RISE®-L

Expandable Lateral 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

RISE®-L

RISE®-L

Expandable Lateral Interbody Spacer

RISE®-L is an expandable lateral interbody spacer designed for minimal impaction and optimal lordosis while allowing indirect decompression.

Adjustable lordosis up to 15° coupled with *in situ* bone graft insertion makes RISE®-L the ideal interbody spacer.

RISE®-L

RISE®-L Adjustable Lordosis

Optimal Fusion

RISE®-L is designed to provide segmental lordosis while the introduction of additional bone graft *in situ* provides an optimal fusion environment.

Minimal Insertion Height

RISE®-L is inserted at a reduced height to minimize impaction and preserve endplate integrity.

Maximum Lordosis and Indirect Decompression

RISE®-L provides up to 15° of adjustable lordosis without compromising indirect decompression.

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

INSTRUMENT OVERVIEW

DISC PREPARATION INSTRUMENTS (CONT'D)

Cobb, 10mm, 7° Up-Angle 675.515

Cobb, 20mm, 7° Up-Angle 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

INSTRUMENT OVERVIEW

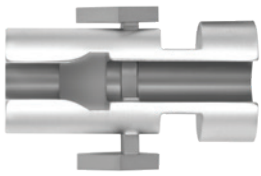
DISC PREPARATION INSTRUMENTS (CONT'D)

Kerrison, 4mm 625.202
Kerrison, 6mm 625.203

Disc Rongeur, 4mm 625.305
Disc Rongeur, 6mm 625.307

ADDITIONAL DISC PREPARATION INSTRUMENTS

T-Handle with Impaction Cap 675.005



Slap Hammer Adaptor 675.002

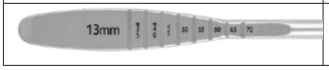
Quick-Connect Guide 675.201

INSTRUMENT OVERVIEW

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

INSTRUMENT OVERVIEW

TRIALS

Trial, Parallel

Trial, Lordotic

18mm Static Trials		
Parallel	Height	Part No.
	5mm	675.006
10° Lordotic	Height	Part No.
	5mm	675.065
	7mm	675.067

22mm Static Trials		
Parallel	Height	Part No.
	5mm	675.043
10° Lordotic	Height	Part No.
	5mm	675.365
	7mm	675.367

Adjustable Trial, Parallel

18mm Adjustable Trials		
Sagittal Profile	Height	Part No.
Parallel	7–15mm	694.110
6° Lordotic	8–16mm	694.112

22mm Adjustable Trials		
Sagittal Profile	Height	Part No.
Parallel	7–15mm	694.201
6° Lordotic	8–16mm	694.202

MIS Handle 673.003

Adjustable Trial Handle 694.418

INSTRUMENT OVERVIEW

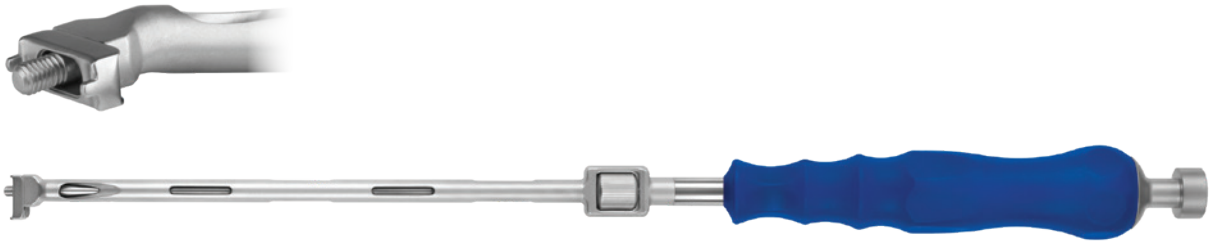
IMPLANT INSERTION INSTRUMENTS

Torque-Limiting Driver, 3.0N 693.600

Lateral Inserter 693.601

MIS Handle 673.003

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



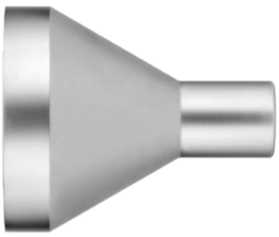
Lateral Angled Inserter 693.602

INSTRUMENT OVERVIEW

GRAFT INTRODUCTION

Threaded Funnel Shaft 693.610

Graft Plunger 693.611



Bone Funnel 681.013

Graft Sleeve, 7mm 693.603

Graft Sleeve, 10mm 693.604

ADDITIONAL INSTRUMENTS

Removal Tool 693.613

Inserter Wrench 693.614

Slide Hammer 694.018

SURGICAL TECHNIQUE

RISE®-L

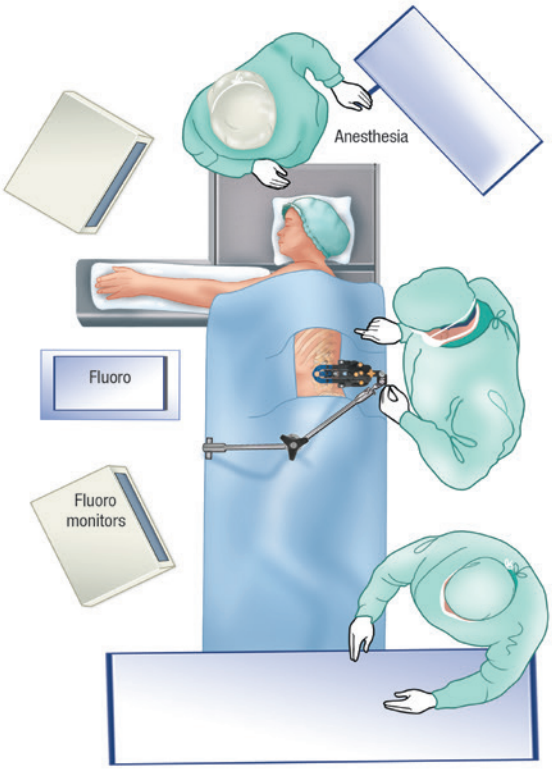
STEP 1 PATIENT PREPARATION

Patient Positioning

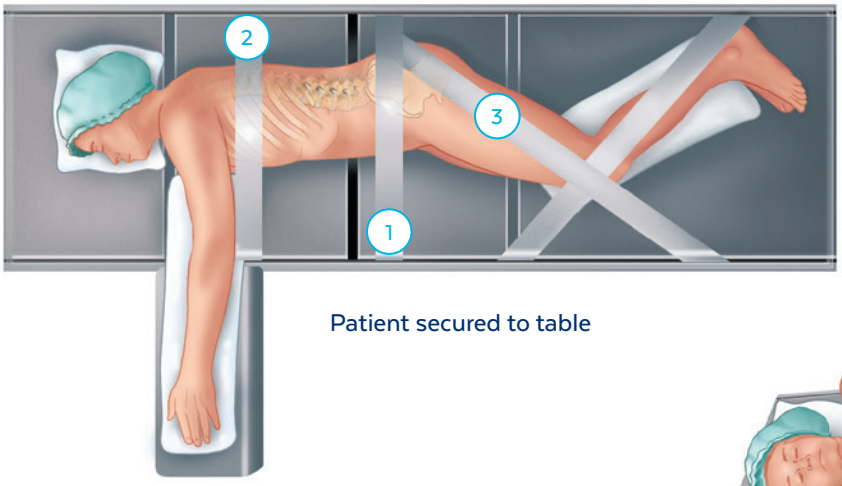
The patient is placed on a flexible surgical table in a straight 90° right lateral decubitus position so that the iliac crest is just over the table break, as shown below.

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; 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.



Patient positioning



Patient secured to table

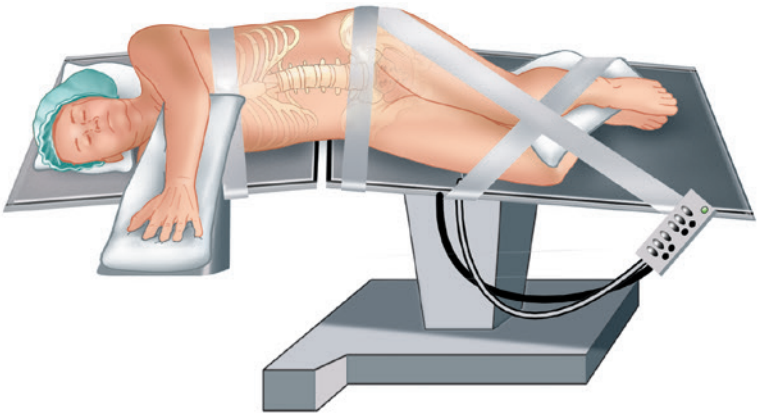
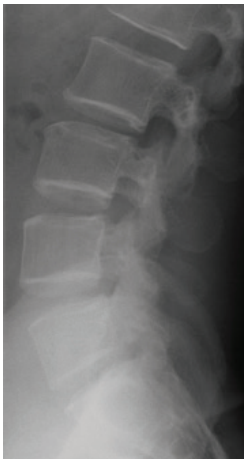


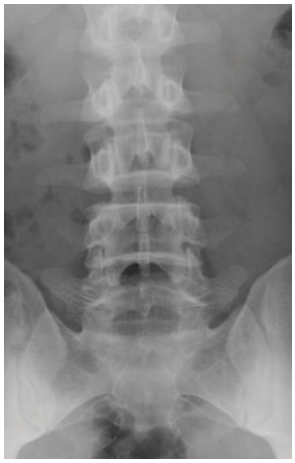
Table flexed

Fluoroscopic 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 at 0° and straight lateral images at 90°.



