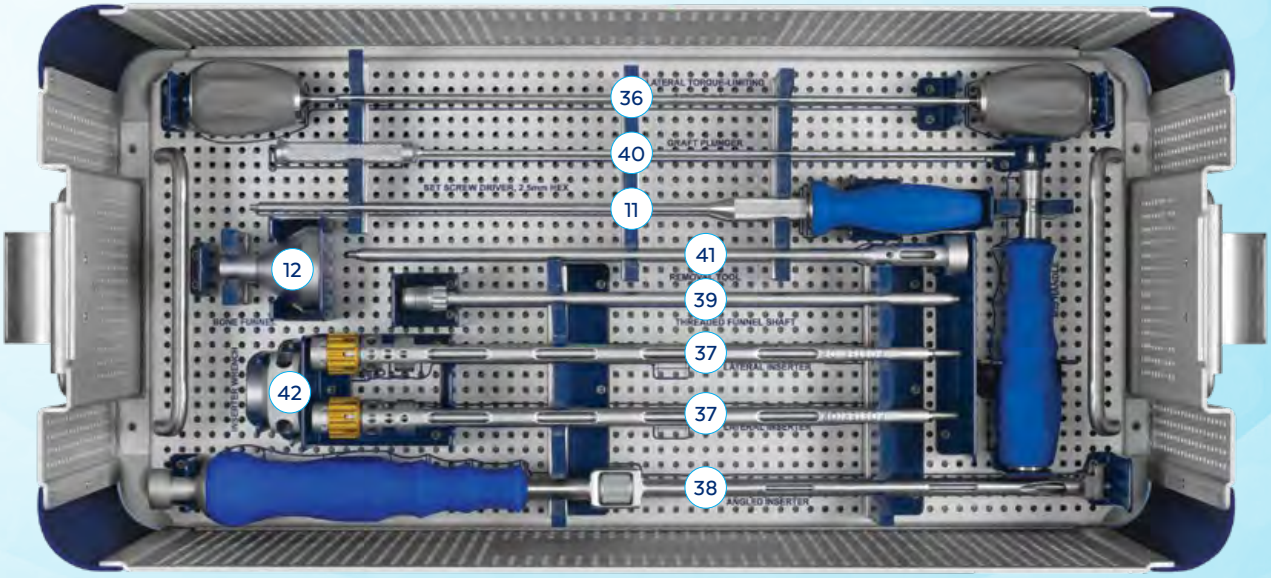
	Part No.	Description	Qty
31	687.675	Adjustable Awl/Drill Sleeve	1
32	687.676	Awl/Drill Depth Adjuster	1
33	687.680	Adjustable Tap Sleeve	1
34	687.681	Tap Depth Adjuster	1
35	687.906	Anti-Torque Holder	1
36	693.600	Lateral Torque-Limiting Driver, 3.0Nm	2
37	693.601	Lateral Inserter	2
38	693.602	Angled Angled Inserter	1
39	693.610	Threaded Funnel Shaft	2
40	693.611	Graft Plunger	2
41	693.613	Removal Tool	1
42	693.614	Inserter Wrench	1
43	694.018	Slide Hammer	1
	6122.0200	Adjustable Trial, 20mm, Parallel	-
	6122.0210	Adjustable Trial, 20mm, Lordotic	-
	694.418	Adjustable Trial Handle	-
	9122.0001	ELSA® Instrument Graphic Case	

*Items in gray are additionally available.

