



SURGICAL TECHNIQUE



LLIF Procedure

Lateral Lumbar Interbody Fusion

with MARS™ 3V & TransContinental®



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

LLIF

Lateral Lumbar Interbody Fusion



The use of a lateral approach to access the thoracolumbar spine has been well documented in literature. In the late 19th century (1894), Menard developed a procedure that allowed greater exposure to the lateral aspect of the spine. Capener, in 1954, built on Menard's advances for the treatment of Pott disease (tuberculosis of the spine).^{1,2} However, their procedures had limitations.

During the past 35 years, surgeons have continued to develop the lateral technique. In 1976 Fraser et al. described a muscle splitting approach to the lumbosacral spine. The exposure gained with this retroperitoneal technique offered successful access to the mid-lumbar and lumbosacral spine.³ O'Brien analyzed his many patients that underwent a left-sided, retroperitoneal approach. The benefit of this was avoidance of canal trauma and elimination of motion by using a large graft.⁴ McAfee et al. presented the first clinical series investigating the use of the lateral retroperitoneal approach for fusion from L1-L5, reporting an overall lower morbidity comparable to traditional approaches.⁵ Building on this, Bertagnoli developed the anterolateral transpsoatic approach for accessing the lumbar disc while avoiding disruption to the posterior elements.⁶ Today, Globus has refined the lateral approach with the introduction of MARS™3V and TransContinental®.

1 Ménard V: *Causes de la paraplégie dans le mal de Pott*. Rev Orthop: 47-64, 1894.

2 Capener N: *The evolution of lateral rhacotomy*. J Bone Joint Surg Br 36: 173-179, 1954.

3 Fraser RD, Gogan WJ. *A Modified Muscle-Splitting Approach to the Lumbosacral Spine*. Spine 17(8): 943-8, 1992.

4 Kozak J, O'Brien J. *Simultaneous Combined Anterior and Posterior Fusion*. An Independent Analysis of a Treatment for the Disabled Low-Back Pain Patient Spine 15(4): 322-328, 1990.

5 McAfee P et al. *Minimally Invasive Anterior Retroperitoneal Approach to the Lumbar Spine: Emphasis on the Lateral BAK*. Spine 23(13): 1476-1484, 1998.

6 Bertagnoli R, Vazquez RJ. *The Anterolateral TransPsoatic Approach(ALPA): a new technique for implanting prosthetic disc-nucleus devices*. J Spinal Disord Tech 16(4): 398-404, 2003.



LLIF

LATERAL LUMBAR INTERBODY FUSION

The MIS lateral approach has been refined with the combination of the MARS™3V retractor and the TransContinental® spacer system.

MARS™3V is a versatile and variable vision system that gives unprecedented control of tissue retraction during the entire procedure.

TransContinental® is a comprehensive spacer system with extensive instrumentation.

MARS™3V

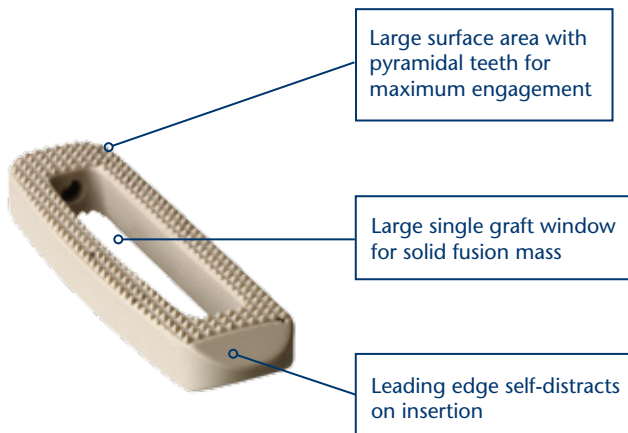
The MARS™3V Retractor provides the versatility, stability, and precision required to access hard-to-reach disc spaces.

- Independent blade retraction
- Individual blade angulation up to 20°
- Lightweight, aluminum components for radiolucency
- Illumination system fits within blade walls for less bulk

TransContinental®

The TransContinental® System is ideal for a minimally invasive approach to help preserve patient anatomy.

- Self-distracting leading edge for ease of insertion
- Radiographic positioning markers for implant placement and orientation
- Comprehensive disc preparation instrumentation
- Trial length indicators provide accurate length assessment on fluoroscopy

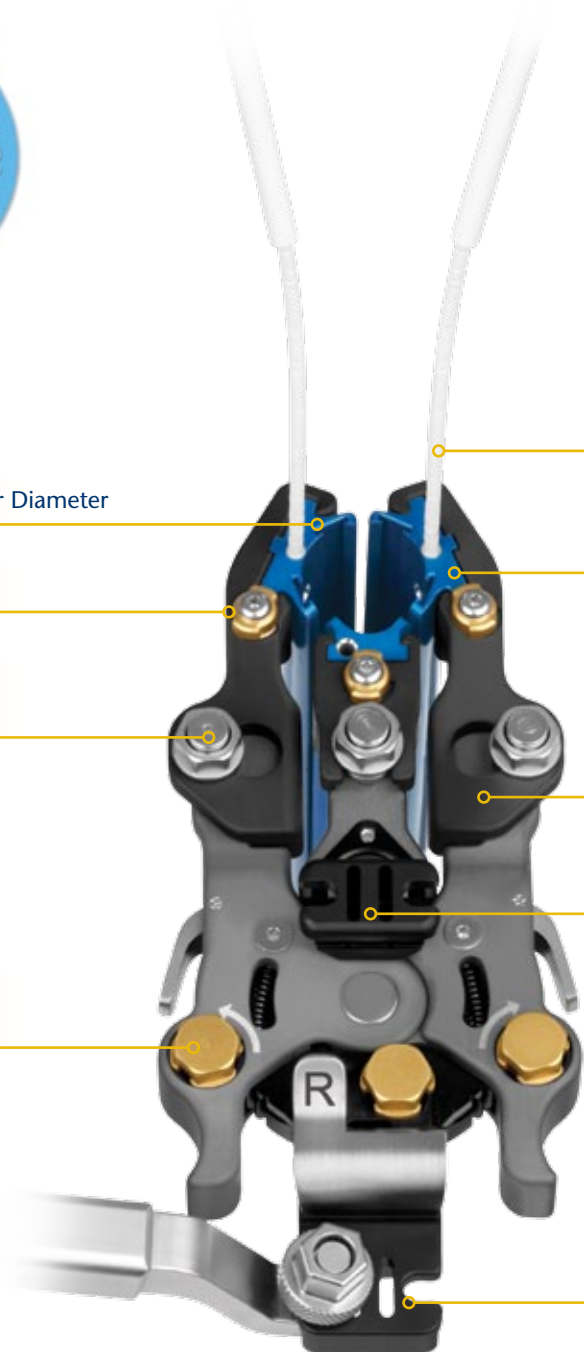


CONTENTS

Distinguishing Characteristics	2
MARS™3V Retractor Overview	4
Implant Overview	5
Instrument Overview	6
Surgical Technique	
1. Patient Preparation	16
2. Initial Dilator Insertion	18
3. Retractor Insertion	19
4. Disc Preparation	25
5. Interbody Insertion	26
<i>Using the Implant Insertion Tool</i>	27
Final Position	28
TransContinental® Implant Set	30
MARS™3V Retractor Set	32
MARS™ Instrument II Set	34
Anterior Disc Prep I Instrument Set	36
Anterior Disc Prep II Instrument Set	38
Lateral Disc Prep Instrument Set	40
TransContinental® Insertion Instruments Set	42
Lateral Angled Disc Prep Instrument Set	44
TransContinental® Angled Trials Set	46
TransContinental® 16mm Wide Implant Set	48
Bayonetted Disc Prep Instrument Set	49
TransContinental® 22mm Implant Set	50
TransContinental® 10° Lordotic Implant Set	52
TransContinental® Coronal Tapered Implant Set	54
Important Information	56

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.

