RISE® TLIF

Expandable Lumbar Interbody Spacer

SURGICAL TECHNIQUE GUIDE

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SURGICAL TECHNIQUE GUIDE

RISE® TLIF

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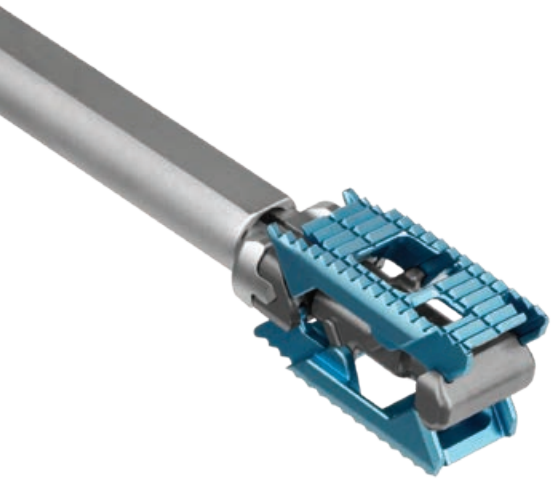
Expandable Lumbar Interbody Spacer



The RISE® Transforaminal Lumbar Interbody Fusion (TLIF) spacer is an innovative expandable lumbar fusion device that represents the future of minimally invasive surgery by optimizing endplate-to-endplate fit and minimizing insertion force.

Insertion of RISE® TLIF is performed at a contracted height to help reduce the amount of nerve root retraction and musculoskeletal resection required.

The continuous expansion of RISE® TLIF is designed to restore disc height, while controlled distraction helps to properly tension the annulus and surrounding ligaments.

Contracted	Partially Expanded	Fully Expanded
		

Minimal Impaction

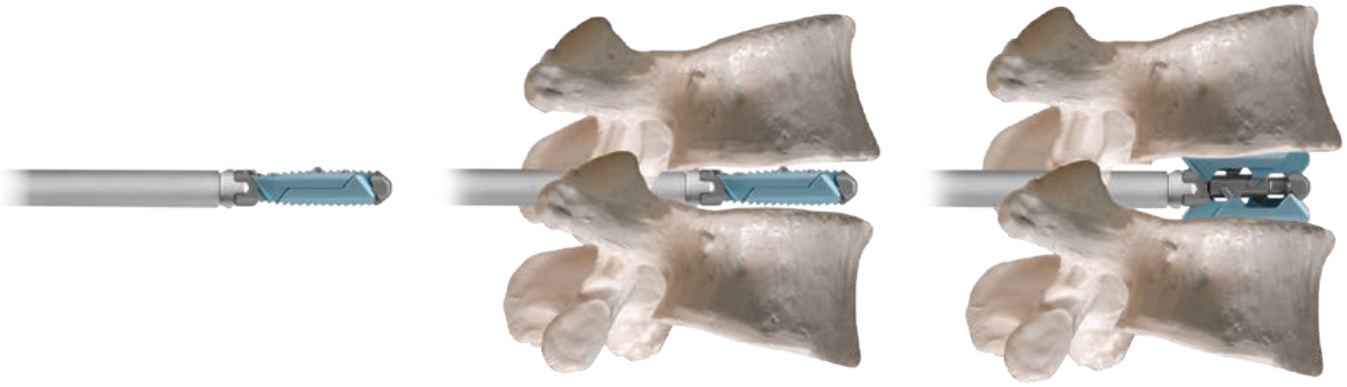
Contracted insertion height eases insertion into the disc space, which may help reduce tissue disruption and the amount of nerve root retraction required.

Controlled Disc Height Restoration

Controlled continuous expansion and distraction is designed to restore disc height and reduce the risk of over-distraction.

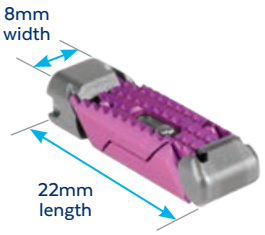
Optimized Fit

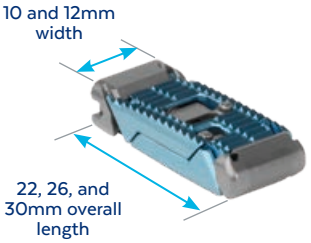
When expanded in the disc space, the implant optimizes endplate-to-endplate fit.

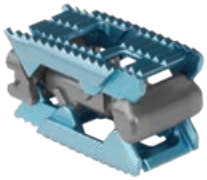


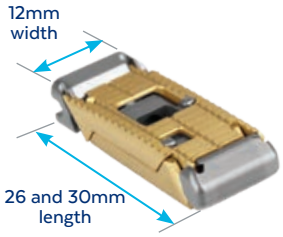
IMPLANT OVERVIEW

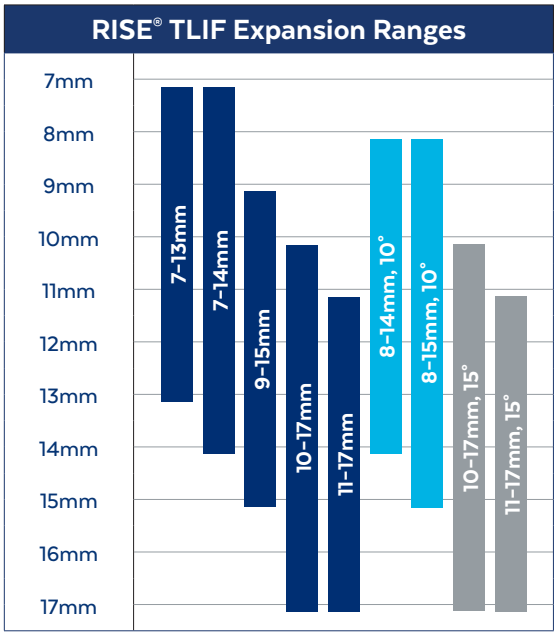
- Contracted insertion height helps minimize impaction force
- Controlled continuous expansion is designed to restore disc height
- Axial graft opening to help promote fusion
- Automatic locking for simple operation
- Convex profile designed to fit anatomy
- Multiple footprint options:
  - 8mm: 8x22mm
  - 10mm: 10x22, 10x26, and 10x30mm
  - 12mm: 12x26 and 12x30mm
- Height expansion options from 7–17mm
- Up to 7mm of expansion
- 4°, 10°, and 15° lordotic options
- One instrument for both insertion and expansion
- Slim design for minimally invasive surgery applications











INSTRUMENT OVERVIEW

SIZERS/SHAVERS

	Height	Part No.
	7mm	668.507
	8mm	668.508
	9mm	668.509
	10mm	668.510
	11mm	668.511
	12mm	668.512
	13mm	668.513
	14mm	668.514
	15mm	668.515
	16mm	668.516
	17mm	668.517

T-Handle 601.800

TRIALING INSTRUMENTS

MIS Handle 673.003

Adjustable Trial 10x26mm, 7–14mm 693.212

Adjustable Trial 10x26mm, 8–15mm, 15° 693.215

Torque-Limiting Palm Handle 694.002

Removable Drive, Right Hand 694.218

MIS Handle 673.003
Adjustable Trial 10x26mm, 7–14mm 693.212
Torque-Limiting Palm Handle 694.002
Removable Drive, Right Hand 694.218
(Assembled)

IMPLANT INSERTER COMPONENTS

Inserter Base 693.001

Torque-Limiting Implant Driver 693.002

Inserter Fork 8mm 693.011

Inserter Fork 10mm 693.012

Inserter Fork 12mm 693.013

Inserter Tube 693.021

Inserter QC Shaft 693.031

Inserter Base 693.001
Torque-Limiting Implant Driver 693.002
Inserter Fork 10mm 693.012
Inserter Tube 693.021
Inserter QC Shaft 693.031
Torque-Limiting Palm Handle 694.002
(Assembled)

OTHER INSTRUMENTS

Spanner Wrench 687.509

Slap Hammer 693.141

SURGICAL TECHNIQUE

RISE®

Please refer to the package insert, also printed at the back of this manual, for complete description, indications, contraindications, precautions, and warnings.

Minimally Invasive Surgery

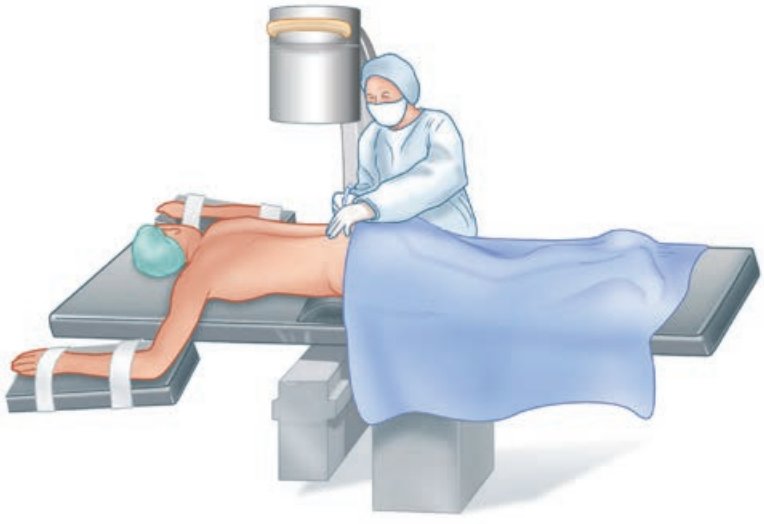
Advances in minimally invasive surgery (MIS) are intended to lessen the disruption to the patient's anatomic structures. Without compromising surgical goals, MIS for interbody fusion has been shown to[1, 2]:

- Reduce soft tissue disruption
- Reduce blood loss
- Reduce scarring
- Reduce postoperative pain
- Shorten hospital stay
- Shorten recovery time

STEP 1 TRANSFORAMINAL ACCESS AND APPROACH

Approach

The patient is placed under anesthesia and positioned prone. Lateral C-arm fluoroscopy or other radiographic methods may be utilized throughout the surgery to ensure correct implant placement. In addition to the described interbody fusion technique, posterior stabilization, such CREO MIS®, must be used at the appropriate level(s).



The incision can be made 4 to 4.5cm lateral to the midline and the trajectory should be in line with the disc. Finger dissect between the multifidus and longissimus muscles until the facet joint is palpable.

1. Peng CW, Yue WM, et al. Clinical and Radiological Outcomes of Minimally Invasive Versus Open Transforaminal Lumbar Interbody Fusion. *SPINE* 34: 1385-1389, 2009.
2. Kim KT, Lee SH, et al. The Quantitative Analysis of Tissue Injury Markers After Mini-Open Lumbar Fusion. *SPINE* 6: 712-716, 2006.

STEP 2 RETRACTION

MARS™3V dilators may be used to retract soft tissue and to surround the facet. Keep downward pressure on the dilators and rotate as needed when approaching the facet. With the initial dilator in place, a series of cannulas are progressively passed over the initial dilator.

Ensure that the Retractor 3 Blade Frame is in the fully closed position and the blades are securely attached to the frame. Slide the retractor over the cannulas and apply gentle downward pressure on the frame.

Before removing the cannulas, articulate all three blades to one full rotation of the silver knobs. Articulating the blades in this manner will help prevent tissue creep as the cannulas are removed.

Once the retractor has been securely positioned and the Articulating Arm Assembly tightened to stabilize the retractor, remove the cannulas.

Use AP fluoroscopy to verify positioning.

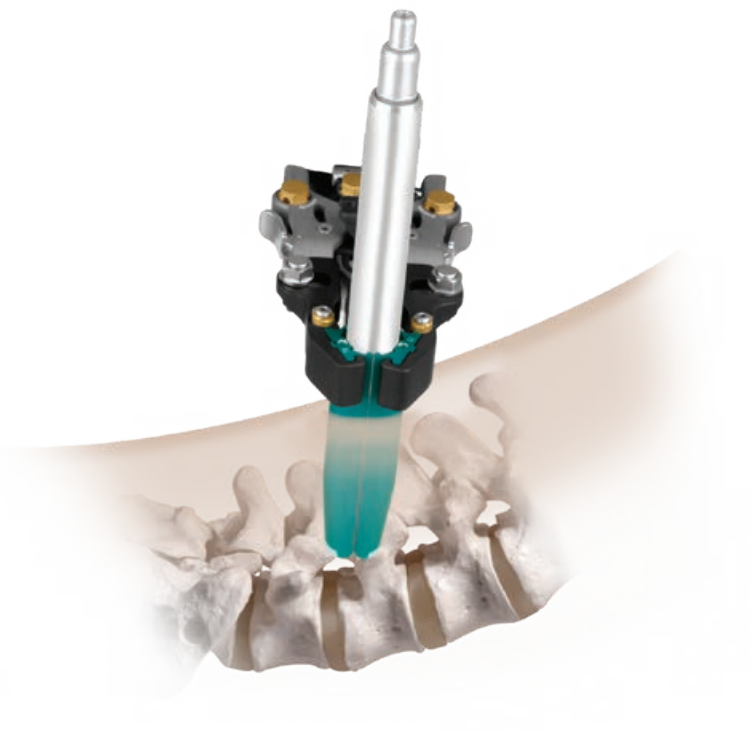


TABLE ARM ATTACHMENT

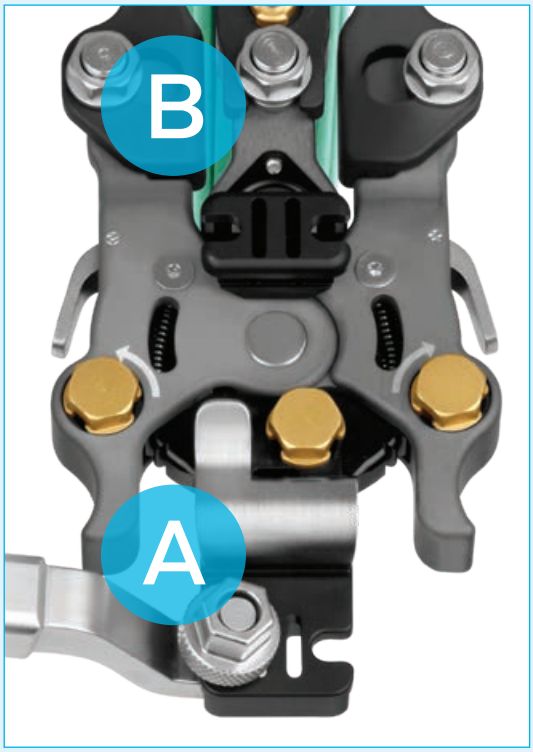
In order to use the MARS™3V Retractor, the Table Arm Attachment must be secured. Attach the Table Clamp onto the bed rail attachment. Insert the Articulating Arm Assembly into the Table Clamp and secure. The opposite end of the Articulating Arm Assembly is then attached to the Retractor 3 Blade Frame.

