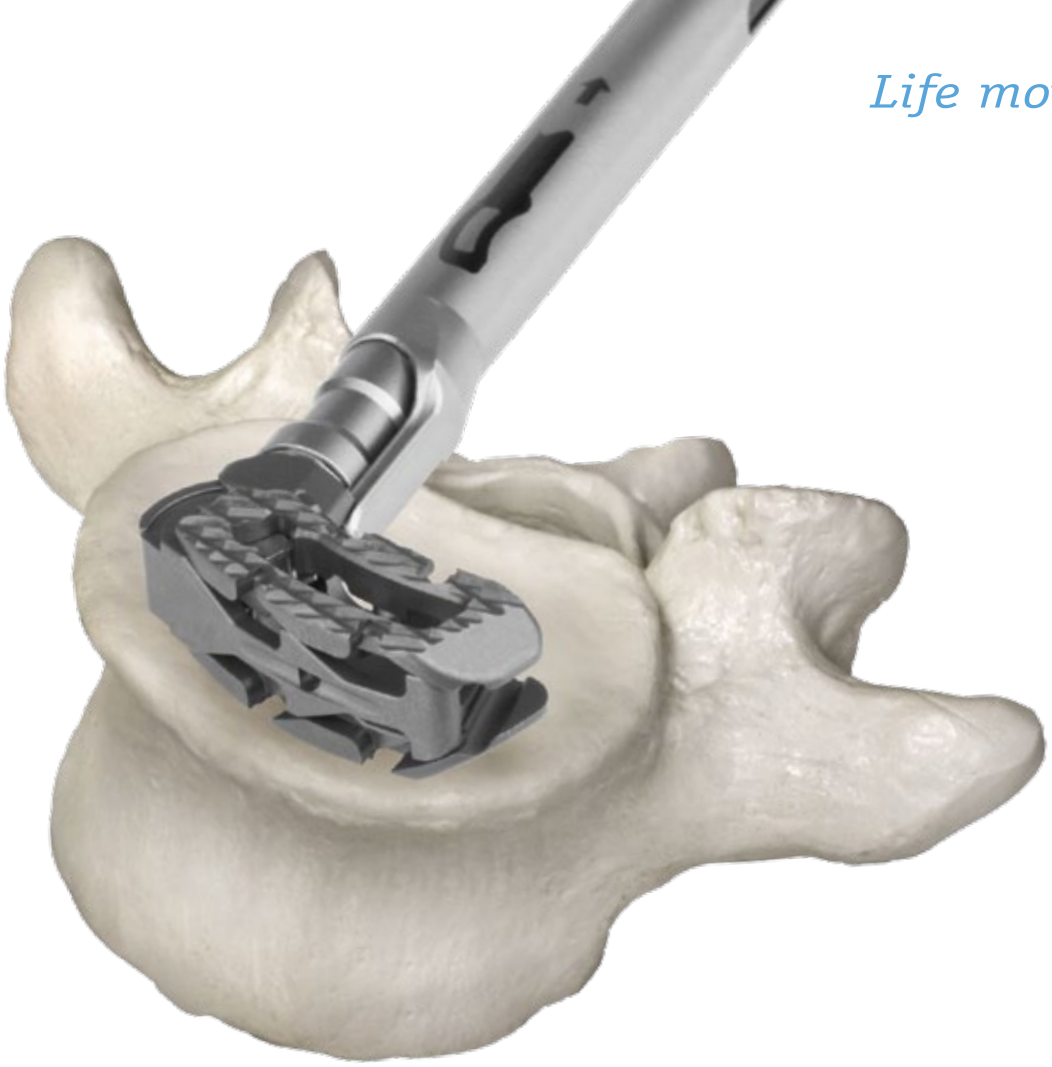
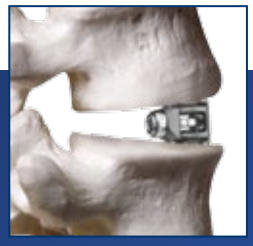
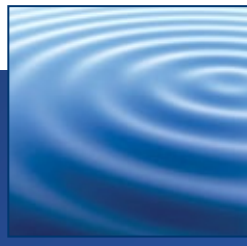
Life moves us



SURGICAL TECHNIQUE



ALTERA™

Articulating Expandable TLIF

GLOBUS MEDICAL

Life moves us

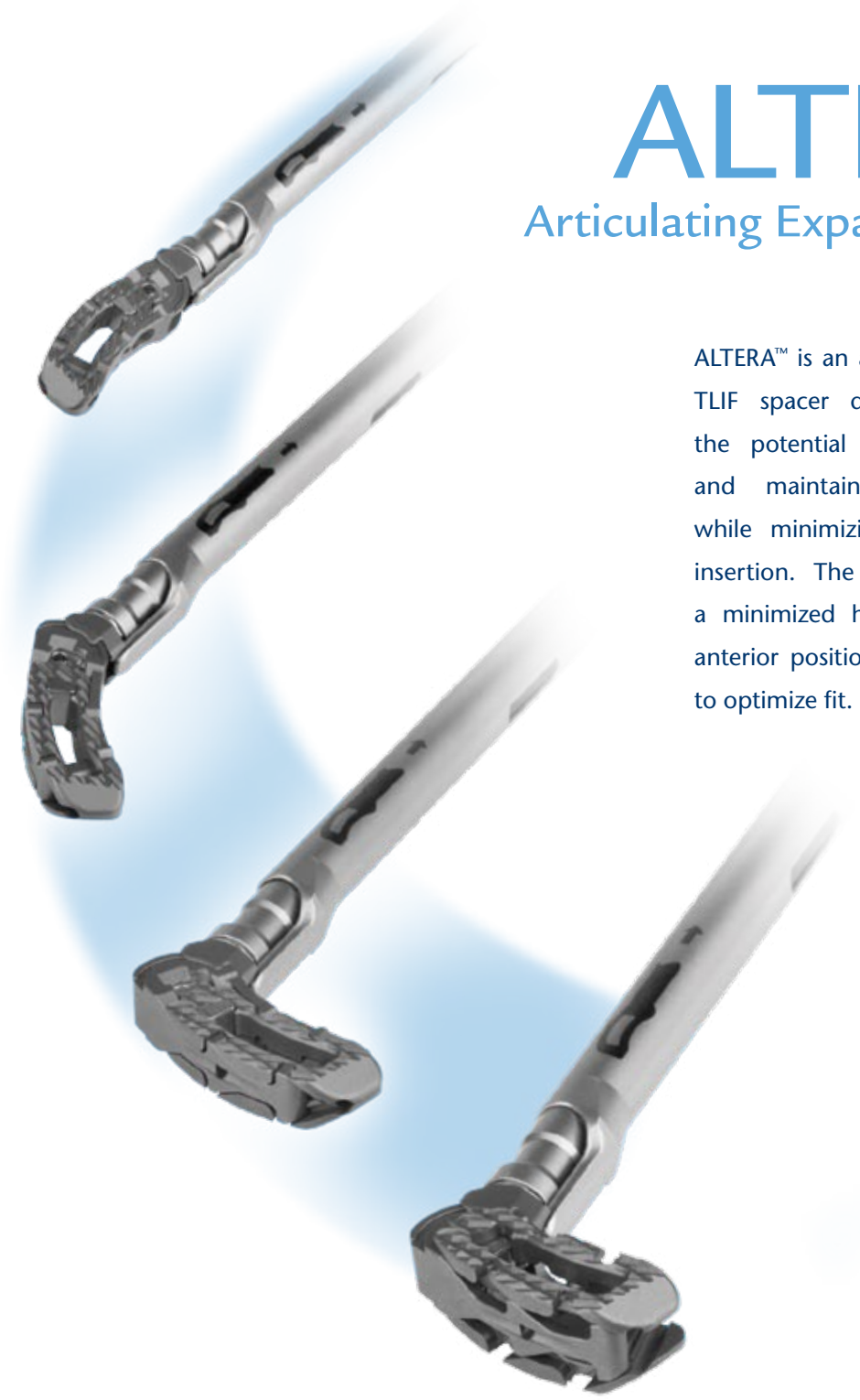
At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

GLOBUS
MEDICAL

www.globusmedical.com



ALTERA™

Articulating Expandable TLIF

ALTERA™ is an articulating expandable TLIF spacer designed to maximize the potential for restoring lordosis and maintaining sagittal balance while minimizing the challenges of insertion. The spacer is inserted at a minimized height, articulated into anterior position, and then expanded to optimize fit.

ALTERA™
ARTICULATING EXPANDABLE TLIF

Sagittal Balance

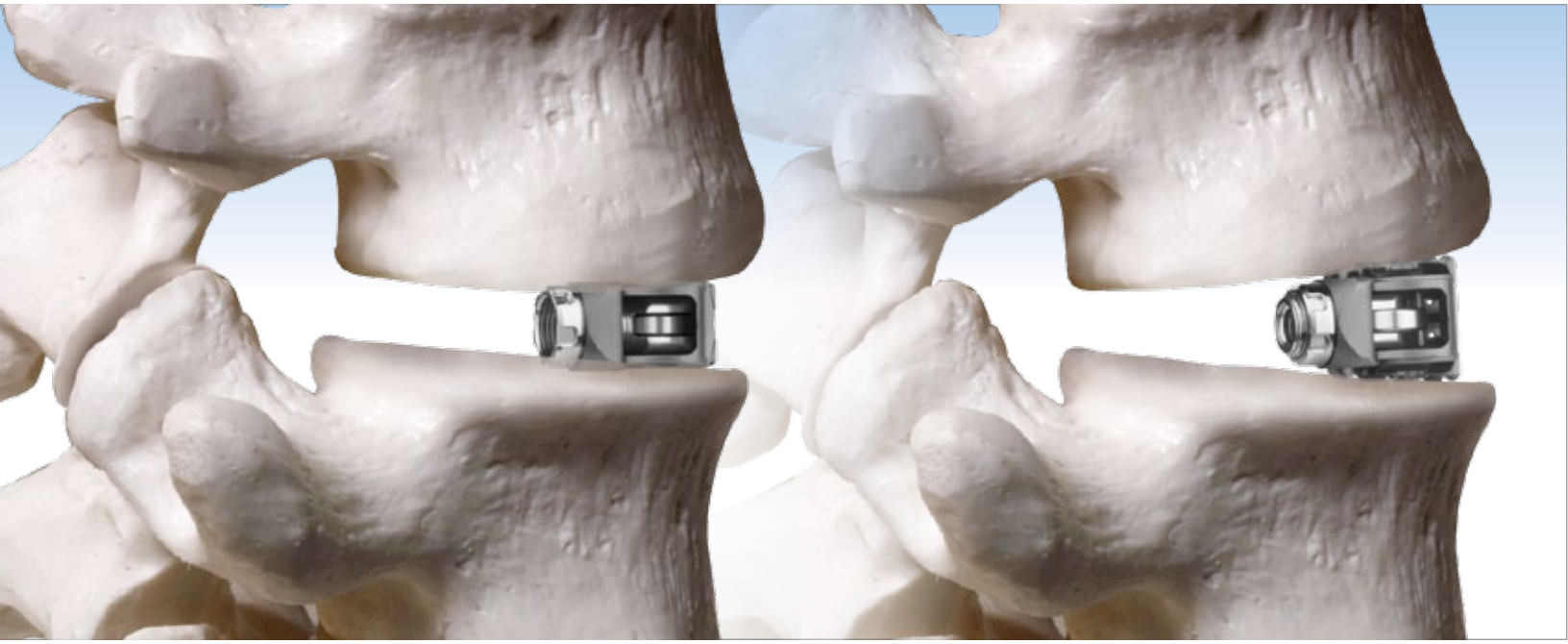
Continuous implant expansion in combination with controlled anterior placement may help to maximize segmental lordosis. In addition, ALTERA™ offers 8° and 15° lordotic implants to potentially aid sagittal balance.

Minimized Nerve Retraction

ALTERA™ is inserted at a minimized height to ease insertion and navigation around the neural elements.

Optimized Placement and Autograft Delivery

ALTERA™'s integrated articulation provides steerable placement within the anterior portion of the disc space and allows for packing autograft into and around the spacer after expansion.



CONTENTS

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

IMPLANT OVERVIEW

Features

- Minimized insertion height allows easier insertion and articulation
- Articulation mechanism allows for steerable anterior placement
- Robust threaded connection between inserter and implant
- 4mm expansion range at all articulation angles, providing all the benefits of an expandable spacer:
  - *Minimized impaction*
  - *Controlled distraction*
  - *Optimized fit*
- Post-expansion access for bone graft
- Two sagittal profiles: 8° and 15°
- Three lengths: 26, 31 and 36mm
- Four expansion ranges: 8–12mm, 9–13mm, 10–14mm and 12–16mm

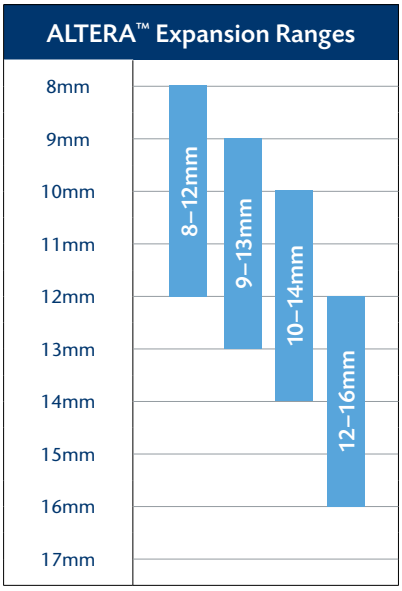
10x26mm

10x31mm

10x36mm

Lateral view: 8°

Lateral view: 15°



INSTRUMENT OVERVIEW

ALTERA™ Insertion Instruments

ALTERA™ Inserter Base 6124.0001

ALTERA™ Inserter Sleeve 6124.0002

ALTERA™ Inserter Threaded Rod 6124.0003

ALTERA™ Inserter Driver Shaft 6124.0004

ALTERA™ Impaction Cap 6124.0005

ALTERA™ Removal Threaded Rod 6124.0006

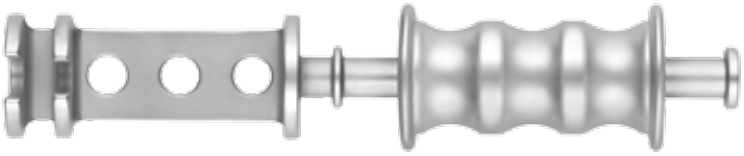
ALTERA™ Insertion Instruments (cont'd)

Torque Limiting Palm Handle, Cannulated, 4.5Nm 6124.0007

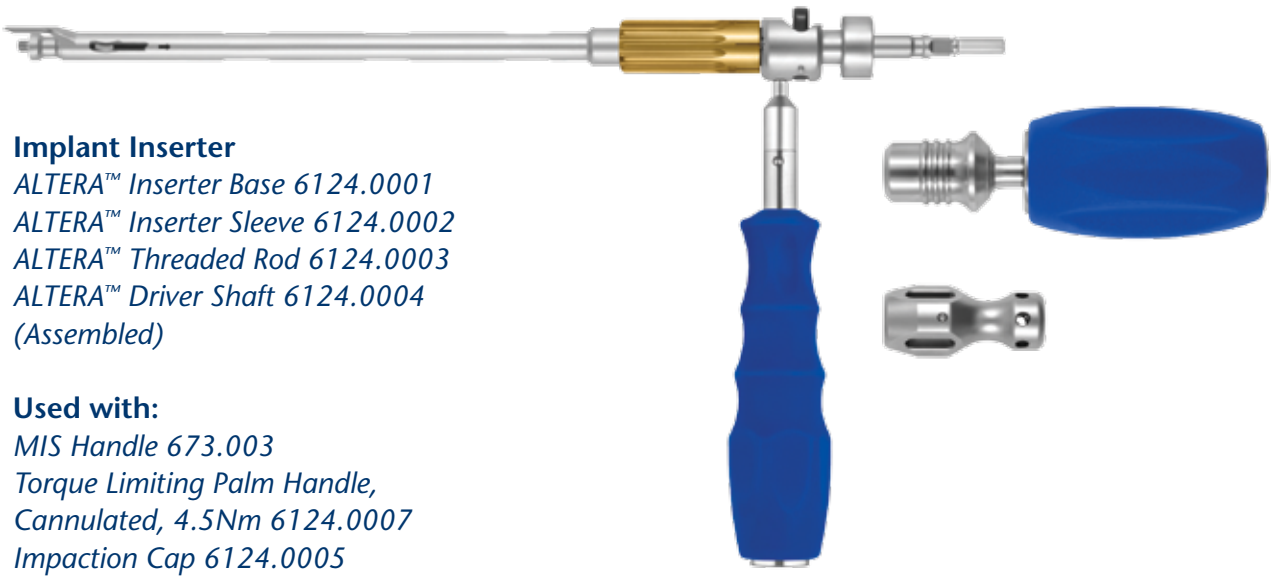
ALTERA™ Spanner Wrench 6124.0008

ALTERA™ Removal Driver 6124.0009

MIS Handle 673.003



Slide Hammer 694.018



Implant Inserter
ALTERA™ Inserter Base 6124.0001
ALTERA™ Inserter Sleeve 6124.0002
ALTERA™ Threaded Rod 6124.0003
ALTERA™ Driver Shaft 6124.0004
(Assembled)

Used with:
MIS Handle 673.003
Torque Limiting Palm Handle, Cannulated, 4.5Nm 6124.0007
Impaction Cap 6124.0005

Note: The 968.901 SIGNATURE® or 904.907 PRESERVE® Instrument Set includes Paddle Distractors and Sizers/Shavers.