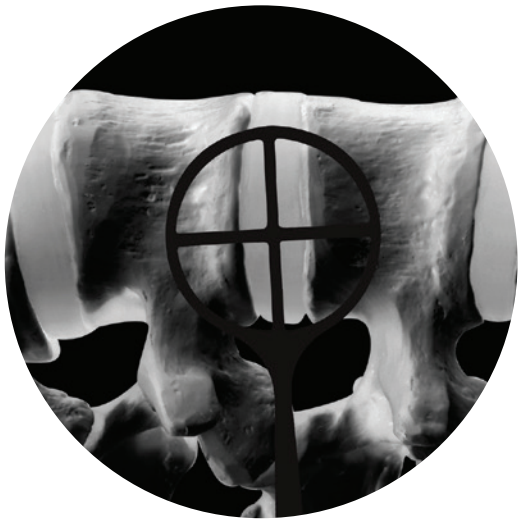
Lateral image



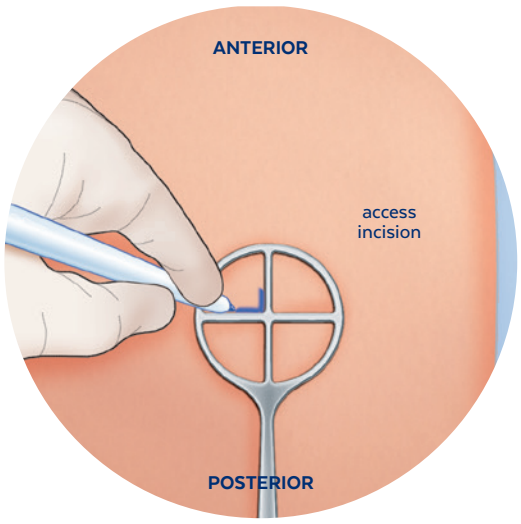
AP image

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

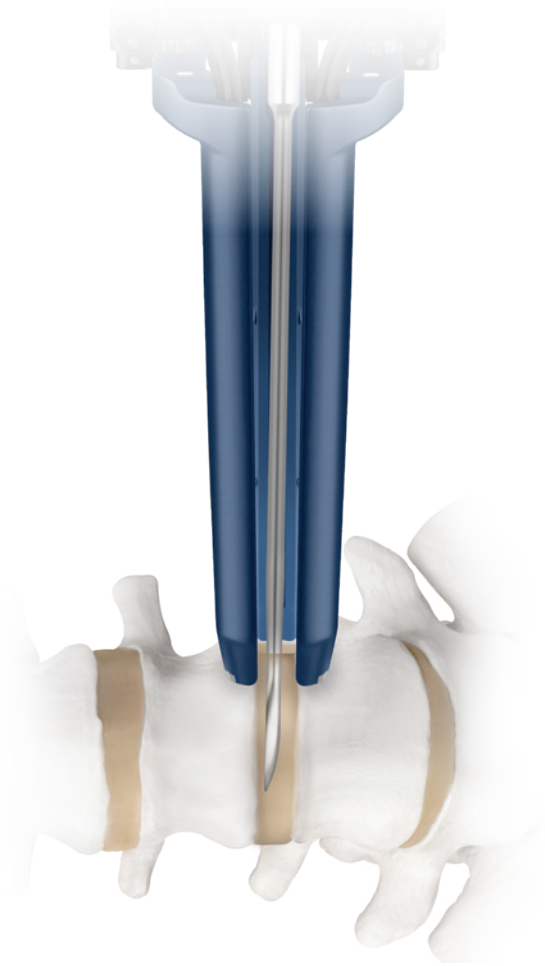
The **Bayonneted Annulotomy Knife** may be used to create a window centered in the anterior half of the annulus, large enough for spacer insertion.

Contralateral Annulus Release

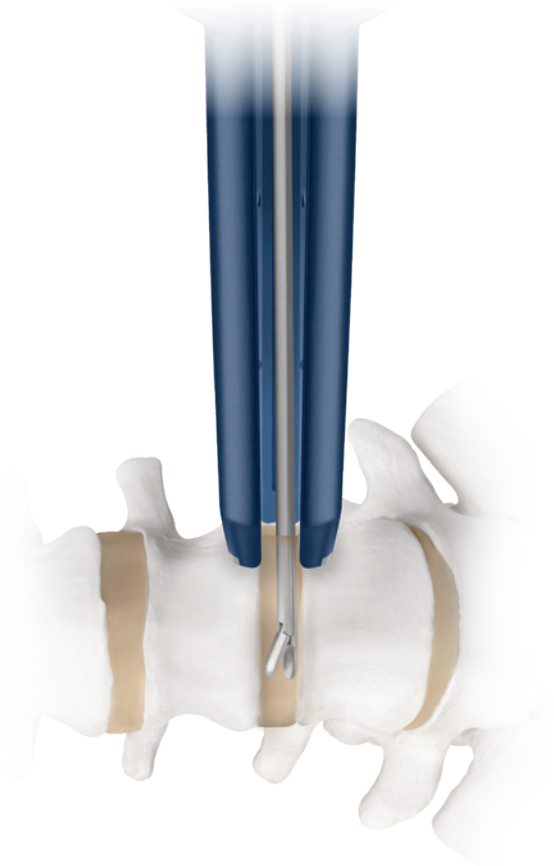
A **Cobb Elevator** may be passed along both endplates through the disc space, far enough to provide release of the contralateral annulus to allow for height restoration upon implant insertion.

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** may be used for disc removal and endplate preparation.



Using Cobb Elevator



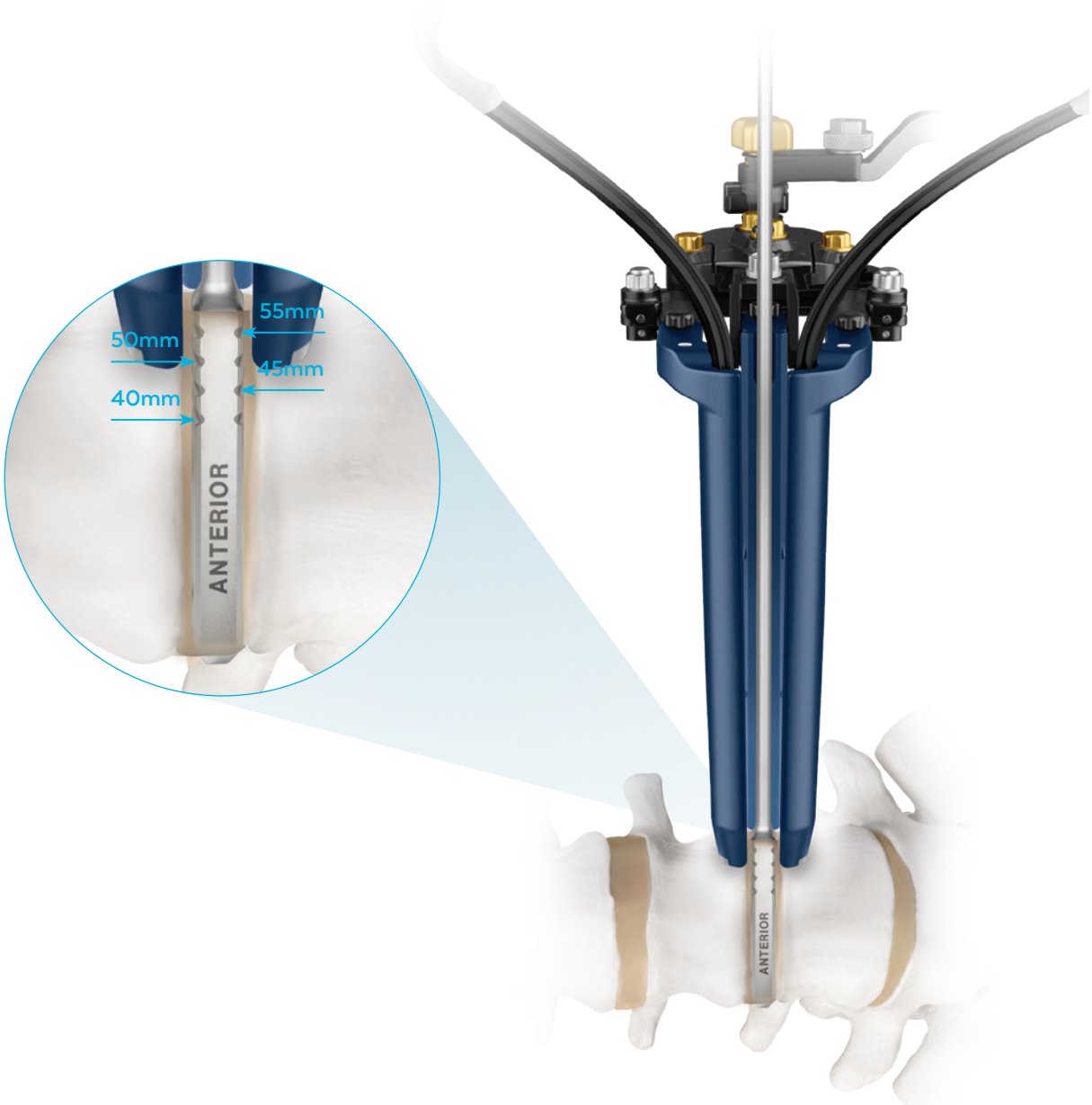
Using Disc Rongeur

STEP 3 DISTRACTION AND IMPLANT SIZING

Static TransContinental® trials should be used to determine implant length. To determine the appropriate implant size, 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 to stabilize the segment.

