RISE® IntraLIF®

Intradiscal Lumbar Interbody Fusion

SURGICAL TECHNIQUE GUIDE

GLOBUSMEDICAL.COM/RISE® IntraLIF® | *Life moves us*

GLOBUS MEDICAL

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

Life moves us

SURGICAL TECHNIQUE GUIDE

RISE® IntraLIF®

RISE® IntraLIF®

Expandable Lateral Interbody Spacer

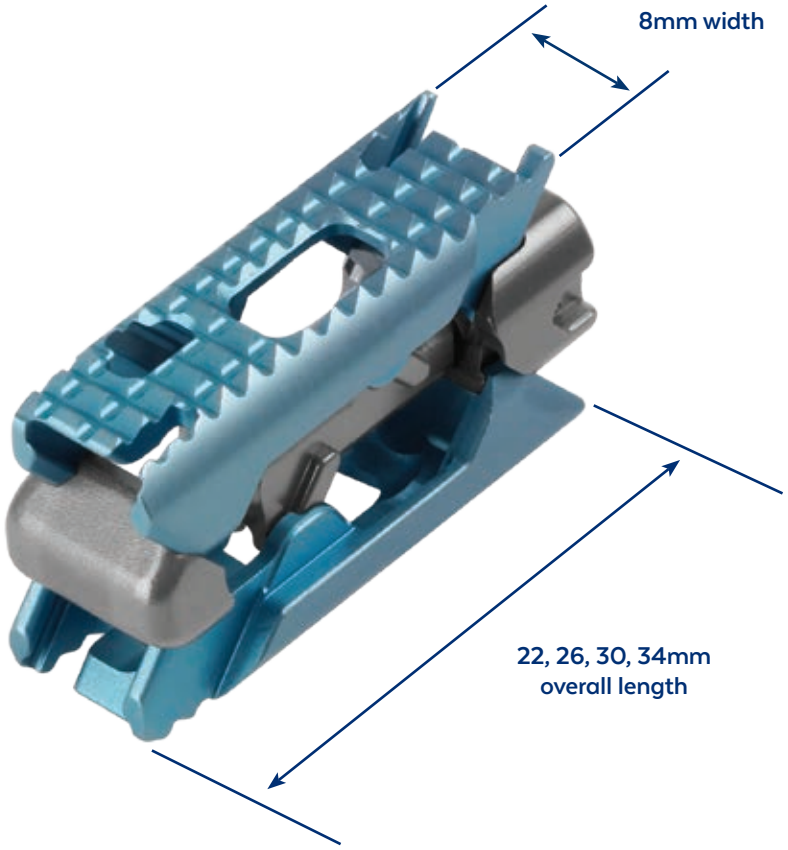
RISE® is an innovative expandable lumbar fusion device that achieves traditional fusion goals through an 8.5mm corridor.

- Minimized Anatomical Disruption
- Protected Corridor Past Nerve Roots
- Optimized Disc Access
- Improved Implant Placement

Leveraging endoscopic access and visualization through the IntraLIF® procedure, RISE® is implanted in a minimally invasive manner and expands *in situ* to distract the disc space and optimize fit.

IMPLANT OVERVIEW

- Contracted insertion height allows for insertion through 8.5mm inner diameter (ID) cannula
- Controlled continuous expansion is designed to restore disc height
- Automatic locking for simple operation
- Convex profile fits anatomy
- Four footprints: 8x22mm, 8x26mm, 8x30mm, 8x34mm
- Height expansion ranges from 7–14mm
- 4° lordotic options
- Streamlined instrumentation for both insertion and expansion



INSTRUMENT OVERVIEW

ACCESS INSTRUMENTS

Dilator, 7mm 693.102

Dilator, 6mm Transition 693.103

Dilator, 8.5mm 693.104

Cannula, Working (7mm ID) 693.112

Cannula, 8.5mm 693.114

Sleeve Impactor, Working (7mm ID) 693.122

Sleeve Impactor, 8.5mm 693.124

DISC PREPARATION INSTRUMENTS

Adjustable Scraper, 7–14mm 693.201

Articulating Curette, Short 693.301

Articulating Curette, Long 693.302

Funnel, 7mm 693.402

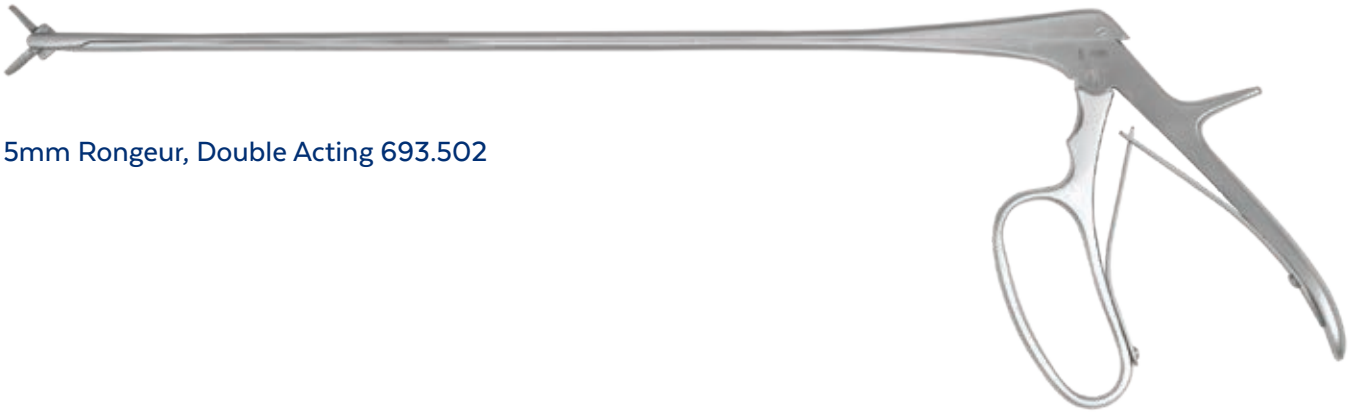
Funnel, 8.5mm 693.404

DISC PREPARATION INSTRUMENTS (CONT'D)

Plunger 693.412

Plunger/Trial 8.5mm 693.414

5mm Rongeur 693.501



5mm Rongeur, Double Acting 693.502

TRIALING INSTRUMENTS

MIS Handle 673.003

Torque-Limiting Palm Handle, 3.0Nm 693.003

Adjustable Trial 8x26mm, 7-14mm 693.211

Removable Drive, Right Hand 694.218

MIS Handle 673.003
Adjustable Trial 8x26mm, 7-14mm 693.211
Torque-Limiting Palm Handle, 3.0Nm 694.003
Removable Drive, Right Hand 694.218
(Assembled)