ELSA®
INSTRUMENT SET 9122.9001







MARS™ 3VL RETRACTOR
INSTRUMENTS I SET 9133.9001

Instruments

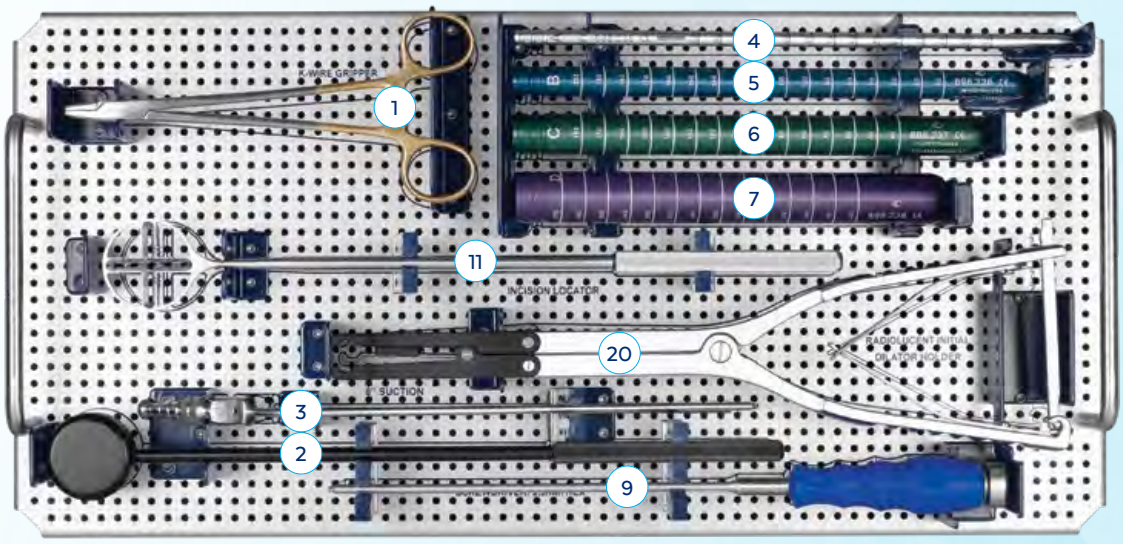
	Part No.	Description	Qty
1	623.003	K-Wire Gripper	1
2	675.403	Flouro Modulator	1
3	675.513	8” Suction	1
4	698.235	Stainless Steel Cannula A	1
5	698.236	Aluminum Cannula B	1
6	698.237	Aluminum Cannula C	1
7	698.238	Aluminum Cannula D	1
8	698.240	Shim Tool, CC	1
9	698.260	Screwdriver, 2.5mm Hex	1
10	698.355	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	