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

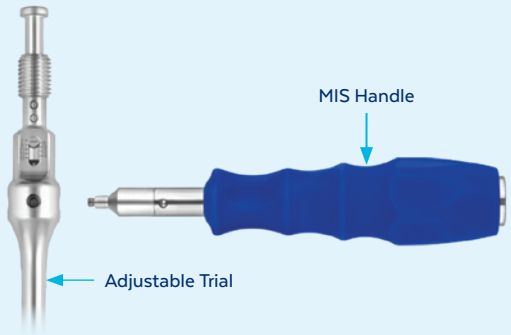


Implant Sizing

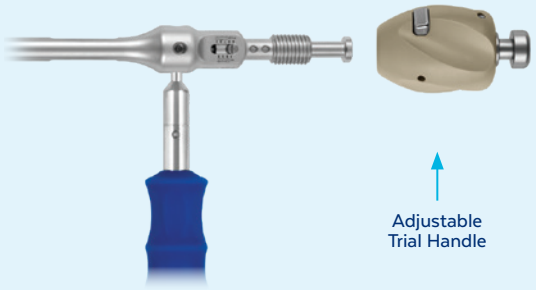
Implant Sizing with the Adjustable Trial

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 snaps on.



3. Contract the Adjustable Trial to the 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 endplate damage.

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

DISTRACTION AND IMPLANT SIZING (CONT'D)

Selecting Implant Height

After the disc height is measured, select an implant with a height range spanning the measured height. For example, if a height between 9mm and 10mm is measured using the trial, select either a 7–14mm parallel implant or an 8–15mm lordotic implant.

Indicator on Adjustable Trial Assembly showing 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 the trial assembly from the disc space.

Disassembling the Adjustable Trial Assembly

To remove the Adjustable Trial Handle, rotate the handle counterclockwise until it tightens. Slightly loosen the handle by rotating it clockwise a 1/4 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.

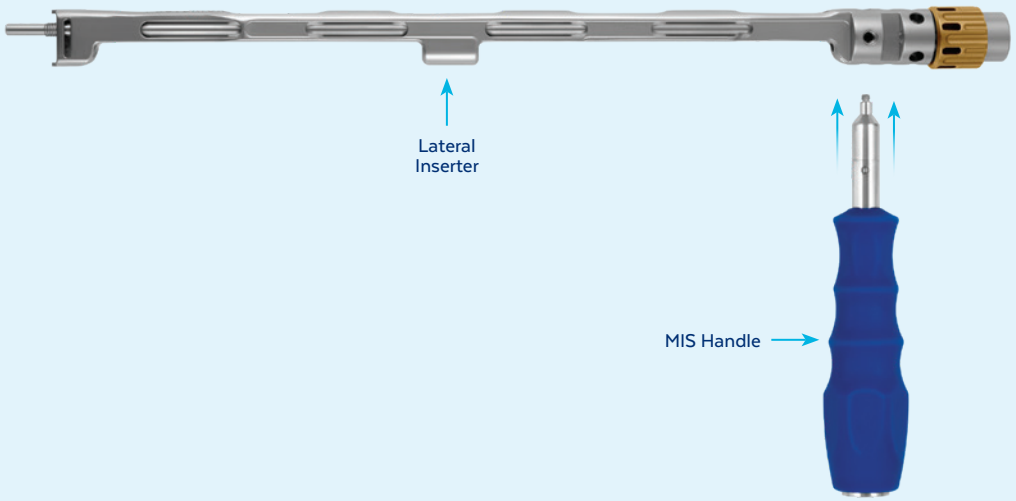
Using Slide Hammer

STEP 4 IMPLANT INSERTION

ASSEMBLING THE INSERTER

Thread the MIS Handle into the **Lateral Inserter,** finger tight. Do not overtighten.

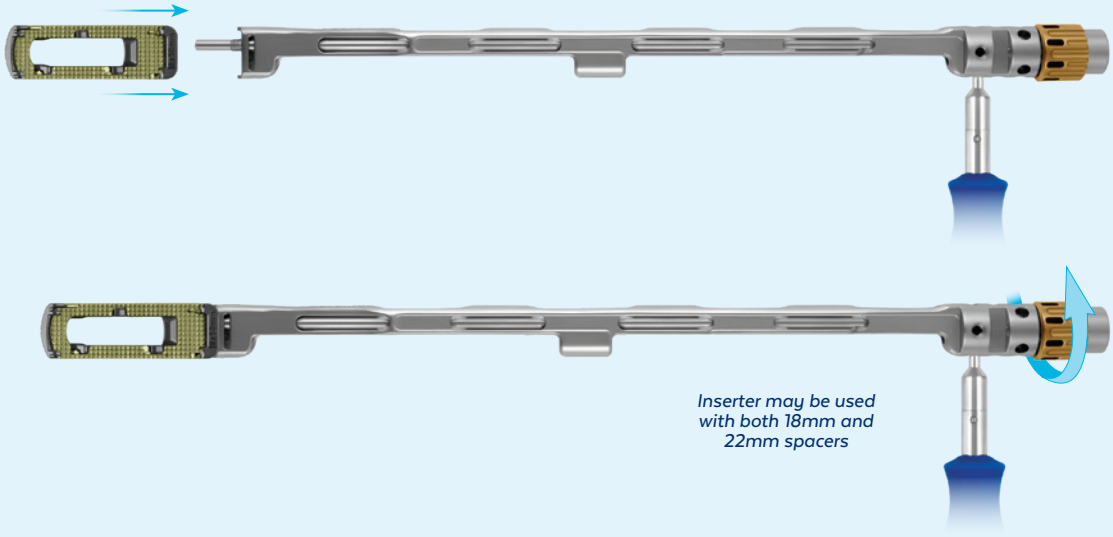
Note: *Four attachment options are available for preferred orientation.*



IMPLANT ATTACHMENT

Select the appropriately sized implant and pack with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

Place the inserter into the threaded hole of the implant and orient the inserter tabs 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.



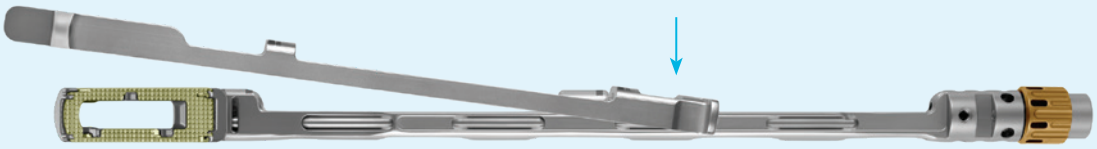
OPTIONAL: GRAFT SLEEVE

The **Graft Sleeve** is used to secure the pre-packed bone graft in the implant during insertion. The flexible spring tips ease implant insertion into the disc space.

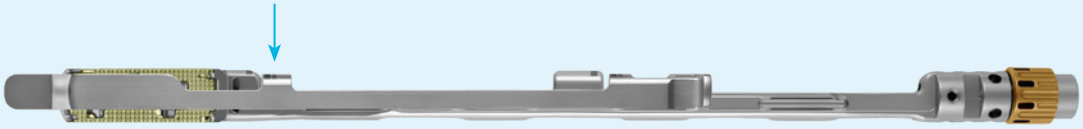
Black lines are etched on the Graft Sleeve and the inserter to assist with assembly. Once the implant is loaded onto the inserter and pre-packed with bone graft, attach the sleeve as shown.

1. Position the sleeve onto the anterior side of the inserter by matching the etched lines on the sleeve and inserter.

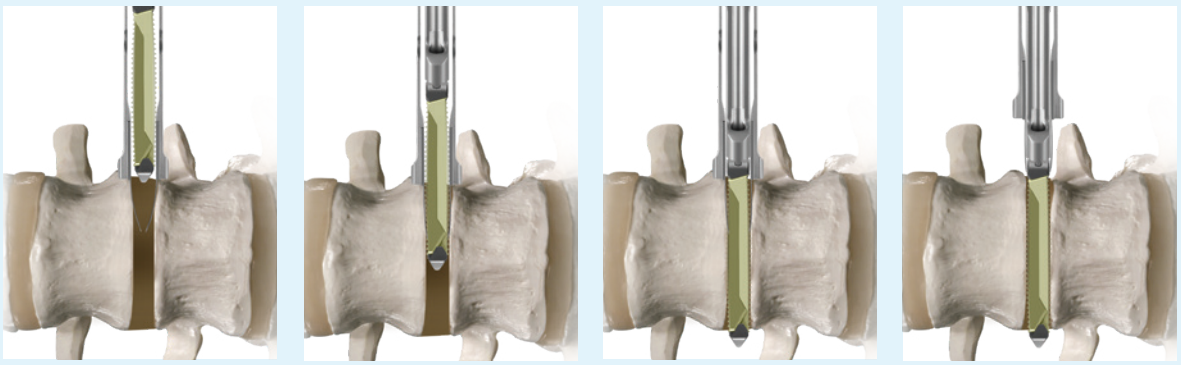
2. Press the proximal end of the sleeve onto the inserter.