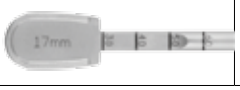
Paddle Distractors

	Height	Part Number
	7mm	668.407
	8mm	668.408
	9mm	668.409
	10mm	668.410
	11mm	668.411

	Height	Part Number
	12mm	668.412
	13mm	668.413
	15mm	668.415
	17mm	668.417

Sizers/Shavers

	Height	Part Number
	7mm	668.507
	8mm	668.508
	9mm	668.509
	10mm	668.510
	11mm	668.511

	Height	Part Number
	12mm	668.512
	13mm	668.513
	15mm	668.515
	17mm	668.517

Note: Banana-shaped Trials, Rasps, Tamps and Handles are contained within the 968.901 SIGNATURE® Instrument Set.

Trials

	Height	Small	Large
	7mm	668.207	668.307
	8mm	668.208	668.308
	9mm	668.209	668.309
	10mm	668.210	668.310
	11mm	668.211	668.311
	12mm	668.212	668.312
	13mm	668.213	668.313
	15mm	668.215	668.315
	17mm	668.217	668.317

Rasps

Rasp, Angled, Serrated 668.020

Rasp, Angled, Knurled 668.021

Tamps

Tamp, Straight 668.040

Tamp, Angled 668.041

Handles

T-Handle 601.800

Quick Coupling Handle 668.160

L-Handle 679.010

ALTERA™ SURGICAL TECHNIQUE

Minimally Invasive Surgery

Advances in minimally invasive surgery are intended to lessen the disruption to patient's anatomic structures. Without compromising surgical goals, minimally invasive surgery 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

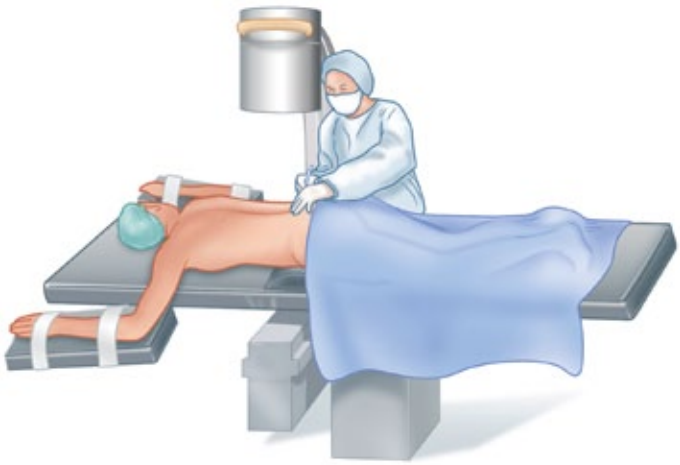
Additional Information

Please refer to the package insert at the back of the this manual for complete description, indications, contraindications, precautions and warnings. ALTERA™ spacers are to be used with supplemental fixation such as the CREO®, REVERE® or REVOLVE® Stabilization Systems. Please refer to the corresponding surgical technique for instructions for use of the selected supplemental fixation system.

Step 1 Transforaminal 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 the correct implant placement. In addition to the described interbody fusion technique, supplemental fixation must be used at the implanted level(s).



The incision can be made 4–4.5cm 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 C.W., Yue W.M., et al. Clinical and Radiological Outcomes of Minimally Invasive Versus Open Transforaminal Lumbar Interbody Fusion. Spine 34:1385-9, 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 Using the Retractor

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

Ensure that the retractor is in the fully closed position and the blades are securely attached to the frame.

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

**Note: The following sets are required to use the MARS™3V Retractor*
998.901 MARS™3V Retractor Instrument Set
932.902 MARS™ Instrument II Set
932.903 MARS™ Instrument III Set

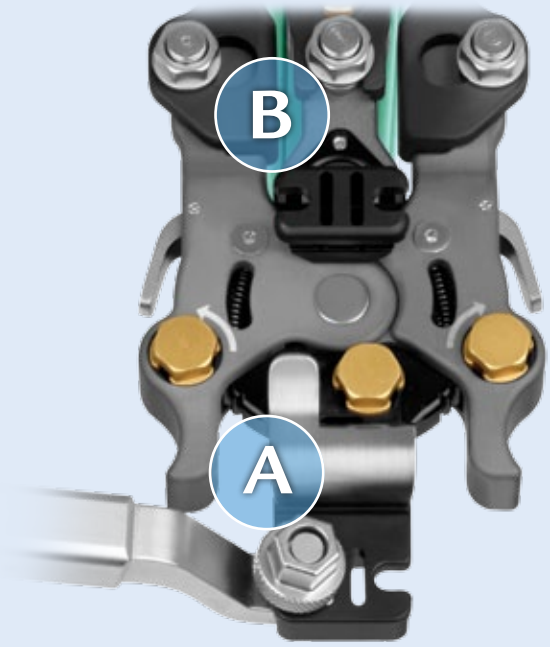
Table Arm Attachment

In order to use MARS™3V, 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 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 assembly 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 assembly to point **B** maintains the retractor position relative to the cephalad and caudad blade position, and translates the posterior blade medially.

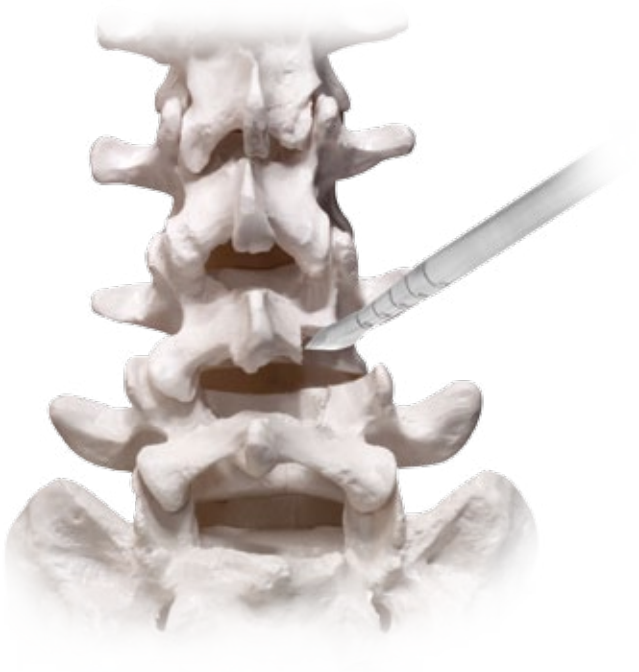


Step 3 Creating Transforaminal Access

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.

**Available in the Posterior Disc Prep Instruments Set II (926.902)*

Approach using the MARS™3V Retractor System



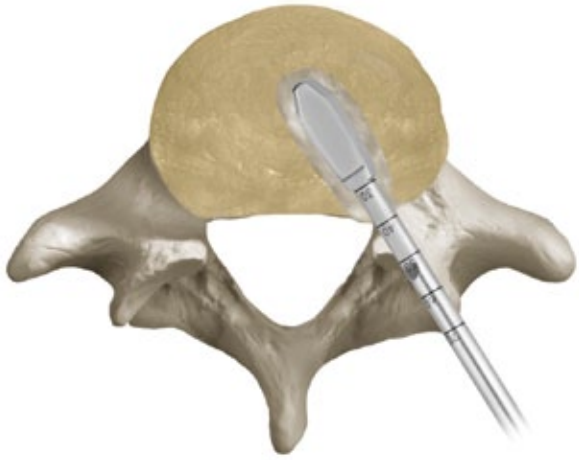
Creating transforaminal access

Step 4 Discectomy/Endplate Preparation

After creating an adequate annular window, remove disc material using rongeurs, rasps, curettes* and other suitable preparation instruments. The annulus should be preserved as much as possible to provide peripheral support for the implant and autograft material. **Sizers/ Shavers** may be used to remove superficial layers of the cartilaginous endplates and expose bleeding bone. 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 maxmizes the potential for a successful fusion.

Note: Sizers/Shavers are available in SIGNATURE® (968.901), CALIBER® (994.010), RISE® (993.903) and PRESERVE® Unilateral (904.907) Instrument Sets.

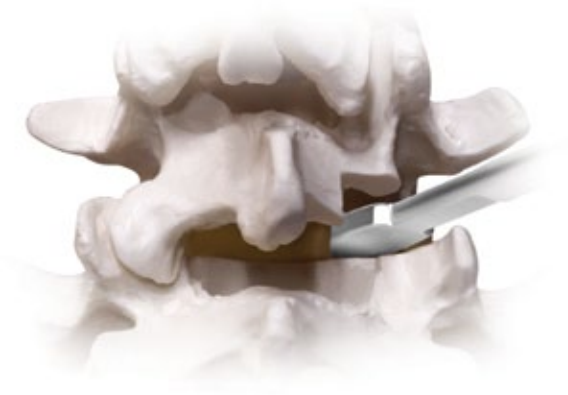
**Curettes are available in the Posterior Disc Prep II Set (926.902)*



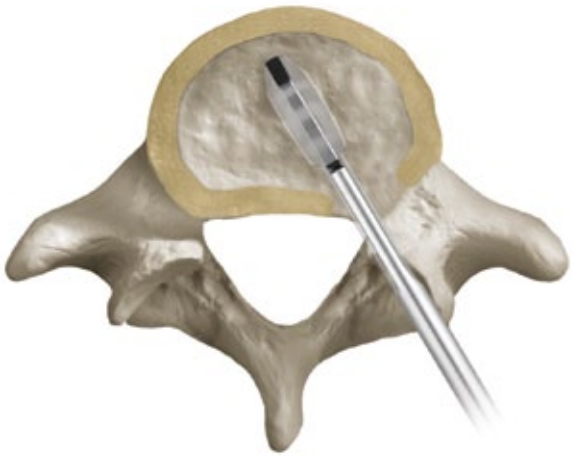
Discectomy using shaver

Step 5 Distraction

Distraction of the disc space aids in visualization, as well as decompression and restoration of disc height. Assemble the desired **Paddle Distractor** onto the **T-Handle**. Start with the smallest distractor, insert into the disc space and rotate 90°. Increase instrument size progressively until the amount of distraction is slightly greater than the intended final height of the implant.



Distraction of disc space using Paddle Distractor

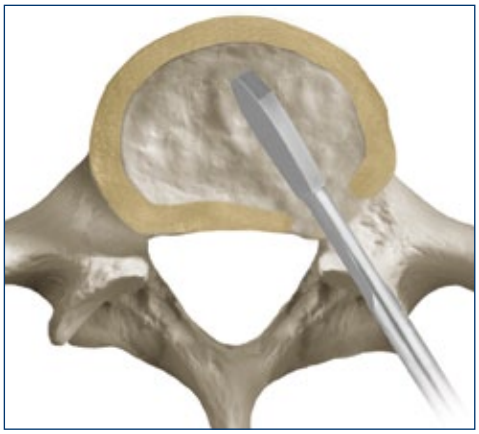


Paddle Distractor in disc space

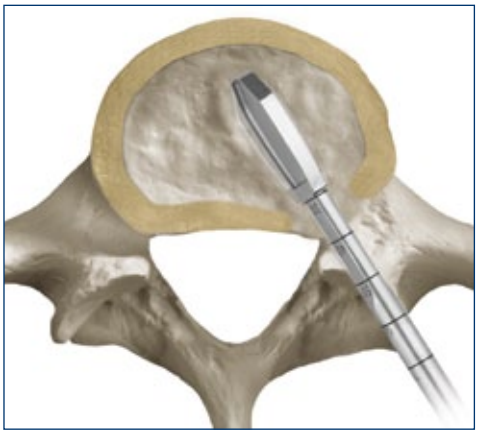
Step 6 Implant Sizing

Paddle Distractors and Sizer/Shavers may be used to size the disc space. Insert and rotate to determine the appropriate implant height.

Note: Use caution while using Sizers/Shavers or Paddle Distractors for sizing to avoid damage to the endplates.



Sizing disc space using Paddle Distractor

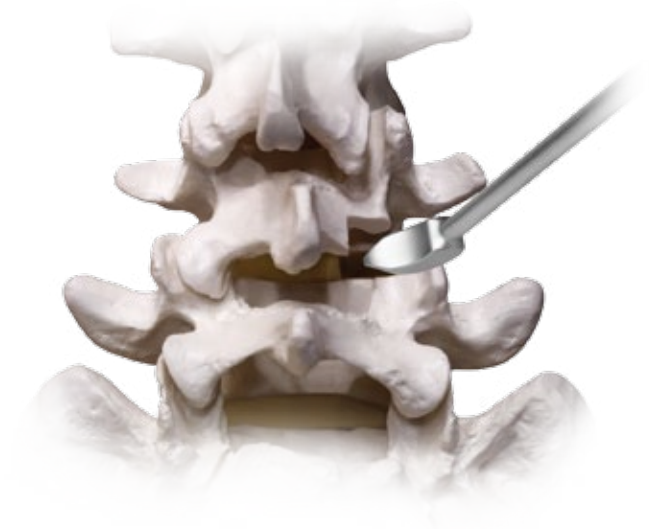


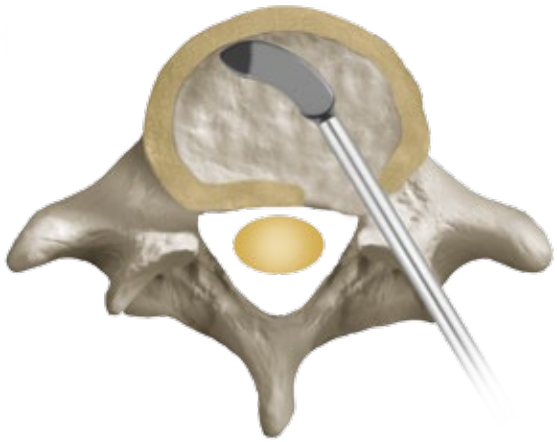
Sizing disc space using Sizer/Shaver

Note: Paddle Distractors and Sizers/Shavers are available in SIGNATURE® (968.901) and PRESERVE® Unilateral (904.907) Instrument Sets.

Alternatively, **SIGNATURE® Trials** may be used. The SIGNATURE® Small Trial corresponds to ALTERA™ 10x31mm and SIGNATURE® Large Trial corresponds to ALTERA™ 10x36mm footprints.

Assemble the desired SIGNATURE® Trial onto the T-Handle. Insert into the disc space, using gentle impaction if needed. Determine which trial best fits the prepared disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment, and may be confirmed using fluoroscopy and tactile feel.





Note: Trials available in the SIGNATURE® (968.901) Instrument Set.