IMPLANT INSERTION INSTRUMENTS

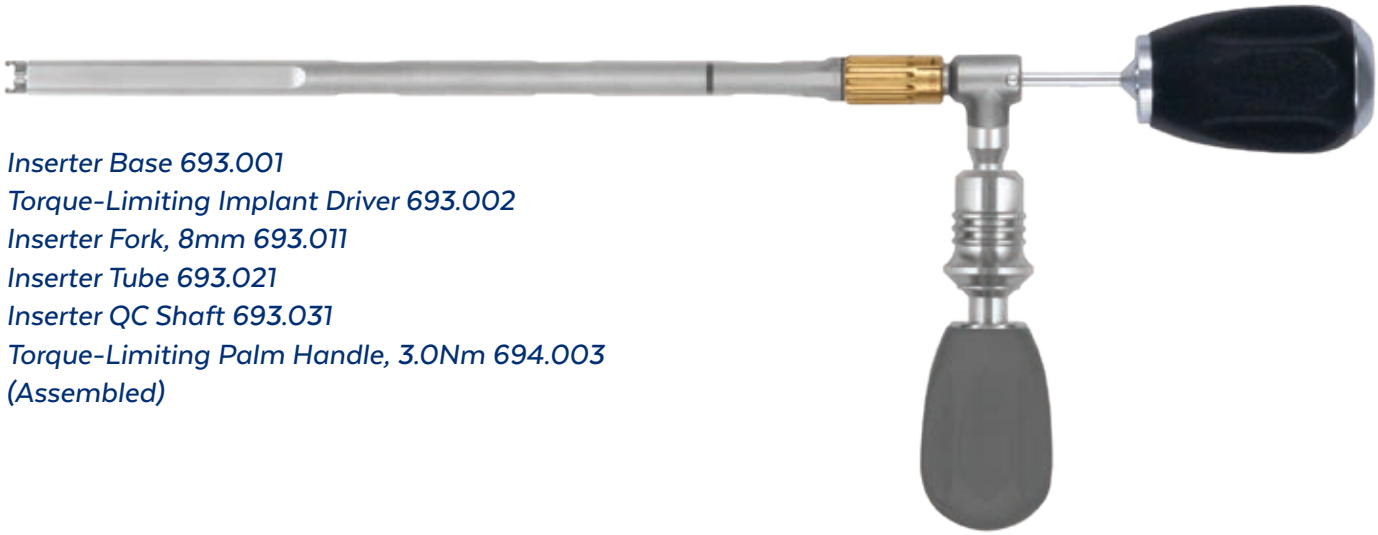
Inserter Base 693.001

Torque-Limiting Implant Driver 693.002

Inserter Fork, 8mm 693.011

Inserter Tube 693.021

Inserter QC Shaft 693.031



Inserter Base 693.001
Torque-Limiting Implant Driver 693.002
Inserter Fork, 8mm 693.011
Inserter Tube 693.021
Inserter QC Shaft 693.031
Torque-Limiting Palm Handle, 3.0Nm 694.003
(Assembled)

OTHER INSTRUMENTS

Spanner Wrench 687.509

Slap Hammer 693.141

SURGICAL TECHNIQUE

RISE® IntraLIF®

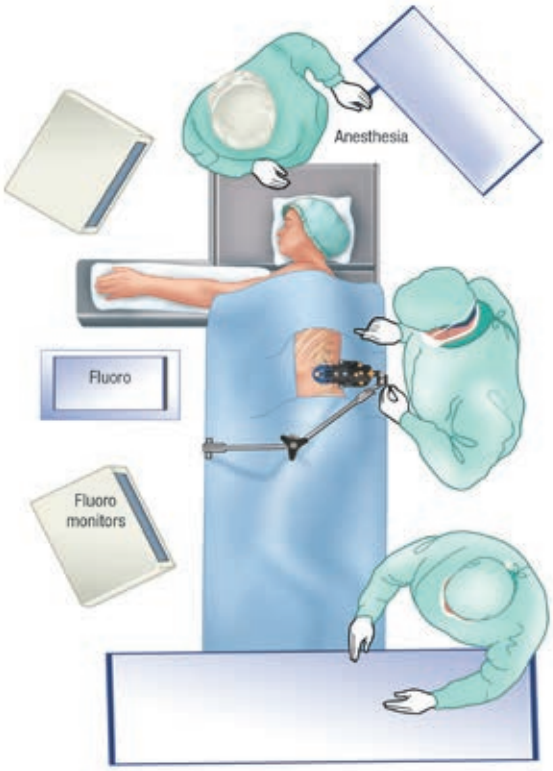
STEP 1 PATIENT PREPARATION

Patient Positioning

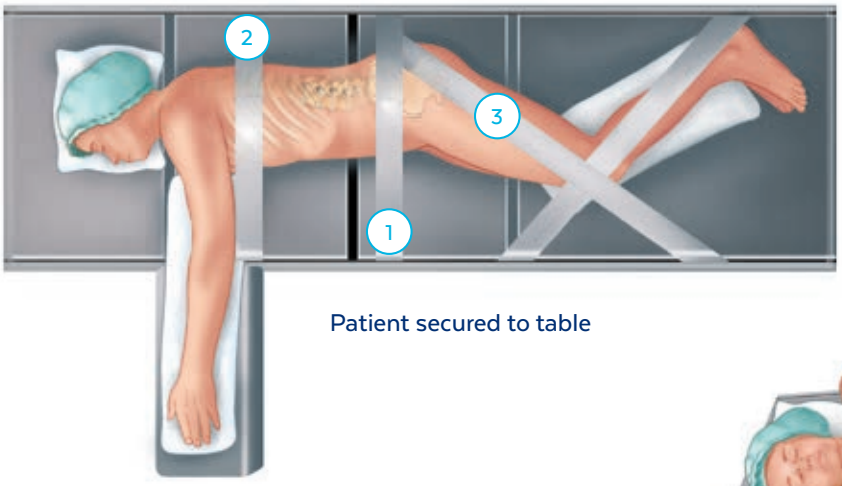
The patient is placed on a flexible surgical table in a straight 90° right lateral decubitus position so that the iliac crest is just over the table break, as shown below.