There are two options for attachment positions on the retractor, as shown at right.

Attaching the arm to point A maintains retractor position relative to the posterior blade position and translates the cephalad and caudad blades laterally when the retractor is opened.

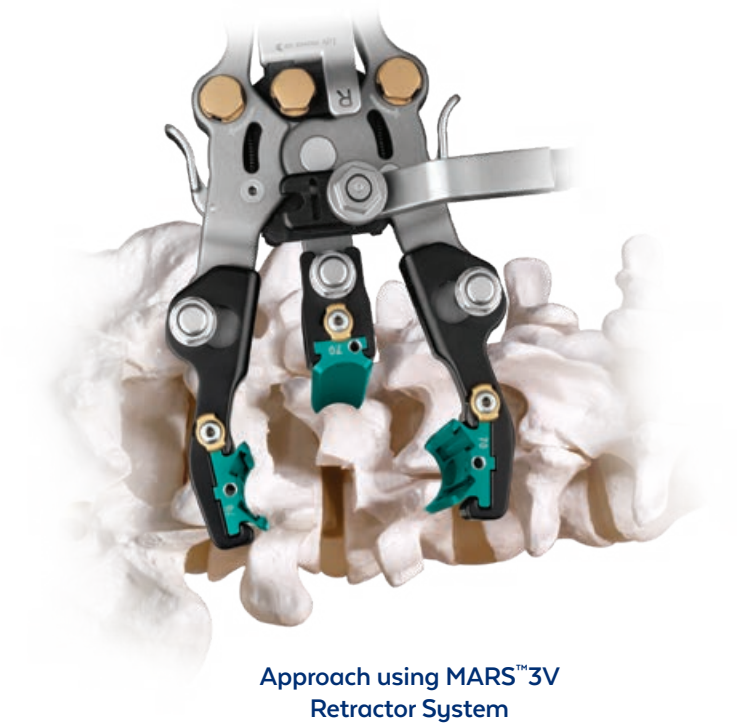
Attaching the arm to point B maintains the retractor position relative to the cephalad and caudad blade position, and translates the posterior blade medially.

Refer to the ***LLIF Surgical Technique Guide (GMTGD32)*** for additional information.

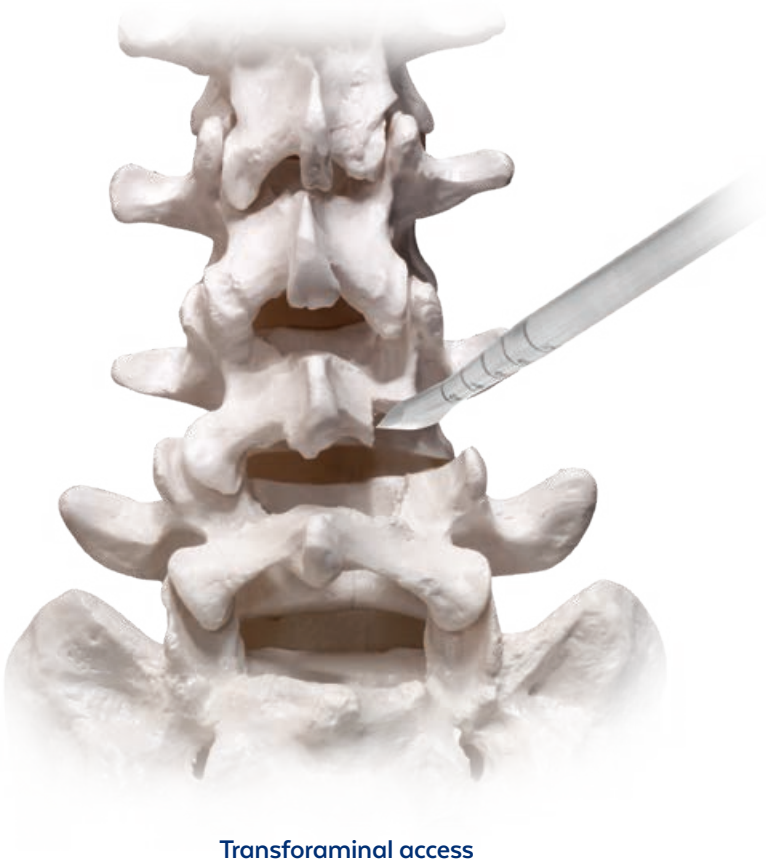


STEP 3 CREATING TRANSFORAMINAL ACCESS

Use an osteotome* to remove the inferior facet of the cephalad vertebrae and the superior facet of the caudal vertebrae at the appropriate level(s). This creates a working transforaminal access window to the disc.



Approach using MARS™3V Retractor System

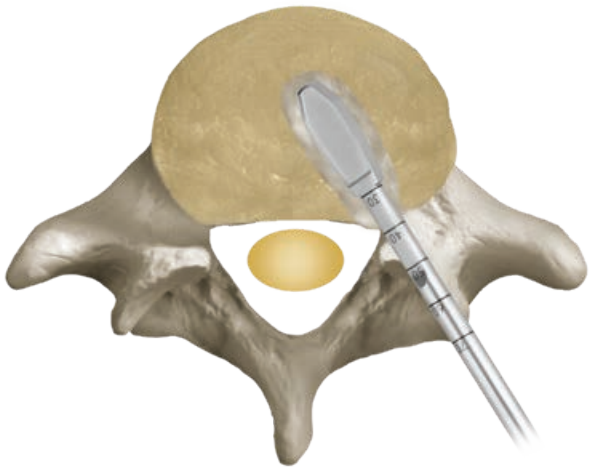


Transforaminal access

**Available in the Posterior Disc Prep Instruments Set II*

STEP 4 DISCECTOMY/ENDPLATE PREPARATION

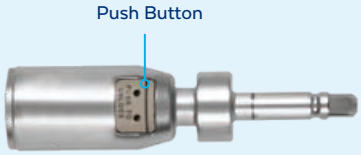
After creating an adequate annular window, remove disc material using rongeurs, rasps, curettes,* and other suitable preparation instruments. **Shavers** may be used to remove superficial layers of the cartilaginous endplates. Insert the smallest shaver into the disc space for further disc removal and endplate preparation, moving to larger shavers as needed. Use caution while using the shavers to avoid damage to the endplate. Careful disc removal and endplate preparation maximizes the potential for a successful fusion.



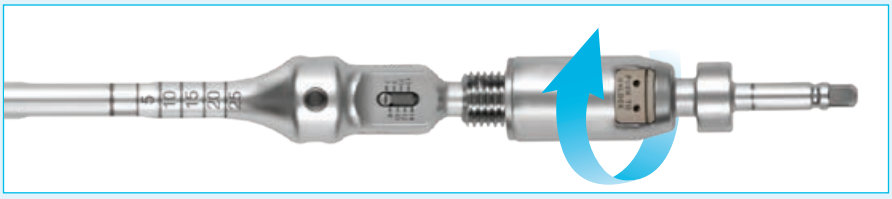
STEP 5 DISTRACTION AND IMPLANT SIZING

ASSEMBLING THE ADJUSTABLE TRIAL ASSEMBLY

1. Ensure that the Removable Drive, Right Hand is in the unlocked position by verifying that the tan push button is protruding beyond the cylinder.



2. Hold the shaft of the trial while turning the removable drive onto the threaded end until it stops and turn back 1/8th of a rotation to reduce tension. To lock, push the protruding push button on the removable drive until it is flush with the cylinder.

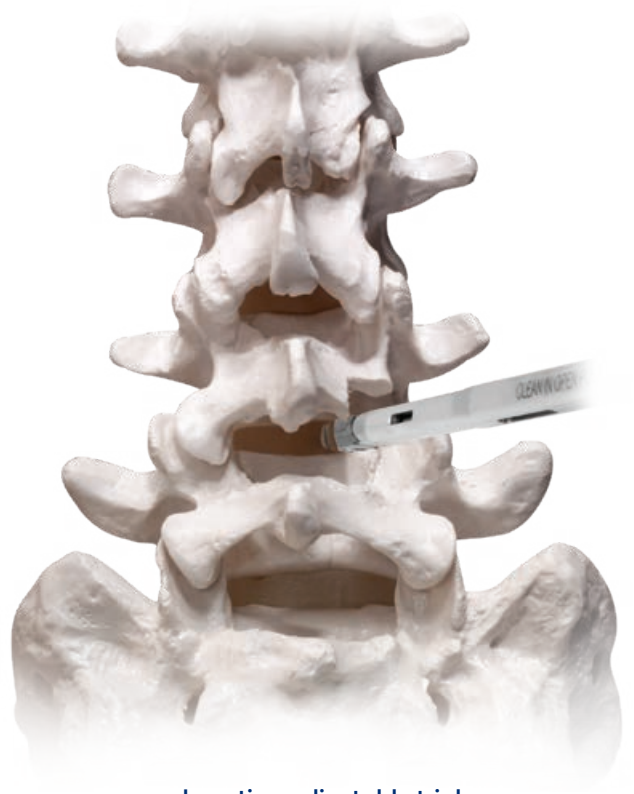


3. Thread the **MIS Handle** into the threaded hole, so the handle can be placed relative to the spine.

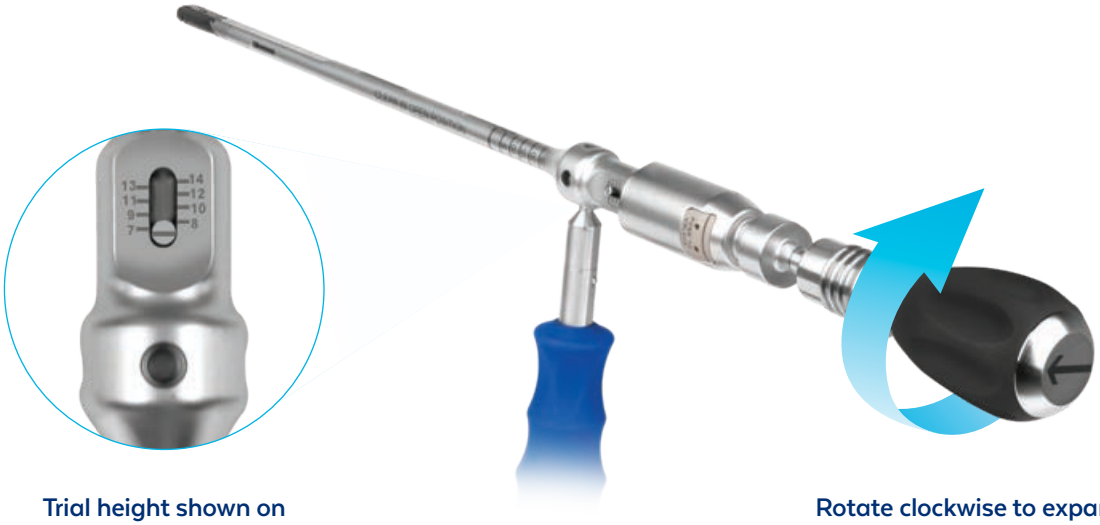
4. Attach the **Torque-Limiting Palm Handle**.

**Available in the Posterior Disc Prep Instruments Set I and II*

Insert the Adjustable Trial Assembly into the disc space at its contracted height. Expand the assembly gradually to the desired height by rotating the Torque-Limiting Palm Handle clockwise. Use caution while expanding to avoid excessive distraction and endplate damage.