MARS™ 3V RETRACTOR OVERVIEW



Low-Profile 18mm Inner Diameter

Blade Lock

Individual Blade Angulation Knob

Independent Blade Retraction Knob

Guided Light Source

Extra Wide Cephalad-Caudad Blades

Radiolucent Arm

Retractor Center Fixation Mount

Posterior Blade Fixation Mount

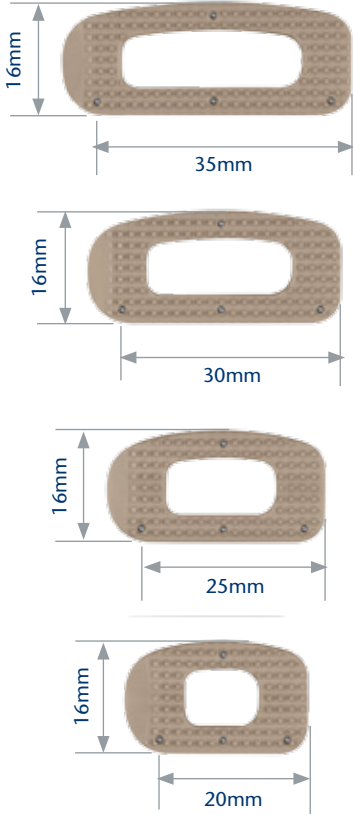
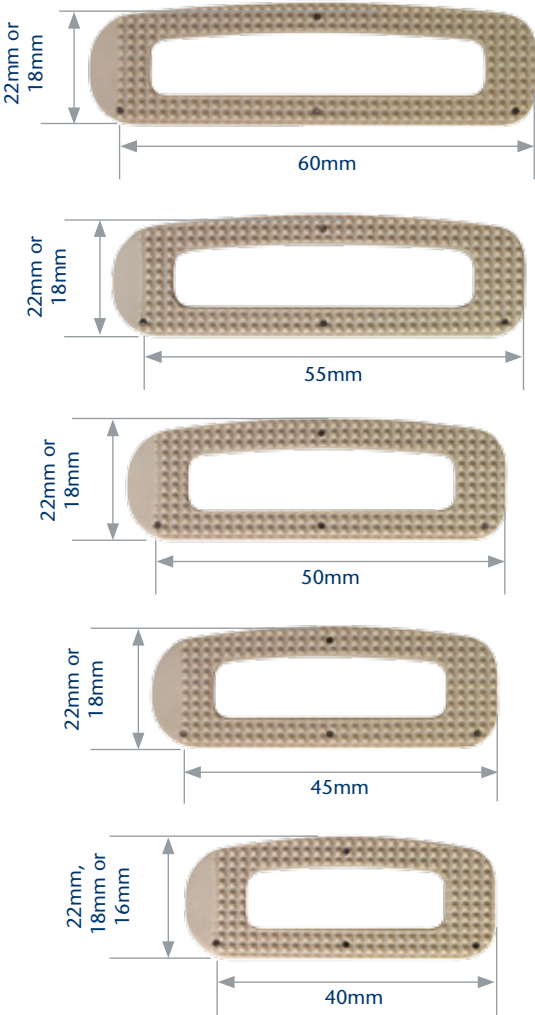
IMPLANT OVERVIEW

TransContinental® Spacer

- Self-distracting leading edge
- Large single chamber for bone graft material
- Five axial footprints
- Three sagittal profiles (0°, 6° and 10° Lordotic)
- Heights of 7–17 mm in 2mm increments
- Pyramidal teeth resist migration

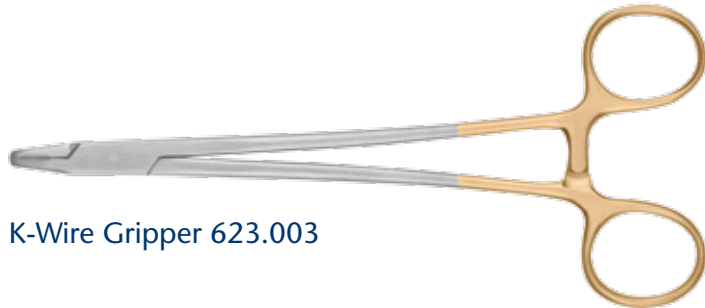
TransContinental® Instrumentation

- MIS compatible system
- Each trial provides precise length measurements
- Holder with sleeve eliminates challenges with implant disengagement



INSTRUMENT OVERVIEW

Access Instruments



K-Wire Gripper 623.003

K-Wire, 350mm 675.399S



Fluoro Modulator 675.403



Incision Locator 675.404



Initial Dilator Holder 675.800



Cannula A 698.205



Cannula B 698.210



Cannula C 698.215



Cannula D 698.220

Retractor Assembly

Retractor Blades		
Length	Posterior Blade	CC Blade
40mm	698.450	698.510
50mm	698.452	698.512
60mm	698.454	698.514
70mm	698.456	698.516
80mm	698.458	698.518
90mm	698.460	698.520
100mm	698.462	698.522
110mm	698.464	698.524
120mm	698.466	698.526
130mm	698.468	698.528
140mm	698.470	698.530
150mm	698.472	698.532
160mm	698.474	698.534
170mm	698.476	698.536



Posterior Blade



CC Blade



Retractor 3 Blade Frame 698.100

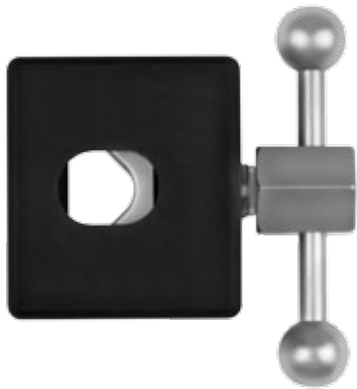
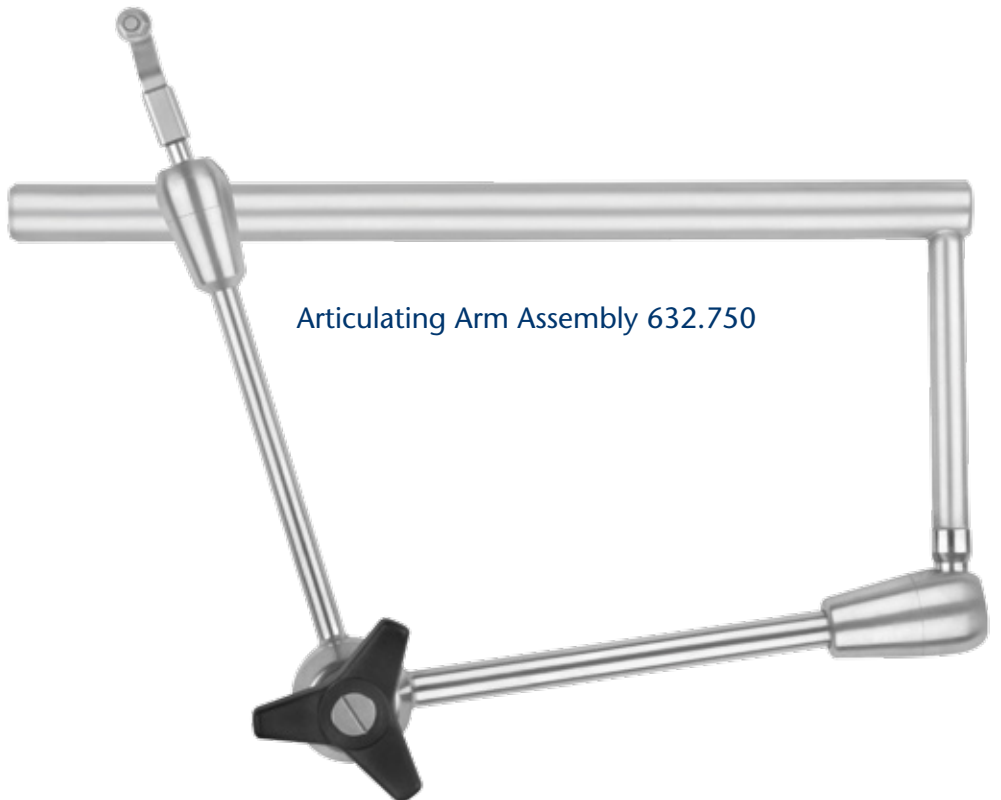