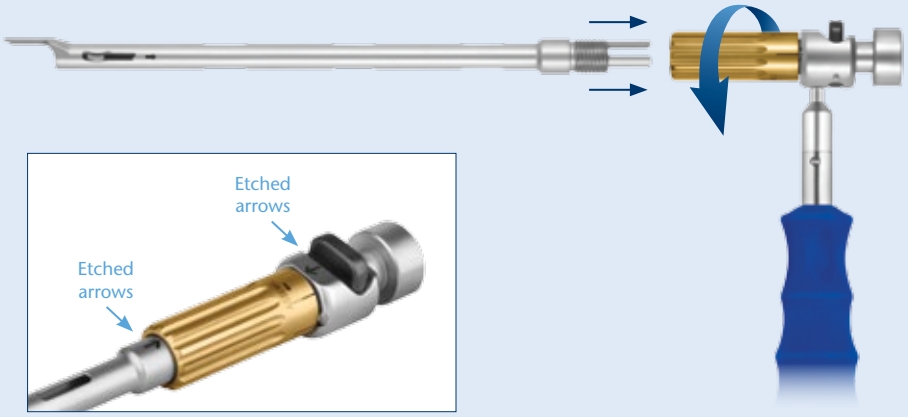
Step 7 Loading the Implant

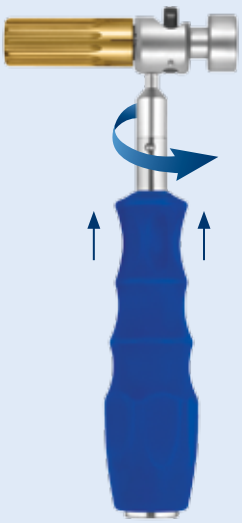
Assembling the Implant Inserter

Refer to instrument overview (page 6) for Implant Inserter components.

1. Thread the **MIS Handle** into the threaded hole on the **ALTERA™ Inserter Base**.

2. Place the **ALTERA™ Inserter Sleeve** into the knurled portion of base and rotate knurled portion counterclockwise until finger tight.

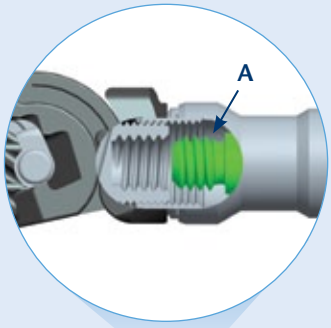




Handle threaded into the base

Note: The etched arrows on the Inserter Base and Inserter Sleeve should be aligned upon insertion.

3. Place the **ALTERA™ Inserter Threaded Rod** inside the **ALTERA™ Inserter Driver Shaft.**



4. To load the implant, engage the external nut on the implant with the driver shaft (A). Once these are aligned, apply gentle pressure against the spring loaded mechanism of the threaded rod (B).

   Insert and rotate the threaded rod clockwise into the threaded portion of the implant, until finger tight. Tighten the threaded rod using the back end of the **ALTERA™ Spanner Wrench** (C).

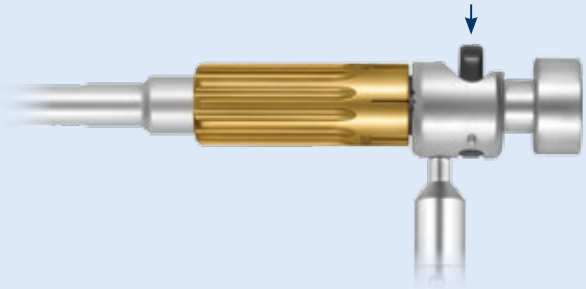
Loading the Implant (cont'd)

Assembling the Implant Inserter (cont'd)

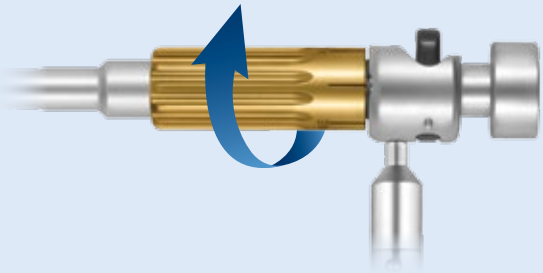
5. Place the driver shaft with the threaded rod and implant into the inserter sleeve. Confirm that the implant can articulate freely. If the implant does not articulate freely, rotate the driver shaft counterclockwise until finger tight to fully contract the implant, then rotate the driver shaft ¼ turn clockwise to allow the implant to articulate freely.

   Confirm the orientation of the sleeve stabilizer prong and implant. It should match the etched diagram on the sleeve.

Compress the black button and slide the driver shaft into the base. Visually confirm that the black button snaps into place.

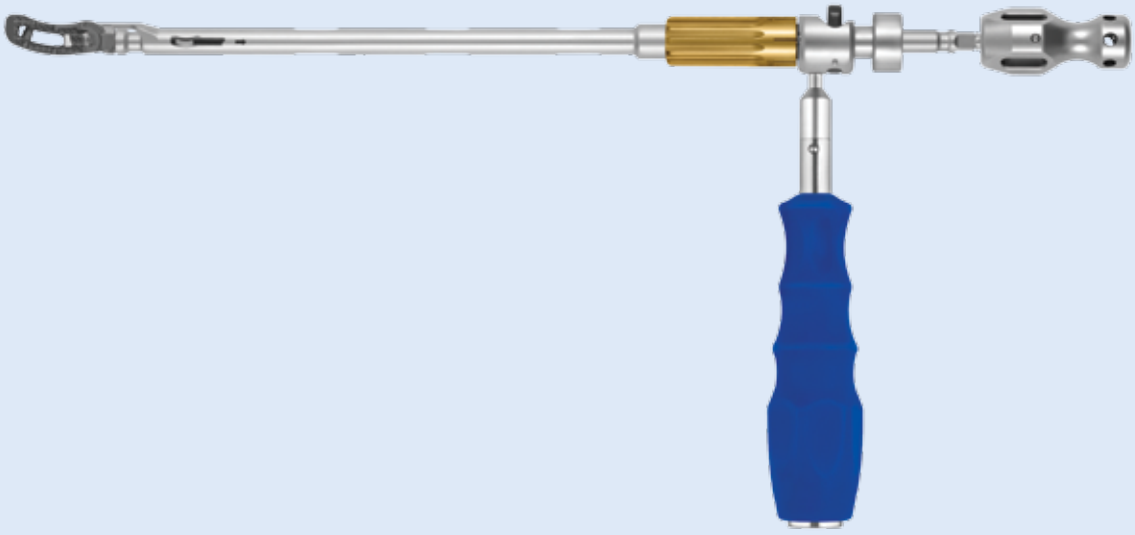


Rotate the knurled portion of the base clockwise, until finger tight, to advance the sleeve and lock the implant into position.



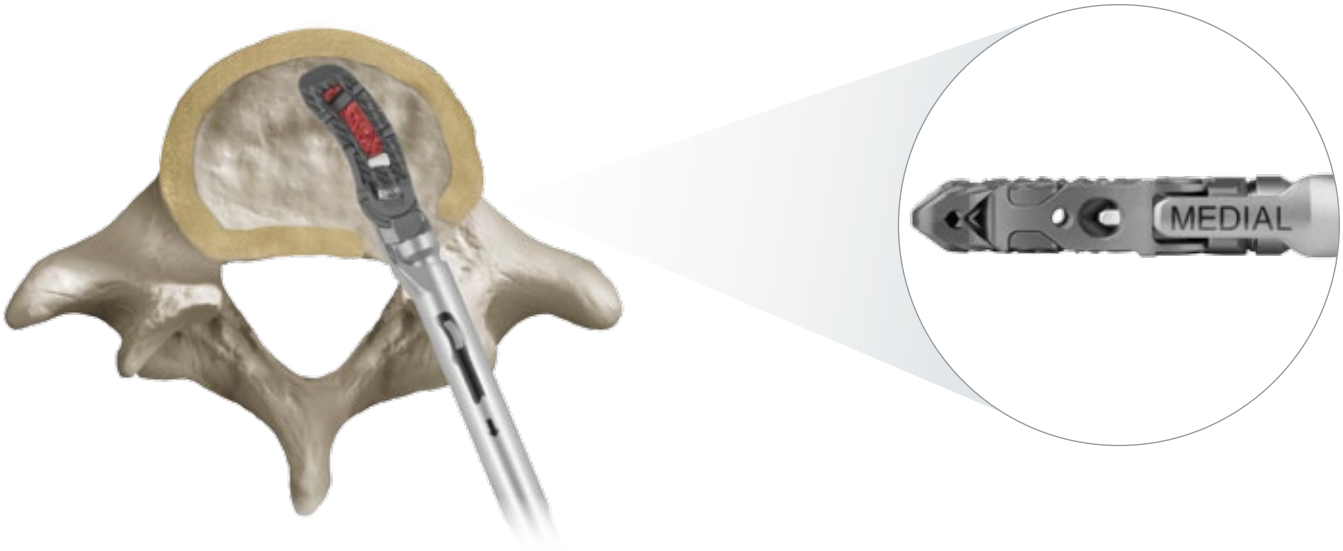
6. Place the **ALTERA™ Impaction Cap** over the back end of the threaded rod and driver shaft, as shown below.

Note: Do not impact on the threaded rod shaft. Only impact the ALTERA™ Inserter Assembly on the impaction cap.



Step 8 Implant Insertion

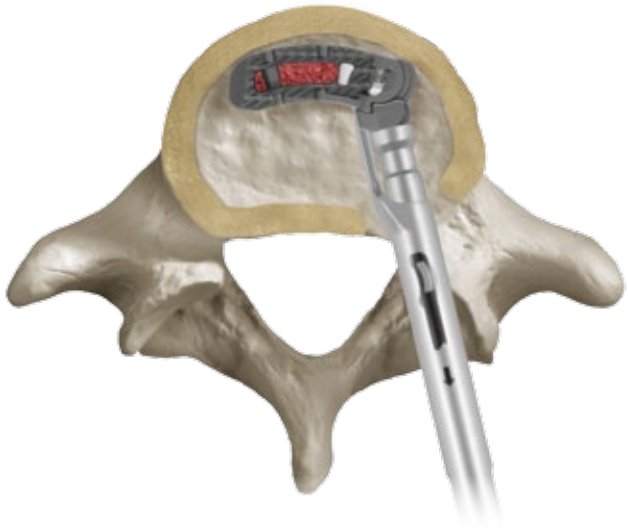
The appropriately sized implant is selected and filled with autogenous bone graft material, tightly packing the device. The implant is then inserted into the disc space in the collapsed state.



Gently impact the ALTERA™ Inserter Assembly into the disc space until the implant approaches the vertebral midline and articulation is needed. Rotate the knurled portion of the Inserter Base counterclockwise to retract the stabilizer prong, allowing the implant to articulate.

Note: The Spanner Wrench may be used to loosen the knurled portion of inserter base.

Continue to gently impact until the implant reaches final position, slightly recessed from the anterior wall of the vertebral body.

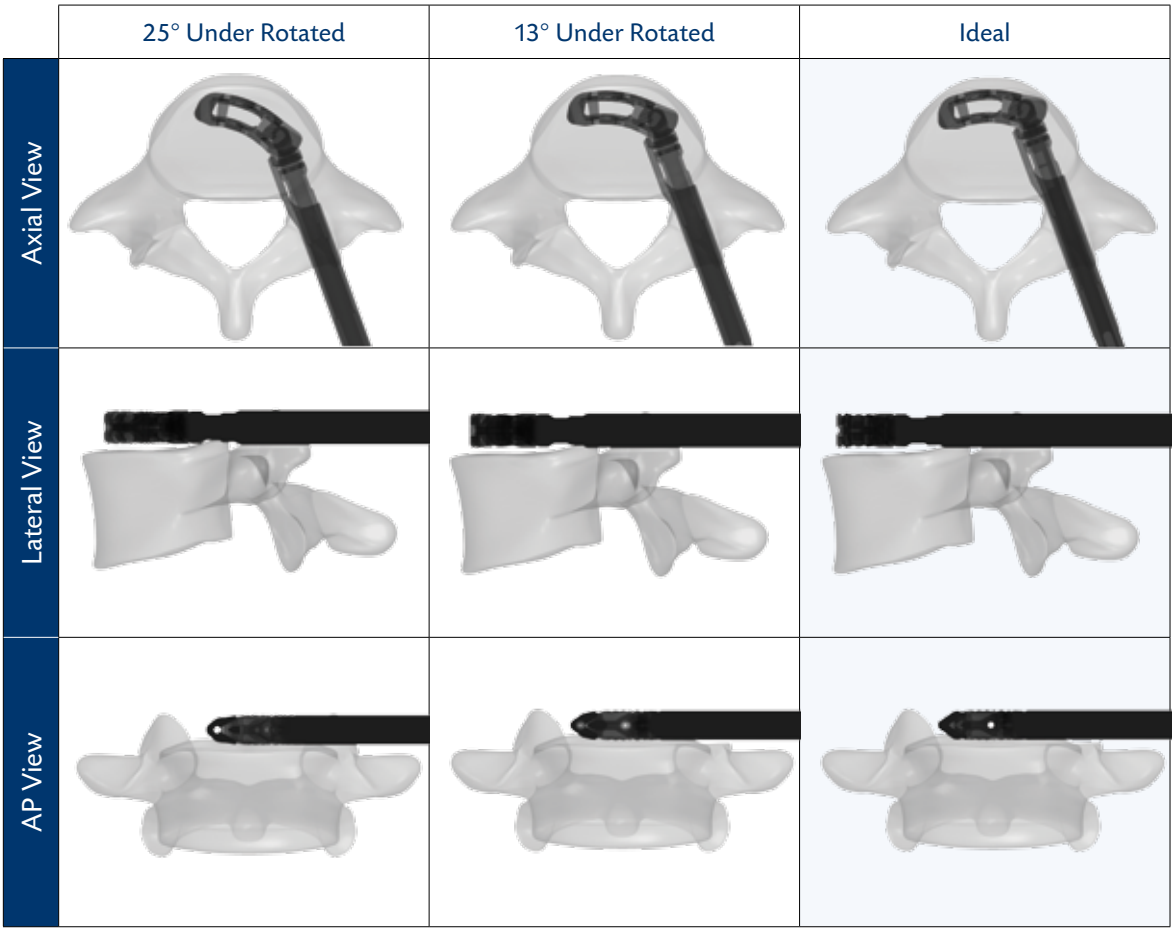


Verify positioning with fluoroscopic imaging, as shown on page 18, prior to implant expansion.

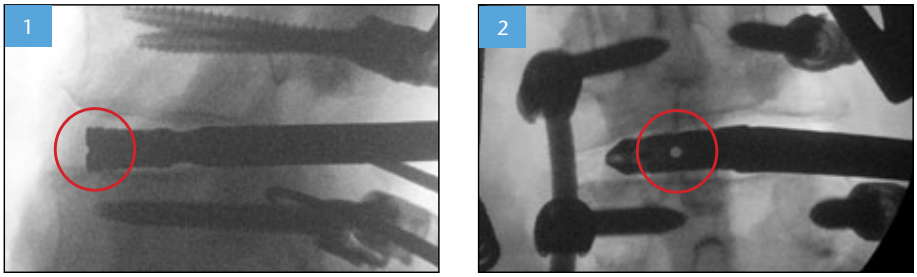
Implant Insertion (cont'd)

Radiographic Identification

The sequence of images below portray the orientation of the implant during the phases of insertion and articulation in the axial, lateral and anterior-posterior (AP) planes.