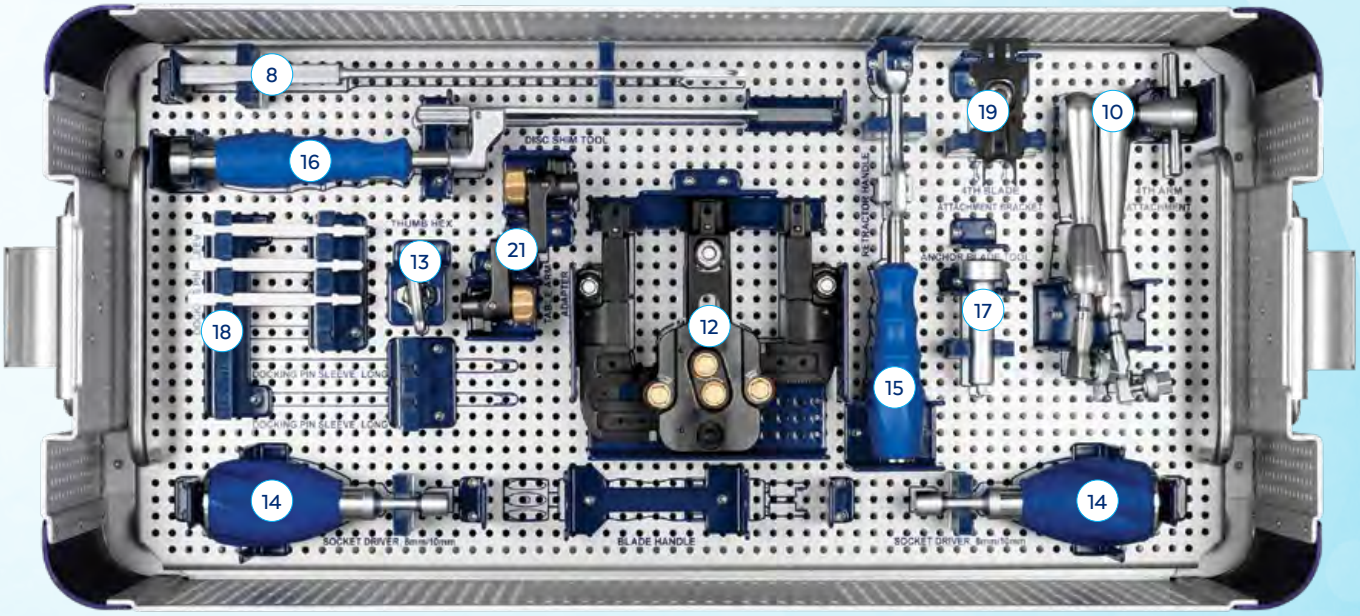
Disposables

Part No.	Description	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

*Items in gray are additionally available.