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

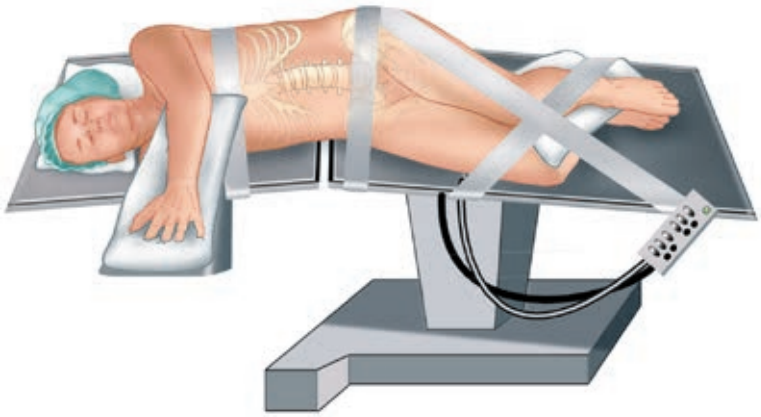


Table flexed

STEP 2 CREATING DISC ACCESS

Needle Insertion

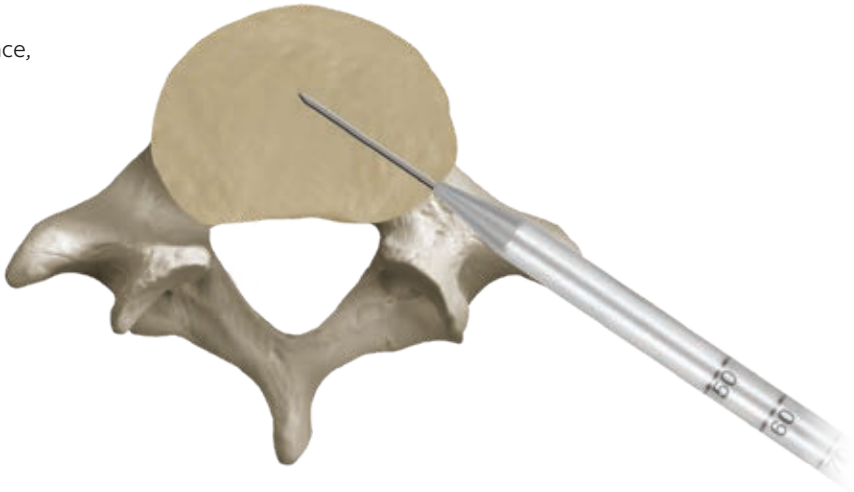
Insert an 18 gauge needle into the disc space from a posterolateral approach, in line with the disc space and adjust accordingly in order to ensure that the intended trajectory is achieved. Remove the stylette from the needle. Insert a K-wire into the disc space and remove the needle.

Dilator Insertion

Once the K-wire is properly positioned in the disc space, slide the **Dilator, 7mm** over the K-wire and advance until it reaches the surface of the disc.

After the dilator has reached the surface of the disc space, proper positioning and trajectory is confirmed using fluoroscopy.

Upon confirmation, the K-wire can then be removed and the dilator can be impacted and docked into the disc space.

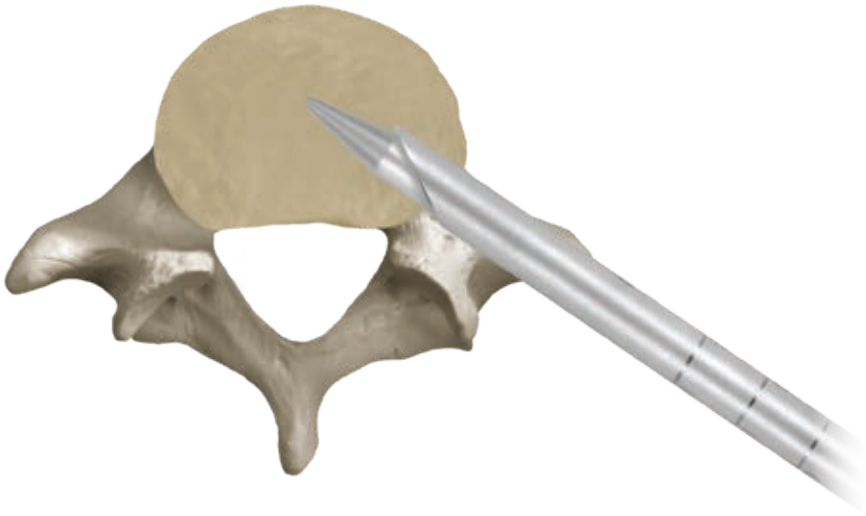


Inserting dilator

Cannula Access

Slide **Cannula, Working (7mm ID)** over the dilator, orienting the beveled opening of the cannula toward the spinal canal. Engage the back of the cannula with the **Sleeve Impactor, Working (7mm ID)**. Impact the cannula to the desired depth in the disc space. Remove the impactor and dilator.

Enhanced visualization can be achieved by repeating the previous steps and inserting a second cannula from the opposite side.



Inserting 7mm cannula

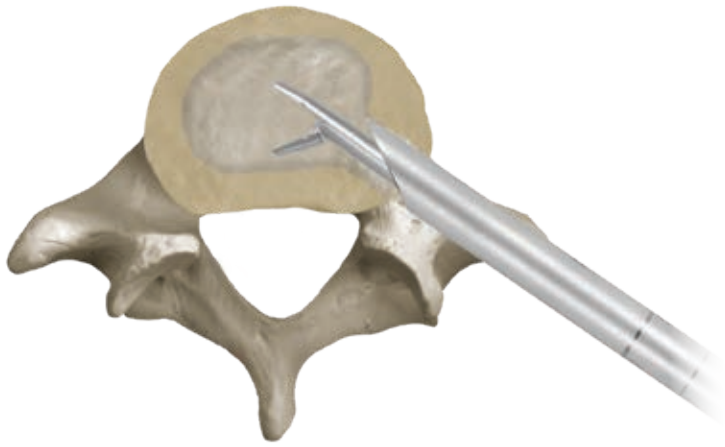
STEP 3 DISCECTOMY/ENDPLATE PREPARATION

After docking the cannula, remove the disc material using the **5mm Rongeurs** and/or **5mm Rongeurs, Double Acting.**