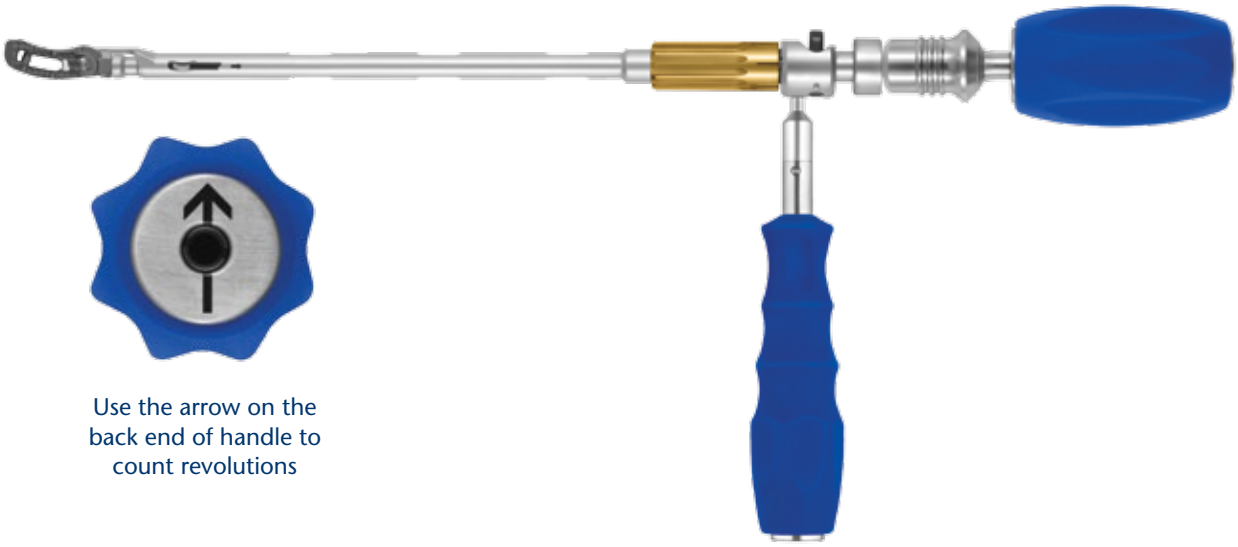
The ideal position of the implant is in the anterior portion and centered across midline of the vertebral body. When this occurs, the following features should be visualized on the fluoroscopic images: 1) the notch on the anterior side of the implant will be visible in the lateral view, and 2) the through hole of the implant will be visible and centered in the AP view.



Step 9 Implant Expansion

Remove the Impaction Cap from the Inserter. Attach the **Torque Limiting Palm Handle, Cannulated, 4.5Nm**. Ensure that the quick connect portion is against the shoulder of the Inserter Base. Expand the implant by rotating the handle clockwise until the desired implant height is achieved.

Expansion should be determined by the tactile feel of the implant in the disc space as it is expanded, gently toggling the implant until the desired fit is achieved as confirmed visually or under fluoroscopy. Minor adjustments in height may be made before the implant is detached from the Inserter by rotating the handle clockwise (expansion) or counterclockwise (collapse).



Use the arrow on the back end of handle to count revolutions

Overall height expansion is determined by counting the number of set screw revolutions of the handle. Each revolution is slightly over 0.5mm of height expansion. The arrow etched on the back end of the handle can be used to count revolutions, as shown below.

The torque limiting handle is designed to allow the user to identify when either the implant has reached its maximum height expansion, or the maximum allowable torque is being applied to the implant.

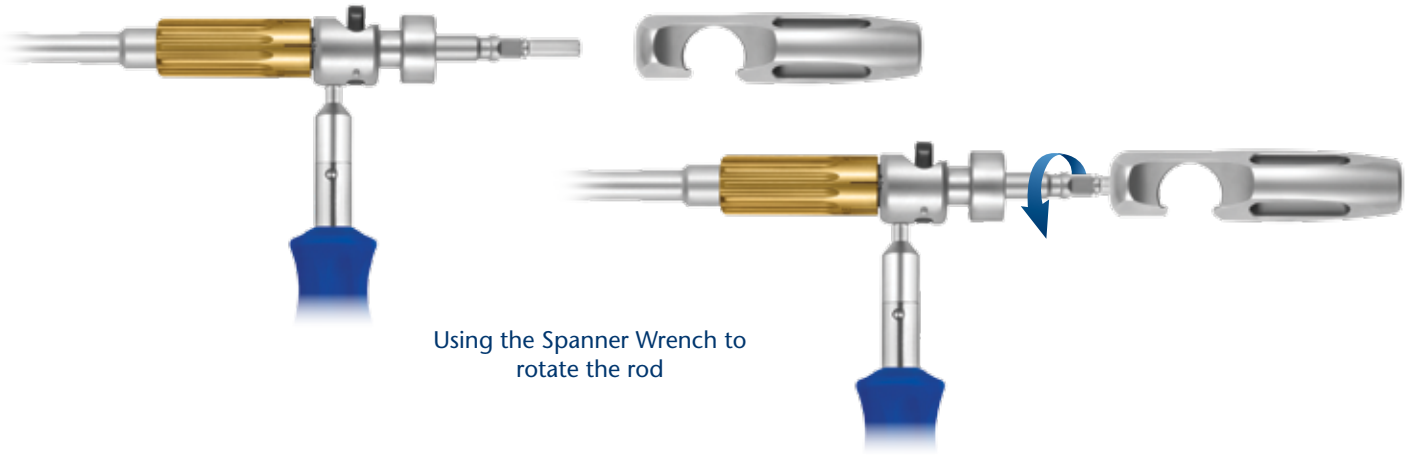
Note: The torque limit is designed to protect the function of the implant. Use caution while expanding the implant to avoid excessive distraction and damage to the vertebral body endplates.

Driver Revolutions Required									
Expansion Range	Final Height (mm)								
	8	9	10	11	12	13	14	15	16
8–12mm	0	2	3.75	5.5	7.0	-	-	-	-
9–13mm	-	0	2	3.75	5.5	7.0	-	-	-
10–14mm	-	-	0	2	3.75	5.5	7.0	-	-
12–16mm	-	-	-	-	0	2	3.75	5.5	7.0

Step 10 Disengaging the Implant

Using fluoroscopy, verify the position before disengaging the implant.

To detach the implant from ALTERA™ Inserter Assembly, remove the palm handle. Rotate the threaded rod counterclockwise and gently pull the assembly away from the implant. If necessary, the threaded rod may be rotated with the Spanner Wrench, as shown below.

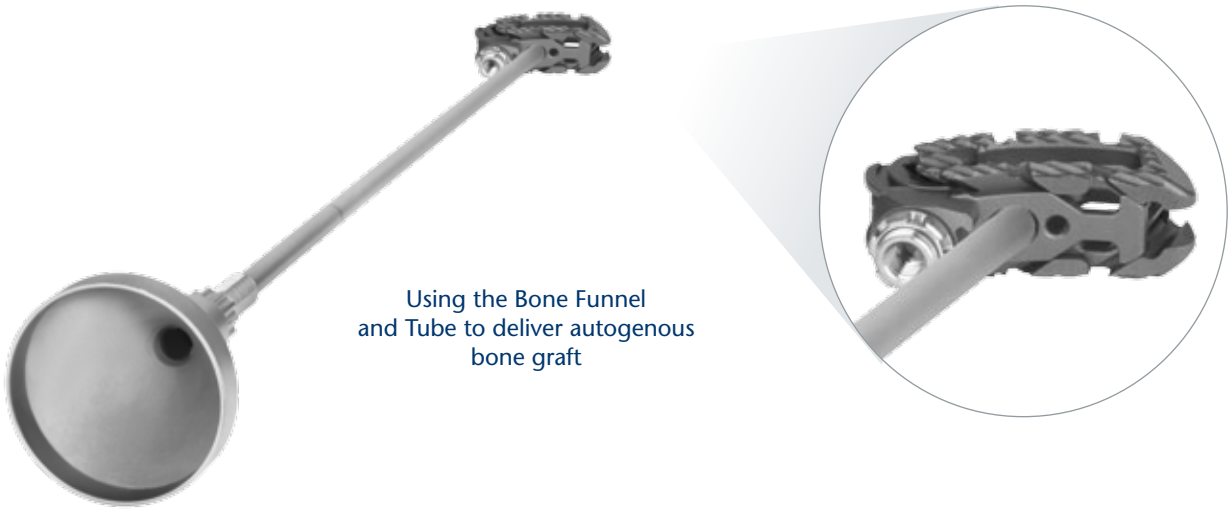


Using the Spanner Wrench to rotate the rod

Step 11 Autograft Packing

After the implant is deployed within the disc space, a Bone Funnel and Bone Funnel Tube* may be used to deliver supplemental autogenous bone graft material into the graft access hole on the posterior side of the implant and into the disc space around the implant. Using the locking nut as a guide, place the bone funnel within the hole, as shown or just outside the hole, to allow additional filling of the implant. Where possible, supplemental autogenous bone graft material should be packed in and around the implant.

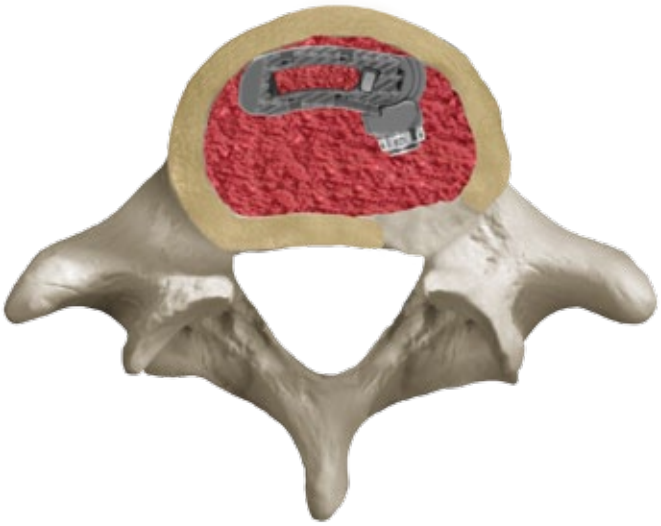
**6124.0010 Bone Funnel Tube, 6124.0011 Bone Funnel Pusher and 681.013 Bone Funnel are additionally available. Alternatively, the Bone Funnel and Pusher contained in the Posterior Disc Prep I Set (926.901) may also be used.*

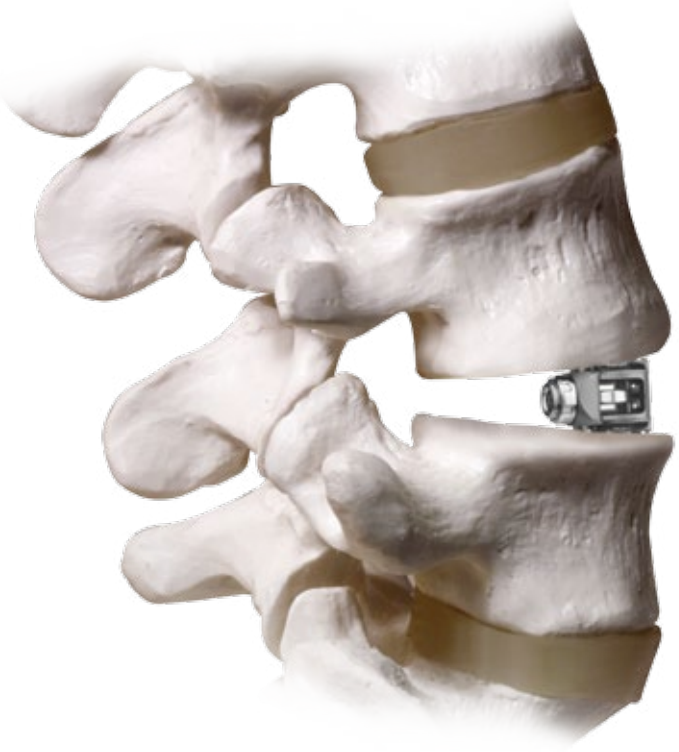


Using the Bone Funnel and Tube to deliver autogenous bone graft

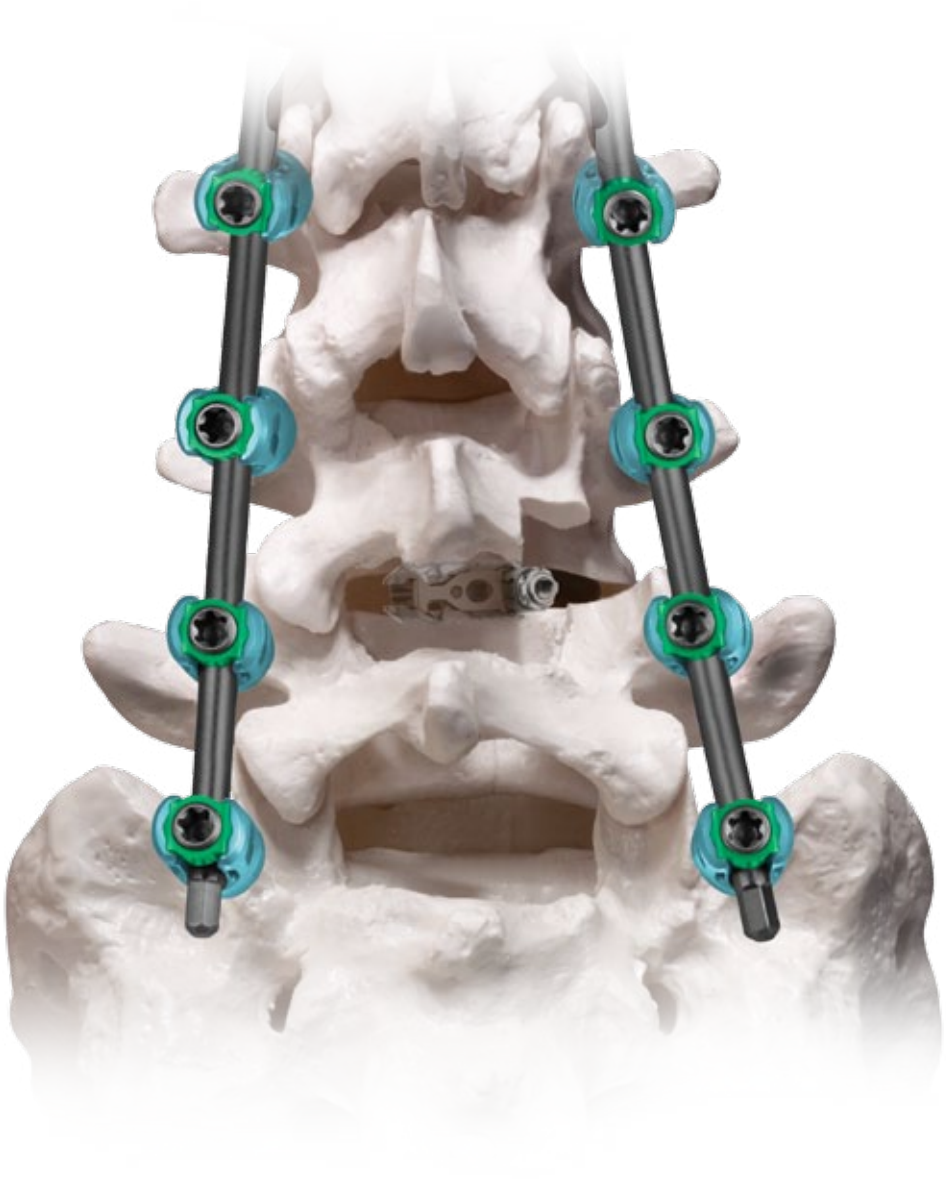
Step 12 Final Positioning

The final position of the ALTERA™ implant is shown below.