MARS™ 3VL RETRACTOR
INSTRUMENTS I SET 9133.9001



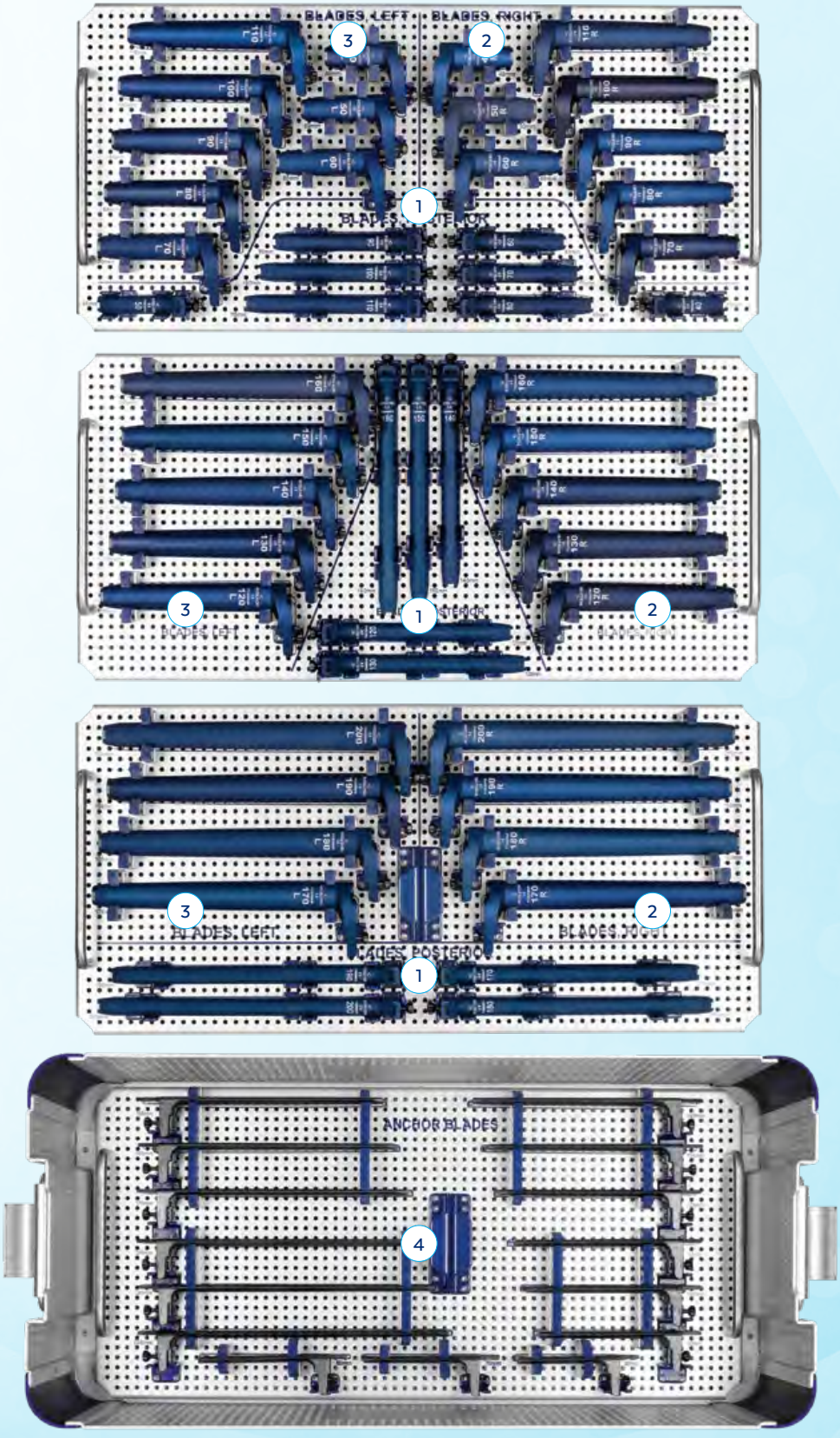


MARS™ 3VL RETRACTOR
INSTRUMENTS II, BLADES SET 9133.9002

	Part No.	Description	Qty
1	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
2	6133.2040	Blade, Right, 40mm	1
	6133.2050	Blade, Right, 50mm	1
	6133.2060	Blade, Right, 60mm	1
	6133.2070	Blade, Right, 70mm	1
	6133.2080	Blade, Right, 80mm	1
	6133.2090	Blade, Right, 90mm	1
	6133.2100	Blade, Right, 100mm	1
	6133.2110	Blade, Right, 110mm	1
	6133.2120	Blade, Right, 120mm	1
	6133.2130	Blade, Right, 130mm	1
	6133.2140	Blade, Right, 140mm	1
	6133.2150	Blade, Right, 150mm	1
	6133.2160	Blade, Right, 160mm	1
	6133.2170	Blade, Right, 170mm	1
	6133.2180	Blade, Right, 180mm	1
	6133.2190	Blade, Right, 190mm	1
	6133.2200	Blade, Right, 200mm	1

	Part No.	Description	Qty
3	6133.3040	Blade, Left, 40mm	1
	6133.3050	Blade, Left, 50mm	1
	6133.3060	Blade, Left, 60mm	1
	6133.3070	Blade, Left, 70mm	1