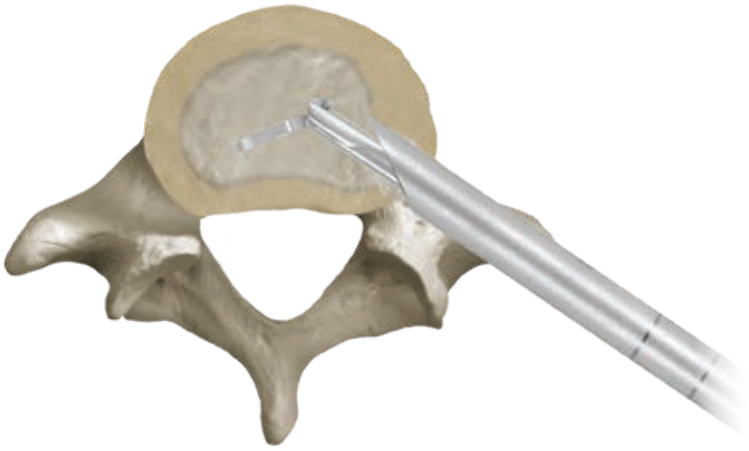
Once a cavity has been created, the **Articulating Curette, Long** or **Articulating Curette, Short** may be used to widen the discectomy by cutting the disc material and scraping the endplates. The rongeurs can then be utilized to remove the loose disc material.

The **Adjustable Scraper, 7–14mm** may be used to remove superficial layers of the cartilaginous endplates. Insert the scraper at its contracted height into the disc space for further disc removal and endplate preparation, dialing up the scraper to larger heights as needed. Use caution while using the scraper to avoid damage to the endplate.

Careful disc removal and endplate preparation maximizes the potential for a successful fusion.



Using 5mm Rongeurs



Using 5mm Articulating Curettes

STEP 4 CANNULA INSERTION

After the disc space has been prepared, insert the **Dilator, 6mm Transition** through the Cannula, Working 7mm ID and into the disc space. Remove the cannula from the disc space. Insert the **Dilator, 8.5mm** over the 6mm dilator, orienting the flats of the dilator to be in line with the endplates. Impact the 8.5mm dilator into the disc space utilizing the Sleeve Impactor, Working (7mm ID.) Remove the 6mm dilator and the impactor.

Insert the **Cannula, 8.5mm** over the 8.5mm dilator, orienting the open side of the beveled opening toward the spinal canal. Impact to the desired depth in the disc space utilizing the **Sleeve Impactor, 8.5mm**. Remove the 8.5mm dilator and impactor.

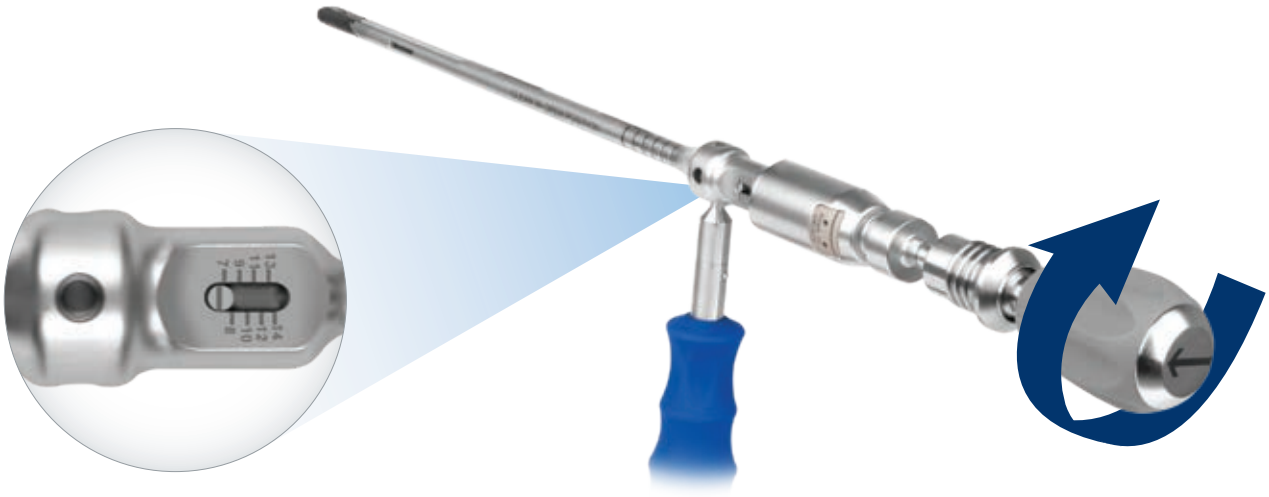
After the discectomy is complete and the cannula has been adequately docked into the disc space, autogenous bone graft should be packed into the disc space. The graft material can be delivered into the disc space by attaching the **Funnel, 8.5mm** to the cannula and using the **Plunger** to help advance the material into the disc space.

STEP 5 DISTRACTION AND IMPLANT SIZING

Insert the **Adjustable Trial 8x26, 7–14mm**, through the cannula, into the disc space at its contracted height. Expand the trial gradually to the desired height by rotating the **Torque-Limiting Palm Handle, 3.0Nm** clockwise. Use caution while expanding the adjustable trial, to avoid excessive distraction and damage to the endplates.

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

Note: Alternatively, the Adjustable Scraper, 7–14mm may be used for distraction and implant sizing. Begin at the smallest size and dial to larger sizes until the desired distraction is achieved. Use caution while using the scraper to avoid damage to the endplates.