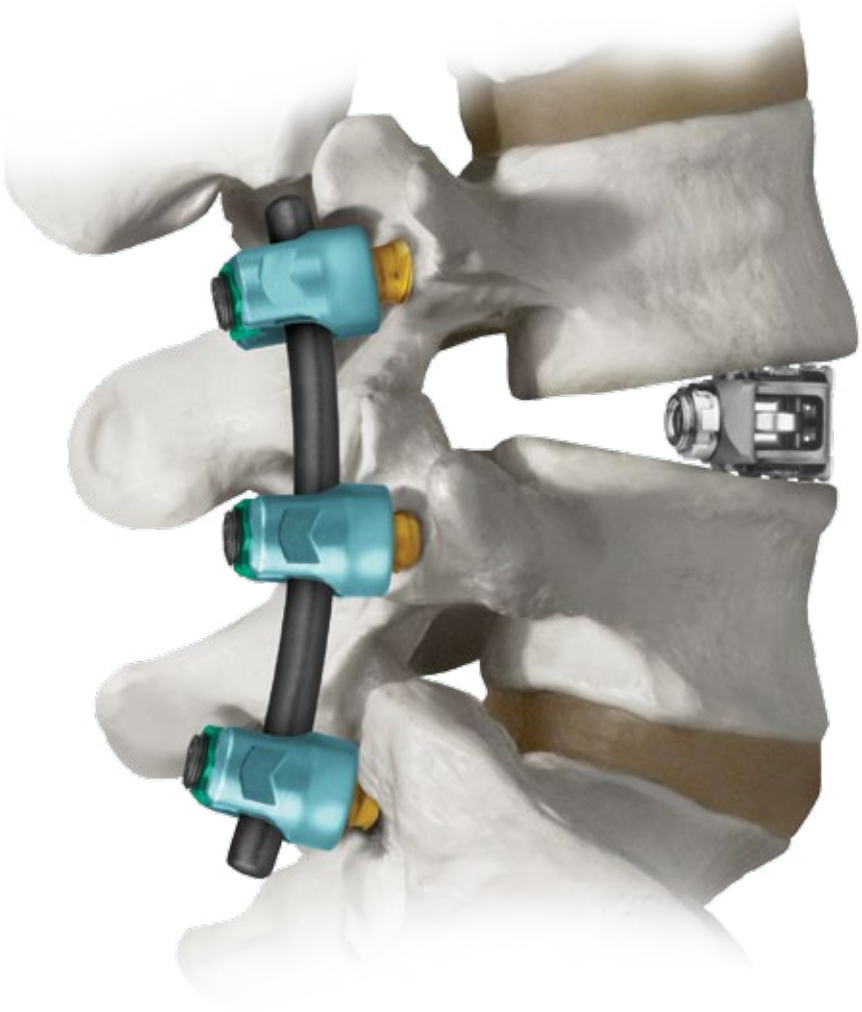




Final Construct



Final Construct with supplemental fixation
using CREO® (posterior view)



Final Construct with supplemental fixation
using CREO® (lateral view)

Optional: Implant Removal

Place the **ALTERA™ Removal Threaded Rod** into the **ALTERA™ Removal Driver Shaft**. Thread clockwise into the back of the implant.

Rotate the knurled portion of the driver shaft counterclockwise, until finger tight, to collapse the implant. Confirm with fluoroscopic imaging. Rotate the knurled portion of the driver shaft 90° clockwise to allow the implant to pivot freely.

Gently pull backwards on the threaded rod and driver shaft assembly. If necessary, the **Slide Hammer** may be attached and impacted backwards out of the disc space.

Implant removal using the Slide Hammer

Supplemental Fixation

In addition to the described interbody fusion, supplemental fixation, such as CREO®, REVERE® or REVOLVE®, must be used at the appropriate level(s). Please refer to the corresponding package insert for important information.

REVOLVE® is a posterior stabilization system designed for minimally invasive surgery (MIS).

REVOLVE® Stabilization System

REVOLVE® Locking Technology

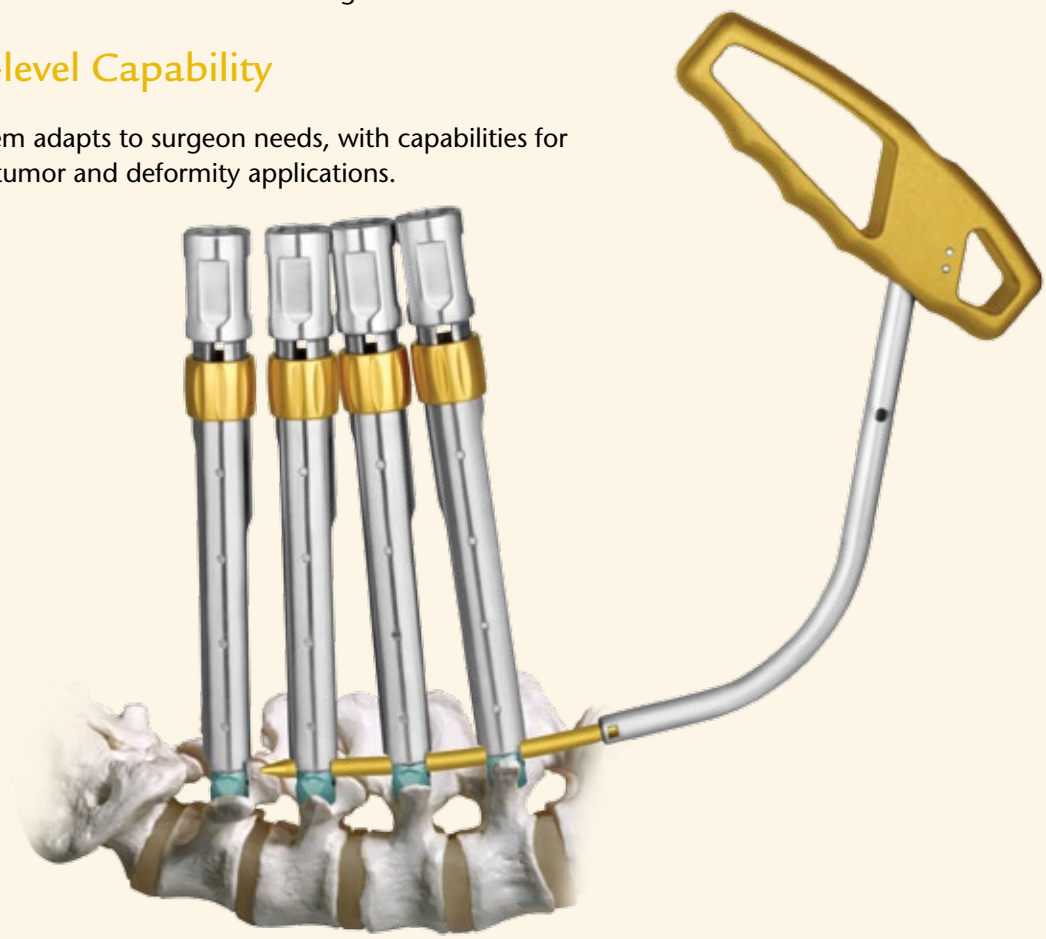
Non-threaded locking caps eliminate cross-threading and challenging with cap placement.

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.



Supplemental Fixation (cont'd)

CREO® and CREO AMP® Stabilization Systems enhance efficiency and ease of use by providing intuitively designed instruments and a variety of implant options for treating complex spinal pathologies. The CREO® platform offers a low-profile implant design in both preassembled and modular screw options with a threaded or non-threaded locking mechanism to accommodate surgeon preferences.

CREO® Stabilization System

Optimized Visualization and Access

CREO® implants are designed with a low profile.

The CREO® reducers are designed with minimal bulk for improved visualization in the surgical field. The engagement interface of the reduction instruments was designed with less run-on-rod to fit in high curves and tight screw-to-screw situations.

Non-Threaded Locking

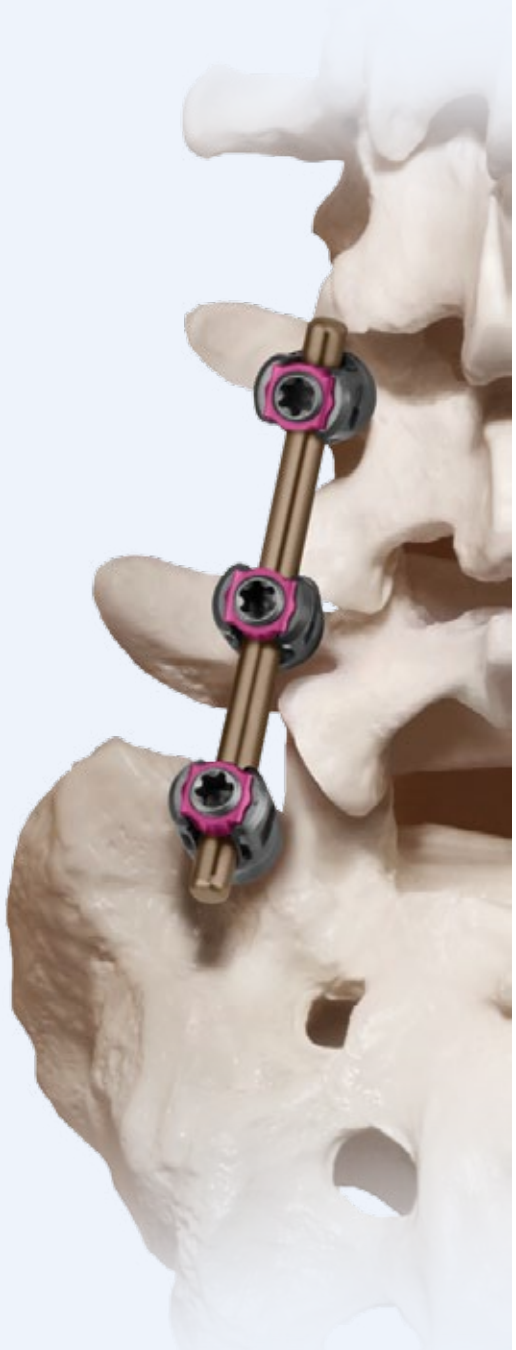
The reliability of patented non-threaded locking technology has been proven over the last several years as the foundation for the REVERE® Stabilization System, effectively eliminating cross-threading.

Designed for deformity correction, the locking cap securely captures the rod while allowing for adjustment of the rod within the screw head.

Efficiency Engineered

The CREO® Semi-Automatic Locking Cap Driver, which holds and dispenses eight locking caps, is 75% faster* than a traditional locking cap driver.

The compact CREO® Reduction Clip with Derotator Attachment allows up to 30mm of gradual reduction and can be coupled for derotation techniques as needed.



**Based on internal testing scenario, actual results may vary per case.*

CREO AMP® Stabilization System

Optimized Visualization

CREO AMP® implants are designed with a low profile. Inserting screw posts prior to screw heads allows for superior decortication and access in TLIF cases.

The CREO AMP® reducers are designed with minimal bulk for improved visualization in the surgical field.

Confidence in Construct Stability

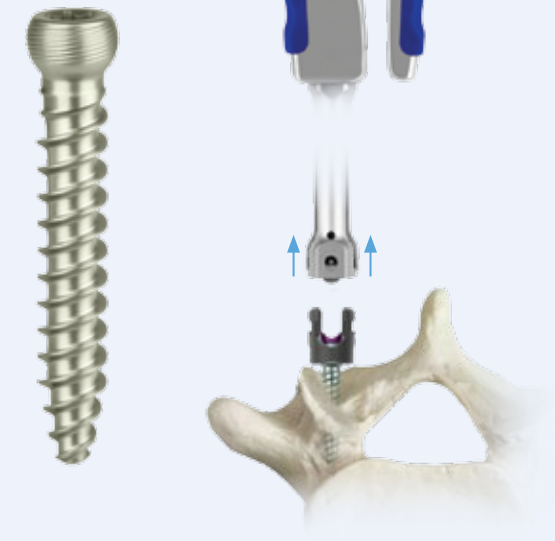
The Inserter Tool is designed to easily assemble screws, incorporating a handle lock/release indicator that ensures a screw head is secured onto the screw post.

Testing shows the intraoperatively assembled CREO AMP® screw is just as strong as CREO® preassembled screws.

Solutions for Complex Spinal Pathologies

The system offers an extensive array of connector options, including polyaxial, side-loading and closed head screws, CREO® head offset connector, sacral plate, and lamina clamp. Connectors can be placed and exchanged *in situ*, offering more versatility for challenging patient anatomy.

The compact CREO® Reduction Clip with Derotator Attachment allows up to 30mm of gradual reduction and can be coupled for derotation techniques as needed.



ALTERA™ IMPLANT SETS

ALTERA™ Implant Sets

ALTERA™ 10x26mm Implant Set 9124.9026

Part No.	Description	Qty
1124.1011	ALTERA™ Spacer, 10x26, 8–12mm, 8°	2
1124.1012	ALTERA™ Spacer, 10x26, 9–13mm, 8°	2
1124.1013	ALTERA™ Spacer, 10x26, 10–14mm, 8°	2
1124.1015	ALTERA™ Spacer, 10x26, 12–16mm, 8°	2
1124.1032	ALTERA™ Spacer, 10x26, 9–13mm, 15°	2
1124.1033	ALTERA™ Spacer, 10x26, 10–14mm, 15°	2
1124.1035	ALTERA™ Spacer, 10x26, 12–16mm, 15°	2
9124.0026	ALTERA™ 10x26mm Implant Module	

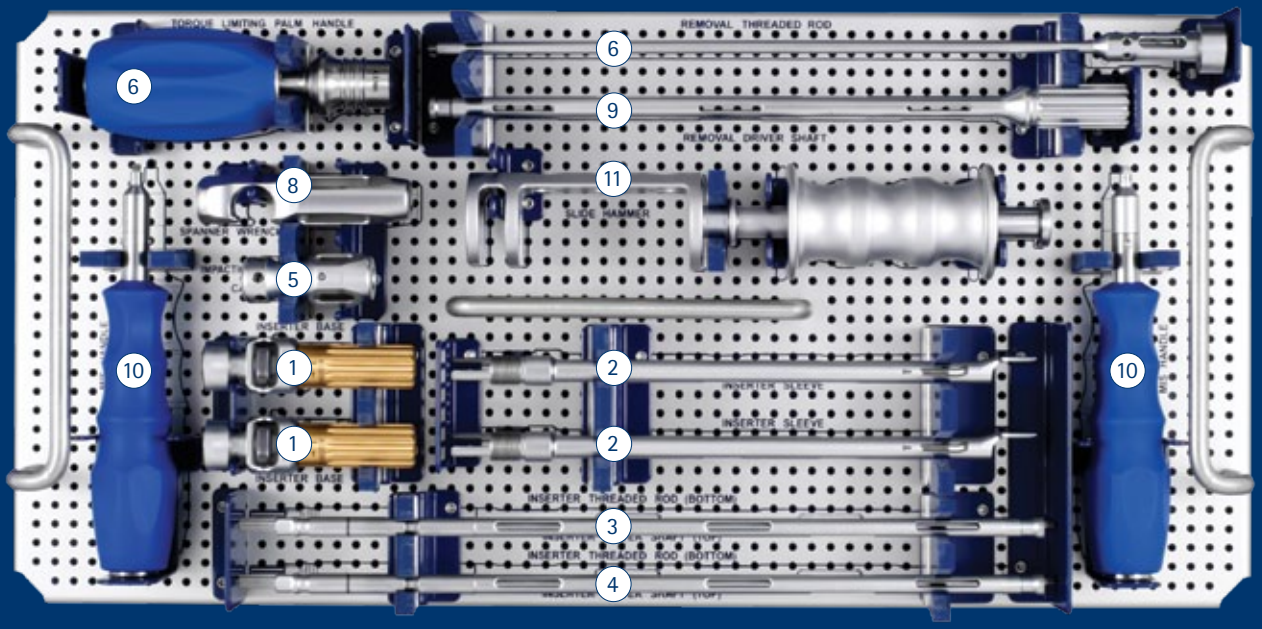
ALTERA™ 10x31mm Implant Set 9124.9031

Part No.	Description	Qty
1124.1111	ALTERA™ Spacer, 10x31, 8–12mm, 8°	2
1124.1112	ALTERA™ Spacer, 10x31, 9–13mm, 8°	2
1124.1113	ALTERA™ Spacer, 10x31, 10–14mm, 8°	2
1124.1115	ALTERA™ Spacer, 10x31, 12–16mm, 8°	2
1124.1132	ALTERA™ Spacer, 10x31, 9–13mm, 15°	2
1124.1133	ALTERA™ Spacer, 10x31, 10–14mm, 15°	2
1124.1135	ALTERA™ Spacer, 10x31, 12–16mm, 15°	2
9124.0031	ALTERA™ 10x31mm Implant Module	

ALTERA™ 10x36mm Implant Set 9124.9036

Part No.	Description	Qty
1124.1211	ALTERA™ Spacer, 10x36, 8–12mm, 8°	2
1124.1212	ALTERA™ Spacer, 10x36, 9–13mm, 8°	2
1124.1213	ALTERA™ Spacer, 10x36, 10–14mm, 8°	2
1124.1215	ALTERA™ Spacer, 10x36, 12–16mm, 8°	2
1124.1232	ALTERA™ Spacer, 10x36, 9–13mm, 15°	2
1124.1233	ALTERA™ Spacer, 10x36, 10–14mm, 15°	2
1124.1235	ALTERA™ Spacer, 10x36, 12–16mm, 15°	2
9124.0036	ALTERA™ 10x36mm Implant Module	