3. Hold the proximal end in place while pressing on the distal end and snap the sleeve onto the inserter.



The Graft Sleeve assembly is now ready to insert into the disc space. It is not necessary to pull up on the sleeve before inserting. If the sleeve tips are above the implant prior to insertion, the sleeve should be completely removed and reassembled before reinserting. Proper use of the sleeve is shown below:



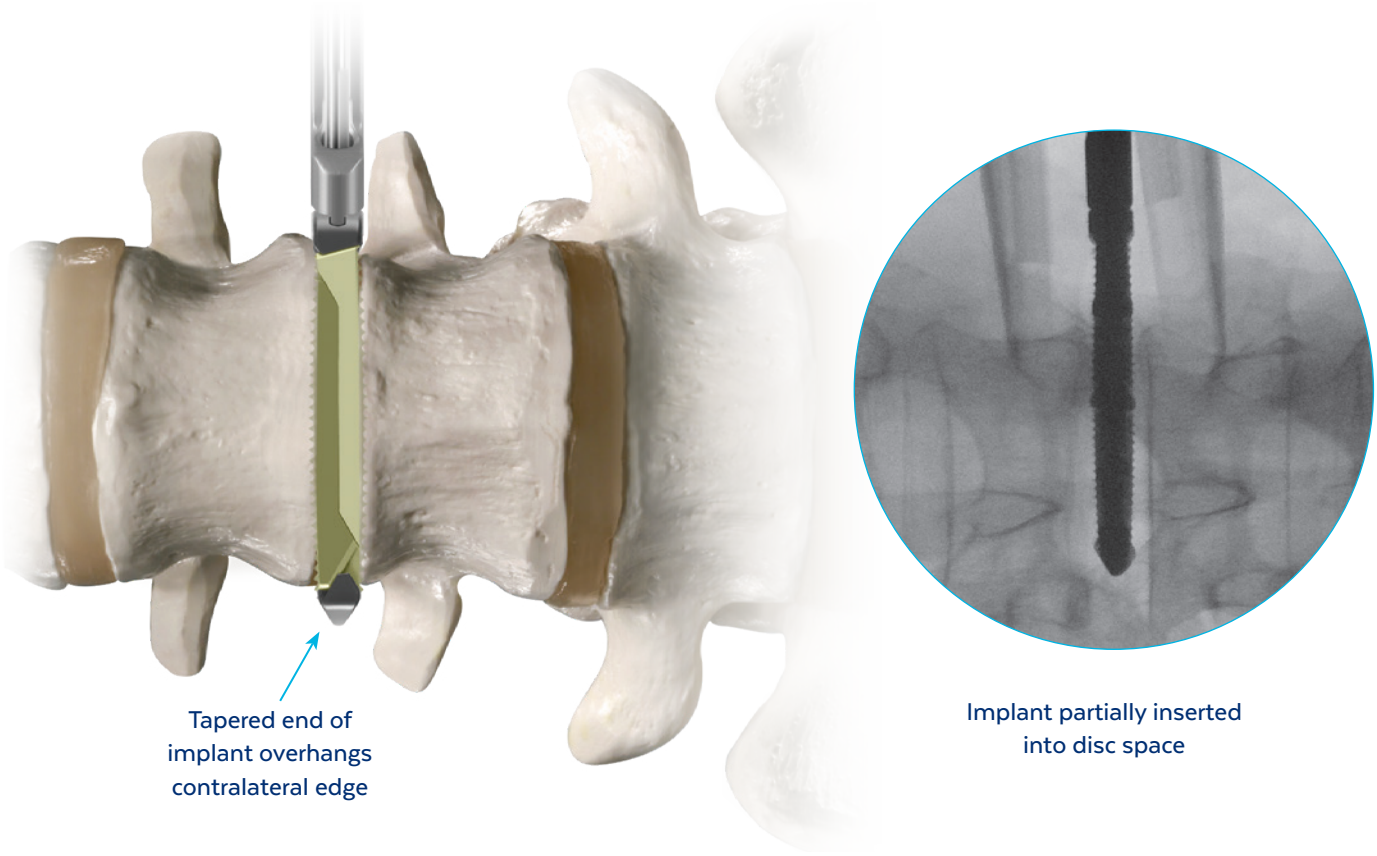
Tips inserted | Implant partially inserted | Implant inserted | Graft Sleeve removed

Once the implant is in the desired position, pull the sleeve away from the implant prior to expanding the implant. If the sleeve is too tight to pull back manually, the Slide Hammer may be used to free the sleeve from the disc space.

When the implant is expanded to final height and desired placement is achieved, remove the Lateral Inserter and Graft Sleeve simultaneously. To disassemble, remove the sleeve from the side of the inserter.

IMPLANT INSERTION (CONT'D)