Trial height shown on side of adjustable trial

Rotate clockwise to expand trial to desired height

Sizing disc space using adjustable trial

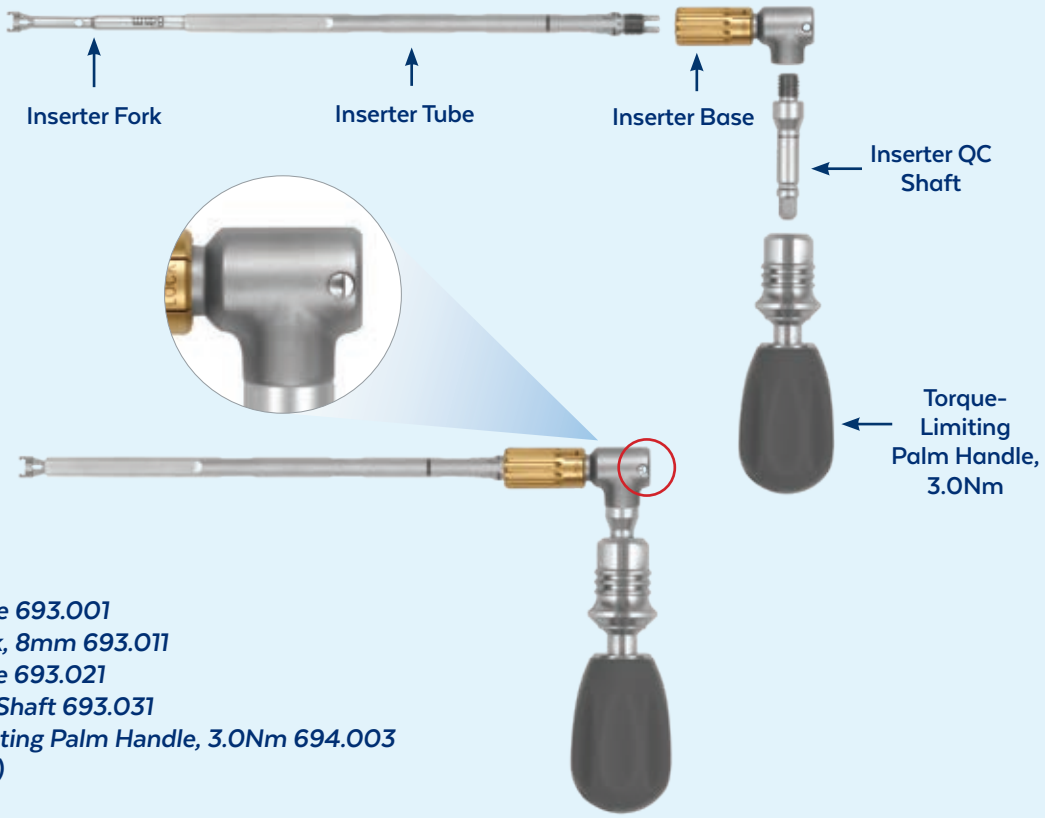
STEP 6 IMPLANT INSERTION

Assemble the inserter as described below:

ASSEMBLING THE IMPLANT INSERTER

Position the instrument as shown below to assemble.

1. Partially thread the **Inserter QC Shaft** into the **Inserter Base.** Do not fully tighten the shaft as it will prevent the **Inserter Fork** from assembling properly in step 5.
2. Slide the **Inserter Tube**, with the flats on the distal end facing upwards, into the Inserter Base until it stops. *Note: The Inserter Tube may also be positioned with the cleaning windows facing upwards.*
3. Thread the gold knob of the Inserter Base counterclockwise until it stops.
4. Select the proper size Inserter Fork that matches the implant to be used.
5. Insert the Inserter Fork into the Inserter Tube until it stops, making sure the tabs of the fork are aligned with the cleaning holes in the tube. The end of the shaft should be visible, halfway through the visualization hole in the Inserter Base (circled in red, below).
6. Tighten the Inserter QC Shaft to lock the fork in the holder.
7. Attach the Torque-Limiting Palm Handle up to the etched line on the Inserter QC Shaft.



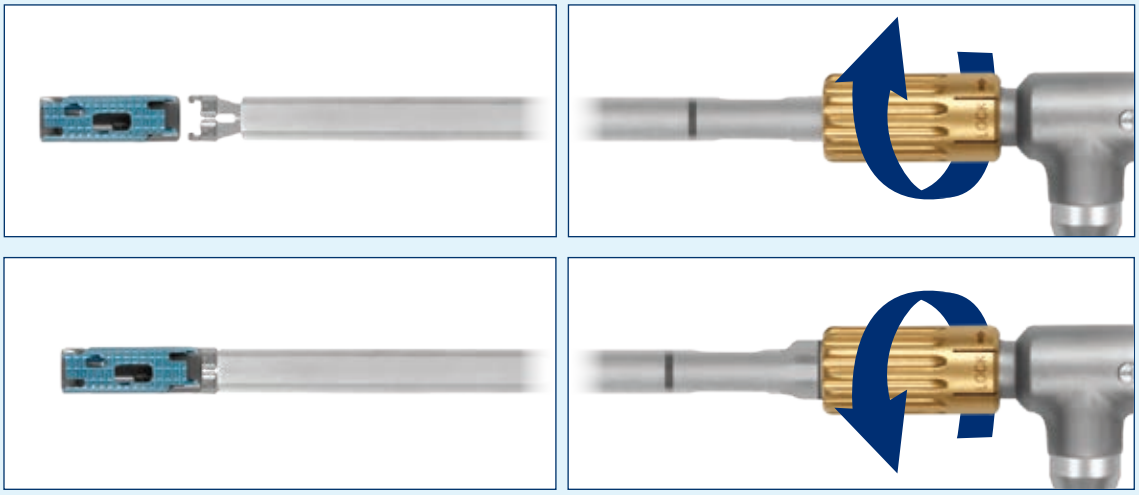
Inserter Base 693.001
Inserter Fork, 8mm 693.011
Inserter Tube 693.021
Inserter QC Shaft 693.031
Torque-Limiting Palm Handle, 3.0Nm 694.003
(Assembled)

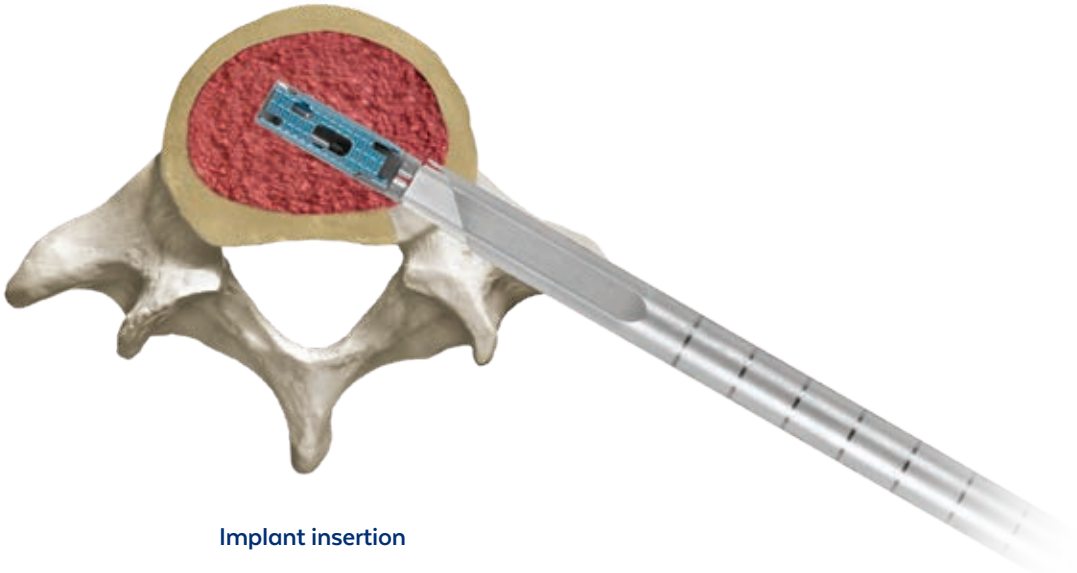
IMPLANT INSERTION (CONT'D)

Select the appropriate sized implant. Using the inserter assembly, insert the implant through the cannula. The implants should be slightly recessed.