ALTERA™ INSTRUMENT SET



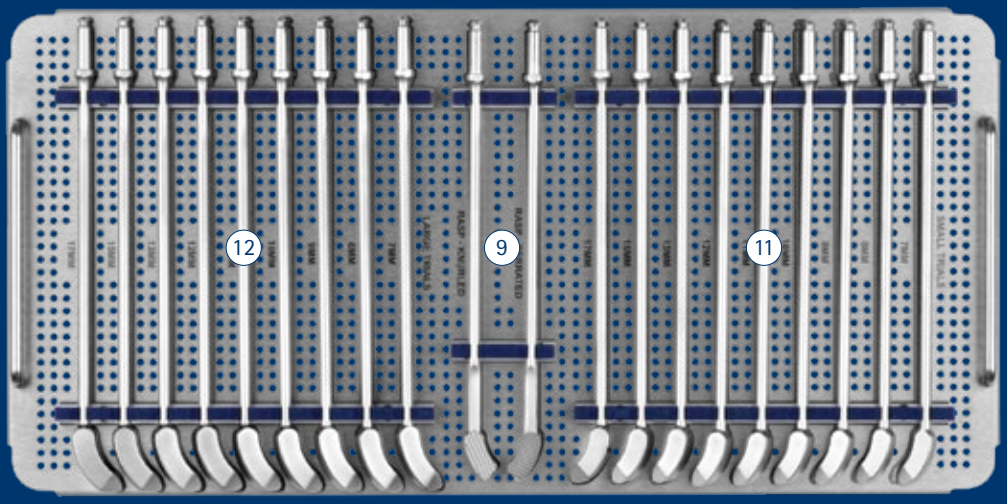
ALTERA™ Instrument Set 9124.9001

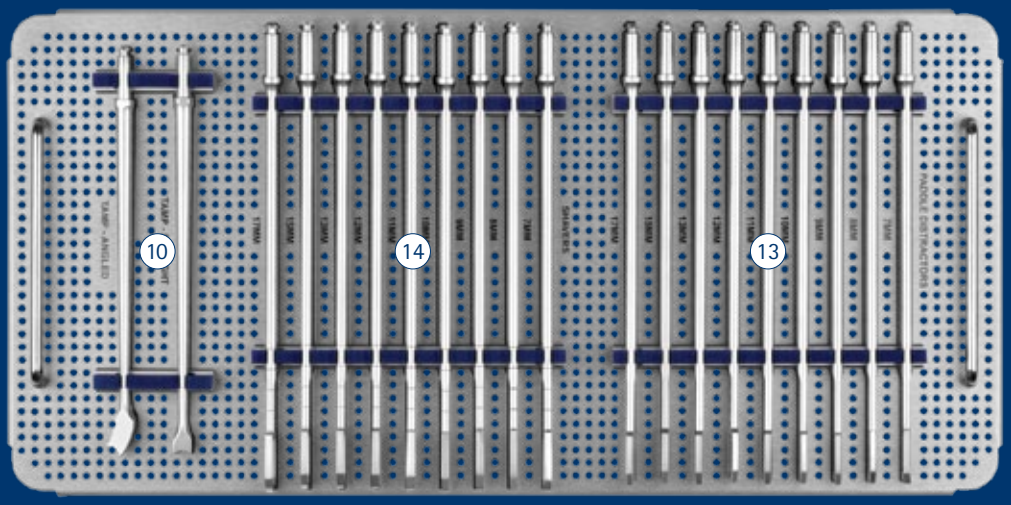
	Instrument		Qty
1	6124.0001	ALTERA™ Inserter Base	2
2	6124.0002	ALTERA™ Inserter Sleeve	2
3	6124.0003	ALTERA™ Inserter Threaded Rod	2
4	6124.0004	ALTERA™ Inserter Driver Shaft	2
5	6124.0005	ALTERA™ Impaction Cap	1
6	6124.0006	ALTERA™ Removal Threaded Rod	1
7	6124.0007	Torque Limiting Palm Handle, Cannulated, 4.5Nm	1
8	6124.0008	ALTERA™ Spanner Wrench	1
9	6124.0009	ALTERA™ Removal Driver Shaft	1
10	673.003	MIS Handle	2
11	694.018	Slide Hammer	1
	9124.0001	ALTERA™ Instrument Graphic Case	

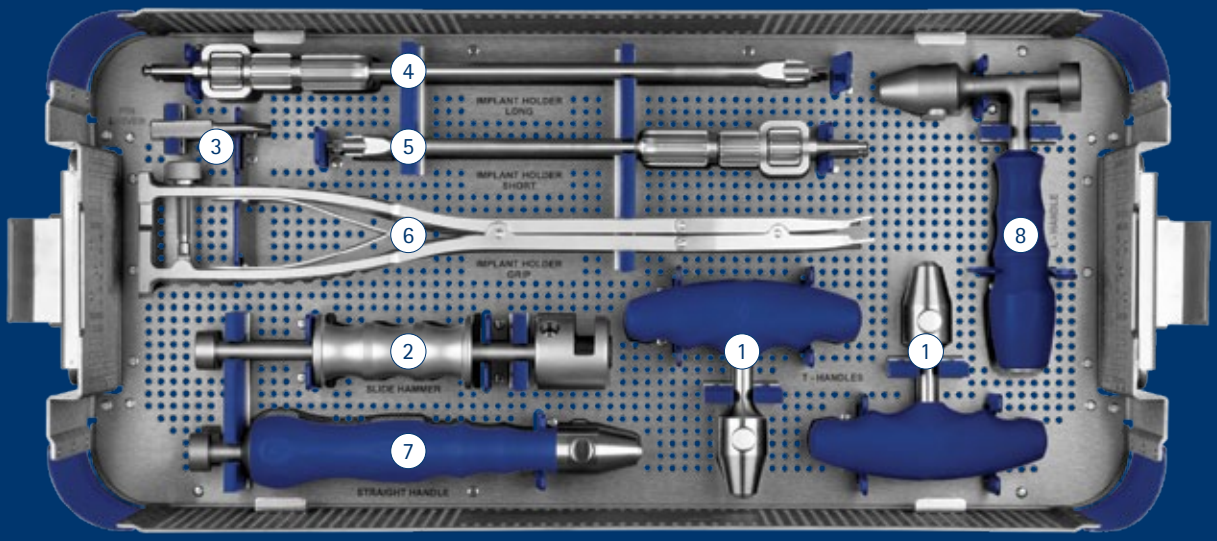
Additionally Available

6124.0010	Bone Funnel Tube
6124.0011	Bone Funnel Pusher
681.013	Bone Funnel

SIGNATURE® INSTRUMENT SET





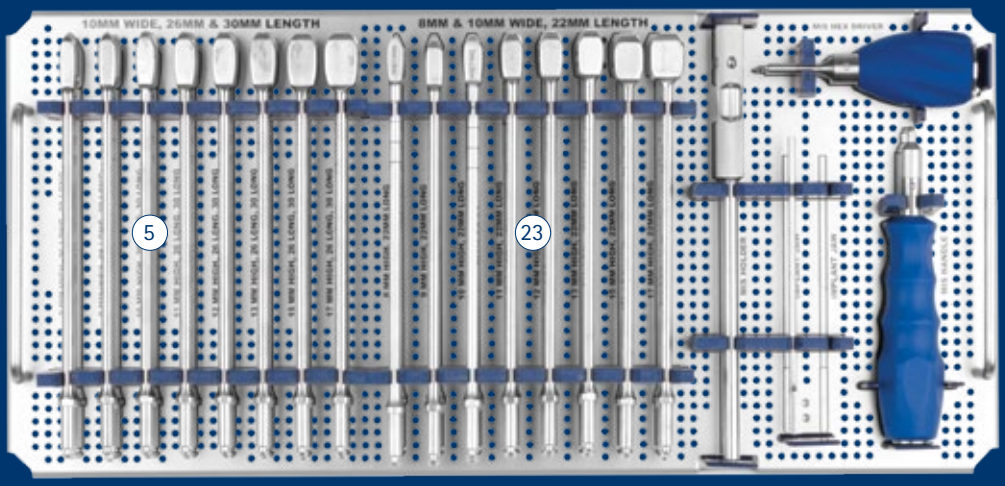


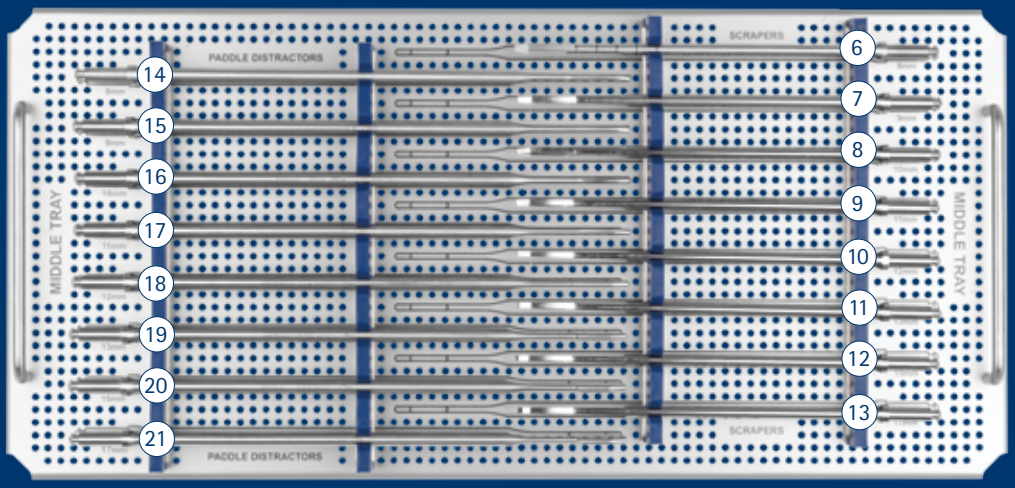
SIGNATURE® Instrument Set 968.901

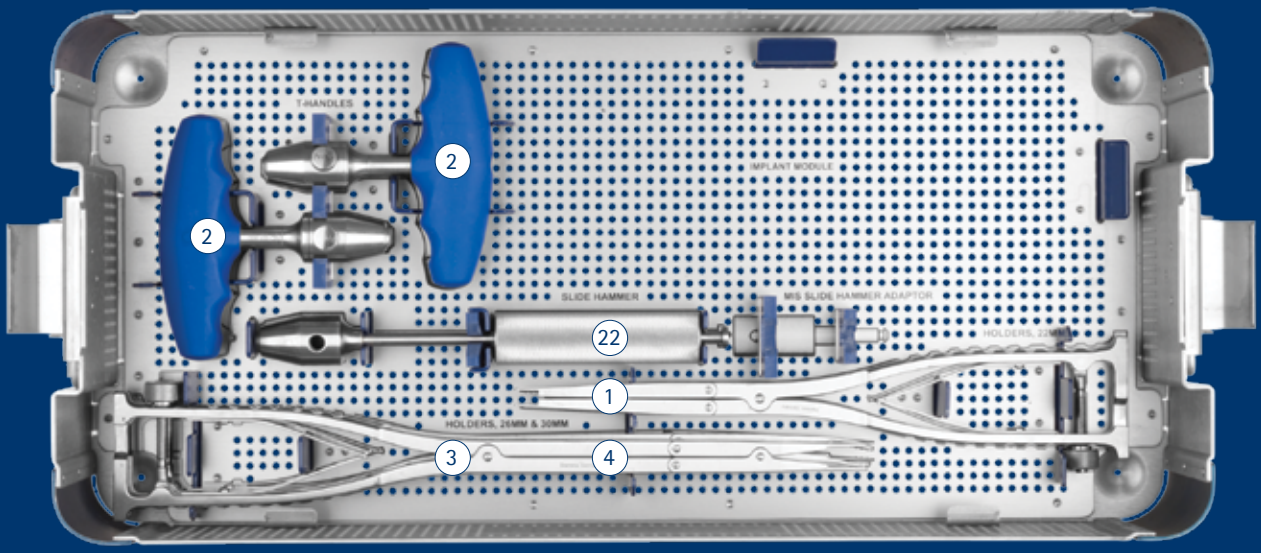
	Instruments		Qty
1	601.800	T-Handle	2
2	622.410	Slide Hammer, Small	1
3	668.050	SIGNATURE® Pin Driver	1
4	668.100	SIGNATURE® Implant Holder, Long	1
5	668.101	SIGNATURE® Implant Holder, Short	1
6	668.150	SIGNATURE® Holder	1
7	668.160	SIGNATURE® Quick Coupling Handle	1
8	679.010	L-Handle	1
9	**Rasps**		
	668.020	SIGNATURE® Rasp, Angled, Serrated	1
	668.021	SIGNATURE® Rasp, Angled, Knurled	1
10	**Tamps**		
	668.040	SIGNATURE® Tamp, Straight	1
	668.041	SIGNATURE® Tamp, Angled	1
11	**Small Trials**		
	668.207	SIGNATURE®, Small, Trial, 7mm	1
	668.208	SIGNATURE®, Small, Trial, 8mm	1
	668.209	SIGNATURE®, Small, Trial, 9mm	1
	668.210	SIGNATURE®, Small, Trial, 10mm	1
	668.211	SIGNATURE®, Small, Trial, 11mm	1
	668.212	SIGNATURE®, Small, Trial, 12mm	1
	668.213	SIGNATURE®, Small, Trial, 13mm	1
	668.215	SIGNATURE®, Small, Trial, 15mm	1
	668.217	SIGNATURE®, Small, Trial, 17mm	1
12	**Large Trials**		
	668.307	SIGNATURE®, Large, Trial, 7mm	1
	668.308	SIGNATURE®, Large, Trial, 8mm	1
	668.309	SIGNATURE®, Large, Trial, 9mm	1
	668.310	SIGNATURE®, Large, Trial, 10mm	1
	668.311	SIGNATURE®, Large, Trial, 11mm	1

	Instruments		Qty
12	**Large Trials (cont'd)**		
	668.312	SIGNATURE®, Large, Trial, 12mm	1
	668.313	SIGNATURE®, Large, Trial, 13mm	1
	668.315	SIGNATURE®, Large, Trial, 15mm	1
	668.317	SIGNATURE®, Large, Trial, 17mm	1
13	**Paddle Distractors**		
	668.407	SIGNATURE® Paddle Distractor, 7mm	1
	668.408	SIGNATURE® Paddle Distractor, 8mm	1
	668.409	SIGNATURE® Paddle Distractor, 9mm	1
	668.410	SIGNATURE® Paddle Distractor, 10mm	1
	668.411	SIGNATURE® Paddle Distractor, 11mm	1
	668.412	SIGNATURE® Paddle Distractor, 12mm	1
	668.413	SIGNATURE® Paddle Distractor, 13mm	1
	668.415	SIGNATURE® Paddle Distractor, 15mm	1
	668.417	SIGNATURE® Paddle Distractor, 17mm	1
14	**Sizers/Shavers**		
	668.507	SIGNATURE® Sizer/Shaver, 7mm	1
	668.508	SIGNATURE® Sizer/Shaver, 8mm	1
	668.509	SIGNATURE® Sizer/Shaver, 9mm	1
	668.510	SIGNATURE® Sizer/Shaver, 10mm	1
	668.511	SIGNATURE® Sizer/Shaver, 11mm	1
	668.512	SIGNATURE® Sizer/Shaver, 12mm	1
	668.513	SIGNATURE® Sizer/Shaver, 13mm	1
	668.515	SIGNATURE® Sizer/Shaver, 15mm	1
	668.517	SIGNATURE® Sizer/Shaver, 17mm	1
	968.001	SIGNATURE® Instruments Graphic Case	