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

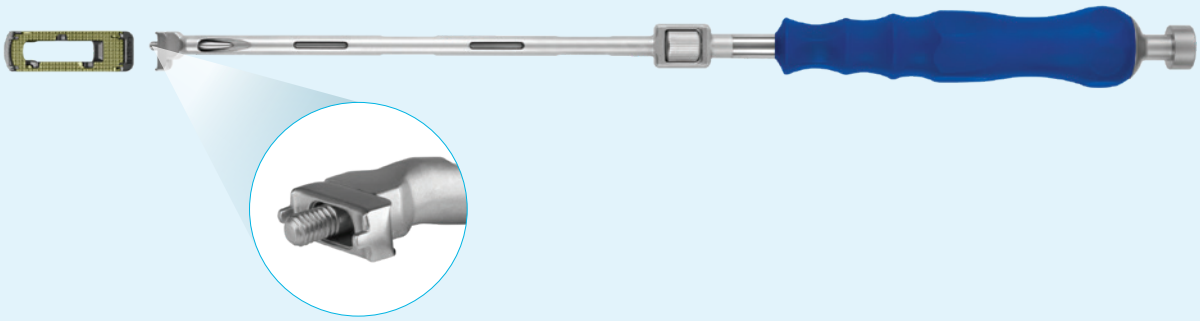


Tapered end of implant overhangs contralateral edge

Implant partially inserted into disc space

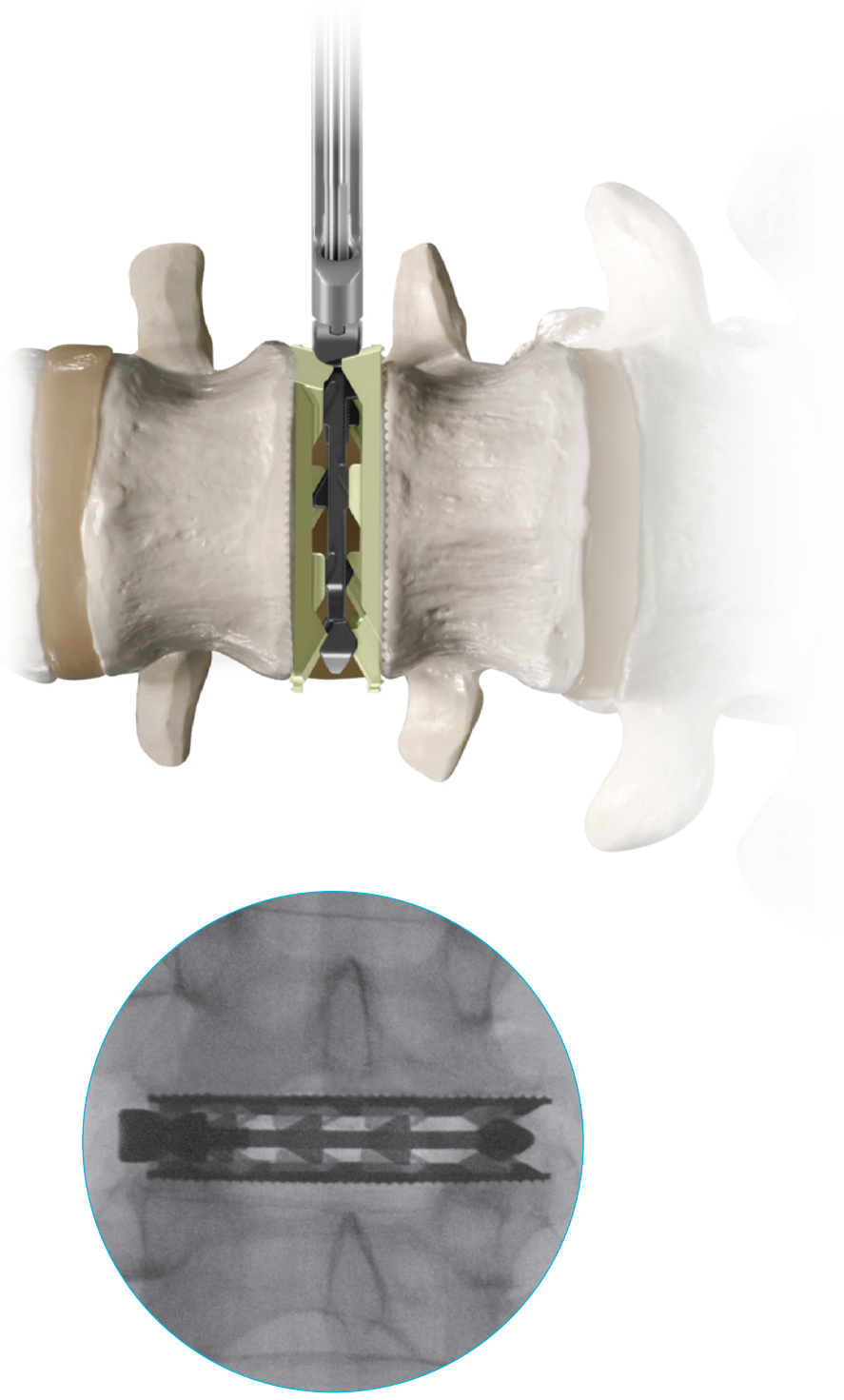
USING THE ANGLED INSERTER

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, orientated to the patient's anterior side.



STEP 5 IMPLANT EXPANSION

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

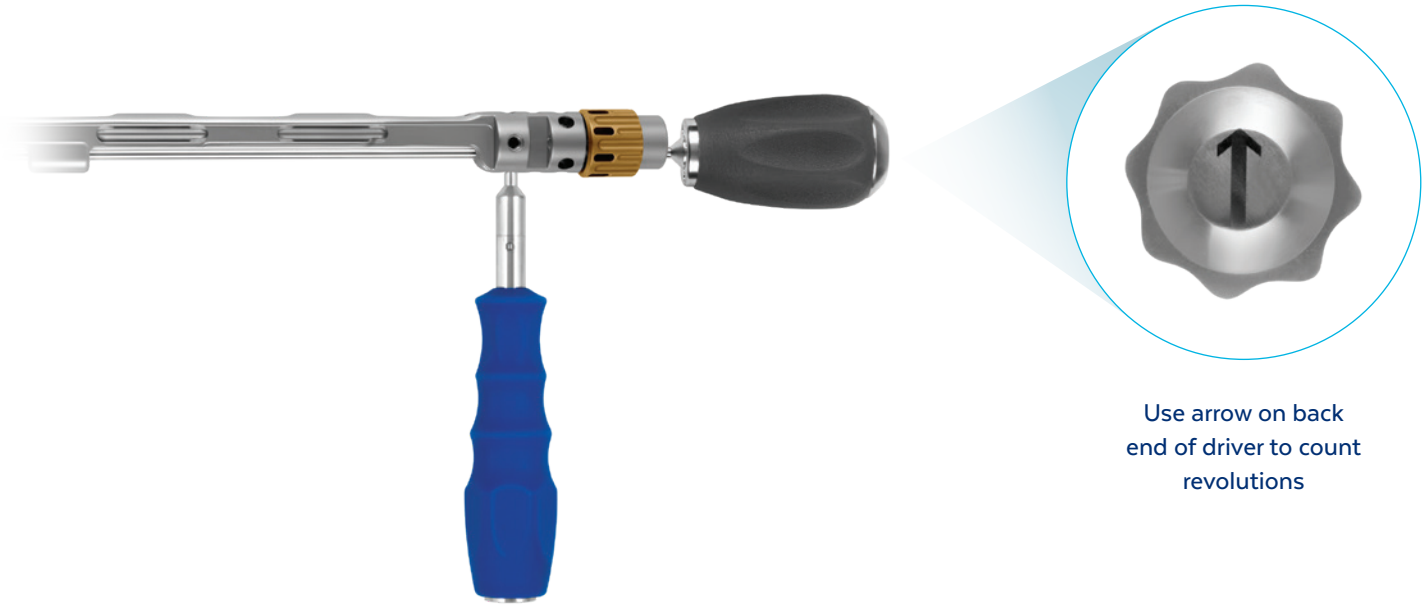


Implant expanded within disc space

Determining Implant Height

Expansion of the implant 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.

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.



Use arrow on back end of driver to count revolutions

Use the torque-limiting driver 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.

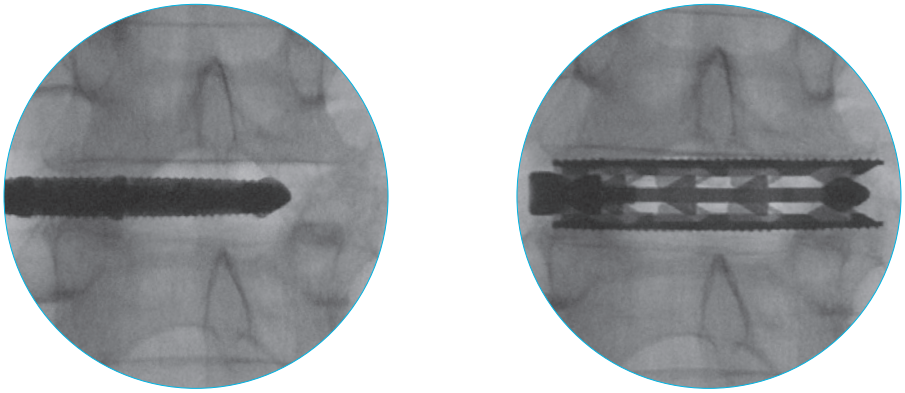
Note: Use caution while expanding the implant to avoid excessive distraction and endplate damage. The torque limit of the driver does not need to be met to ensure proper fit.

RISE®-L Required Revolutions											
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

RISE®-L Adjustable Lordosis Expansion								
Drive Screw Revolutions	0	2	4	6	8	10	12	14
Anterior Height (mm)	7	8	9	10	11	12	13	14
Posterior Height (mm)	6.0	6.5	6.9	7.4	7.9	8.3	8.8	9.3
Lordotic Angle	3°	4.7°	6.4°	8.1°	9.8°	11.5°	13.2°	15°

STEP 6 RADIOGRAPHIC CONFIRMATION

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



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

Using Inserter Wrench

Optional: 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 slots of the sides of the implant. Rotate the gold thumbwheel clockwise to tighten the inserter onto the implant. Once the inserter is reattached, reduce the implant height. Contract the implant until *two finger tight,* rotating counterclockwise. The implant can be repositioned as necessary.

STEP 7 BONE GRAFT

The **Threaded Funnel Shaft** holds 2.4cc of autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone and can be pre-loaded. This bone graft 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 into the implant until tightly packed.

The volume of graft required to fill a RISE®-L spacer is dependent on the selected implant size and expansion. Track the volume used to determine when the implant is filled.

The table below shows the approximate graft volume for each implant configuration.

RISE®-L							
Part No.	Length (mm)	Height (mm)	Graft Volume (cm^3)	Part No.	Length (mm)	Height (mm)	Graft Volume (cm^3)
18mm Width				22mm Width			
193.302	40	7-14	1.5-3.8	193.402	40	7-14	1.8-4.6
193.303	45	7-14	1.8-4.5	193.403	45	7-14	2.2-5.4
193.304	50	7-14	2.2-5.3	193.404	50	7-14	2.6-6.3
193.305	55	7-14	2.5-6.0	193.405	55	7-14	3.0-7.2
193.306	60	7-14	2.8-6.7	193.406	60	7-14	3.4-8.0
193.312	40	10-17	2.3-4.6	193.412	40	10-17	2.7-5.5
193.313	45	10-17	2.7-5.5	193.413	45	10-17	3.3-6.5
193.314	50	10-17	3.3-6.4	193.414	50	10-17	3.9-7.6
193.315	55	10-17	3.7-7.3	193.415	55	10-17	4.4-8.6
193.316	60	10-17	4.2-8.1	193.416	60	10-17	5.0-9.6
193.322	40	8-15	1.7-4.0	193.422	40	8-15	2.0-4.7
193.323	45	8-15	2.0-4.8	193.423	45	8-15	2.4-5.6
193.324	50	8-15	2.4-5.6	193.424	50	8-15	2.9-6.6
193.325	55	8-15	2.8-6.3	193.425	55	8-15	3.3-7.4
193.326	60	8-15	3.1-7.1	193.426	60	8-15	3.7-8.3
193.332	40	10-17	2.1-4.4	193.432	40	10-17	2.4-5.1
193.333	45	10-17	2.5-5.2	193.433	45	10-17	2.9-6.1
193.334	50	10-17	2.9-6.1	193.434	50	10-17	3.4-7.1
193.335	55	10-17	3.3-6.9	193.435	55	10-17	3.9-8.1
193.336	60	10-17	3.7-7.7	193.436	60	10-17	4.4-9.0
RISE®-L Adjustable Lordotic							
Part No.	Length (mm)	Height (mm)	Graft Volume (cm^3)	Part No.	Length (mm)	Height (mm)	Graft Volume (cm^3)
18mm Width				22mm Width			
193.502	40	7-14	1.4-2.8	193.602	40	7-14	1.7-3.3
193.503	45	7-14	1.7-3.4	193.603	45	7-14	2.1-4.0
193.504	50	7-14	2.0-4.0	193.604	50	7-14	2.5-4.7
193.505	55	7-14	2.4-4.6	193.605	55	7-14	2.9-5.3
193.506	60	7-14	2.7-5.1	193.606	60	7-14	3.3-6.0

Using Graft Plunger with Threaded Funnel Shaft

OPTIONAL: IMPLANT REMOVAL

For implant removal, the implant inserter may be repositioned onto the implant and the height reduced 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 remove the implant.