IMPLANT ATTACHMENT

With the Inserter Tube fully threaded counterclockwise, place the implant between the tips of the Inserter Fork. Rotate the tube clockwise until the implant is secure.





Implant insertion

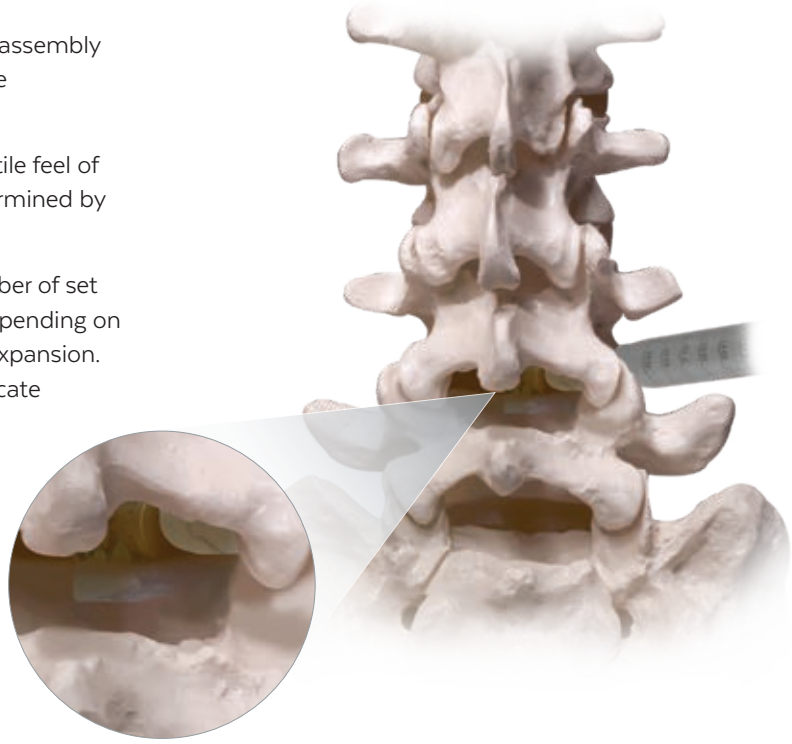
STEP 7 IMPLANT EXPANSION

Insert the **Torque-Limiting Implant Driver** into the inserter assembly and rotate the driver clockwise to expand the implant to the appropriate height.

Expansion of the implant should be determined by the tactile feel of the implant in the disc space as it is expanded. This is determined by gently toggling the implant until the desired fit is achieved.

The overall height can be determined by counting the number of set screw revolutions of the Torque-Limiting Implant Driver. Depending on the implant, approximately 1.75 revolutions equal 1mm of expansion. The arrow at the end of the driver may be used to help indicate revolutions.

Note: If inserting two RISE® implants, count the number of revolutions of the set screw and/or confirm implant heights using fluoroscopy to ensure that both implants are expanded to the same height.



RISE® IntraLIF® Required Revolutions											
Implant Size	**Final Height (mm)***										
	7	8	9	10	11	12	13	14	15	16	17
7-13mm	0	1.75	3.25	5.0	6.75	8.25	10.0	-	-	-	-
7-14mm	0	1.75	3.25	5.0	6.75	8.25	10.0	11.75	-	-	-

**Revolutions rounded to the nearest quarter*

Use the arrow on back end of driver to count revolutions

SUPPLEMENTAL FIXATION

In addition to the described interbody fusion technique, posterior stabilization, such as ZYFUSE® or REVOLVE®, must be used at the appropriate level(s).

REVOLVE® is a posterior stabilization system designed for minimally invasive surgery (MIS), in which virtually every step of the MIS procedure has been enhanced.

The ZYFUSE® Facet Fixation System supports a percutaneous technique requiring only one incision, per treated level. This approach supports a minimally invasive technique.

REVOLVE® Stabilization System

REVOLVE® Locking Technology

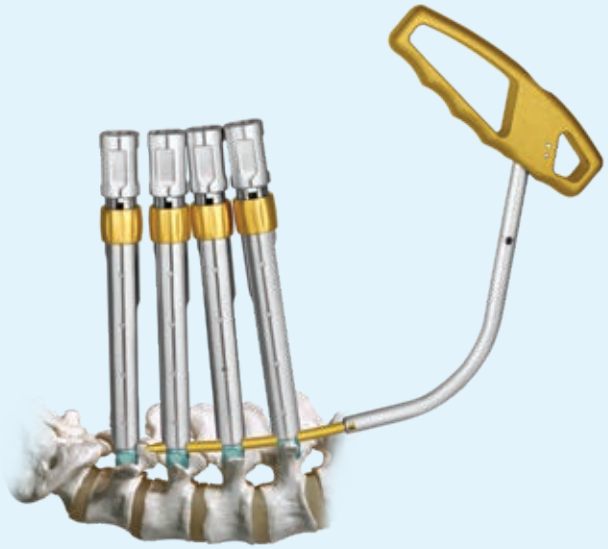
Non-threaded locking caps eliminate cross-threading and challenges with cap placement.

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.



REVOLVE® Stabilization System

Flexible Approach

Versatile system design includes instruments to facilitate a minimally invasive or traditional approach.

Optimized Implant Design

Unparalled design allows compression and intraoperative flexibility to adjust the implant length up to 10mm, without compromising the position of the bone threads.

Consolidated Delivery

Streamlined instrumentation consolidates key procedural steps associated with traditional facet fixation to help promote quicker implant delivery and reduce surgical time.