Table Clamp 632.500

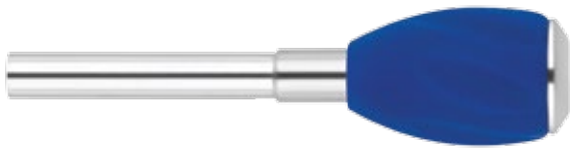


Articulating Arm Assembly 632.750

Retractor Instruments



Suction 8" 675.513



10mm Socket Driver 632.150



Frame Handle 698.230



Hook and Latch Driver 698.250



Shim Tool 698.230



Docking Pin Tool 698.260

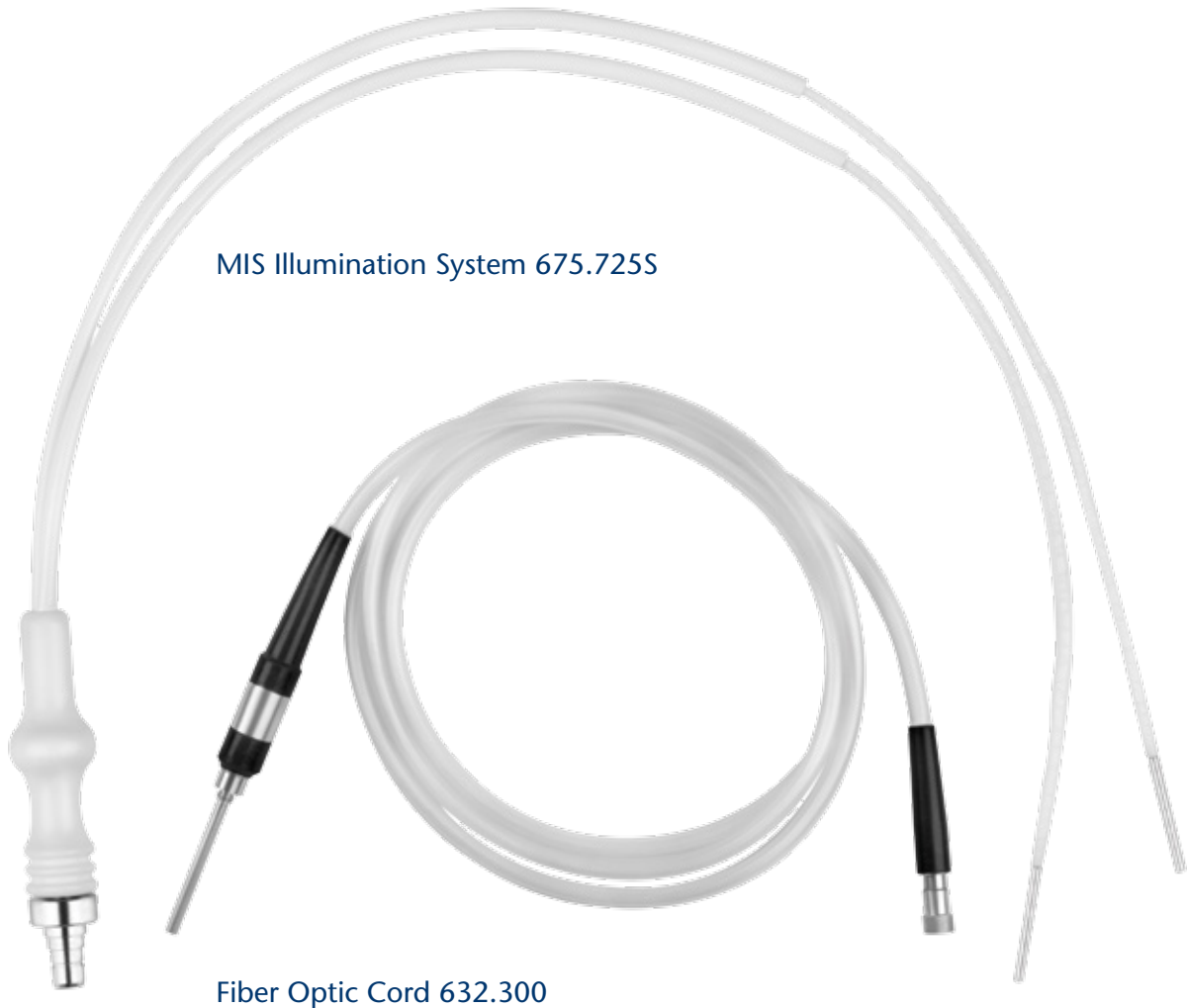


Disc Shim Tool 698.330



Docking Pin Sleeve 698.350

Light Components



MIS Illumination System 675.725S

Fiber Optic Cord 632.300



Adapter, ACMI 632.305



Adapter, Wolf 632.306



Adapter, Olympus 632.307



Adapter, Storz 632.308

Disc Prep Instruments



Bayoneted Annulotomy Knife 675.405S



Cobb Elevator, Straight, 20mm 675.503



Cobb Elevator, Straight, 10mm 675.504



Rasp 675.505



Disc Rotary Cutter 675.506



Disc Box Cutter 675.507

Disc Prep Instruments (cont'd)



Thin Rasp, 12x20mm 675.510



Cobb, 7° Up-Angled, 10mm 675.515

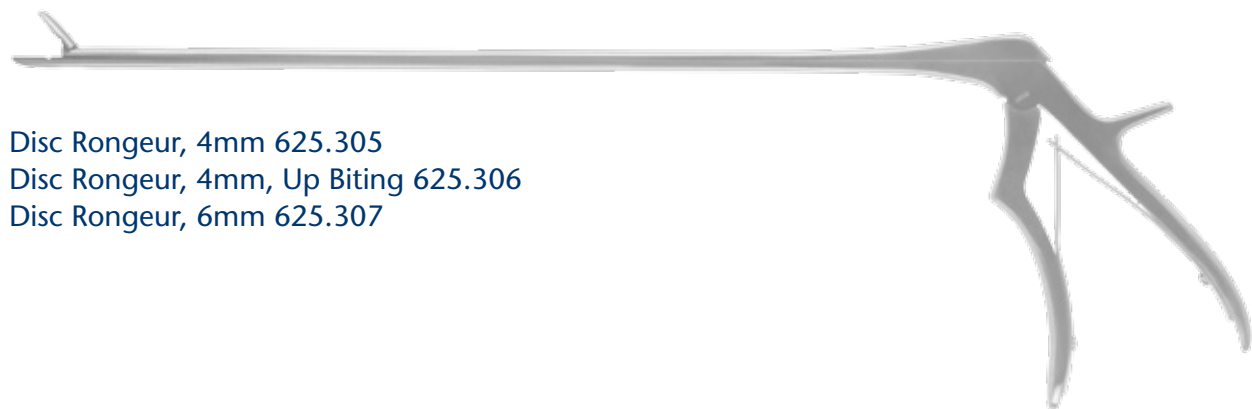


Cobb, 7° Up-Angled, 10mm 675.516



Kerrison, 4mm 625.202

Kerrison, 6mm 625.203









Disc Rongeur, 4mm 625.305

Disc Rongeur, 4mm, Up Biting 625.306

Disc Rongeur, 6mm 625.307

Scrapers



	Height	Part Number
	7mm	675.607
	9mm	675.609
	11mm	675.611
	13mm	675.613
	15mm	675.615
	17mm	675.617

Curettes



Cobb Elevator, Angled, 18mm 625.102

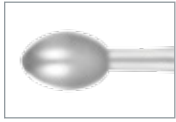


Ring Curette, 10mm 625.401



Ring Curette, 15mm 625.402

Curettes (cont'd)



Bone Curette, 7.5 x 11.5mm, Straight 625.407



Bone Curette, 7.5 x 11.5mm, Up-Angled 625.408



Ring Curette, 10mm, Straight 675.518



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



Cup Curette, 6.5 x 9.5mm, Straight 675.525

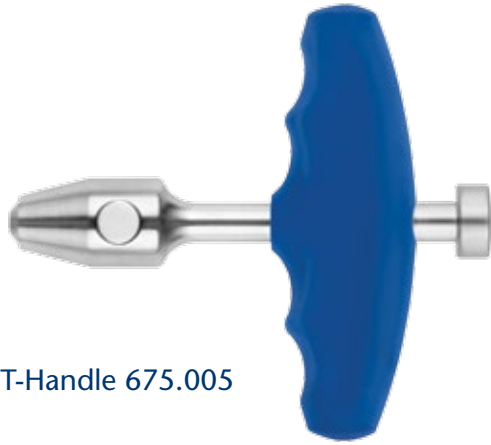


Cup Curette, 6.5 x 9.5mm, 15° Up-Angled 675.526



Cup Curette, 6.5 x 9.5mm, 90° Down-Angled 675.527

Handles



T-Handle 675.005



L-Handle 679.010

Insertion Instruments



Trial, Parallel



Trial, Lordotic

Height	Trials	
	Parallel	Lordotic 6°
5mm	675.006	675.106
7mm	675.007	675.107
9mm	675.009	675.109
11mm	675.011	675.111
13mm	675.013	675.113
15mm	675.015	675.115
17mm	675.017	675.117

Insertion Instruments (cont'd)