	6133.3080	Blade, Left, 80mm	1
	6133.3090	Blade, Left, 90mm	1
	6133.3100	Blade, Left, 100mm	1
	6133.3110	Blade, Left, 110mm	1
	6133.3120	Blade, Left, 120mm	1
	6133.3130	Blade, Left, 130mm	1
	6133.3140	Blade, Left, 140mm	1
	6133.3150	Blade, Left, 150mm	1
	6133.3160	Blade, Left, 160mm	1
	6133.3170	Blade, Left, 170mm	1
	6133.3180	Blade, Left, 180mm	1
	6133.3190	Blade, Left, 190mm	1
	6133.3200	Blade, Left, 200mm	1
4	6133.4060	Anchor Blade, 60mm	1
	6133.4070	Anchor Blade, 70mm	1
	6133.4080	Anchor Blade, 80mm	1
	6133.4090	Anchor Blade, 90mm	1
	6133.4100	Anchor Blade, 100mm	1
	6133.4110	Anchor Blade, 110mm	1
	6133.4120	Anchor Blade, 120mm	1
	6133.4130	Anchor Blade, 130mm	1
	6133.4140	Anchor Blade, 140mm	1
	6133.4150	Anchor Blade, 150mm	1
	6133.4160	Anchor Blade, 160mm	1
	6133.4170	Anchor Blade, 170mm	1
	6133.4180	Anchor Blade, 180mm	1
	6133.4190	Anchor Blade, 190mm	1
	6133.4200	Anchor Blade, 200mm	1
	9133.0002	MARS™ 3VL Retractor Instruments II Graphic Case	