Inserting adjustable trial

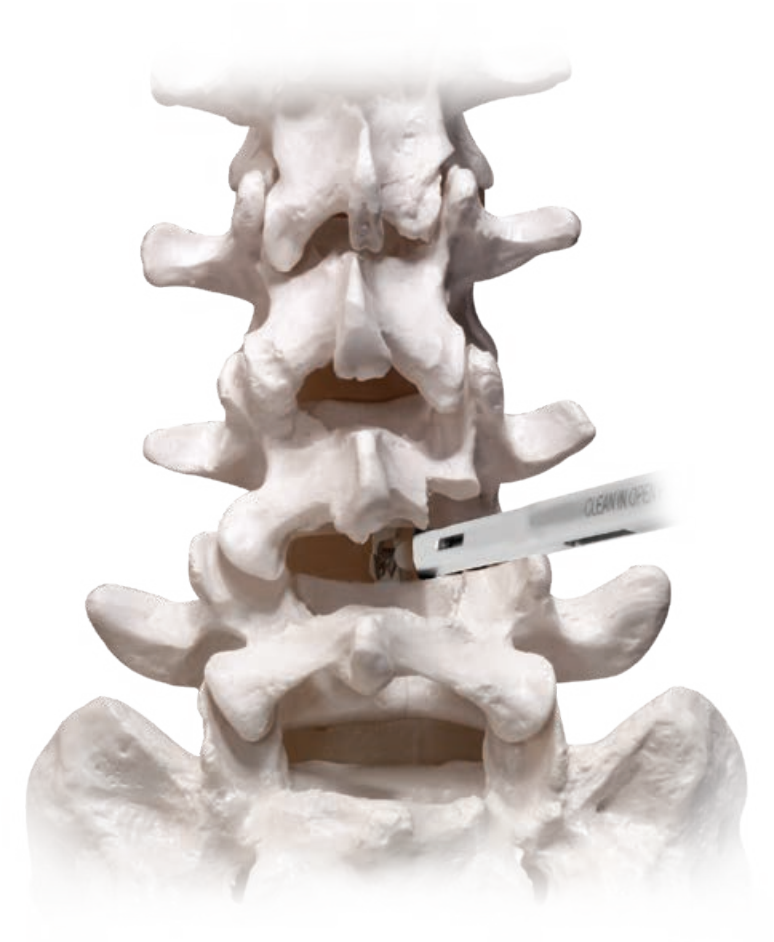


Trial height shown on side of trial

Rotate clockwise to expand trial to desired height

DISTRACTION AND IMPLANT SIZING (CONT'D)

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.



Implant size confirmed

Note: Alternatively, the shaver/sizers may be used for distraction. Begin with the smallest shaver and use larger sizes until the desired distraction is achieved. Use caution while using shavers to avoid damage to the endplate.

STEP 6 IMPLANT INSERTION

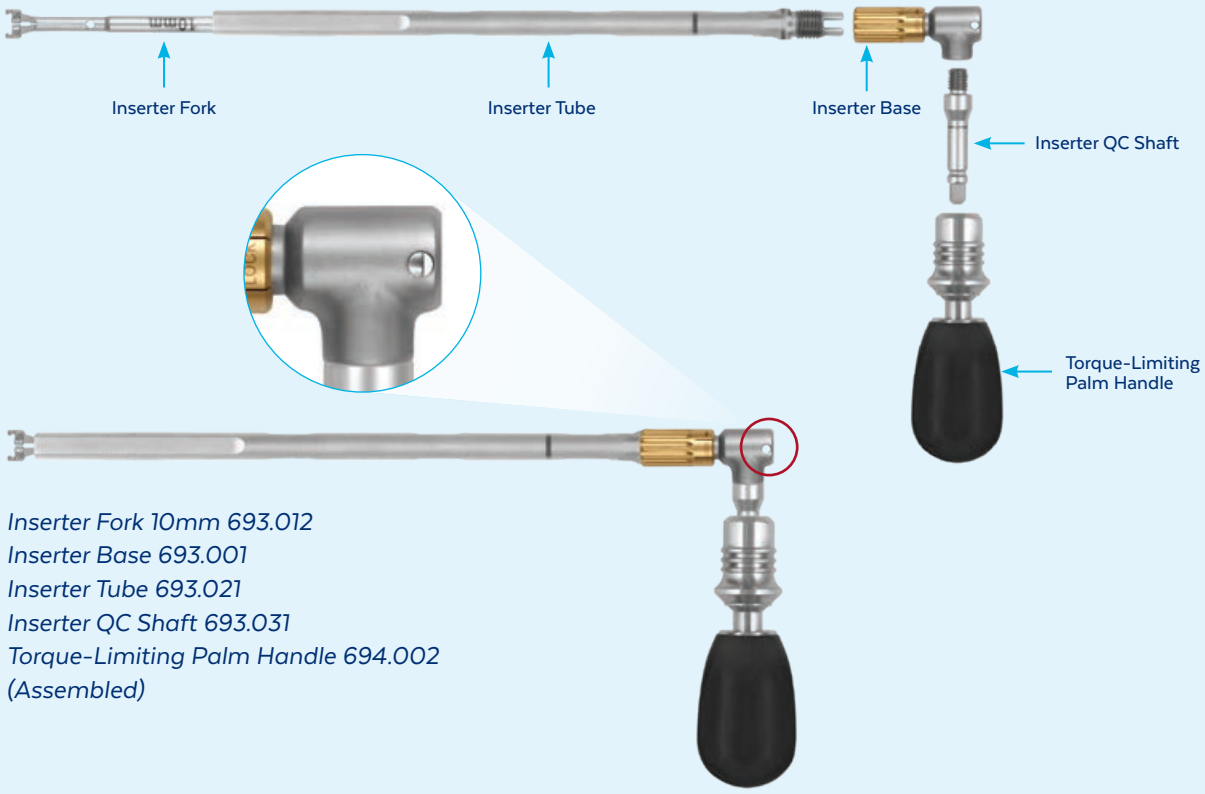
Assemble the inserter as described below.

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, aligning up to the etched line on the Inserter QC Shaft.

Note: Do not torque out the Torque-Limiting Palm Handle during implant inserter assembly.



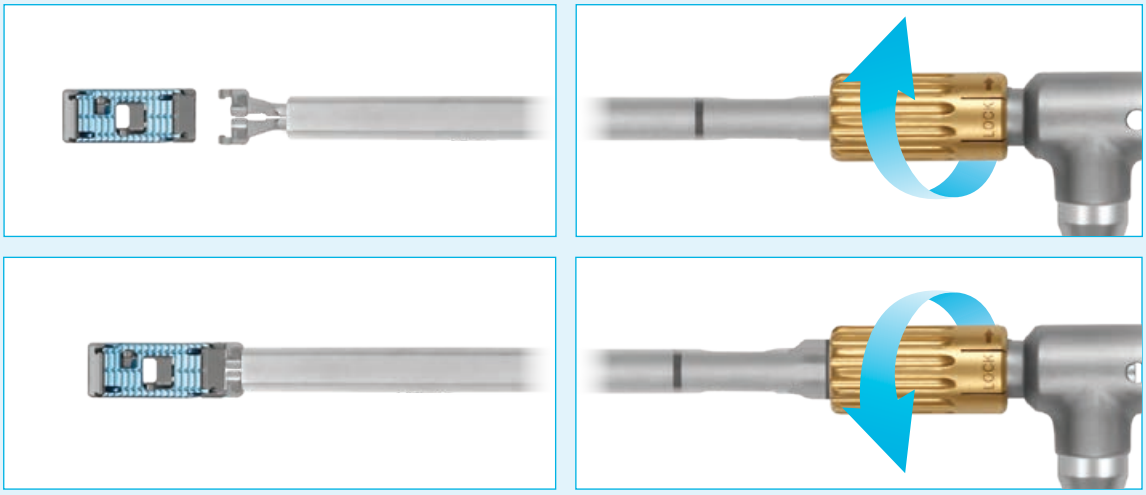
Inserter Fork 10mm 693.012
Inserter Base 693.001
Inserter Tube 693.021
Inserter QC Shaft 693.031
Torque-Limiting Palm Handle 694.002
(Assembled)

IMPLANT INSERTION (CONT'D)

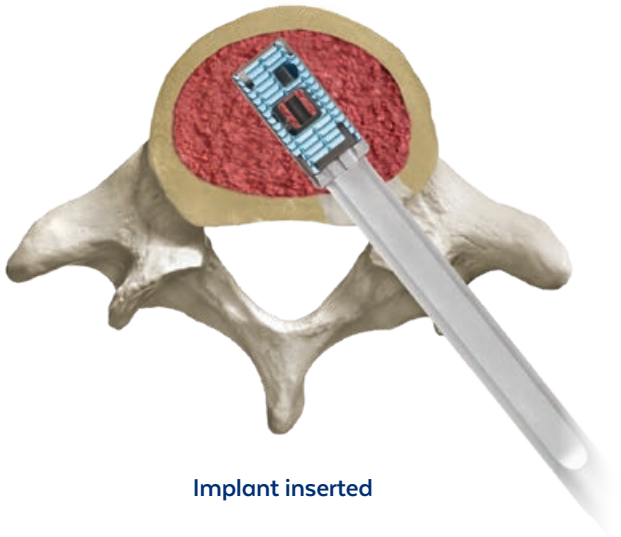
Select an appropriate sized implant and pack autogenous bone graft material into the graft chamber.

IMPLANT ATTACHMENT

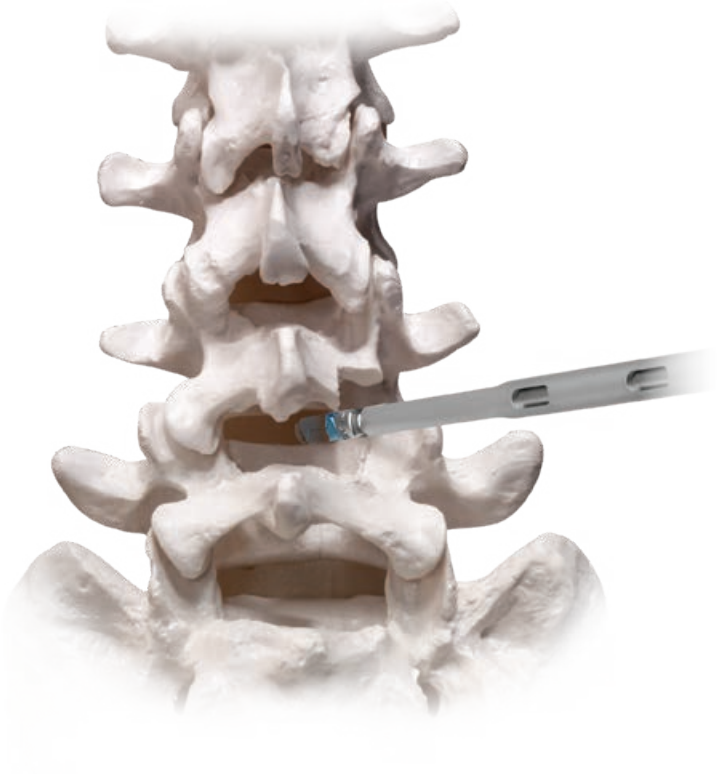
With the Inserter Tube threaded counterclockwise, attach the implant by placing it between the tips of the Inserter Fork. Rotate the tube clockwise until the implant is secure.



Insert the implant into the disc space using the Implant Inserter Assembly.

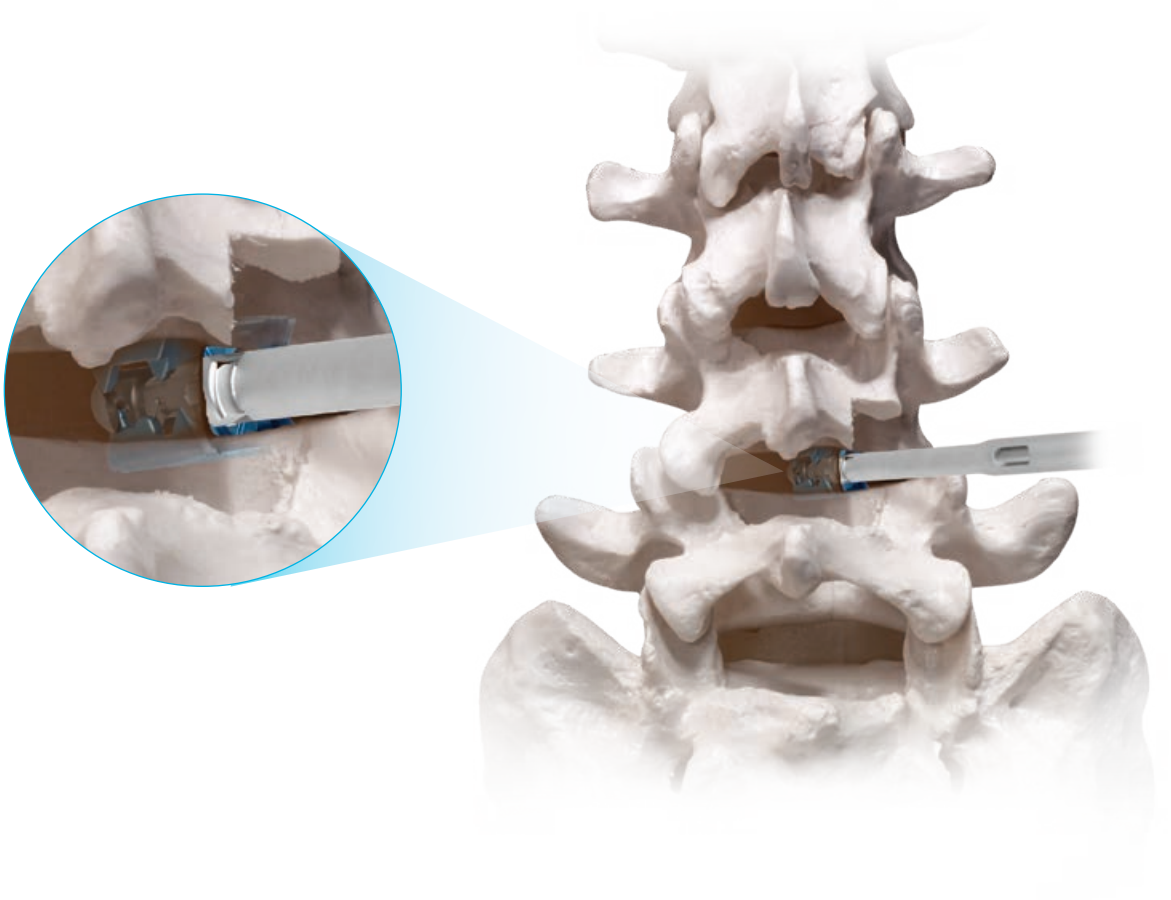


Implant inserted



STEP 7 IMPLANT EXPANSION

Insert the **Torque-Limiting Implant Driver** through the Implant Inserter Assembly, engaging the drive screw in the implant. 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 drive 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 drive screw and/or confirm implant heights using fluoroscopy to ensure that both implants are expanded to the same height.