Slide Hammer, Long 675.004



Implant Insertion Tool 664.500



Insertion Sleeve 675.501



*Implant Insertion Tool 664.500,
Insertion Sleeve 675.501 (Assembled)*



Implant Positioner 675.502

LLIF

SURGICAL TECHNIQUE

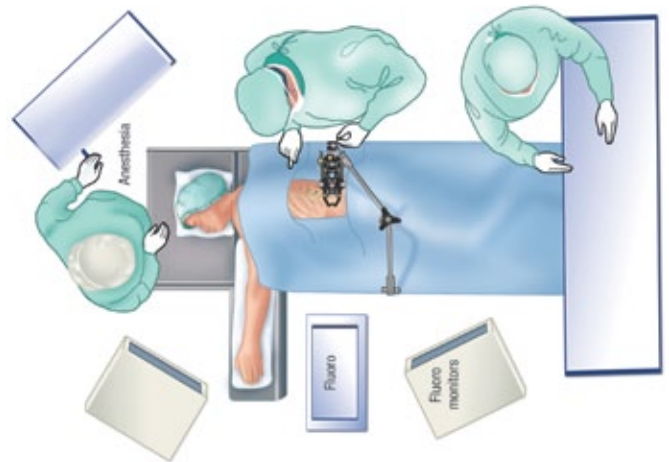
Step 1 Patient Preparation

Patient Positioning

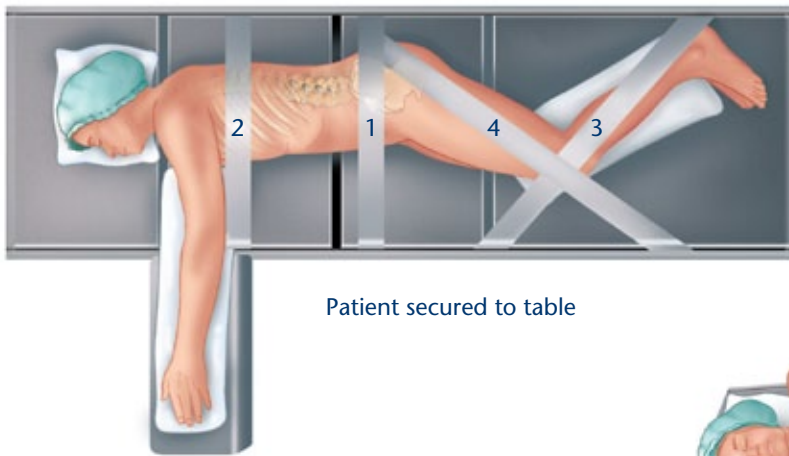
The patient is placed on a flexible surgical table in a true 90° right lateral decubitus position so that the iliac crest is just over the table break, as shown below.

The patient is then secured to the table at the following locations: (1) Just beneath the iliac crest; (2) Over the thoracic region, just under the shoulder; (3) From the back of the table, over the ankle, and (4) past the knee to the front of the table.

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



Patient positioning



Patient secured to table

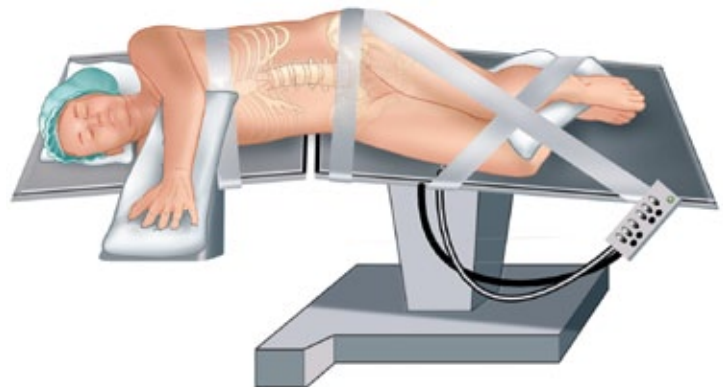


Table flexed

X-Ray Confirmation

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



Lateral image



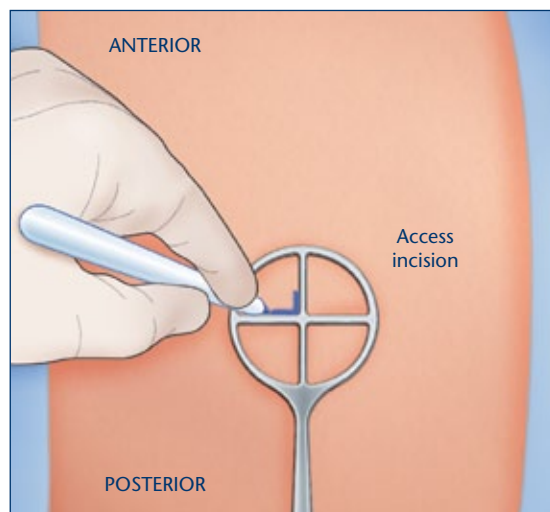
AP image

Incision Location

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



Using Incision Locator

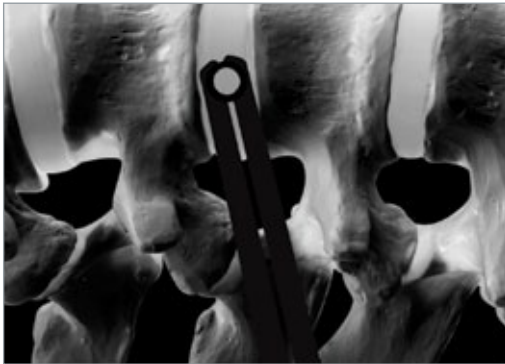


Marking the incision locations

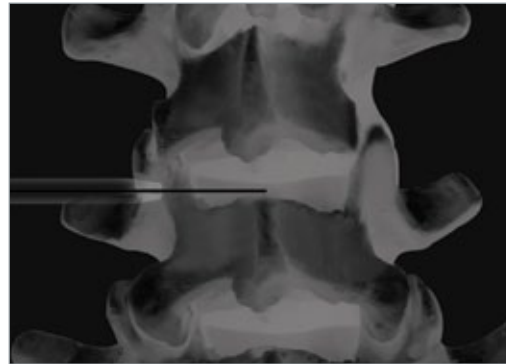
Initial Dilator Insertion

The initial dilator is inserted and AP fluoroscopy is used to confirm proper initial dilator alignment. A K-wire is inserted through the initial dilator into the disc space, in preparation for sequential dilation.

The **Initial Dilator Holder** may be used to steady the dilator and maintain distance from x-ray field while imaging.



Initial dilator position



K-wire inserted

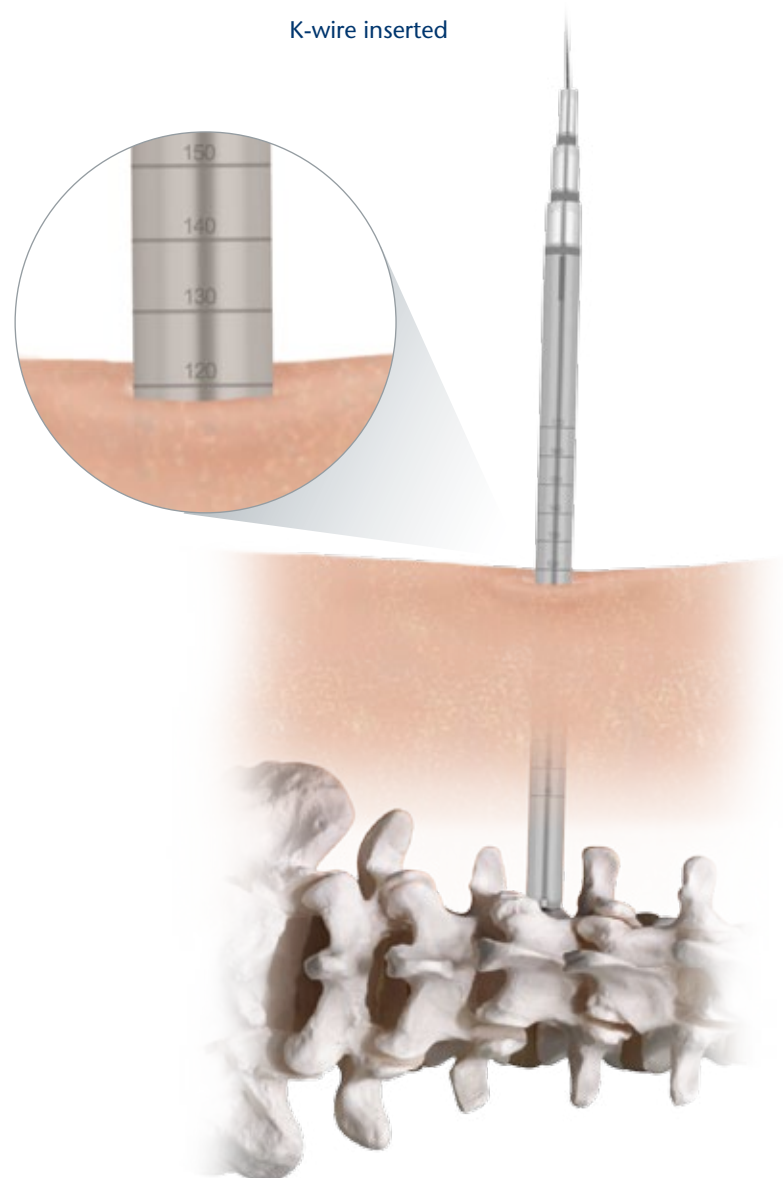
Sequential Dilation

With the K-wire in place, a series of cannulas are passed over the initial dilator, spreading the tissue to prepare for retractor insertion.