PRESERVE® INSTRUMENT SET



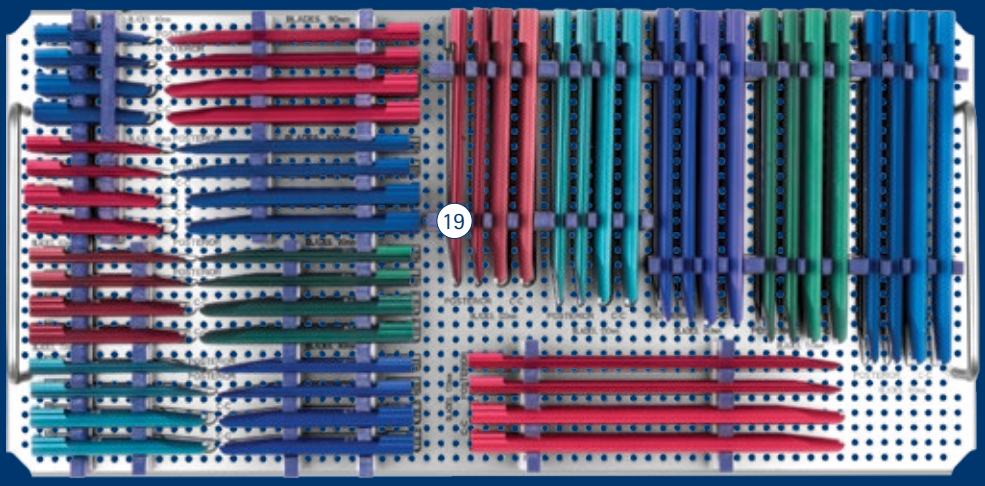


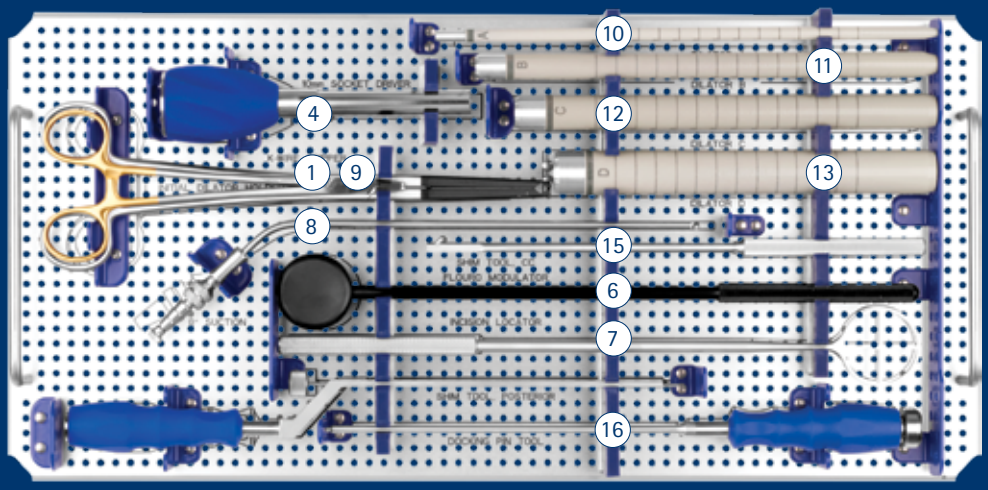


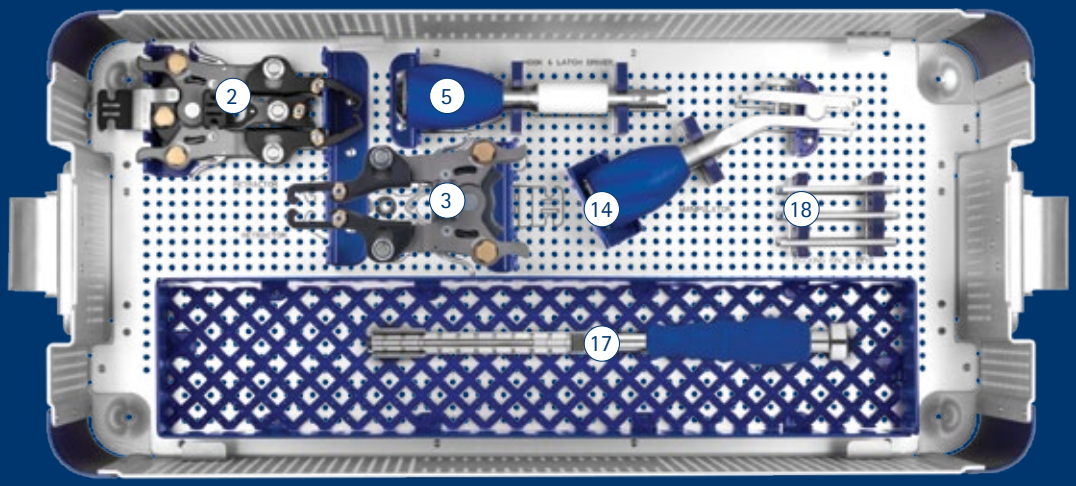
PRESERVE® Posterior Unilateral Instrument Set 904.907

	Instruments		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, 8x22mm, 9mm, SUSTAIN® Oblique, Small	1
	673.110	Trial Shaft, 8x22mm, 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	

MARS™ 3V RETRACTOR SET







MARS™3V Retractor Set 998.901

	Instruments		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		
	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

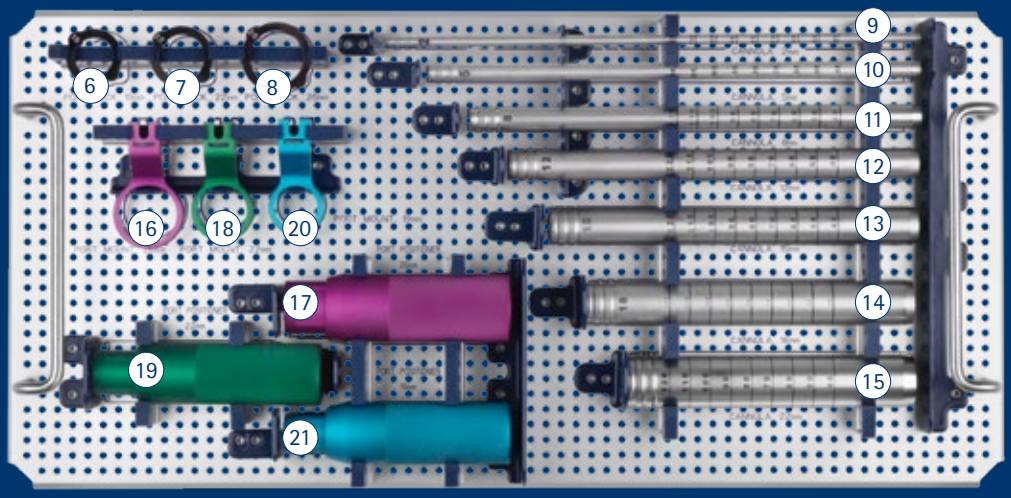
Retractor Blades		Qty
698.476	Blade, Posterior, 170mm	2
698.510	Blade, CC, 40mm	2
698.512	Blade, CC, 50mm	2
698.514	Blade, CC, 60mm	2
698.516	Blade, CC, 70mm	2
698.518	Blade, CC, 80mm	2
698.520	Blade, CC, 90mm	2
698.522	Blade, CC, 100mm	2
698.524	Blade, CC, 110mm	2
698.526	Blade, CC, 120mm	2
698.528	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

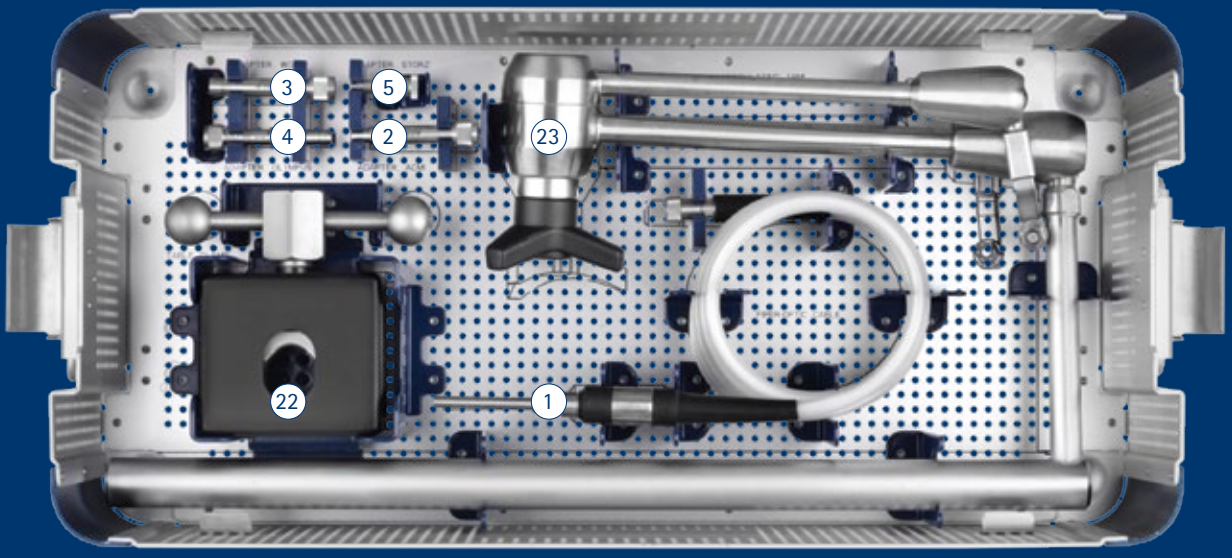
Disposables

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 highlighted in gray are additionally available.

MARS™ INSTRUMENTS II SET



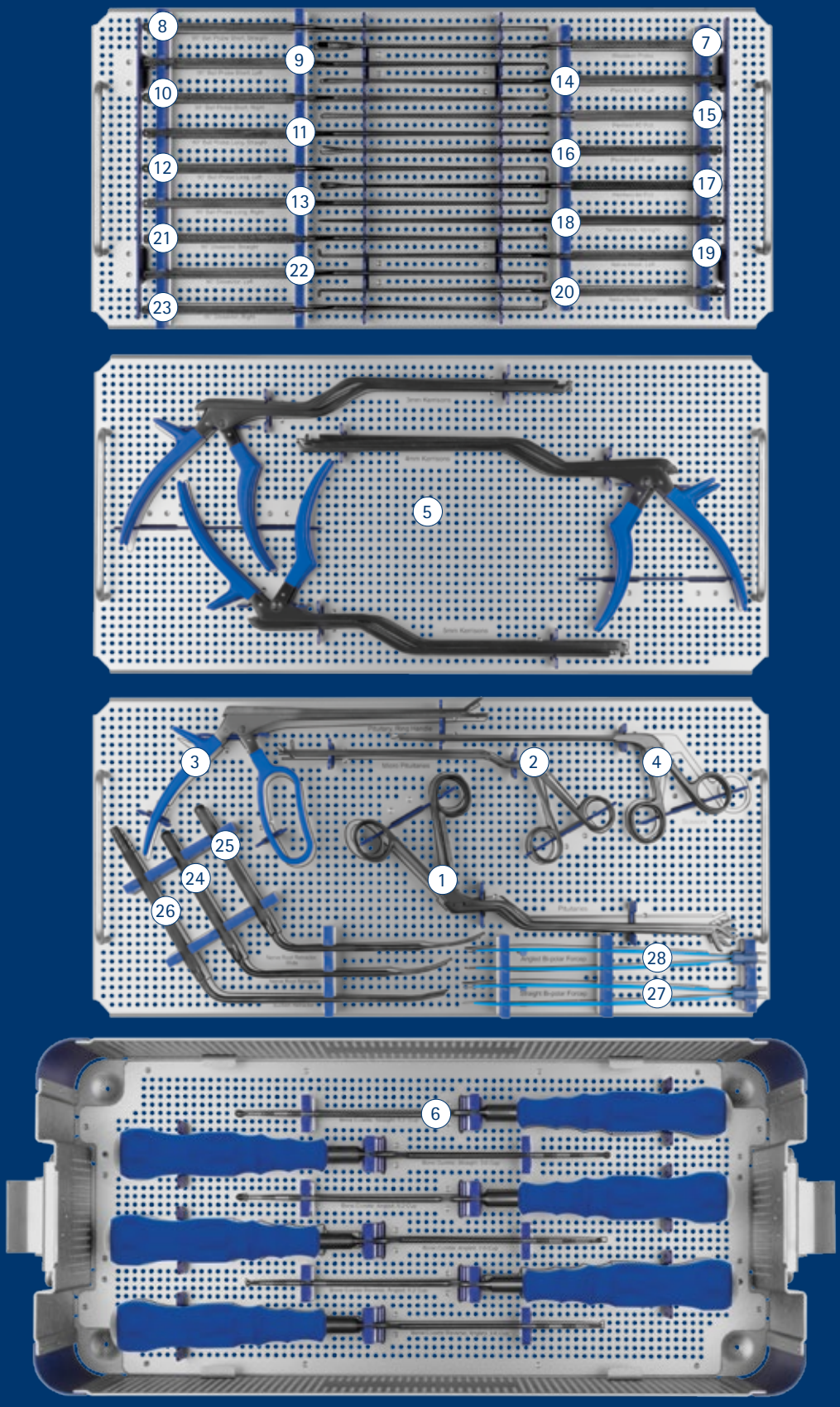


MARS™ Instrument II Set 932.902

	Instruments		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	

Items highlighted in gray are additionally available.