Use arrow on back end of driver to count revolutions

IMPLANT EXPANSION (CONT'D)

The Torque-Limiting Implant Driver is designed to allow the user to identify when either of the following conditions has occurred:

- The implant has reached its maximum height expansion

OR

- The implant is exerting the maximum allowable output of distraction force on the vertebral endplates.

Use caution while expanding the implant to avoid excessive distraction and endplate damage.

The maximum expansion of an implant can be verified by tracking the revolutions of the driver and referencing the expansion range chart printed on the implant module.

Drive Screw Revolutions Required											
Expansion Ranges	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	-	-	-
8–14mm	-	0	1.75	3.25	5.0	6.75	8.25	10.0	-	-	-
8–15mm	-	0	1.75	3.25	5.0	6.75	8.25	10.0	11.75	-	-
9–15mm	-	-	0	1.75	3.25	5.0	6.75	8.25	10.0	-	-
10–17mm	-	-	-	0	1.75	3.25	5.0	6.75	8.25	10.0	11.75
11–17mm	-	-	-	-	0	1.75	3.25	5.0	6.75	8.25	10.0

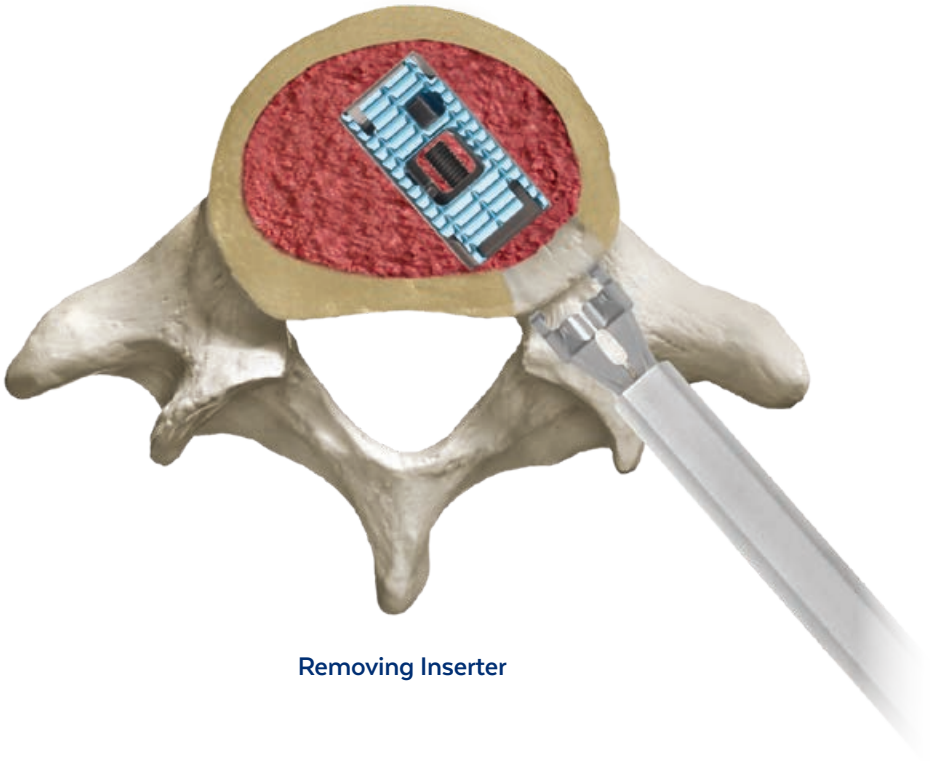
RISE® Inserter

*Revolutions rounded to the nearest quarter

STEP 8 FINAL POSITIONING

Using fluoroscopy, verify implant position before disengaging. Once the desired position is achieved, disengage the inserter from the implant by first removing the Torque-Limiting Implant Driver. Then rotate the gold knob on the Inserter Base counterclockwise until disengaged. The **Spanner Wrench** can be used to loosen the gold knob if necessary.

If repositioning is needed, the implant must be fully contracted before repositioning.



Removing Inserter

OPTIONAL: IMPLANT REMOVAL

For removal, the implant height may be reduced by inserting the Torque-Limiting Implant Driver into the back of the implant and rotating counterclockwise. Forceps or other manual surgical instruments may then be used to grasp and extract the implant. Alternatively, the implant may be rotated 90° and extracted using forceps or other manual surgical instruments.

SUPPLEMENTAL FIXATION

RISE® implants are intended for use with supplemental fixation, such as posterior stabilization. CREO MIS® may be used for posterior stabilization.

CREO MIS® STABILIZATION SYSTEM

Minimized Soft Tissue Disruption

Extended screw heads provide a small outer diameter to help reduce soft tissue disruption and screw sleeve interference.

Powerful MIS Correction

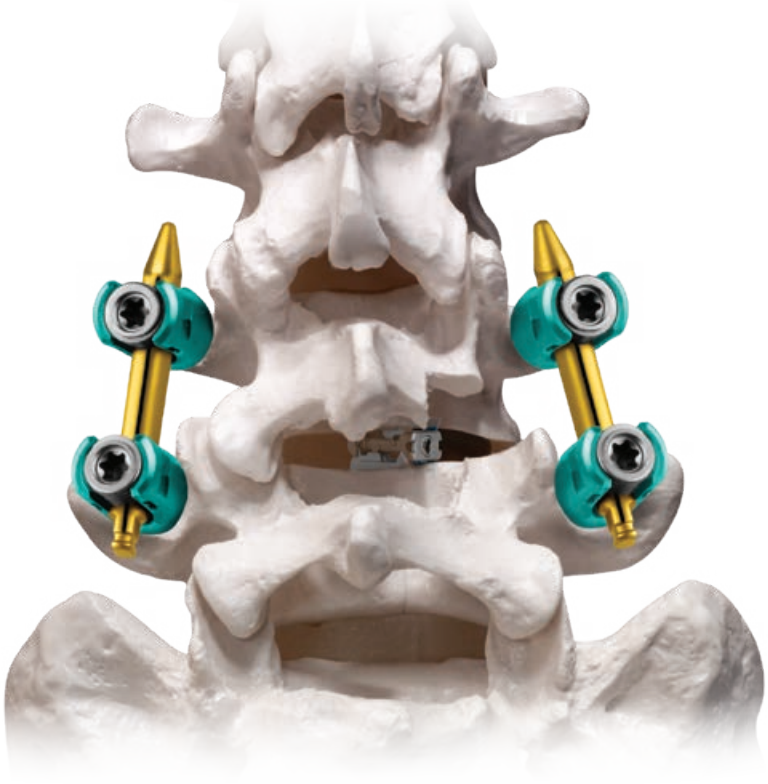
Deformity Adapters rigidly attach to the extended screw head and allow for screw manipulation and deformity correction.*

Integrated Rod Reduction

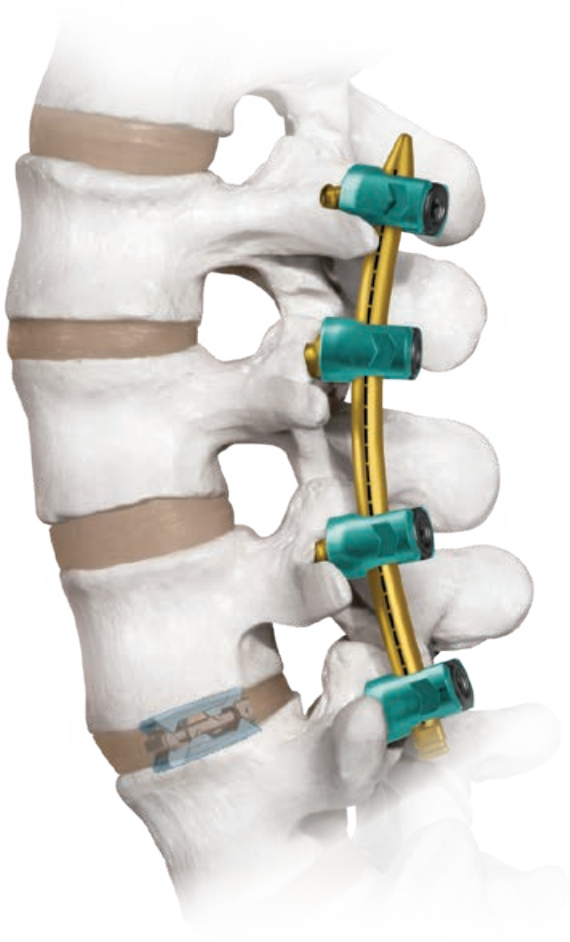
Ensures proper thread alignment while capturing, reducing, and locking the rod in one simplified step.

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

FINAL CONSTRUCTS



Posterior view



Lateral view

RISE®
IMPLANT SETS

RISE® 8mm Implant Set 993.904

Part No.	Description	Qty
193.001	RISE® Spacer 8x22mm, 7–13mm	2
193.051	RISE® Spacer 8x22mm, 9–15mm	2
193.011	RISE® Spacer 8x22mm, 11–17mm	2
193.021	RISE® Spacer 8x22mm, 8–14mm, 10°	2
193.041	RISE® Spacer 8x22mm, 11–17mm, 15°	2
993.004	RISE® 8mm Implant Module	

RISE® 10mm Implant Set 993.905

Part No.	Description	Qty
193.101	RISE® Spacer 10x22mm, 7–13mm	2
193.102	RISE® Spacer 10x26mm, 7–14mm	2
193.103	RISE® Spacer 10x30mm, 7–14mm	2
193.151	RISE® Spacer 10x22mm, 9–15mm	2
193.111	RISE® Spacer 10x22mm, 11–17mm	2
193.112	RISE® Spacer 10x26mm, 10–17mm	2
193.113	RISE® Spacer 10x30mm, 10–17mm	2
193.121	RISE® Spacer 10x22mm, 8–14mm, 10°	2
193.122	RISE® Spacer 10x26mm, 8–15mm, 10°	2
193.123	RISE® Spacer 10x30mm, 8–15mm, 10°	2
193.141	RISE® Spacer 10x22mm, 11–17mm, 15°	2
193.142	RISE® Spacer 10x26mm, 10–17mm, 15°	2
193.143	RISE® Spacer 10x30mm, 10–17mm, 15°	2
993.005	RISE® 10mm Implant Module	
993.907	RISE® Implant Graphic Case	

RISE® 12mm Implant Set 993.906

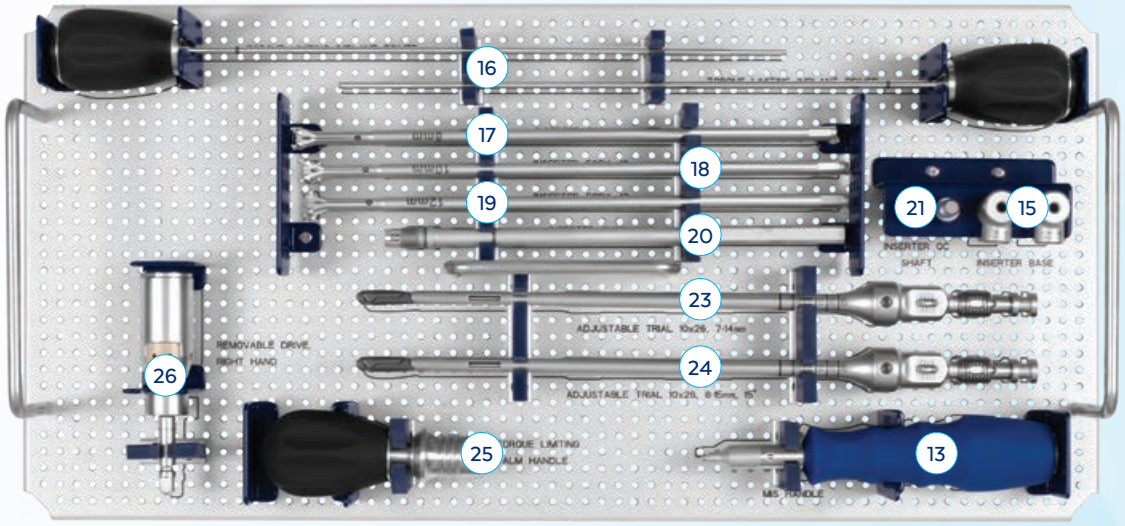
Part No.	Description	Qty
193.202	RISE® Spacer 12x26mm, 7–14mm	2
193.203	RISE® Spacer 12x30mm, 7–14mm	2
193.212	RISE® Spacer 12x26mm, 10–17mm	2
193.213	RISE® Spacer 12x30mm, 10–17mm	2
193.222	RISE® Spacer 12x26mm, 8–15mm, 10°	2
193.223	RISE® Spacer 12x30mm, 8–15mm, 10°	2
193.242	RISE® Spacer 12x26mm, 10–17mm, 15°	2
193.243	RISE® Spacer 12x30mm, 10–17mm, 15°	2
993.006	RISE® 12mm Implant Module	