Cannula D should only be used if additional dilation is necessary following **Cannula B, C**. However, if Cannula D is used, it must be removed prior to insertion of the retractor.

Blade Length

Depth markings on each cannula are used to estimate retractor blade length. The targeted depth indicator will be the first visible marking above the incision site. To ensure sufficient length, 10mm should be added to the blade length reading.



Step 3 Retractor Insertion

Retractor Assembly

Select the appropriate blades and insert into each of the three blade mounts of the **Retractor 3 Blade Frame**.

The **Posterior Blade** is inserted into the posterior blade mount.

The **CC Blades** (cephalad-caudal) are inserted into the cephalad and caudal blade mounts.



Posterior Blade



CC Blade



Ensure that the blades are properly seated into the retractor at each of the three positions. Secure the blades using the **Hook and Latch Driver**. Position the driver on the latch and rotate 90° clockwise to lock the blade in place.

The blades can be changed intraoperatively when a different blade length is required. The blades have angled holes that accept the driver. Insert the hook and tighten down the white sleeve to hold the blade securely. This provides a secure connection to remove the blade.



Using the Hook and Latch Driver to secure blades



Using the Hook and Latch Driver to change blades

Retractor Insertion (cont'd)

Retractor Positioning

Ensure that the retractor is in the fully closed position and the blades are securely attached to the frame. The access incision should allow the blades to retract and angulate.

Slide the retractor over Cannula C and apply gentle downward pressure on the frame.

Before removing the cannulas, angulate all three blades to one full turn of the silver knobs. Retract all three blades to two clicks using the gold knobs, starting with the blade closest to the iliac crest. Angulating and retracting 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, remove the cannulas and verify position of the retractor before removing the k-wire.

Use AP fluoroscopy to verify the correct positioning on the spine and to confirm that retractor blades are parallel with the disc space.

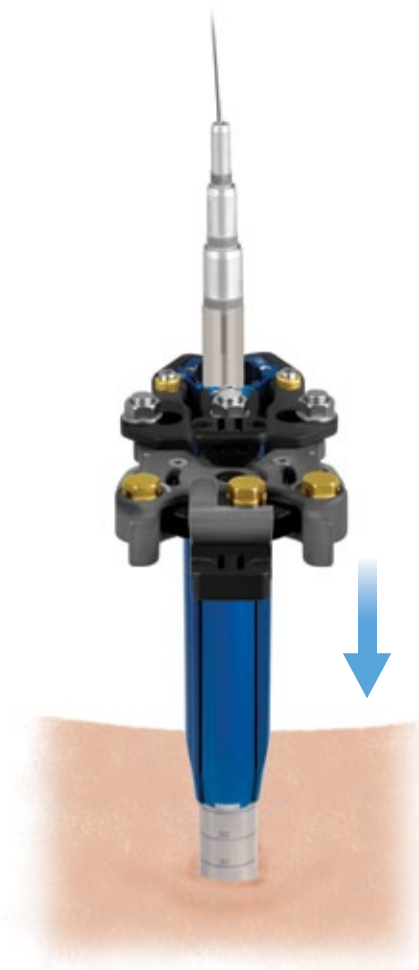
Table Arm Attachment

Attach the **Table Clamp** over the drape and onto the bed rail attachment. Insert the Articulating Arm Assembly into the clamp and secure.

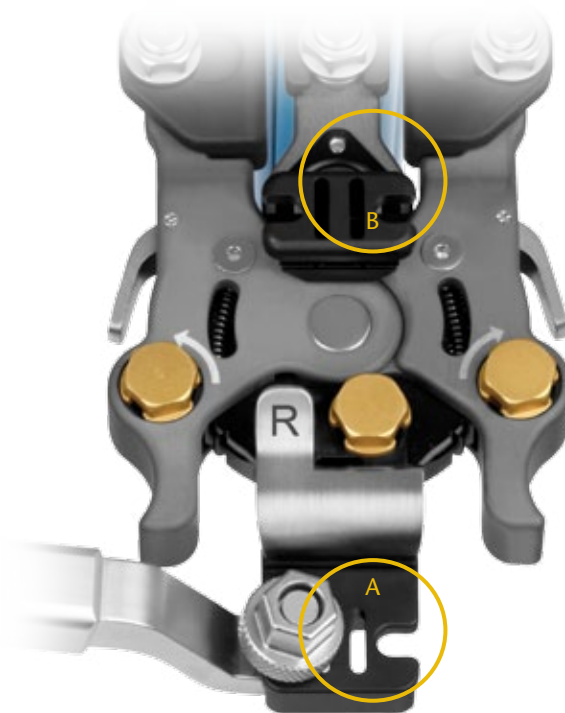
The opposite end of the assembly arm is then attached to the retractor. There are two options for attachment positions on the retractor, as shown at right.

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

Attaching the arm assembly to point B maintains the retractor position relative to the center of the frame and retracts all three blades when the retractor is opened.



Positioning retractor



Articulating Arm attachment locations

Table Arm Attachment (cont'd)

Insert the Articulating Arm Assembly into the desired attachment position and tighten the thumb screw using the **10mm Socket Driver**. Position the arm and lock in place by tightening the black star handle on the arm assembly.

Minimal torque is required to tighten the thumb screw with the driver.

Manipulation of the retractor can be achieved with the **Frame Handle** that fits over arm attachment point B.



Using a Frame Handle

Light Cable Insertion

The **MIS Illumination System** has two light cables which can be inserted into the CC Blades.

The light cables should be inserted through the blade to a depth providing optimal visibility.

The **Fiber Optic Cord** attaches to the light source used for head lamps or endoscopes. The adapters accommodate an **ACMI**, **Olympus**, **Storz**, or **Wolf** light source.

Note: The Fiber Optic Cord is reusable and must not be discarded.



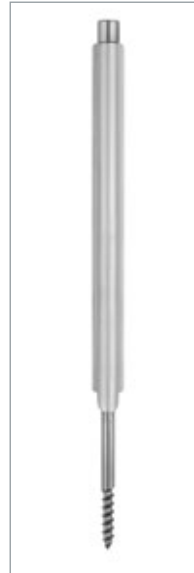
Retractor Insertion (cont'd)

Cephalad-Caudad Blade Anchoring

For additional retractor stability, **Docking Pins** can be inserted into the vertebral body through the CC Blades to increase retractor stability when expanding blades for greater exposure as shown below.

Select the appropriate size pin and insert into the **Docking Pin Sleeve**. The pin assembly can slide down the T-slot on either side of the blade. The **Docking Pin Tool** has a hex feature that mates with the head of the pin. Rotate the tool clockwise to engage pin threads into the bone.

To remove the pins, re-engage the hex of the tool into the pin head and rotate counterclockwise to disengage from the bone.