FINAL CONSTRUCT

Posterior View

Lateral View

RISE® IntraLIF®
IMPLANT SET 993.902

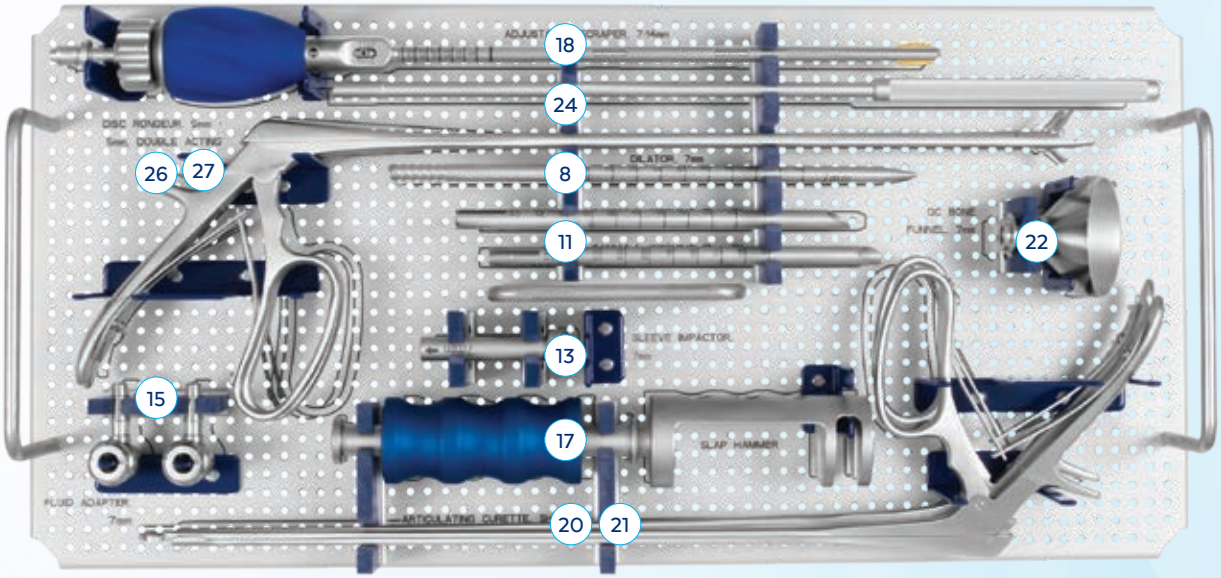
Part No.	Description	Qty
193.001	RISE® Spacer 8x22mm, 7–13mm	2
193.002	RISE® Spacer 8x26mm, 7–14mm	2
193.003	RISE® Spacer 8x30mm, 7–14mm	2
193.004	RISE® Spacer 8x34mm, 7–14mm	2
993.002	RISE® IntraLIF® Implant Module	