The **Removal Tool** is also available. If the implant inserter cannot be reattached onto the implant, the torque-limiting driver can be used manually to reduce the implant height by inserting into the drive screw and rotating counterclockwise. Thread the Removal Tool into the proximal end of the implant and use the Slide Hammer to remove the implant if necessary.

Forceps or other manual surgical instruments may also be used to grasp and extract the implant.

SUPPLEMENTAL FIXATION

This device is intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). CREO® MIS or REVOLVE®, highlighted below, are posterior stabilization systems that may be used with the RISE-L® Spacer.

CREO MIS® Stabilization System

Minimized Muscle Disruption

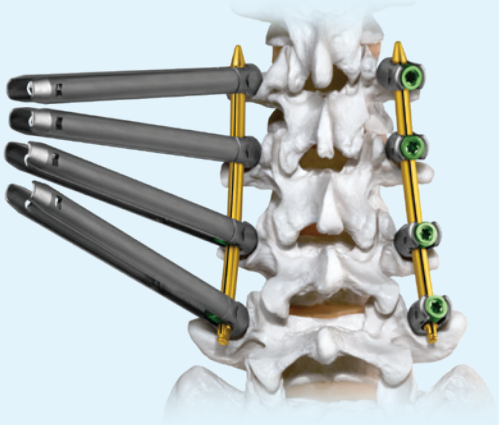
Extended screw heads provide a minimized outer diameter to help reduce muscle disruption and screw sleeve interference.

Powerful MIS Correction

Deformity adapters rigidly attach to the extended screw head and allow for screw manipulation and deformity correction.*

Integrated Rod Reduction

Ensures proper thread alignment while capturing, reducing, and locking the rod in one simplified step.



REVOLVE® Stabilization System

REVOLVE® Locking Technology

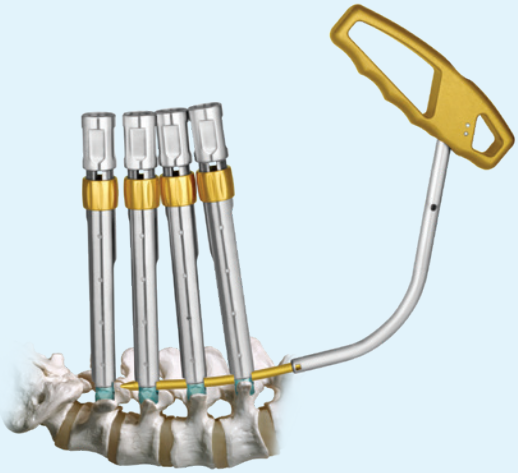
Non-threaded locking caps eliminate cross-threading and challenges with cap placement.

Powerful Rod Reduction

Provides fixation irrespective of complexity, due to integrated, streamlined rod reduction and a strong screw-sleeve connection.

Multi-Level Capability

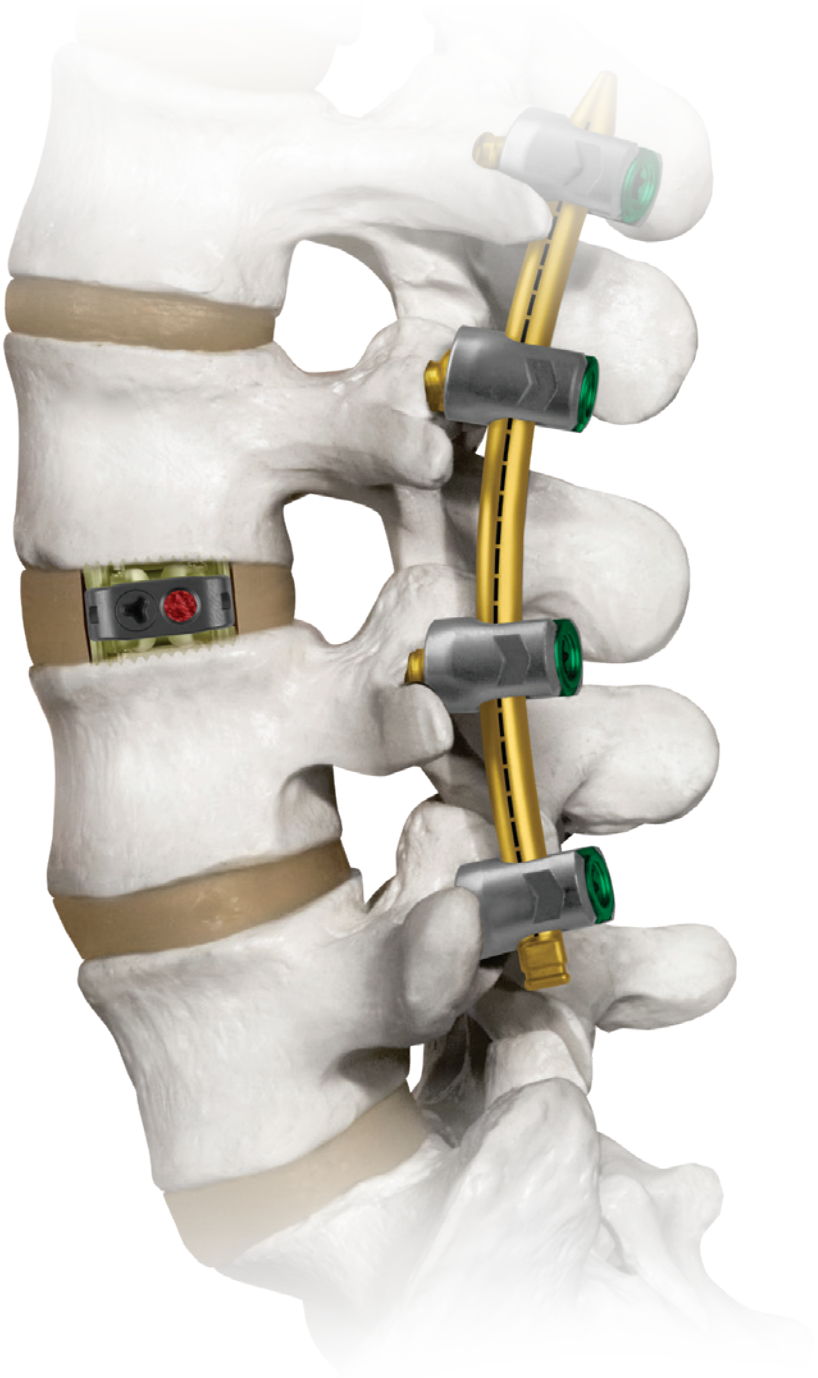
The system adapts to surgeon needs with capabilities for trauma, tumor, and deformity applications.