Docking pin assembly



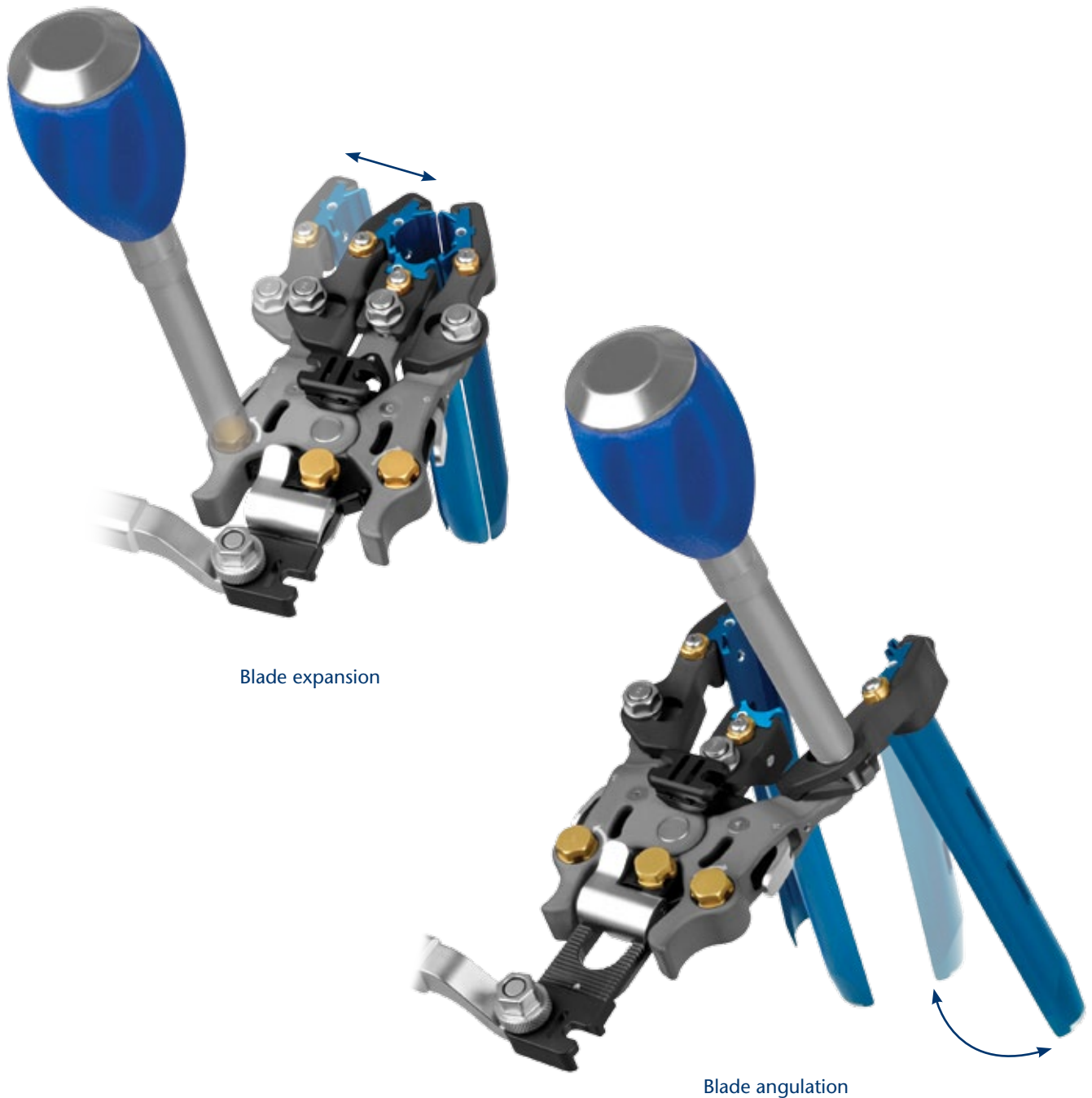
Docking pin assembly loaded



Blade Expansion

Each blade may be independently expanded using the 10mm Socket Driver to rotate the respective gold hex nut in the direction indicated by the arrow.

Each blade may be angled up to 20° using the driver. Place the driver onto the silver hex nut and rotate the instrument clockwise, allowing the blade to tilt to the desired position.



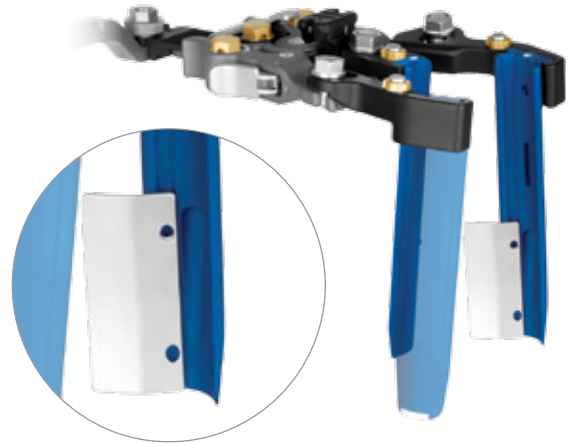
Retractor Insertion (cont'd)

Blade Expansion (cont'd)

Widening Shim

While expanding the CC Blades, **Widening Shims** can be used to help prevent soft tissue creep between blades.

The **Shim Tool, CC**, is used to slide the Widening Shim down the T-slot on either side of the blades, for an additional 22mm of blade width.



Lengthening Shim

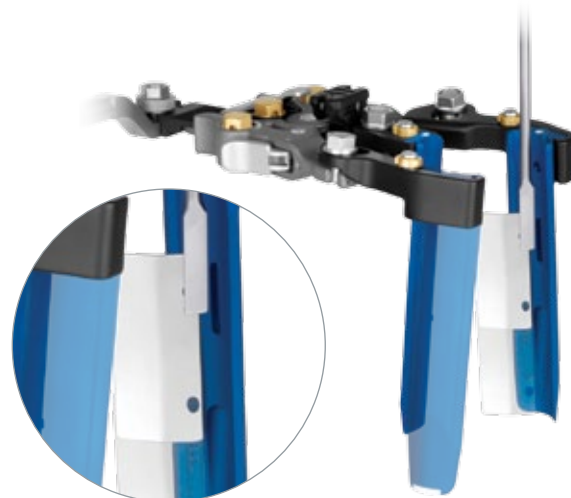
While angulating the CC Blades, **Lengthening Shims** can be used to help prevent soft tissue creep between blades by increasing the length of the blade to maintain bone contact.

The Shim Tool, CC, is used to push the Lengthening Shim down the right T-slot of the blades.



Shim Removal

Both Widening and Lengthening Shims have angled holes to accept the hook on the Shim Tool, CC. Insert the hook and pull upward to remove the shim.



Step

4

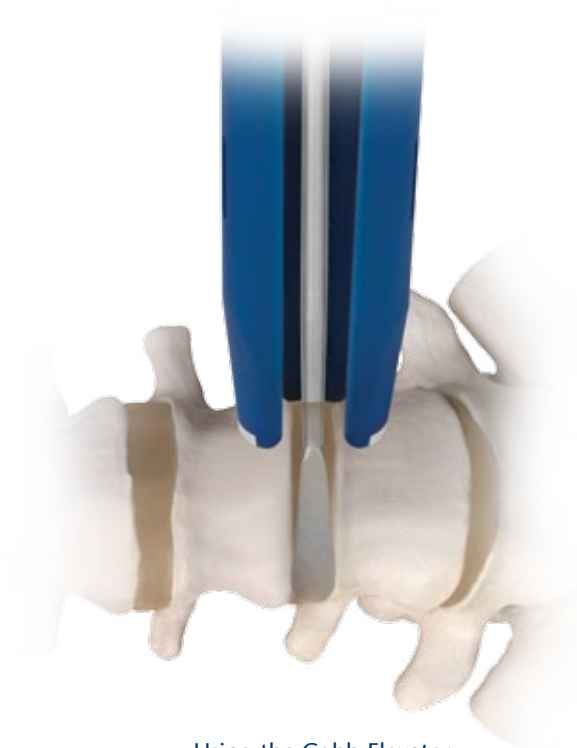
Disc Preparation

Annulotomy

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

Contralateral Annulus Release

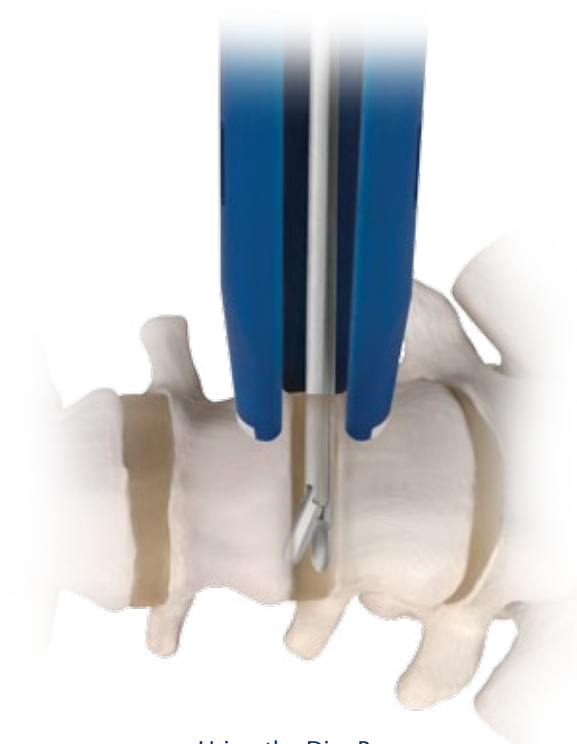
A **Cobb Elevator** is passed along both endplates through the disc space, far enough to provide release of the contralateral annulus. This allows for height restoration upon insertion of the implant.