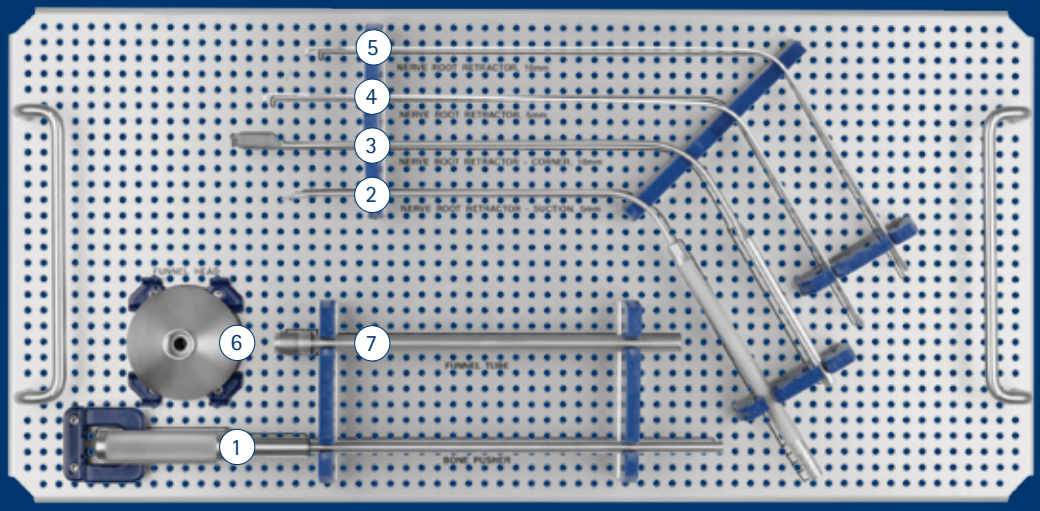
MARS™ INSTRUMENTS III SET

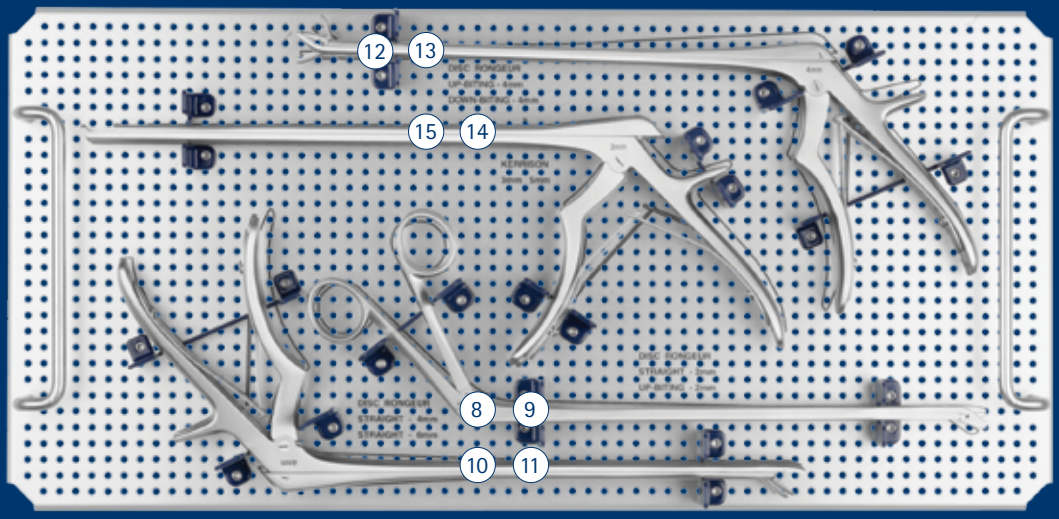


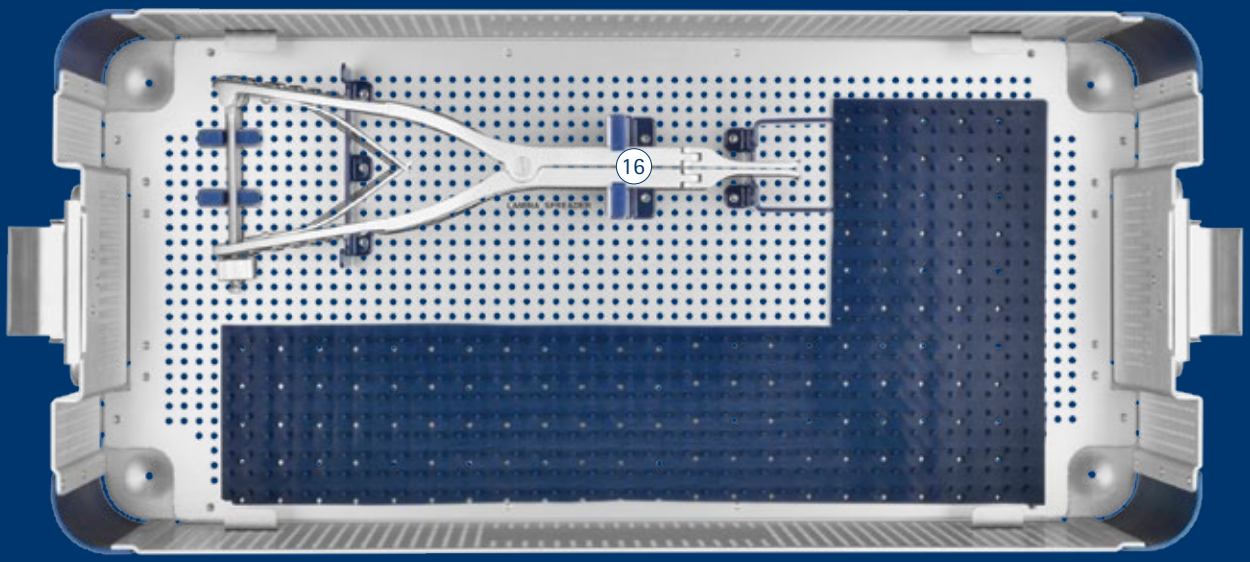
MARS™ Instrument III Set 932.903

	Instruments		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
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
28	632.677	Bi-polar Forcep, Angled, Bayoneted, US Connection	1
	932.003	MARS™ Instrument Graphic Case	

POSTERIOR DISC PREP INSTRUMENTS I SET



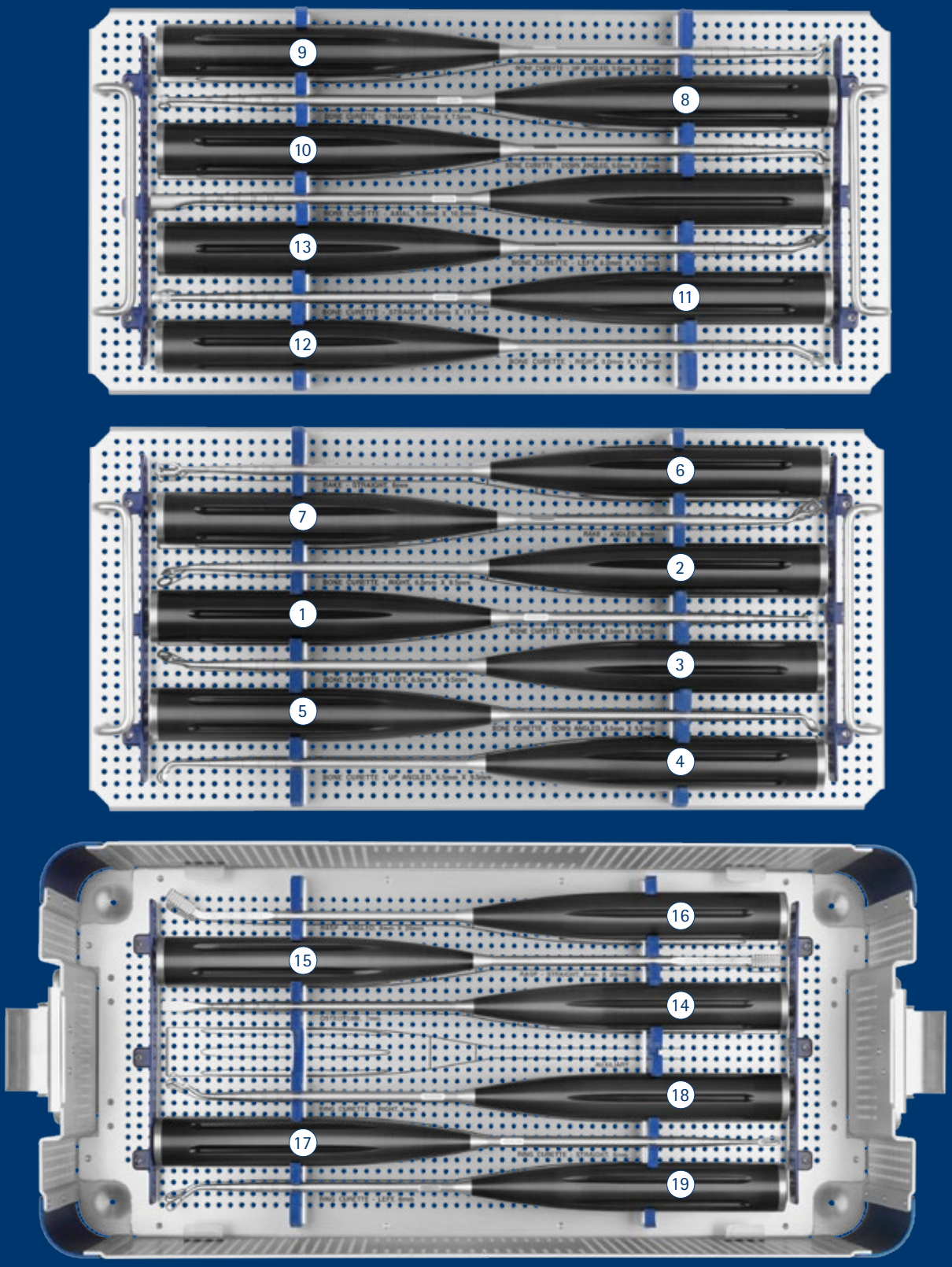




Posterior Disc Prep Instruments I Set 926.901

	Instruments		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	

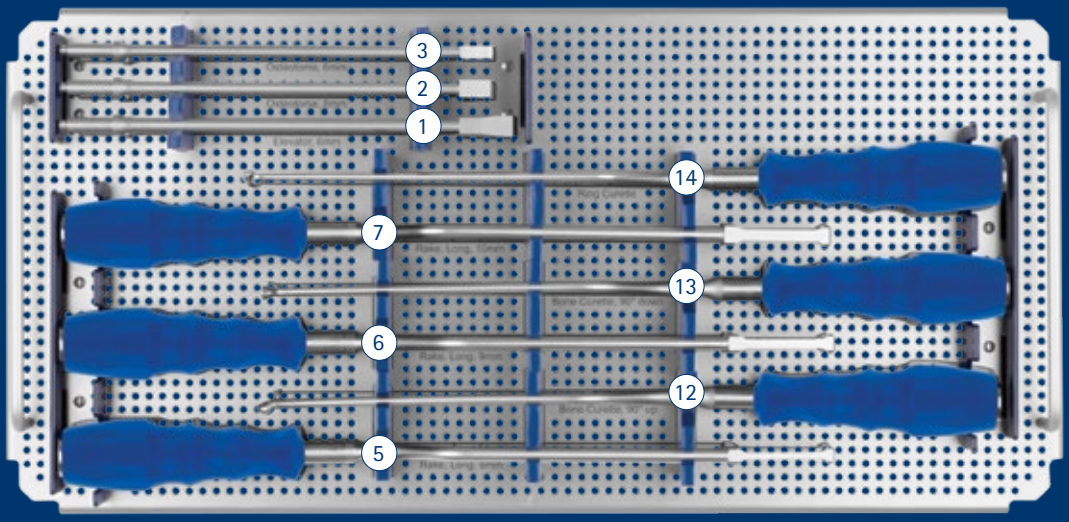
POSTERIOR DISC PREP INSTRUMENTS II SET

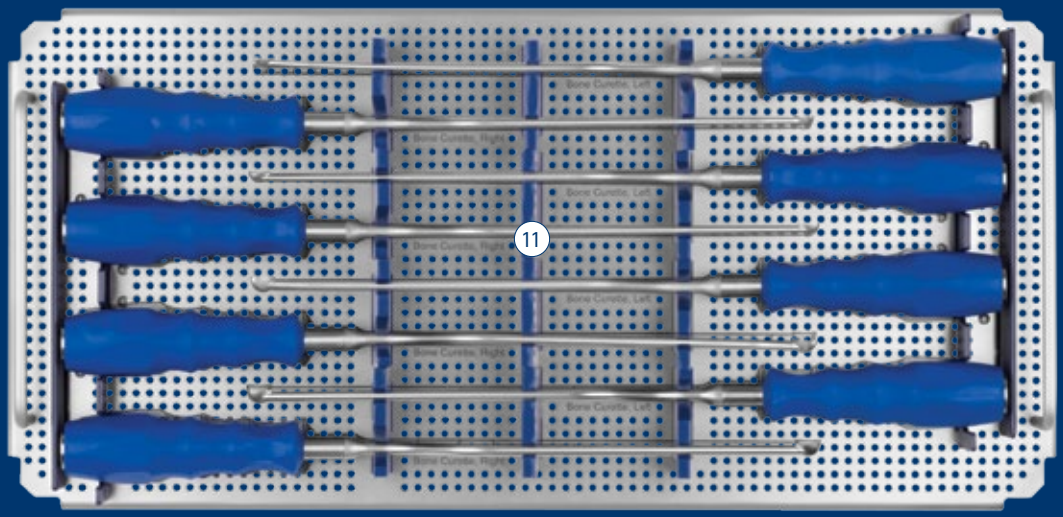


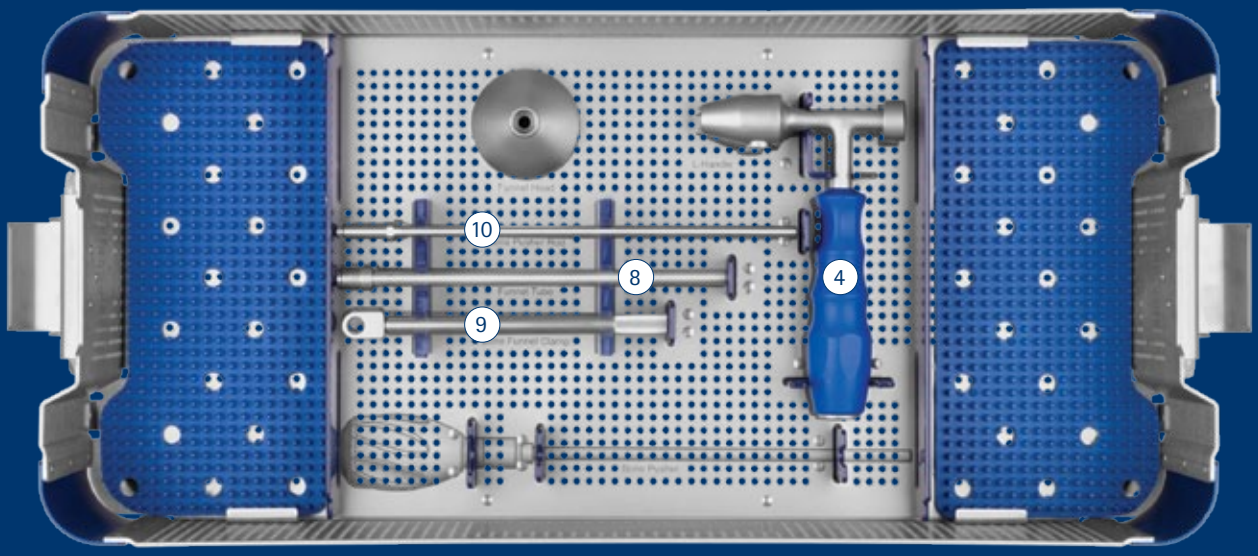
Posterior Disc Prep Instruments II Set 926.902

	Instruments		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	

MIS LUMBAR DISCECTOMY INSTRUMENT SET







MIS Lumbar Discectomy Instrument Set 979.901

	Instruments		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
12	679.026	Bone Curette, Straight, 10.0 Serrated Cup	1
13	679.027	Bone Curette, Angled, 10.0 Serrated Cup	1
14	679.028	Bone Curette, Straight, 10.0 Serrated Cup	1
15	679.031	Bone Curette, Angled, 12.0 Serrated Cup, Bayoneted, LH	1
16	679.032	Bone Curette, Straight, 12.0 Serrated Cup, Bayoneted, LH	1
17	679.033	Bone Curette, Angled, 12.0 Serrated Cup, Bayoneted, RH	1
18	679.034	Bone Curette, Straight, 12.0 Serrated Cup, Bayoneted, RH	1
19	679.041	Bone Curette, 10.7 Serrated Cup, 90° Up	1
20	679.042	Bone Curette, 10.7 Serrated Cup, 90° Down	1
21	679.051	Ring Curette, 6mm	1
22	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

Items highlighted in gray are additionally available.

IMPORTANT INFORMATION ON THE ALTERA™ ARTICULATING EXPANDABLE TLIF SPACER

DESCRIPTION

The ALTERA™ Spacer is an expandable lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The ALTERA™ Spacer accommodates various surgical approaches to the lumbar spine (posterior or transforaminal [posterolateral]) and allows articulation upon insertion. The devices are available in various height ranges, allowing continuous expansion within the range, to fit the anatomical needs of a wide variety of patients. This device is to be filled with autogenous bone graft material. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

The ALTERA™ Spacer is made from titanium alloy, as specified in ASTM F136, F1295, and F1472. Internal components are made from radiolucent PEEK polymer and cobalt chromium molybdenum alloy, as specified in ASTM F2026 and F1537, respectively.

INDICATIONS

The ALTERA™ Spacer is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). 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. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The ALTERA™ Spacer is to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation.

WARNINGS

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

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

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.

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

Components of this system are manufactured from PEEK radiolucent polymer, titanium alloy and cobalt chromium molybdenum alloy. Mixing of stainless steel 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.

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.

The ALTERA™ Spacer has not been evaluated for safety and compatibility in the MR environment. The ALTERA™ Spacer has not been tested for heating or migration in the MR environment.

CONTRAINDICATIONS

Use of the ALTERA™ Spacer is contraindicated in patients with the following conditions:

1. Active systemic infection, infection or inflammation 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 patient not willing to cooperate with postoperative instruction.
7. Any condition not described in the indications for use.
8. Fever or leukocytosis.
9. Pregnancy.
10. 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.
11. Any case not needing a fusion.
12. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
13. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
14. Spondylolisthesis unable to be reduced to Grade 1.
15. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
16. Any case that requires the mixing of metals from two different components or systems.
17. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
18. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

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

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

IMPORTANT INFORMATION ON THE ALTERA™ ARTICULATING EXPANDABLE TLIF SPACER

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.

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

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

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

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

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

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

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

REV A

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

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

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