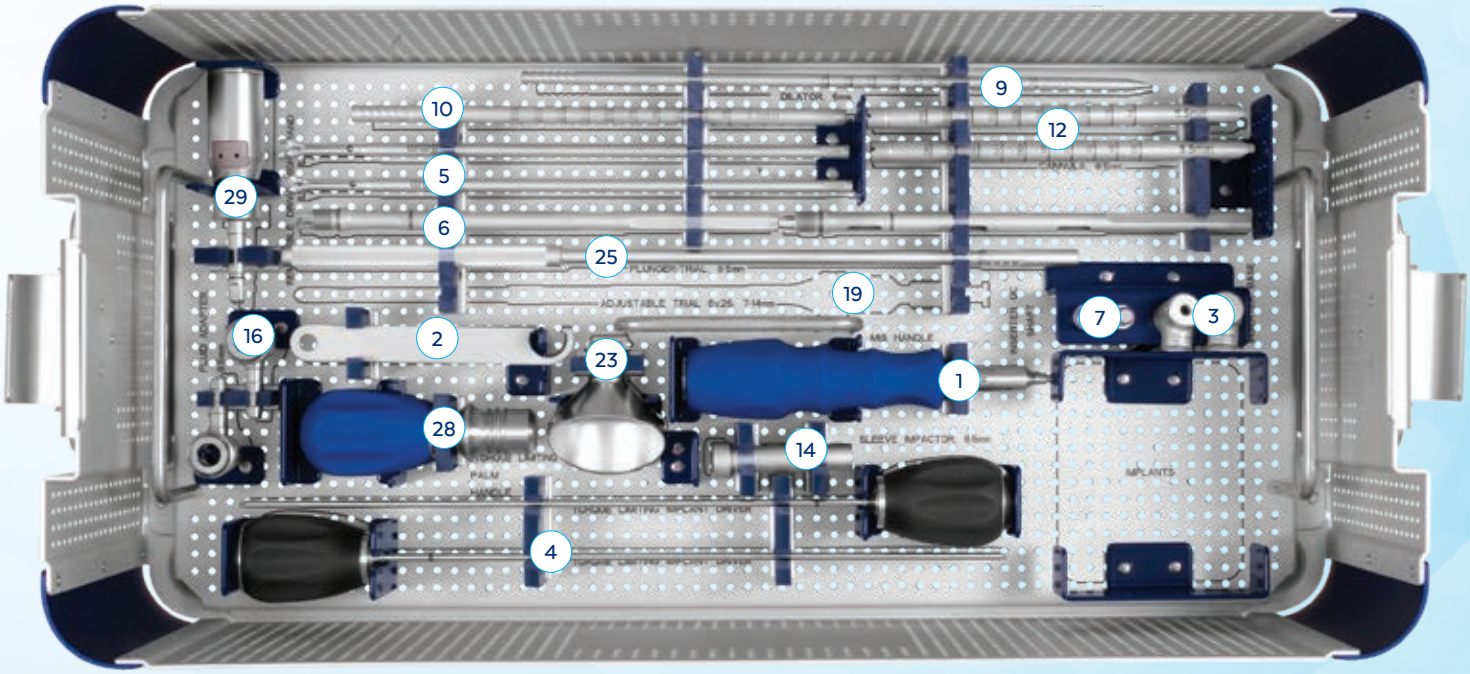
RISE® IntraLIF®
IMPLANT SET 993.902

RISE® IntraLIF®
INSTRUMENT SET 993.901

	Part No.	Description	Qty
1	673.003	MIS Handle	1
2	687.509	Spanner Wrench	1
3	693.001	Inserter Base	2
4	693.002	Torque-Limiting Implant Driver	2
5	693.011	Inserter Fork, 8mm	2
6	693.021	Inserter Tube	2
7	693.031	Inserter QC Shaft	2
8	693.102	Dilator, 7mm	1
9	693.103	Dilator, 6mm Transition	1
10	693.104	Dilator, 8.5mm	1
11	693.112	Cannula, Working (7mm ID)	2
12	693.114	Cannula, 8.5mm	2
13	693.122	Sleeve Impactor, Working (7mm ID)	1
14	693.124	Sleeve Impactor, 8.5mm	1
15	693.132	Fluid Adapter, 7mm	2
16	693.134	Fluid Adapter, 8.5mm	2
17	693.141	Slap Hammer	1
18	693.201	Adjustable Scraper, 7-14mm	1
19	693.211	Adjustable Trial, 8x26, 7-14mm	1
20	693.301	Articulating Curette, SHORT	1
21	693.302	Articulating Curette, LONG	1
22	693.402	Funnel, 7mm	1
23	693.404	Funnel, 8.5mm	1
24	693.412	Plunger	1
25	693.414	Plunger/Trial, 8.5mm	1
26	693.501	5mm Rongeur	1
27	693.502	5mm Rongeur, Double Acting	1
28	694.003	Torque-Limiting Palm Handle, 3.0Nm	1
29	694.218	Removable Drive, Right Hand	1
	993.001	RISE® IntraLIF® Graphic Case	

RISE® IntraLIF®
INSTRUMENT SET 993.901





RISE® IntraLIF®
INSTRUMENT SET 993.919

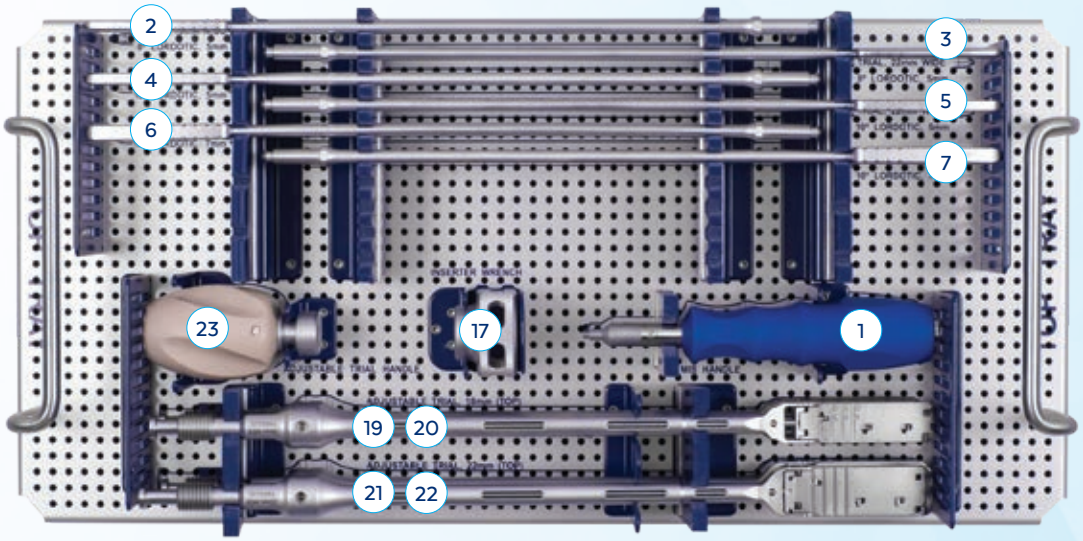
	Part No.	Description	Qty
1	673.003	MIS Handle	2
2	675.006	TransContinental® LLIF Trial, 0, 5mm	1
3	675.043	TransContinental® 22mm Trial, Parallel, 5mm	1
4	675.065	TransContinental® 18mm Trial, 10 Lordotic, 5mm	1
5	675.067	TransContinental® 18mm Trial, 10 Lordotic, 7mm	1
6	675.365	TransContinental® 22mm 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® IntraLIF® Instruments Graphic Case	

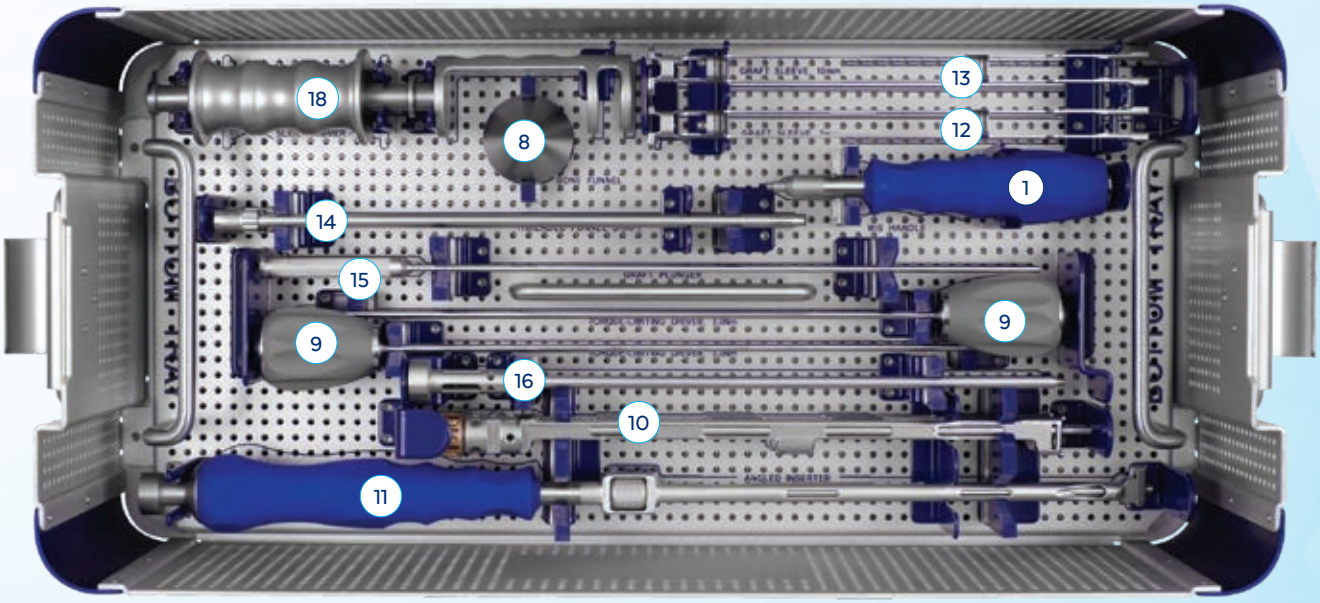
Additionally Available

19	694.110	Adjustable Trial, 18mm
20	694.201	Adjustable Trial, 22mm
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® IntraLIF®
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	132ºC (270ºF)	4 minutes	30 minutes
Steam	Pre-vacuum	134ºC (273ºF)	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

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