Using the Cobb Elevator

Disc Space Preparation

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



Using the Disc Rongeur

Step 5 Interbody Insertion

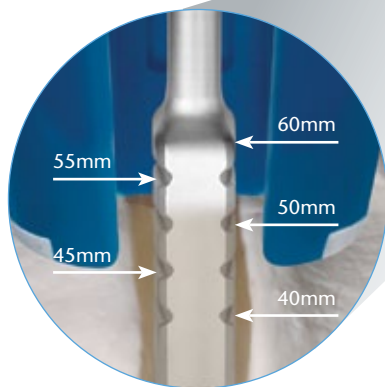
Implant Sizing

To determine the appropriate spacer size for the desired segment, first insert the smallest **Trial** into the disc space, moving to larger trials as 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. Use AP fluoroscopy to confirm that the implant is centered and lateral fluoroscopy to ensure that the implant is in the appropriate AP position.

The trial's anterior side is labeled "Anterior" and matches the profile of the TransContinental® Spacer.



Implant Sizing
(55mm disc space is shown)

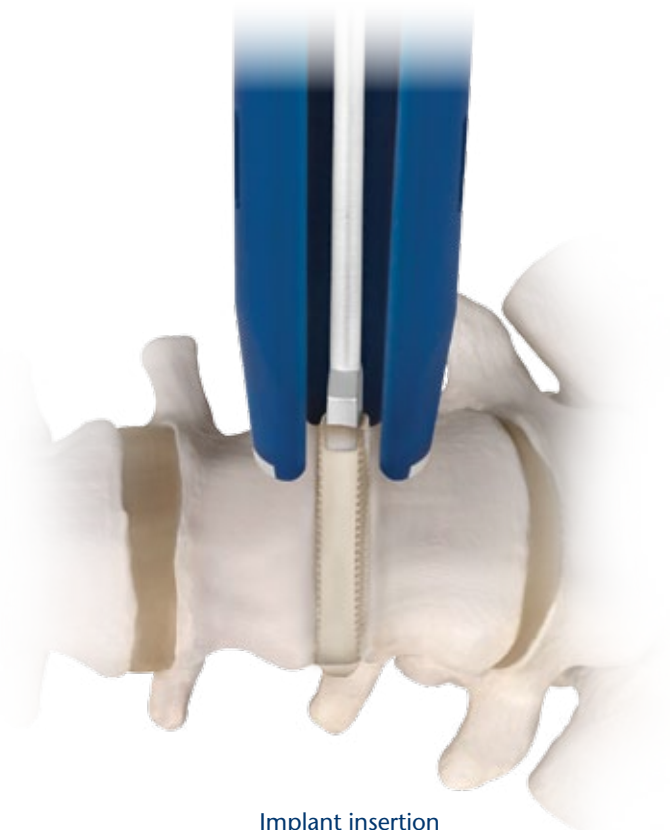


Implant Insertion

Select the appropriately sized TransContinental® Spacer and gently insert into the intervertebral space using the **Implant Holder** and **Tamp**. AP fluoroscopy should be used to facilitate implant placement.

Once the position is confirmed, the implant is released from the holder.

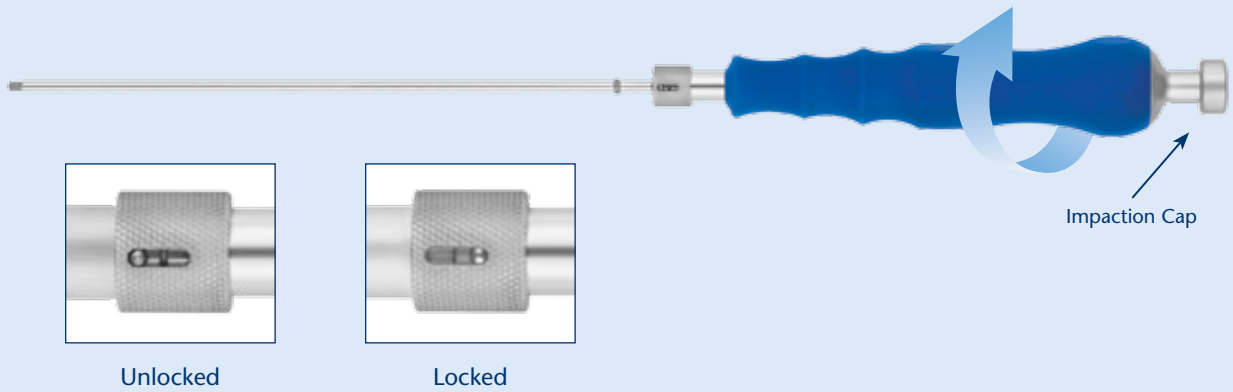
The TransContinental® Spacer is intended to be used with supplemental fixation.



Implant insertion

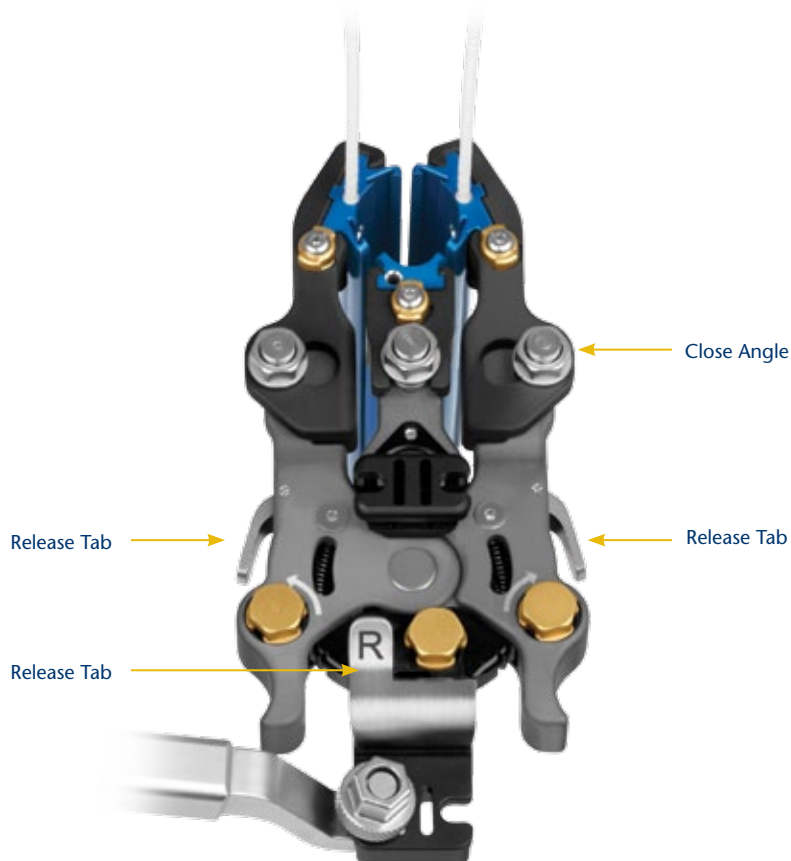
Using the Implant Insertion Tool

Ensure the **Implant Insertion Tool** is in the unlocked position. Thread the implant to the tool by rotating the handle clockwise. Lock the tool by sliding the locking nut forward. Insert the implant. To disengage, unlock and rotate the handle counterclockwise.



Closure

Once the procedure is completed, use the 10mm Socket Driver to angle all blades to the 0° starting position. Return all blades to the closed position by compressing the three release tabs on the back and sides of the retractor.