**CREO MIS® Deformity Adapters are compatible with the CREO® Reduction Derotator.*

FINAL POSITION - AP VIEW

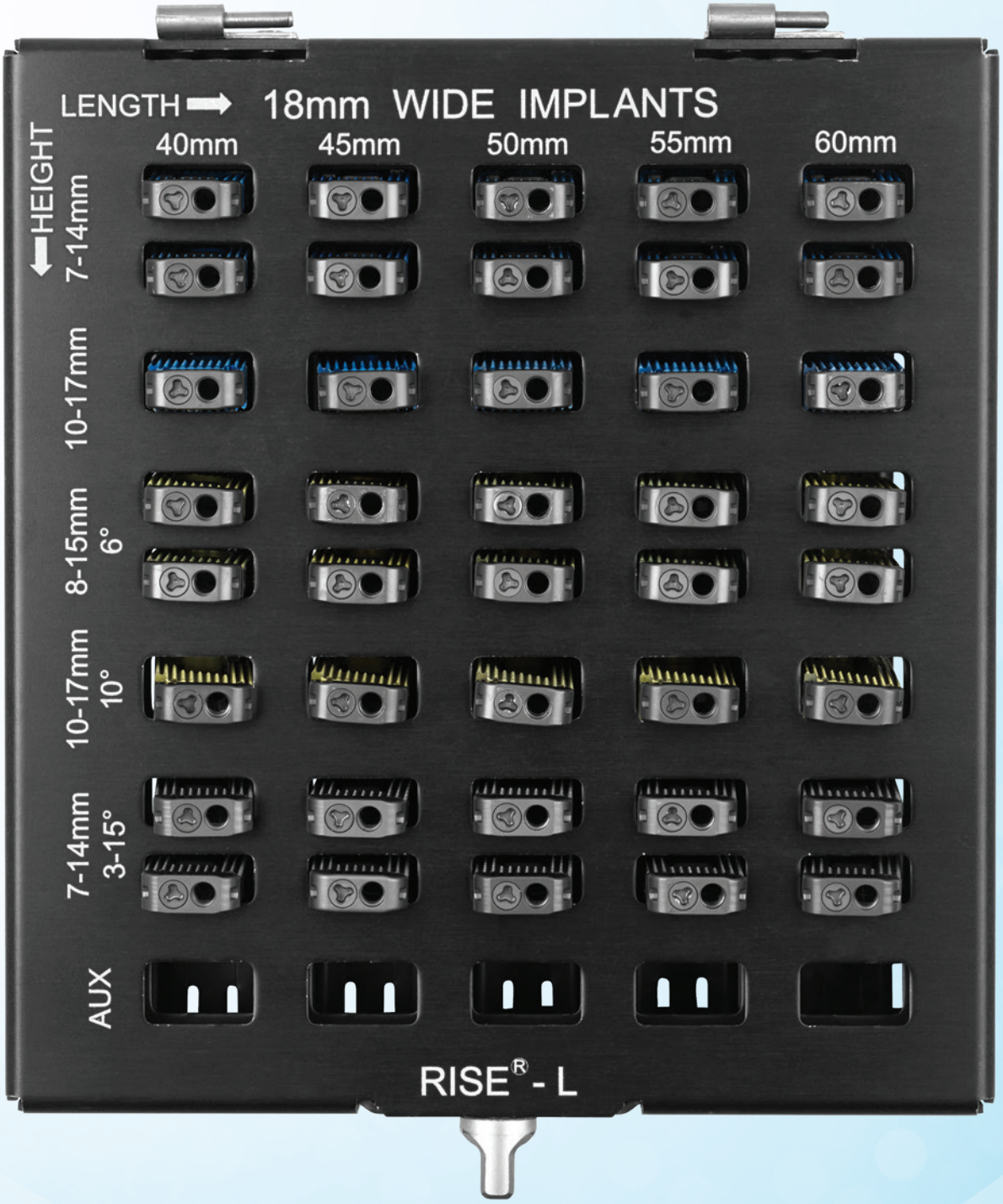
FINAL POSITION - LATERAL VIEW



RISE®-L
18mm IMPLANT SET 993.918

Part No.	Description	Qty
193.302	RISE-L® Spacer, 18x40mm, 7-14mm	2
193.303	RISE-L® Spacer, 18x45mm, 7-14mm	2
193.304	RISE-L® Spacer, 18x50mm, 7-14mm	2
193.305	RISE-L® Spacer, 18x55mm, 7-14mm	2
193.306	RISE-L® Spacer, 18x60mm, 7-14mm	2
193.312	RISE-L® Spacer, 18x40mm, 10-17mm	1
193.313	RISE-L® Spacer, 18x45mm, 10-17mm	1
193.314	RISE-L® Spacer, 18x50mm, 10-17mm	1
193.315	RISE-L® Spacer, 18x55mm, 10-17mm	1
193.316	RISE-L® Spacer, 18x60mm, 10-17mm	1
193.322	RISE-L® Spacer, 18x40mm, 8-15mm, 6°	2
193.323	RISE-L® Spacer, 18x45mm, 8-15mm, 6°	2
193.324	RISE-L® Spacer, 18x50mm, 8-15mm, 6°	2
193.325	RISE-L® Spacer, 18x55mm, 8-15mm, 6°	2
193.326	RISE-L® Spacer, 18x60mm, 8-15mm, 6°	2
193.332	RISE-L® Spacer, 18x40mm, 10-17mm, 10°	1
193.333	RISE-L® Spacer, 18x45mm, 10-17mm, 10°	1
193.334	RISE-L® Spacer, 18x50mm, 10-17mm, 10°	1
193.335	RISE-L® Spacer, 18x55mm, 10-17mm, 10°	1
193.336	RISE-L® Spacer, 18x60mm, 10-17mm, 10°	1
193.502	RISE-L® Spacer, 18x40mm, 7-14mm, 3-15°	2
193.503	RISE-L® Spacer, 18x45mm, 7-14mm, 3-15°	2
193.504	RISE-L® Spacer, 18x50mm, 7-14mm, 3-15°	2
193.505	RISE-L® Spacer, 18x55mm, 7-14mm, 3-15°	2
193.506	RISE-L® Spacer, 18x60mm, 7-14mm, 3-15°	2
993.018	RISE-L® 18mm Module	1
993.020	RISE-L® Implants Graphic Case	1

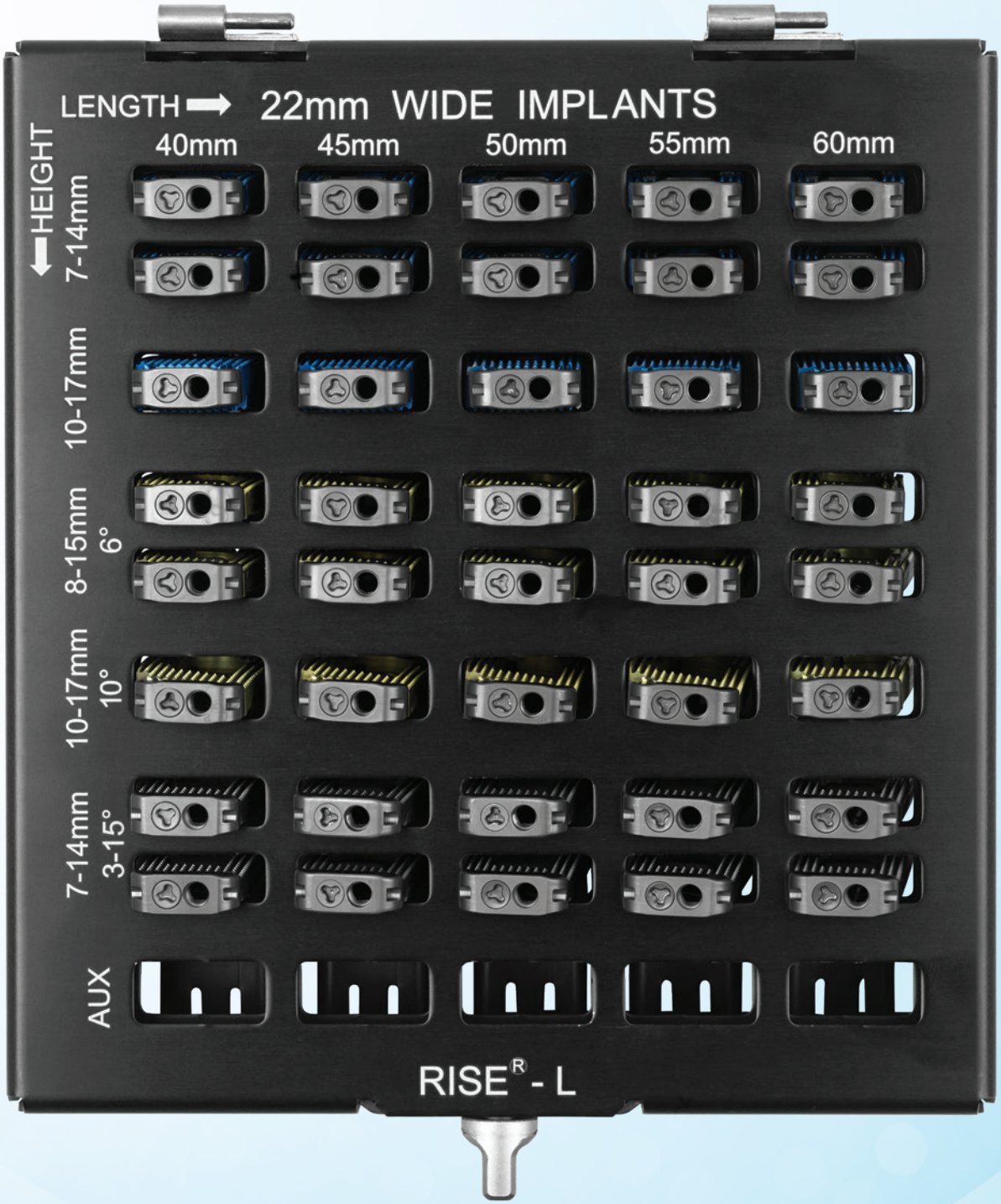
RISE®-L
18mm IMPLANT SET 993.918



RISE®-L
22mm IMPLANT SET 993.922

Part No.	Description	Qty
193.402	RISE®-L Spacer, 22x40mm, 7-14mm	2
193.403	RISE®-L Spacer, 22x45mm, 7-14mm	2
193.404	RISE®-L Spacer, 22x50mm, 7-14mm	2
193.405	RISE®-L Spacer, 22x55mm, 7-14mm	2
193.406	RISE®-L Spacer, 22x60mm, 7-14mm	2
193.412	RISE®-L Spacer, 22x40mm, 10-17mm	1
193.413	RISE®-L Spacer, 22x45mm, 10-17mm	1
193.414	RISE®-L Spacer, 22x50mm, 10-17mm	1
193.415	RISE®-L Spacer, 22x55mm, 10-17mm	1
193.416	RISE®-L Spacer, 22x60mm, 10-17mm	1
193.422	RISE®-L Spacer, 22x40mm, 8-15mm, 6°	2
193.423	RISE®-L Spacer, 22x45mm, 8-15mm, 6°	2
193.424	RISE®-L Spacer, 22x50mm, 8-15mm, 6°	2
193.425	RISE®-L Spacer, 22x55mm, 8-15mm, 6°	2
193.426	RISE®-L Spacer, 22x60mm, 8-15mm, 6°	2
193.432	RISE®-L Spacer, 22x40mm, 10-17mm, 10°	1
193.433	RISE®-L Spacer, 22x45mm, 10-17mm, 10°	1
193.434	RISE®-L Spacer, 22x50mm, 10-17mm, 10°	1
193.435	RISE®-L Spacer, 22x55mm, 10-17mm, 10°	1
193.436	RISE®-L Spacer, 22x60mm, 10-17mm, 10°	1
193.602	RISE®-L Spacer, 22x40mm, 7-14mm, 3-15°	2
193.603	RISE®-L Spacer, 22x45mm, 7-14mm, 3-15°	2
193.604	RISE®-L Spacer, 22x50mm, 7-14mm, 3-15°	2
193.605	RISE®-L Spacer, 22x55mm, 7-14mm, 3-15°	2
193.606	RISE®-L Spacer, 22x60mm, 7-14mm, 3-15°	2
993.022	RISE®-L 22mm Module	