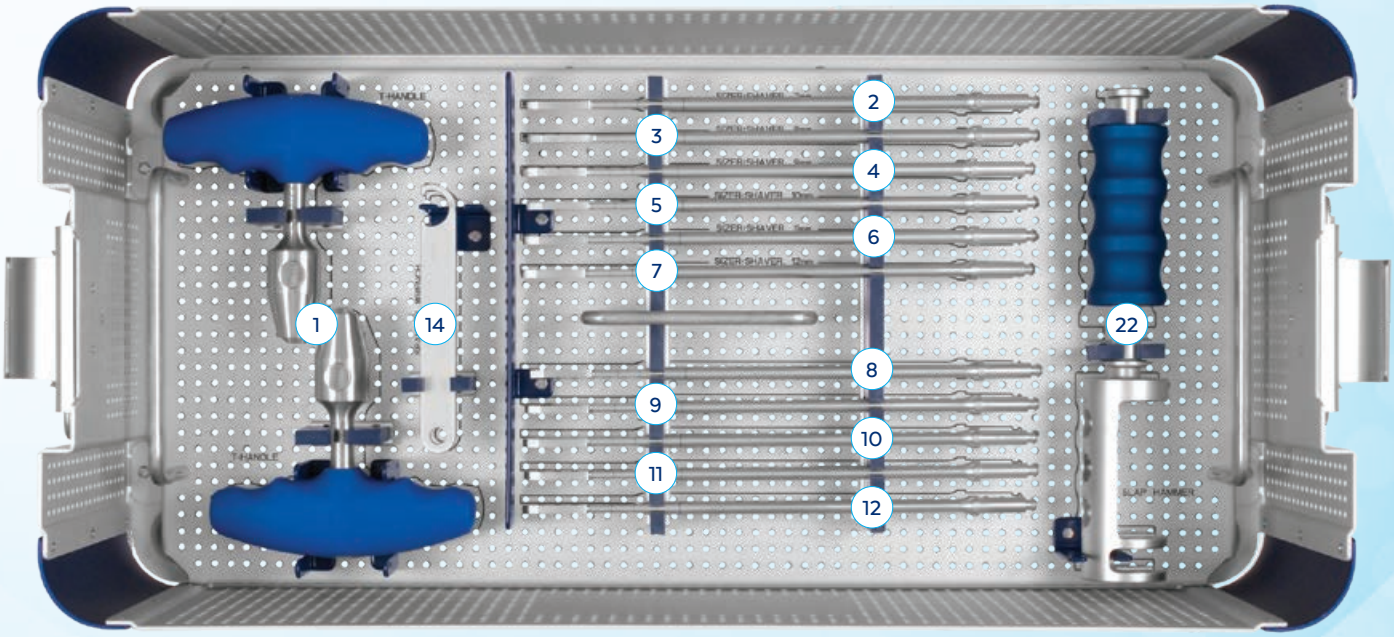
RISE®
IMPLANT SETS

RISE®
INSTRUMENT SET 993.903

		Instrument	Qty
1	601.800	T-Handle	2
2	668.507	Sizer/Shaver, 7mm	1
3	668.508	Sizer/Shaver, 8mm	1
4	668.509	Sizer/Shaver, 9mm	1
5	668.510	Sizer/Shaver, 10mm	1
6	668.511	Sizer/Shaver, 11mm	1
7	668.512	Sizer/Shaver, 12mm	1
8	668.513	Sizer/Shaver, 13mm	1
9	668.514	Sizer/Shaver, 14mm	1
10	668.515	Sizer/Shaver, 15mm	1
11	668.516	Sizer/Shaver, 16mm	1
12	668.517	Sizer/Shaver, 17mm	1
13	673.003	MIS Handle	1
14	687.509	Spanner Wrench	1
15	693.001	Inserter Base	2
16	693.002	Torque-Limiting Implant Driver	2
17	693.011	Inserter Fork, 8mm	2
18	693.012	Inserter Fork, 10mm	2
19	693.013	Inserter, 12mm	2
20	693.021	Inserter Tube	2
21	693.031	Inserter QC Shaft	2
22	693.141	Slap Hammer	1
23	693.212	Adjustable Trial 10x26, 7–14mm	1
24	693.215	Adjustable Trial 10x26, 8–15mm, 15°	1
25	694.002	Torque-Limiting Palm Handle	1
26	694.218	Removable Drive, Right Hand	1
	993.003	RISE® Instrument Graphic Case	

RISE®
INSTRUMENT SET 993.903





MARS™3V
RETRACTOR SET 998.901

	Instrument		Qty
1	623.003	K-Wire Gripper	1
2	698.100	Retractor 3 Blade Frame	1
3	632.102	Retractor 2 Blade Frame	1
4	632.150	10mm Socket Driver	1
5	698.250	Hook and Latch Driver	1
6	675.403	Flouro Modulator	1
7	675.404	Incision Locator	1
8	675.513	8” Suction	1
9	675.800	Radiolucent Initial Dilator Holder	1
10	698.205	Cannula A	1
11	698.210	Cannula B	1
12	698.215	Cannula C	1
13	698.220	Cannula D	1
14	698.230	Frame Handle	1
15	698.240	Shim Tool, CC	1
16	698.260	Docking Pin Tool	1
17	698.330	Disc Shim Tool	1
18	698.350	Docking Pin Sleeve	4

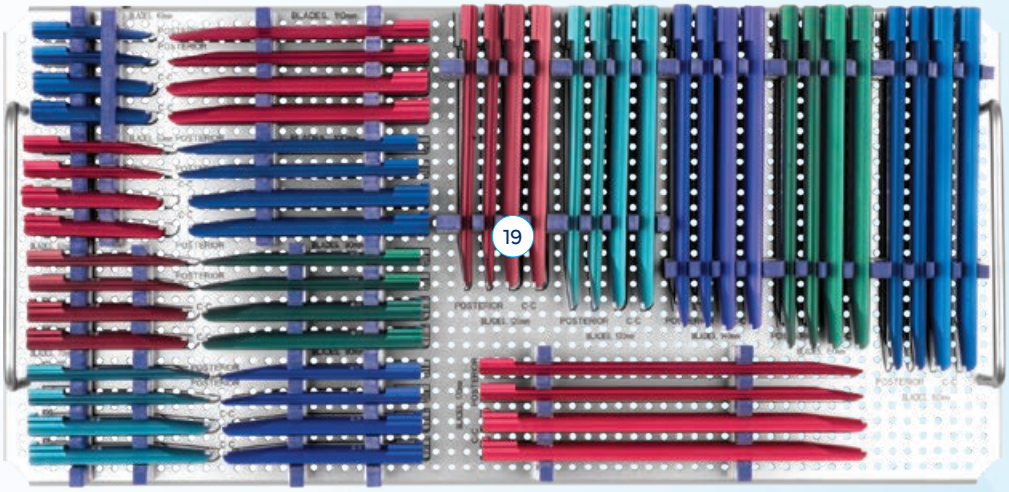
19	Retractor Blades		Qty
	698.450	Blade, Posterior, 40mm	2
	698.452	Blade, Posterior, 50mm	2
	698.454	Blade, Posterior, 60mm	2
	698.456	Blade, Posterior, 70mm	2
	698.458	Blade, Posterior, 80mm	2
	698.460	Blade, Posterior, 90mm	2
	698.462	Blade, Posterior, 100mm	2
	698.464	Blade, Posterior, 110mm	2
	698.466	Blade, Posterior, 120mm	2
	698.468	Blade, Posterior, 130mm	2
	698.470	Blade, Posterior, 140mm	2
	698.472	Blade, Posterior, 150mm	2
	698.474	Blade, Posterior, 160mm	2
	698.476	Blade, Posterior, 170mm	2

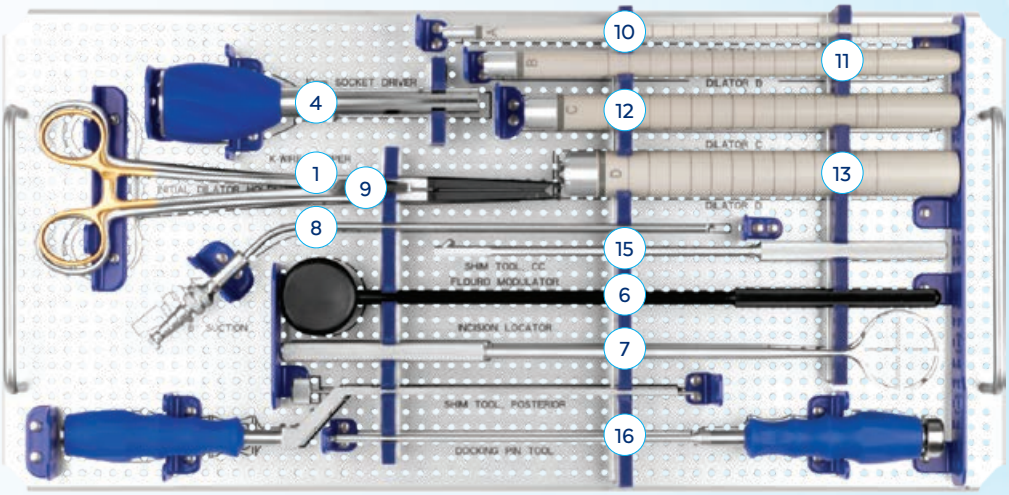
Retractor Blades (Cont’d)		Qty
698.510	Blade, CC, 40mm	2
698.512	Blade, CC, 50mm	2
698.514	Blade, CC, 60mm	2
698.516	Blade, CC, 70mm	2
698.518	Blade, CC, 80mm	2
698.520	Blade, CC, 90mm	2
698.522	Blade, CC, 100mm	2
698.524	Blade, CC, 110mm	2
698.526	Blade, CC, 120mm	2
698.528	Blade, CC, 130mm	2
698.530	Blade, CC, 140mm	2
698.532	Blade, CC, 150mm	2
698.534	Blade, CC, 160mm	2
698.536	Blade, CC, 170mm	2

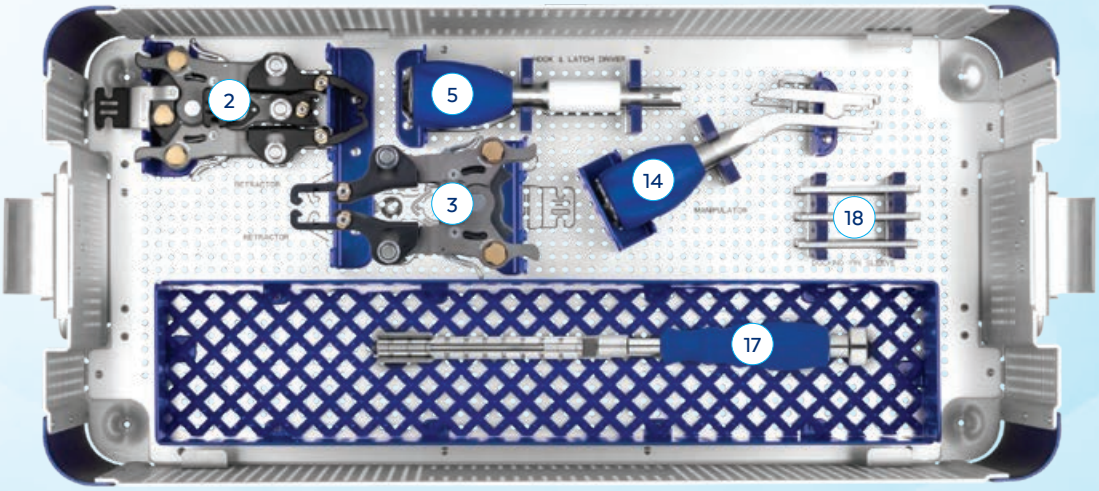
Disposables		Qty
632.678S	Bipolar Forceps, 10” Bayo, 1.0mm Tip	1
698.600S	MARS™3V Disposable Kit	1
698.300S	Lengthening Shim	2
698.305S	Widening Shim	2
698.310S	Docking Pin, 10mm	2
698.315S	Docking Pin, 20mm	2
698.325S	Disc Shim, Aluminum	1
698.326S	Disc Shim, Stainless Steel	

Items in gray are additionally available.