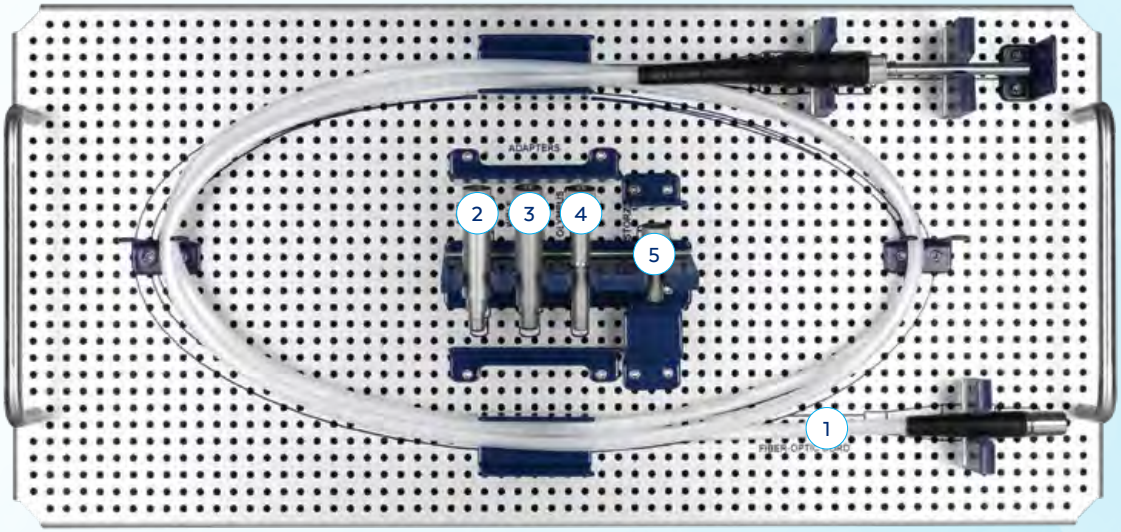
MARS™ 3VL RETRACTOR
INSTRUMENTS II, BLADES SET 9133.9002

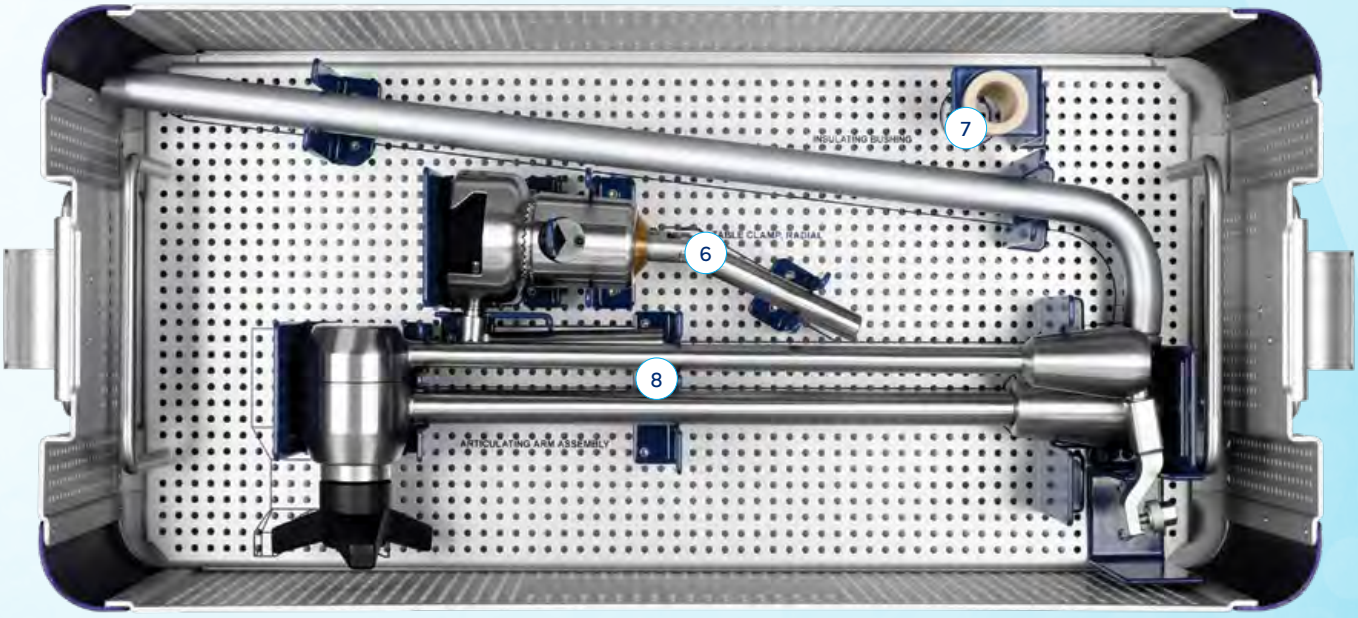


MARS™3VL
INSTRUMENTS III, MOUNTS SET 9133.9003

	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
INSTRUMENTS III, MOUNTS SET 9133.9003