RISE®-L
22mm IMPLANT SET 993.922



RISE®-L
INSTRUMENT SET 993.919

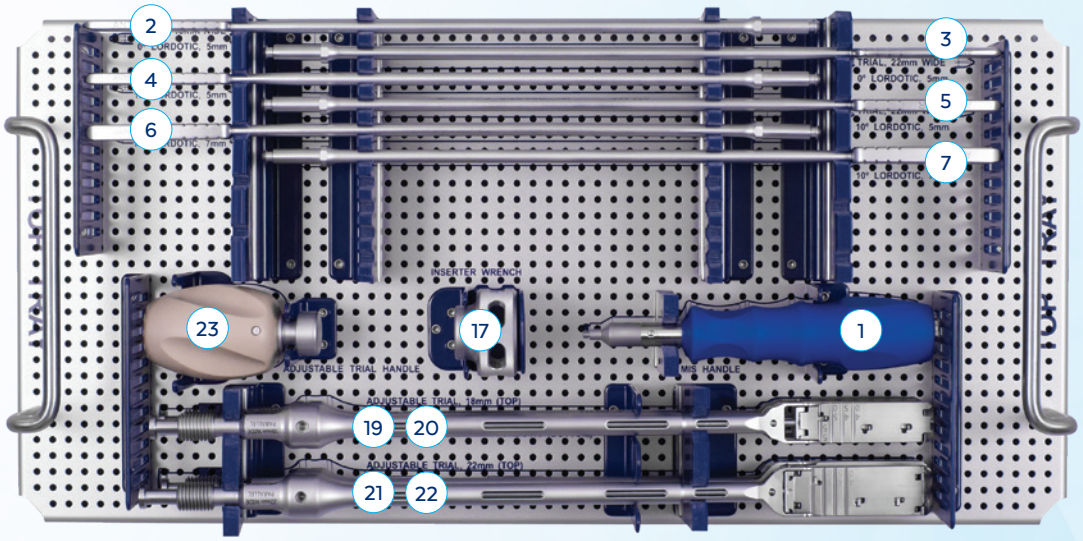
	Part No.	Description	Qty
1	673.003	MIS Handle	2
2	675.006	TransContinental® LLIF Trial, 0°, 5mm	1
3	675.043	TransContinental® 22mm Trial, Parallel, 5mm	1
4	675.065	TransContinental® 18mm Trial, 10° Lordotic, 5mm	1
5	675.067	TransContinental® 18mm Trial, 10° Lordotic, 7mm	1
6	675.365	TransContinental® 22mm Trial, 10° Lordotic, 5mm	1
7	675.365	TransContinental® 22mm Trial, 10° Lordotic, 5mm	1
8	681.013	Bone Funnel	1
9	693.600	Lateral Torque-Limiting Driver, 3.0Nm	2
10	693.601	Lateral Inserter	2
11	693.602	Lateral Angled Inserter	1
12	693.603	Graft Sleeve, 7mm	1
13	693.604	Graft Sleeve, 10mm	1
14	693.610	Threaded Funnel Shaft	2
15	693.611	Graft Plunger	2
16	693.613	Removal Tool	1
17	693.614	Inserter Wrench	1
18	694.018	Slide Hammer	1
	993.019	RISE®-L Instruments Graphic Case	

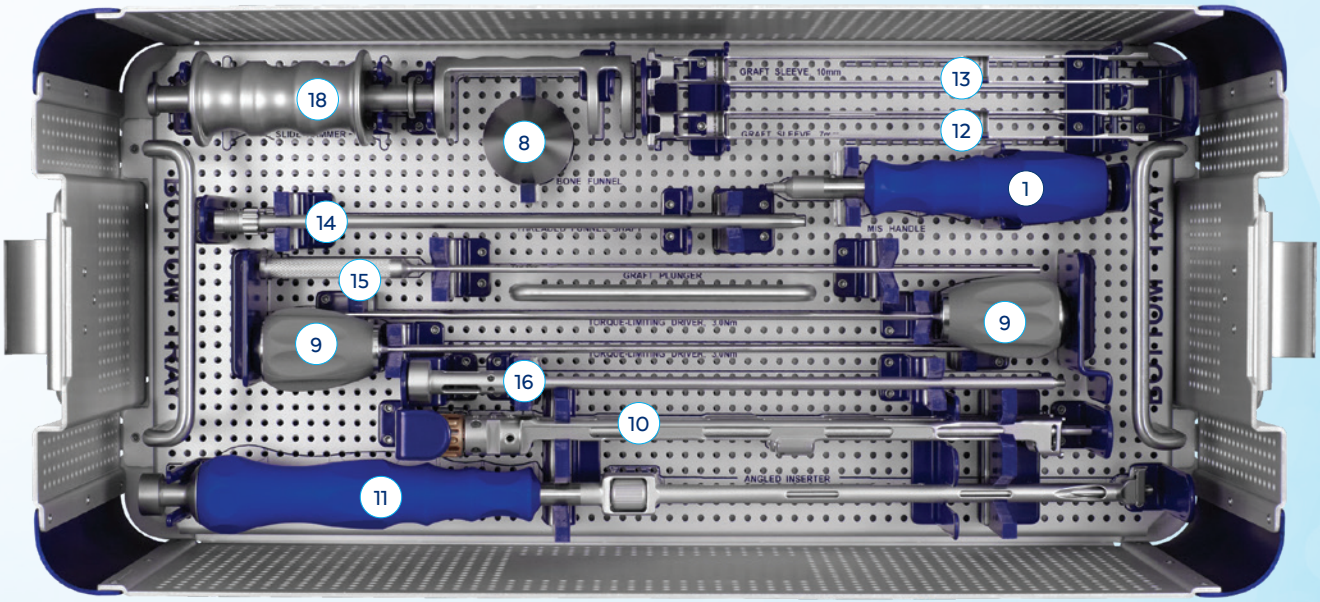
Additionally Available

19	694.110	Adjustable Trial, 18mm
20	694.112	Adjustable Trial, 18mm Lordotic
21	694.201	Adjustable Trial, 22mm
22	694.202	Adjustable Trial, 22mm Lordotic
23	694.418	Adjustable Trial Handle

Items in gray are additionally available.

RISE®-L
INSTRUMENT SET 993.919





IMPORTANT INFORMATION ON THE RISE® SPACER

DESCRIPTION

RISE® Spacers are lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. RISE® Spacers are provided in different shapes to accommodate various surgical approaches to the lumbar spine (posterior, transforaminal [posterolateral] or lateral) and can expand to the desired height. The implants are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. This device is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

RISE® Spacers are manufactured from titanium alloy, as specified in ASTM F136 and F1295. An internal component is manufactured from radiolucent PEEK polymer, as specified in ASTM F2026.

INDICATIONS

The RISE® Spacer is an interbody fusion device intended for use at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or 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 RISE® Spacer is to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. This device is intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

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.

Possible adverse effects which may occur include: failed fusion or pseudarthosis leading to implant breakage; allergic reaction to implant materials; device fracture or failure; device migration or loosening; decrease in bone density; pain, discomfort, or abnormal sensations due to the presence of the device; injury to nerves, vessels, and organs; venous thrombosis, lung embolism and cardiac arrest; and death.

Components of this system are manufactured from titanium alloy. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Mixing of implant components with different materials is not recommended, for metallurgical, mechanical, and functional reasons.

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.

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.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

For optimal implant performance, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

MRI SAFETY INFORMATION

The RISE® Spacers are 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 RISE® Spacers are 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 RISE® 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

CONTRAINDICATIONS AND POSSIBLE ADVERSE EFFECTS

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.

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.

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 in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below. 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
Steam	Pre-vacuum	134°C (273°F)	3 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 (U.S.A.) Law 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		

DI162A Rev J

NOTES

NOTES

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Audubon, PA 19403
www.globusmedical.com

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Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

CE 0297

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04.24 Rev F