MARS™3V
RETRACTOR SET 998.901



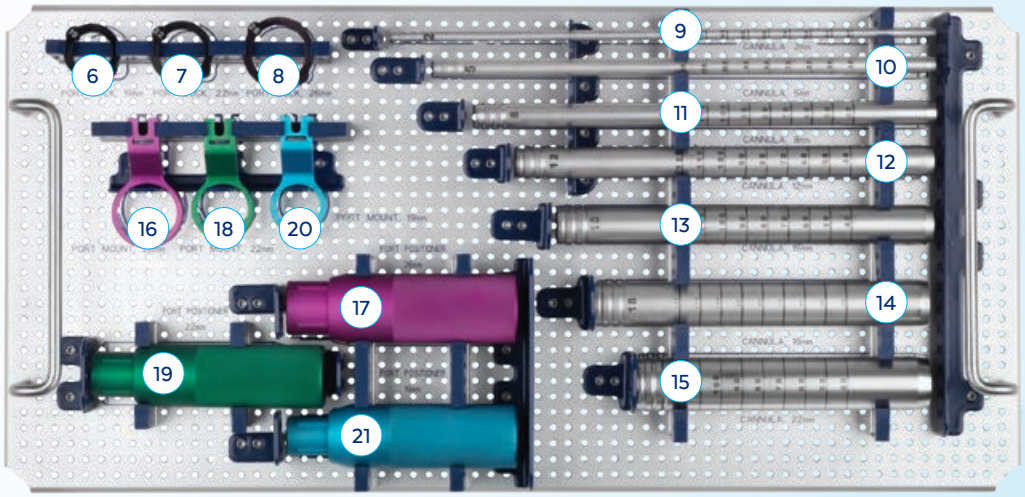


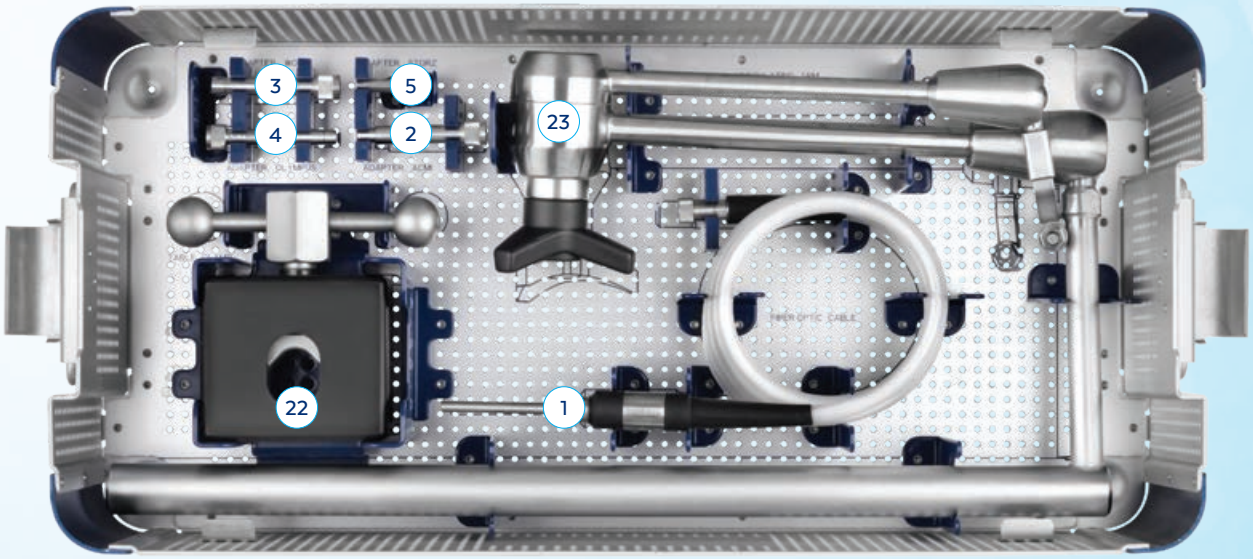


MARS™
INSTRUMENT II SET 932.902

	Instrument		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	632.310S	Light Cable	1
7	632.390	Port Lock, 19mm	1
8	632.391	Port Lock, 22mm	1
9	632.392	Port Lock, 26mm	1
10	632.401	2mm Cannula	1
11	632.402	5mm Cannula	1
12	632.403	8mm Cannula	1
13	632.404	12mm Cannula	1
14	632.405	15mm Cannula	1
15	632.406	18mm Cannula	1
16	632.407	22mm Cannula	1
17	632.408	26mm Port Mount	1
18	632.409	26mm Port Positioner	1
19	632.410	22mm Port Mount	1
20	632.411	22mm Port Positioner	1
21	632.412	19mm Port Mount	1
22	632.413	19mm Port Positioner	1
23	632.500	Table Clamp	1
24	632.750	Articulating Arm Assembly	1
	932.002	MARS™ Instrument II Graphic Case	

MARS™
INSTRUMENT II SET 932.902



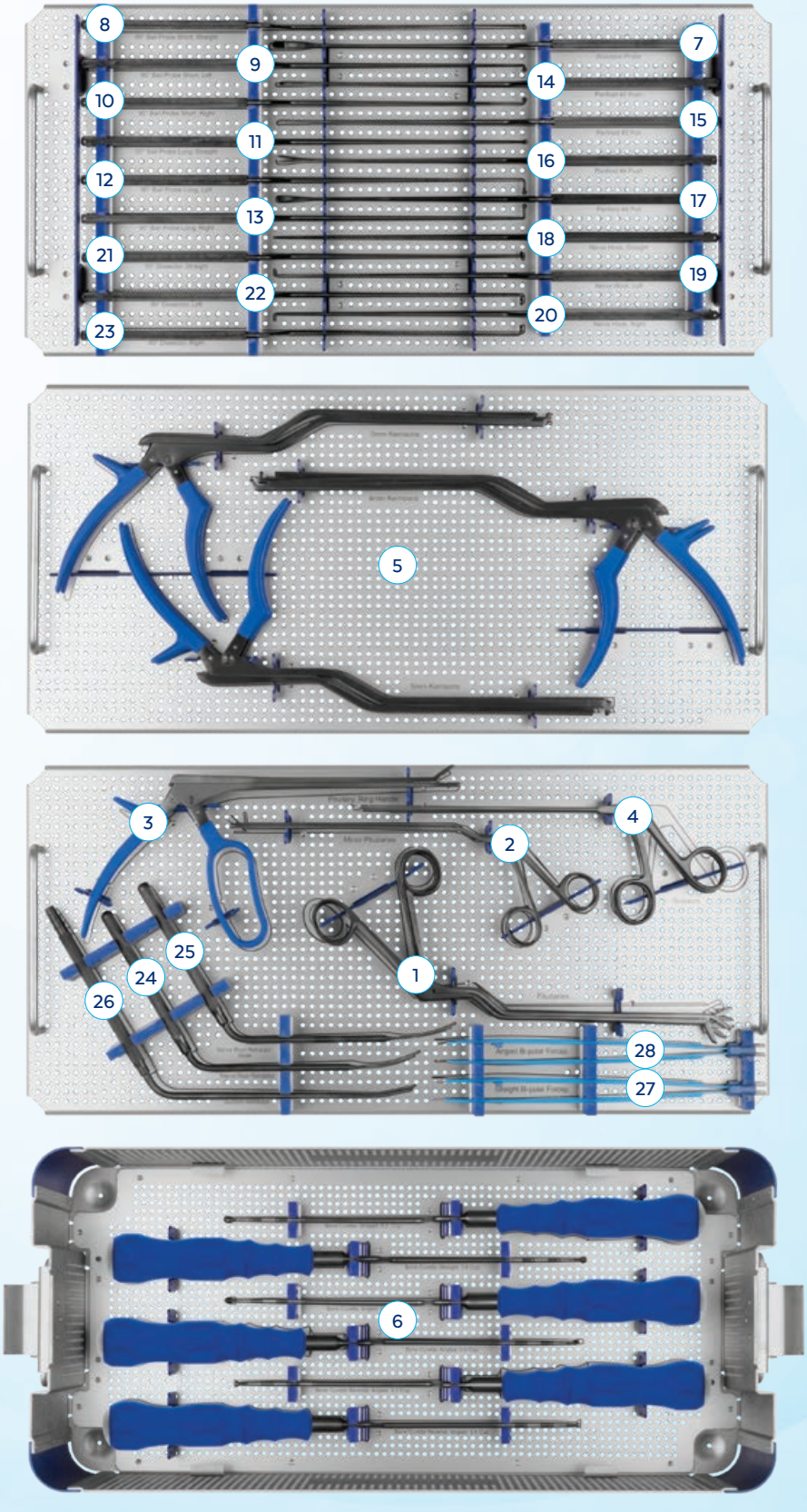


MARS™
INSTRUMENT III SET 932.903

	Instrument		Qty
1	632.600	Pituitary, 2mm Bayoneted	1
	632.601	Pituitary, 2mm, Down-Biting, Bayoneted	1
	632.602	Pituitary, 2mm, Up-Biting, Bayoneted	1
	632.605	Pituitary, 4mm, Up-Biting, Bayoneted	1
2	632.610	Micro Pituitary, 2mm, Up-Biting, Bayoneted	1
	632.611	Micro Pituitary, 2mm, Bayoneted	1
3	632.615	Pituitary, Ring Handle, 2mm	1
4	632.616	Scissors, Straight	1
	632.618	Scissors, Curved Left	1
	632.619	Scissors, Curved Right	1
5	632.620	Kerrison 40°, 3mm, Bayoneted	1
	632.621	Kerrison 90°, 3mm, Bayoneted	1
	632.622	Kerrison 40°, 4mm, Bayoneted	1
	632.623	Kerrison 90°, 4mm, Bayoneted	1
	632.624	Kerrison 40°, 5mm, Bayoneted	1
	632.625	Kerrison 90°, 5mm, Bayoneted	1
6	632.630	Bone Curette Straight, 5.2 Cup, Bayoneted	1
	632.631	Bone Curette Straight, 3.6 Cup, Bayoneted	1
	632.632	Bone Curette Angled, 5.2 Cup, Bayoneted	1
	632.633	Bone Curette Angled, 3.6 Cup, Bayoneted	1
	632.634	Bone Curette Reverse Angled, 5.2 Cup, Bayoneted	1
	632.635	Bone Curette Reverse Angled, 3.6 Cup, Bayoneted	1
7	632.640	Woodson Probe	1
8	632.641	90° Ball Probe Short, Straight, Bayoneted	1
9	632.642	90° Ball Probe Short, Left, Bayoneted	1
10	632.643	90° Ball Probe Short, Right, Bayoneted	1
11	632.644	90° Ball Probe Long, Straight, Bayoneted	1
12	632.645	90° Ball Probe Long, Left, Bayoneted	1
13	632.646	90° Ball Probe Long, Right, Bayoneted	1

	Instrument		Qty
14	632.650	Penfield #2 Push, Bayoneted	1
15	632.651	Penfield #2 Pull, Bayoneted	1
16	632.652	Penfield #4 Push, Bayoneted	1
17	632.653	Penfield #4 Pull, Bayoneted	1
18	632.655	Nerve Hook, Straight, Bayoneted	1
19	632.656	Nerve Hook, Left, Bayoneted	1
20	632.657	Nerve Hook, Right, Bayoneted	1
21	632.660	90° Dissector, Straight, Bayoneted	1
22	632.661	90° Dissector, Left, Bayoneted	1
23	632.662	90° Dissector, Right, Bayoneted	1
24	632.673	Nerve Root Retractor	1
25	632.674	Nerve Root Retractor, Wide	1
26	632.675	Suction Retractor	1
27	632.676	Bi-Polar Forcep, Straight, Bayoneted, US Connection	1
	632.677	Bi-Polar Forcep, Angled, Bayoneted, US Connection	1
	932.003	MARS™ Instrument Graphic Case	