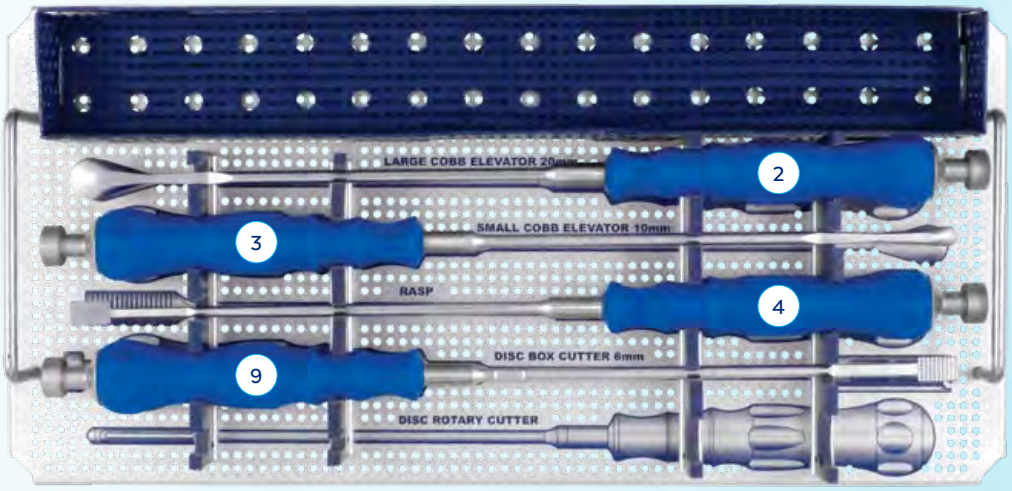


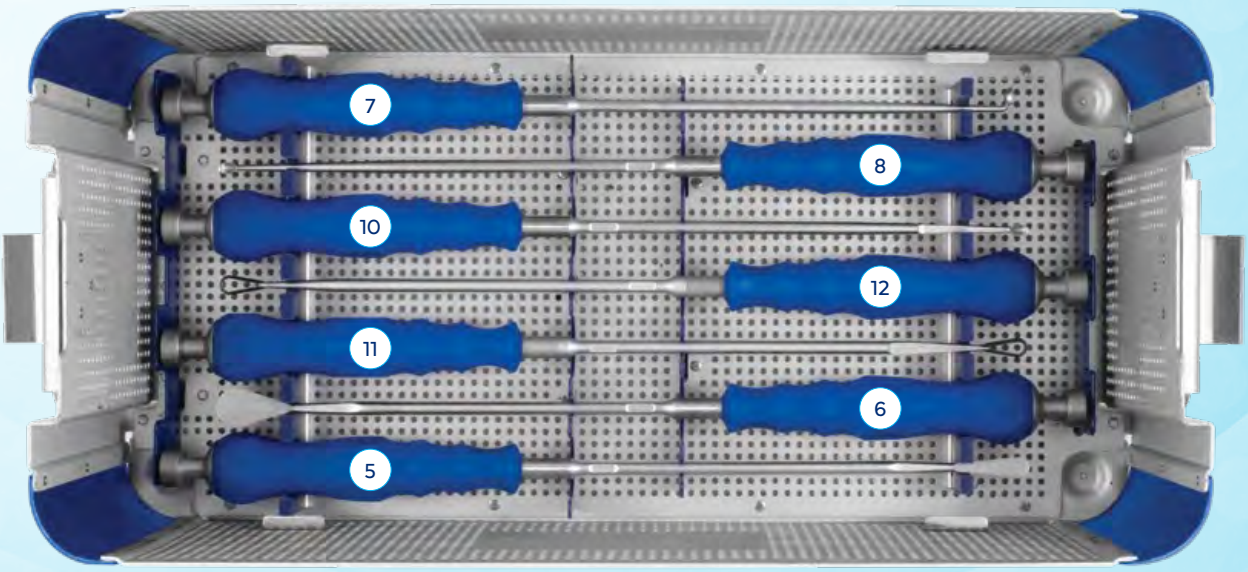
LATERAL DISC PREP
INSTRUMENT SET 975.914

	Part No.	Description	Qty
1	675.005	T-Handle with Impaction Cap	2
2	675.503	Large Cobb Elevator	1
3	675.504	Small Cobb Elevator	1
4	675.510	Thin Rasp, 12x20mm	1
5	675.515	Cobb, 10mm, 7° Up-Angled	1
6	675.516	Cobb, 20mm, 7° Up-Angled	1
7	675.518	Ring Curette, 10mm, Straight	1
8	675.519	Ring Curette, 10mm, 7° Up-Angle Tip	1
9	675.520	Double Rasp	1
10	675.525	Cup Curette, 6.5x9.5mm, Straight	1
11	675.526	Cup Curette, 6.5x9.5mm, 15° Up-Angle	1
12	675.527	Cup Curette, 6.5x9.5mm, 90° Down-Angle	1
13	675.605	Scraper, 5mm	1
	675.607	Scraper, 7mm	1
	675.609	Scraper, 9mm	1
	675.611	Scraper, 11mm	1
	675.613	Scraper, 13mm	1
	675.615	Scraper, 15mm	1
	675.617	Scraper, 17mm	1
	675.855	Paddle Distractor, 5mm	1
	675.857	Paddle Distractor, 7mm	1
	675.859	Paddle Distractor, 9mm	1
	675.861	Paddle Distractor, 11mm	1
	675.863	Paddle Distractor, 13mm	1
	675.170S	Bipolar Forceps Bayonetted, Straight	-
	675.171S	Bipolar Forceps Bayonetted, Angled	-
	975.008	TransContinental® Graphic Case - Disc Prep	

*Items in gray are additionally available.