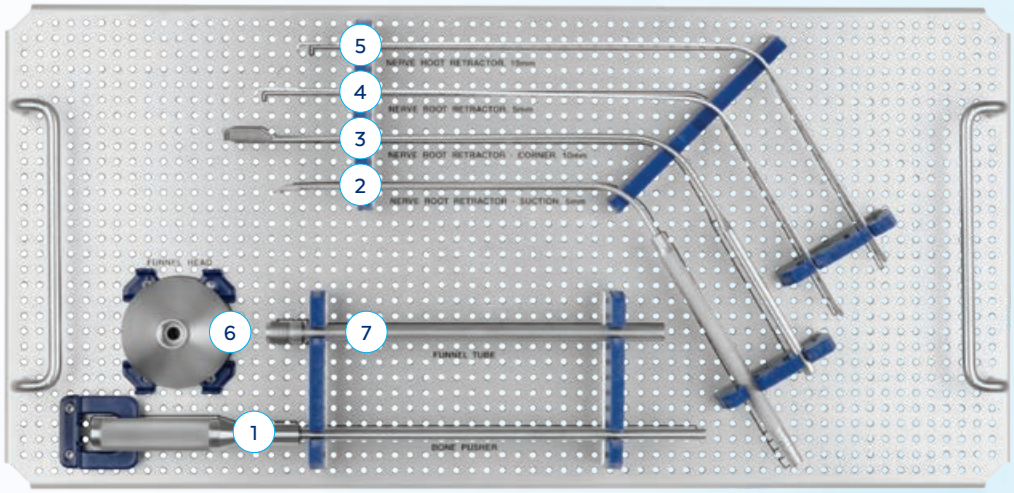
MARS™
INSTRUMENT III SET 932.903

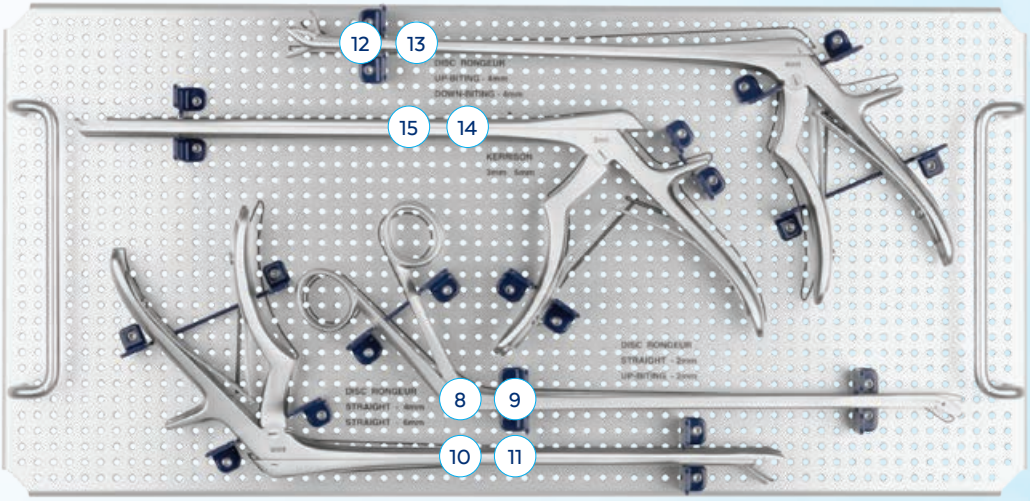


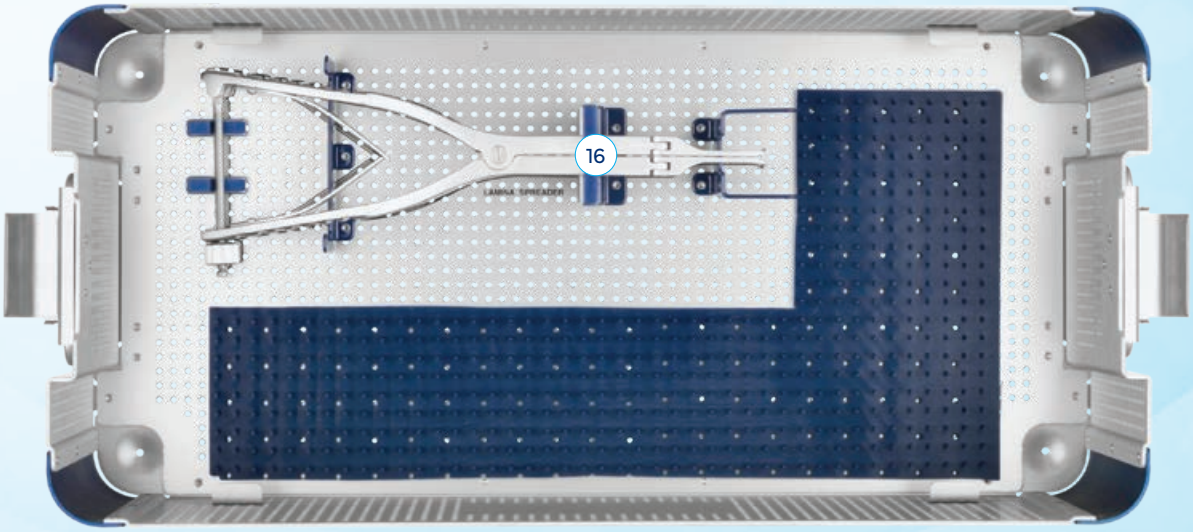
POSTERIOR DISC PREP
INSTRUMENTS I SET 926.901

	Instrument		Qty
1	626.210	Push Rod Assembly, Bone Funnel	1
2	626.215	Nerve Retractor, 5mm, Suction	1
3	626.220	Nerve Retractor, Corner	1
4	603.061	Nerve Root Retractor, Fine, 5mm	1
5	603.062	Nerve Root Retractor, Medium, 10mm	1
6	679.015	Bone Funnel	1
7	679.015	Bone Funnel - Tube	1
8	626.235	Disc Rongeur, 250x2mm, Straight	1
9	626.236	Disc Rongeur, 250x2mm, Up-Biting	1
10	626.240	Disc Rongeur, 250x4mm, Straight	1
11	626.241	Disc Rongeur, 250x6mm, Straight	1
12	626.242	Disc Rongeur, 250x4mm, Up-Biting	1
13	626.243	Disc Rongeur, 250x4mm, Down-Biting	1
14	626.250	Kerrison, 250x3mm, Straight	1
15	626.252	Kerrison, 250x5mm, Straight	1
16	626.260	Lamina Spreader, Hinged	1
	926.102	Graphic Case	

POSTERIOR DISC PREP
INSTRUMENTS I SET 926.901



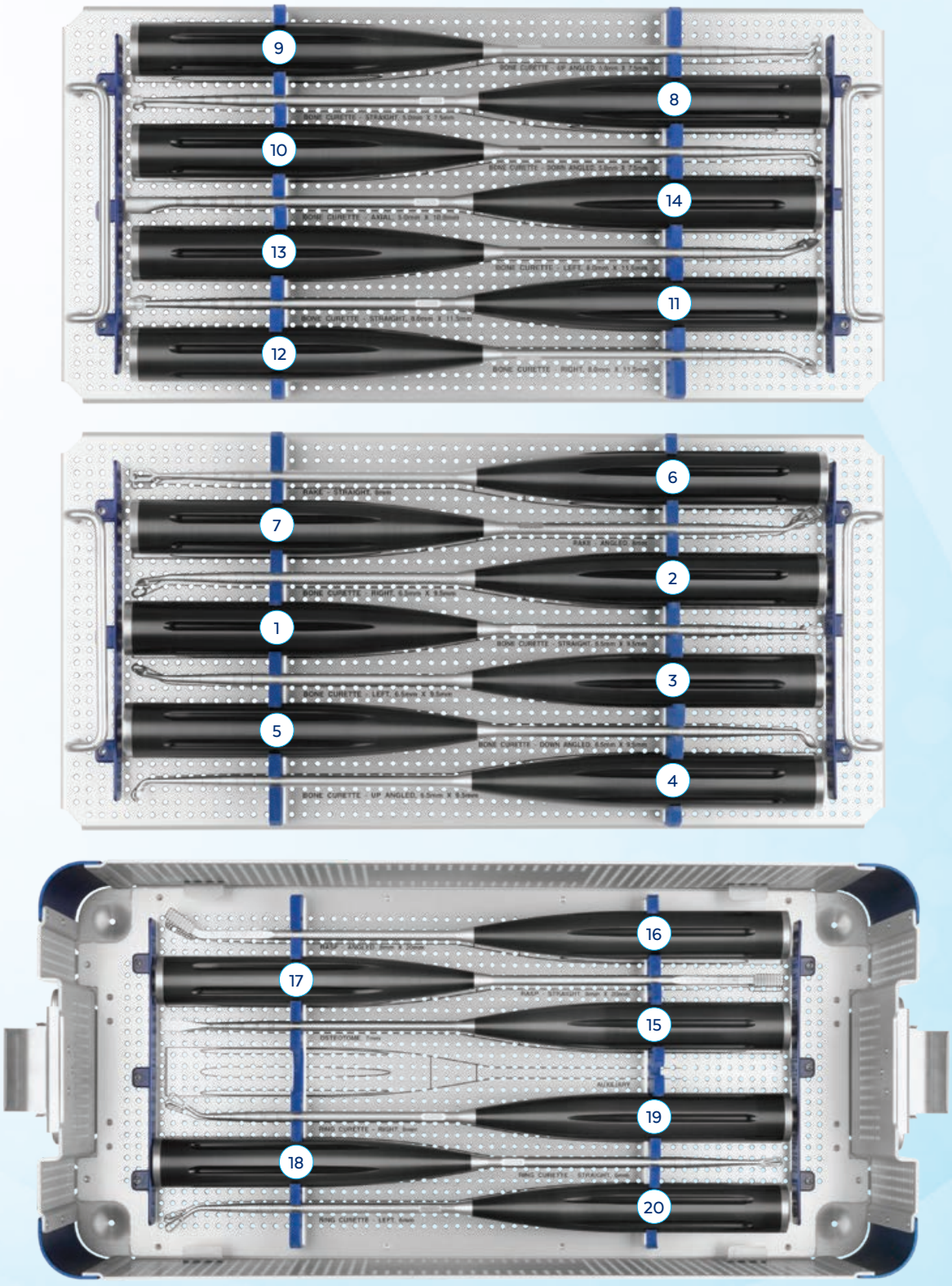




POSTERIOR DISC PREP
INSTRUMENTS II SET 926.902

	Instrument		Qty
1	626.150	Bone Curette, 6.5x9.5mm, Straight	1
2	626.151	Bone Curette, 6.5x9.5mm, Right	1
3	626.152	Bone Curette, 6.5x9.5mm, Left	1
4	626.153	Bone Curette, 6.5x9.5mm, Up-Pushing	1
5	626.154	Bone Curette, 6.5x9.5mm, Down-Pushing	1
6	626.190	Rake, 8mm, Straight	1
7	626.191	Rake, 8mm, Angled	1
8	626.140	Bone Curette, 5.0x7.5mm, Straight	1
9	626.143	Bone Curette, 5.0x7.5mm, Up-Pushing	1
10	626.144	Bone Curette, 5.0x7.5mm, Down-Pushing	1
11	626.160	Bone Curette, 8.0x11.5mm, Straight	1
12	626.161	Bone Curette, 8.0x11.5mm, Right	1
13	626.162	Bone Curette, 8.0x11.5mm, Left	1
14	626.170	Bone Curette, 5.0x10mm, Axial	1
15	626.180	Osteotome, 7mm	1
16	626.185	Rasp, 8x20mm, Knurled, Straight	1
17	626.186	Rasp, 8x20mm, Knurled, Angled	1
18	626.200	Ring Curette, 6mm, Straight	1
19	626.201	Ring Curette, 6mm, Angled Right	1
20	626.202	Ring Curette, 6mm, Angled Left	1
	926.101	Graphic Case II	

POSTERIOR DISC PREP
INSTRUMENTS II SET 926.902



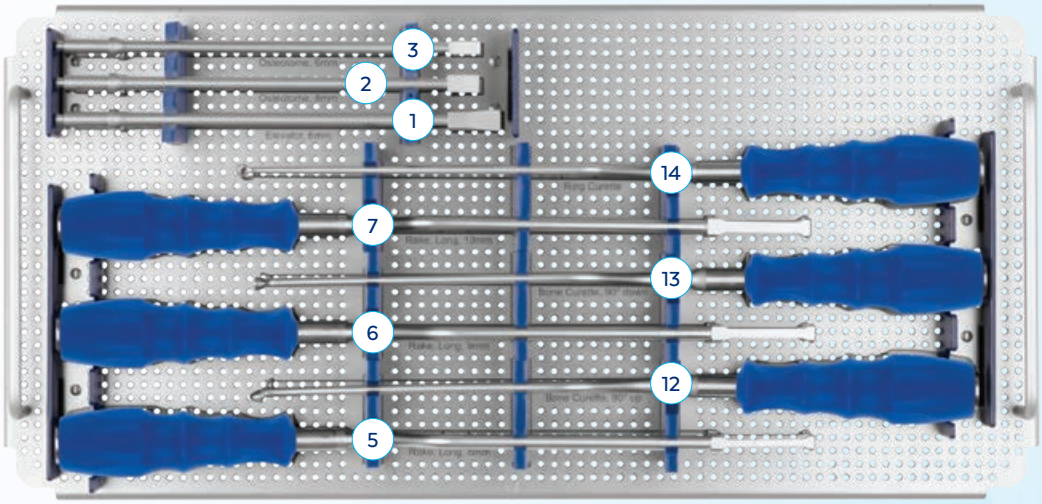
MIS LUMBAR DISCECTOMY
INSTRUMENT SET 979.901

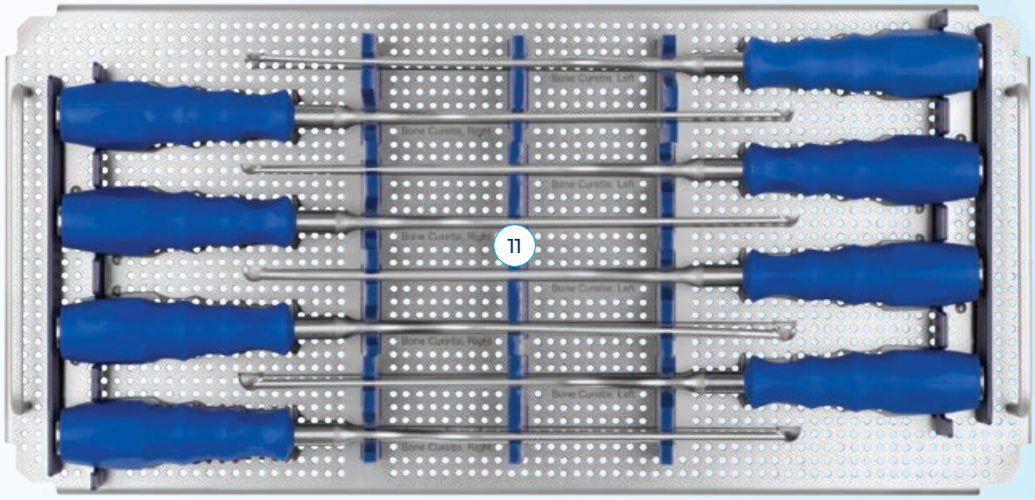
	Instrument		Qty
1	679.005	Elevator 6mm	1
2	679.007	Osteotome, 8mm QR	1
3	679.008	Osteotome, 6mm QR	1
4	679.010	L-Handle	1
5	679.011	Rake, Long 8mm, Bayoneted	1
6	679.012	Rake, Long 9mm, Bayoneted	1
7	679.013	Rake, Long 10mm, Bayoneted	1
8	679.015	Bone Funnel	1
9	679.016	Bone Funnel Clamp	1
10	679.017	Bone Pusher Rod	1
11	679.025	Bone Curette, 10.0 Serrated Cup	1
	679.026	Bone Curette, Straight, 10.0 Serrated Cup	1
	679.027	Bone Curette, Angled, 10.0 Serrated Cup	1
	679.028	Bone Curette, Straight, 10.0 Serrated Cup	1
	679.031	Bone Curette, Angled, 12.0 Serrated Cup, Bayoneted, LH	1
	679.032	Bone Curette, Straight, 12.0 Serrated Cup, Bayoneted, LH	1
	679.033	Bone Curette, Angled, 12.0 Serrated Cup, Bayoneted, RH	1
	679.034	Bone Curette, Straight, 12.0 Serrated Cup, Bayoneted, RH	1
12	679.041	Bone Curette, 10.7 Serrated Cup, 90° Up	1
13	679.042	Bone Curette, 10.7 Serrated Cup, 90° Down	1
14	679.051	Ring Curette, 6mm	1
	979.001	MIS Discectomy Instruments Graphic Case	