LATERAL DISC PREP
INSTRUMENT SET 975.914

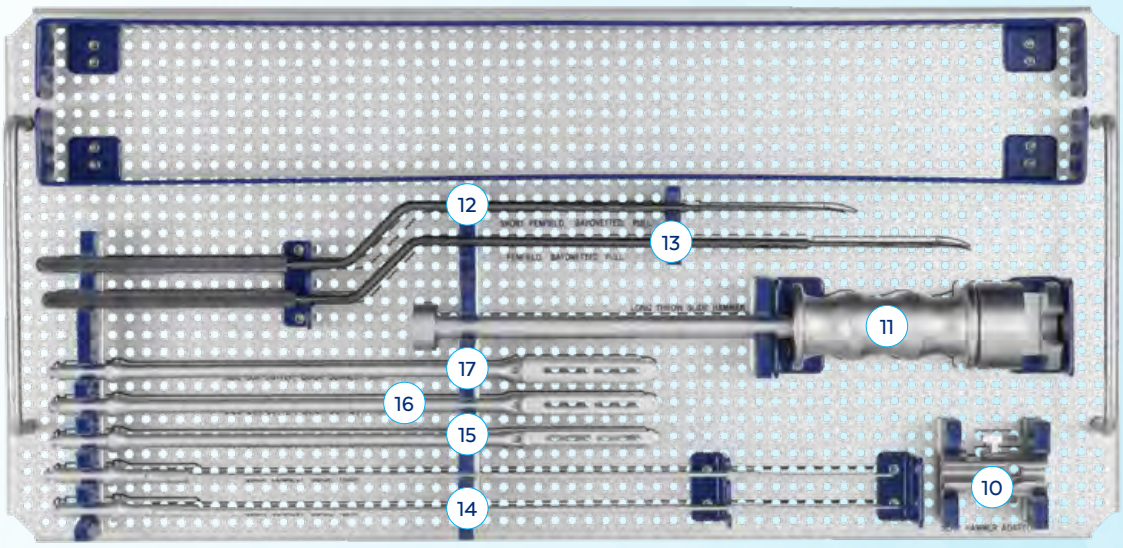


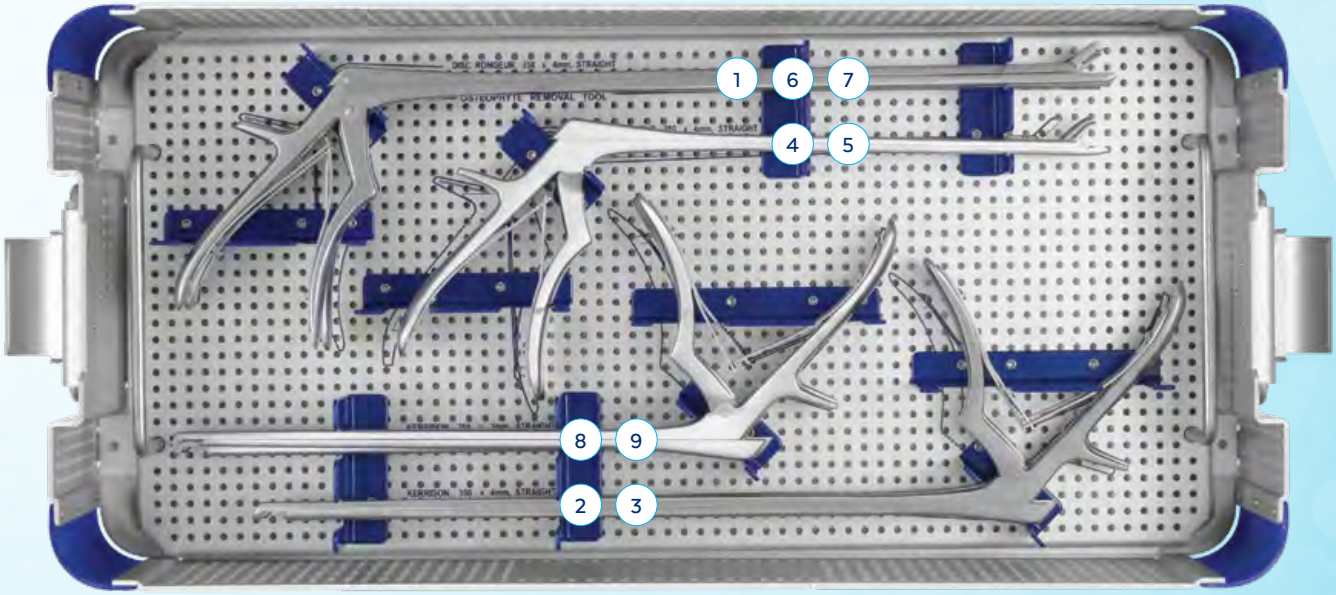


LATERAL DISC PREP II
INSTRUMENT SET 975.917

	Part No.	Description	Qty
1	6105.2016	Osteophyte Removal Tool	1
2	625.202	Kerrison, 4mm	1
3	625.203	Kerrison, 6mm	1
4	625.305	Disc Rongeur, 4mm	1
5	625.307	Disc Rongeur, 6mm	1
6	626.240	Disc Rongeur, 250x4mm, Straight	1
7	626.241	Disc Rongeur, 250x6mm, Straight	1
8	626.250	Kerrison, 250x3mm, Straight	1
9	626.252	Kerrison, 250x5mm, Straight	1
10	675.002	Slap Hammer Adaptor	1
11	675.004	Long Throw Slide Hammer	1
12	675.173	Penfield, Bayonetted, Pull	1
13	675.174	Penfield #4, Pull, 190mm	1
14	675.201	Quick-Connect Guide, 12mm	2
15	675.533	Disc Box Cutter, 5mm	1
16	675.534	Disc Box Cutter, 7mm	1
17	675.535	Disc Box Cutter, 9mm	1
	975.017	LLIF Disc Prep II Graphic Case	

LATERAL DISC PREP II
INSTRUMENT SET 975.917





IMPORTANT INFORMATION ON THE ELSA® 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 FOR USE

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.

PRECAUTION

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.
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

IMPORTANT INFORMATION ON THE ELSA® SPACERS

- 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.
- 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.

SYMBOL TRANSLATION			
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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www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
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