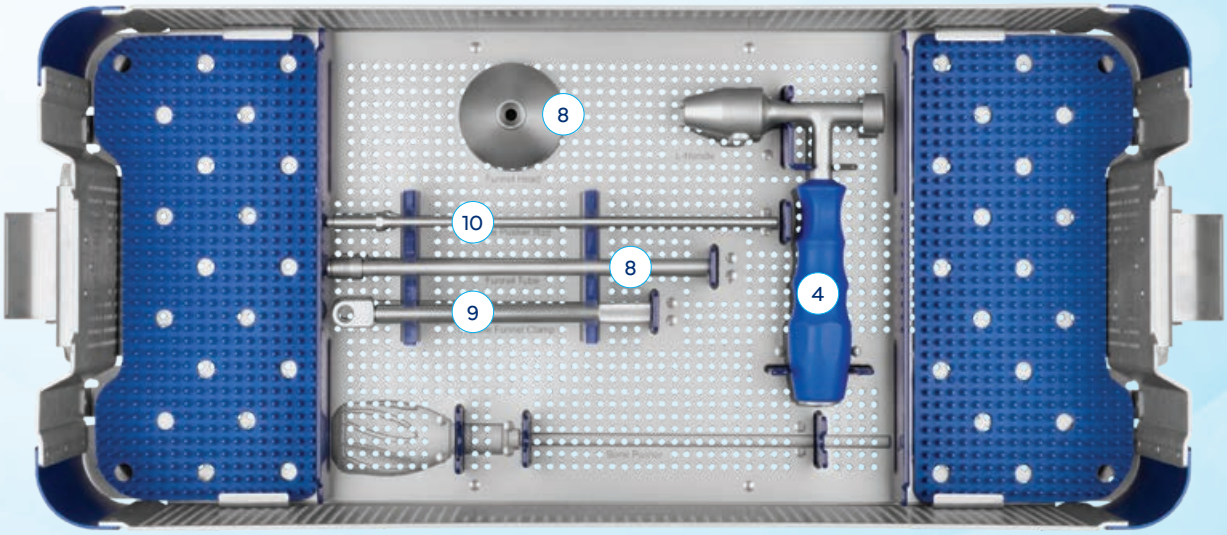
Additionally Available

673.018	Push Rod, Bone Funnel
679.021	Bone Curette, Angled, 10.7 Serrated Cup
679.022	Bone Curette, Straight, 10.7 Serrated Cup
679.023	Bone Curette, Angled, 10.7 Serrated Cup
679.024	Bone Curette, Straight, 10.7 Serrated Cup
679.061	Bone Curette, 10.0 Rectangle Cup, 75° Up
679.062	Bone Curette, 10.0 Rectangle Cup, 75° Down
679.063	Bone Curette, 12.0 Rectangle Cup, 75° Up
913.001	MIS Lumbar Discectomy Graphic Case

MIS LUMBAR DISCECTOMY
INSTRUMENT SET 979.901



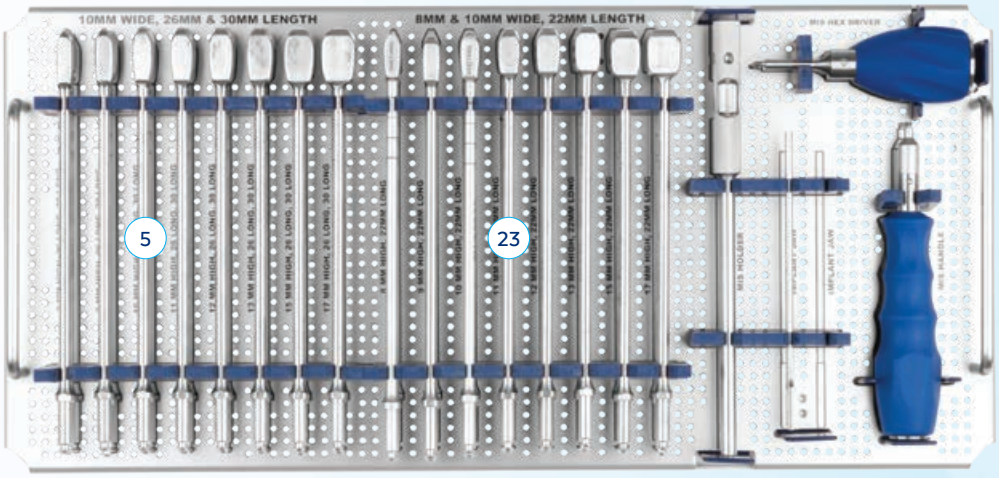


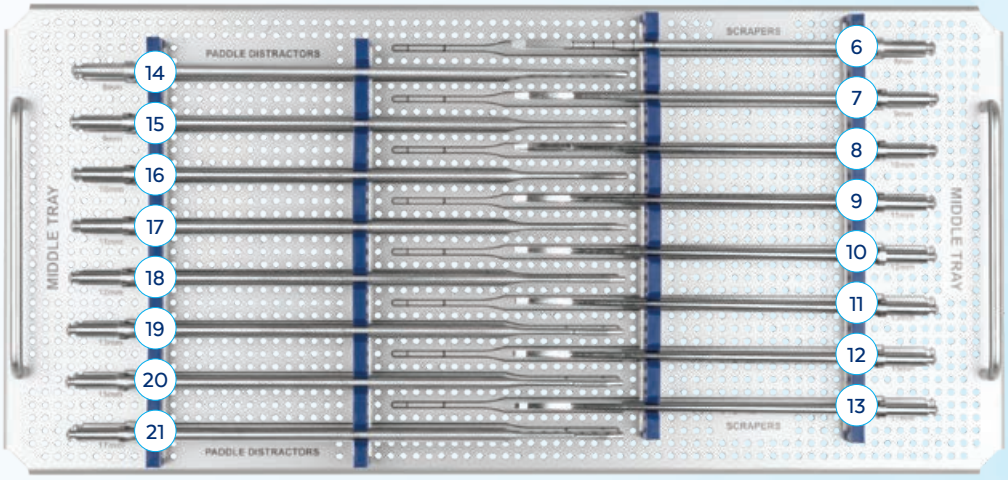


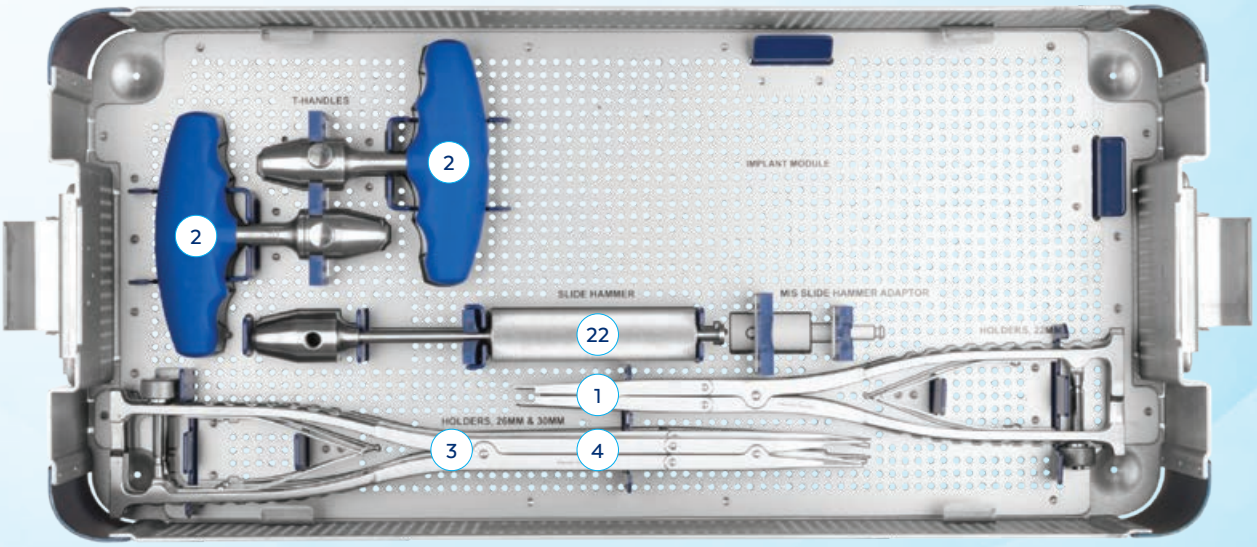
PRESERVE® POSTERIOR UNILATERAL INSTRUMENT SET 904.907

		Instrument	Qty
1	601.001	Implant Holder	1
2	601.800	T-Handle	2
3	604.001	Holder, Straight	1
4	604.002	Holder, Angled	1
5	604.108	Trial, SUSTAIN®-R Oblique, 26mm length, 8mm	1
	604.109	Trial, SUSTAIN®-R Oblique, 26mm length, 9mm	1
	604.110	Trial, SUSTAIN®-R Oblique, 26mm length, 10mm	1
	604.111	Trial, SUSTAIN®-R Oblique, 26mm length, 11mm	1
	604.112	Trial, SUSTAIN®-R Oblique, 26mm length, 12mm	1
	604.113	Trial, SUSTAIN®-R Oblique, 26mm length, 13mm	1
	604.115	Trial, SUSTAIN®-R Oblique, 26mm length, 15mm	1
	604.117	Trial, SUSTAIN®-R Oblique, 26mm length, 17mm	1
	604.208	Trial, SUSTAIN®-R Oblique, 30mm length, 8mm	1
	604.209	Trial, SUSTAIN®-R Oblique, 30mm length, 9mm	1
	604.210	Trial, SUSTAIN®-R Oblique, 30mm length, 10mm	1
	604.211	Trial, SUSTAIN®-R Oblique, 30mm length, 11mm	1
	604.212	Trial, SUSTAIN®-R Oblique, 30mm length, 12mm	1
	604.213	Trial, SUSTAIN®-R Oblique, 30mm length, 13mm	1
	604.215	Trial, SUSTAIN®-R Oblique, 30mm length, 15mm	1
	604.217	Trial, SUSTAIN®-R Oblique, 30mm length, 17mm	1
6	604.308	Scraper, Oblique, 8mm	1
7	604.309	Scraper, Oblique, 9mm	1
8	604.310	Scraper, Oblique, 10mm	1
9	604.311	Scraper, Oblique, 11mm	1
10	604.312	Scraper, Oblique, 12mm	1
11	604.313	Scraper, Oblique, 13mm	1
12	604.315	Scraper, Oblique, 15mm	1
13	604.317	Scraper, Oblique, 17mm	1
14	604.808	Paddle Distractor, 8mm	1
15	604.809	Paddle Distractor, 9mm	1
16	604.810	Paddle Distractor, 10mm	1
17	604.811	Paddle Distractor, 11mm	1
18	604.812	Paddle Distractor, 12mm	1
19	604.813	Paddle Distractor, 13mm	1
20	604.815	Paddle Distractor, 15mm	1
21	604.817	Paddle Distractor, 17mm	1
22	673.017	Slide Hammer, Quick Disconnect	1
23	673.108	Trial Shaft, 8x22mm wide, 8mm, SUSTAIN® Oblique, Small	1
	673.109	Trial Shaft, 8mm wide, 9mm, SUSTAIN® Oblique, Small	1
	673.110	Trial Shaft, 8mm wide, 10mm, SUSTAIN® Oblique, Small	1
	673.111	Trial Shaft, 8x22mm wide, 11mm, SUSTAIN® Oblique, Small	1
	673.112	Trial Shaft, 8x22mm wide, 12mm, SUSTAIN® Oblique, Small	1
	673.113	Trial Shaft, 8x22mm wide, 13mm, SUSTAIN® Oblique, Small	1
	673.115	Trial Shaft, 8x22mm wide, 15mm, SUSTAIN® Oblique, Small	1
	673.117	Trial Shaft, 8x22mm wide, 17mm, SUSTAIN® Oblique, Small	1
	673.208	Trial Shaft, 10x22mm wide, 8mm, SUSTAIN® Oblique, Small	1
	673.209	Trial Shaft, 10x22mm wide, 9mm, SUSTAIN® Oblique, Small	1
	673.210	Trial Shaft, 10x22mm wide, 10mm, SUSTAIN® Oblique, Small	1
	673.211	Trial Shaft, 10x22mm wide, 11mm, SUSTAIN® Oblique, Small	1
	673.212	Trial Shaft, 10x22mm wide, 12mm, SUSTAIN® Oblique, Small	1
	673.213	Trial Shaft, 10x22mm wide, 13mm, SUSTAIN® Oblique, Small	1
	673.215	Trial Shaft, 10x22mm wide, 15mm, SUSTAIN® Oblique, Small	1
	673.217	Trial Shaft, 10x22mm wide, 17mm, SUSTAIN® Oblique, Small	1
	904.009	PRESERVE® Posterior Unilateral Instruments	

PRESERVE® POSTERIOR UNILATERAL
INSTRUMENT SET 904.907







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

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

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

PACKAGING

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

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

HANDLING AND USE

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

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

CLEANING

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

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

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

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

CONTACT INFORMATION

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

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

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 container/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 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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