Final Position



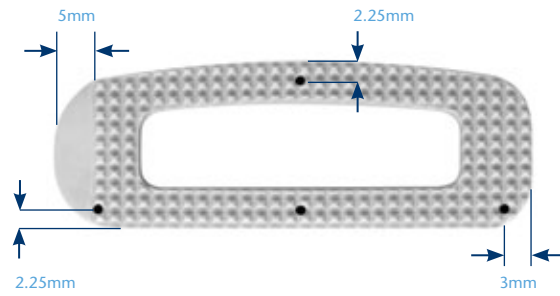
AP view
(radiographic markers shown)



Sagittal view
(radiographic markers shown)

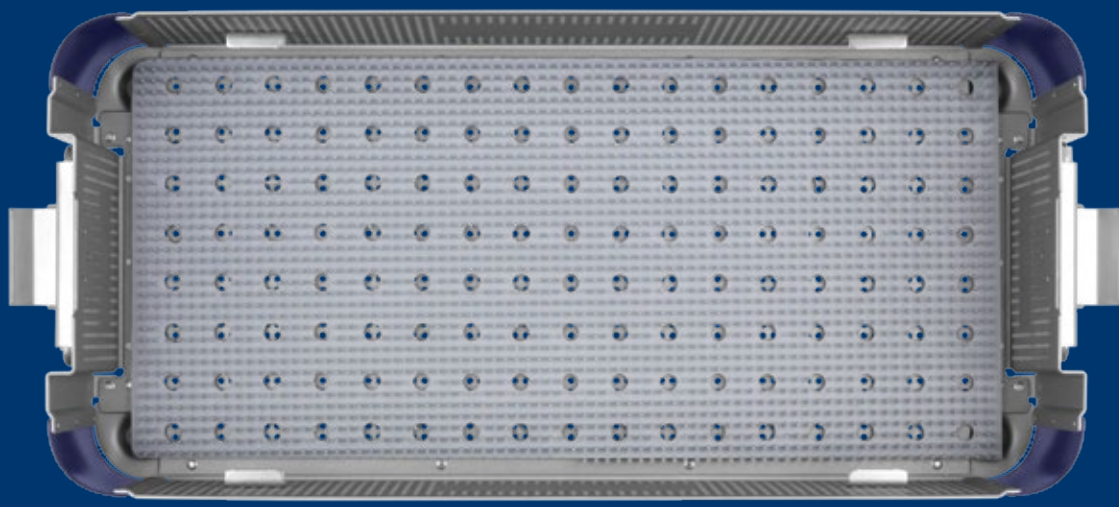
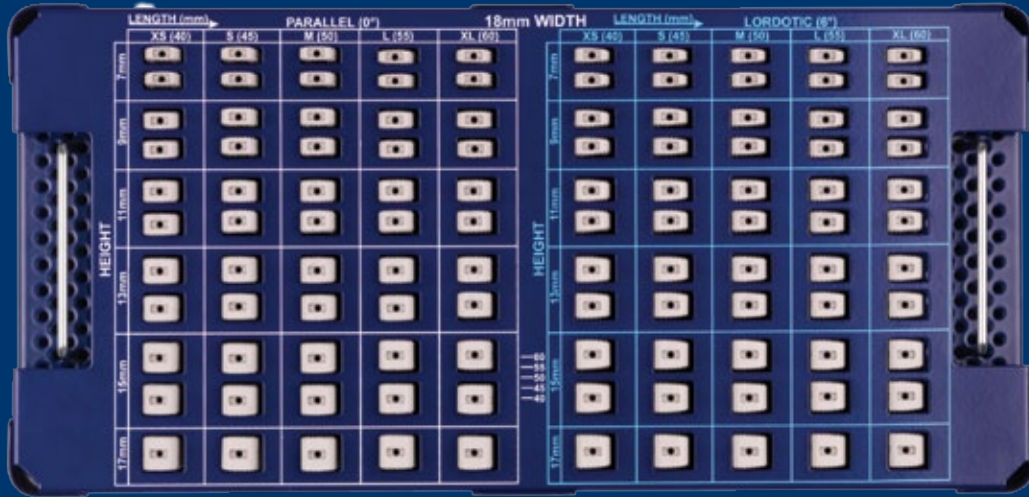


Axial view



Radiographic markers positions

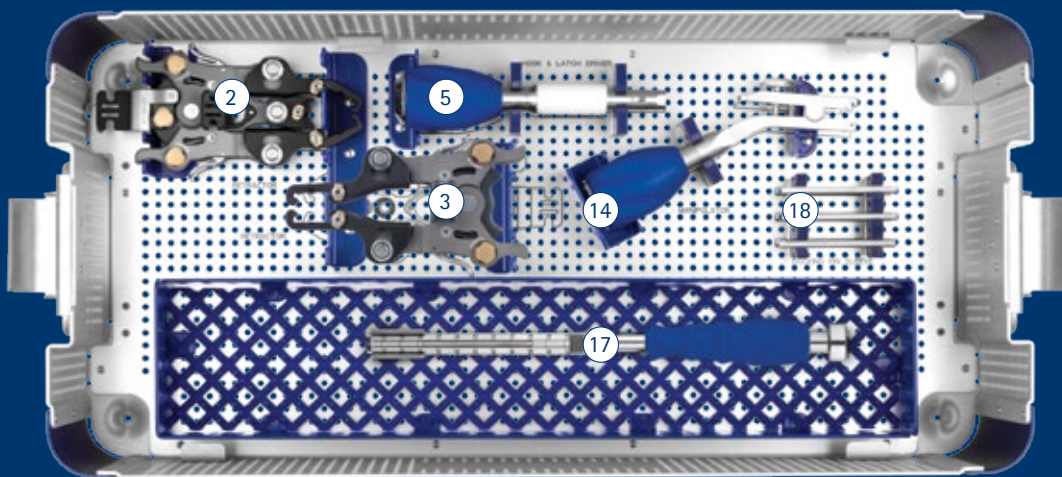
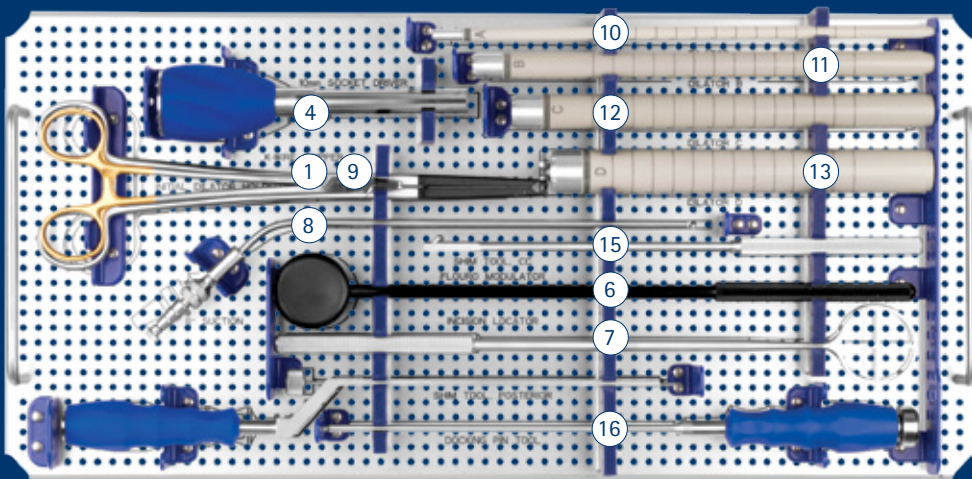
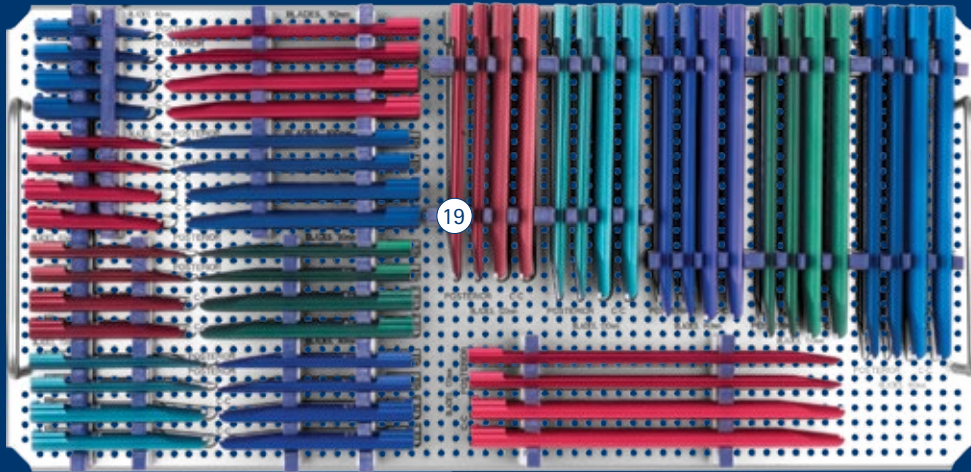
TransContinental® IMPLANT SET



TransContinental® Implant Set 975.916

Part No.	Description	Qty	Part No.	Description	Qty
375.007	TransContinental® Spacer, Small, 0°, 7mm	2	375.513	TransContinental® Spacer, Large, 6°, 13mm	2
375.009	TransContinental® Spacer, Small, 0°, 9mm	2	375.515	TransContinental® Spacer, Large, 6°, 15mm	2
375.011	TransContinental® Spacer, Small, 0°, 11mm	2	375.517	TransContinental® Spacer, Large, 6°, 17mm	1
375.013	TransContinental® Spacer, Small, 0°, 13mm	2	375.607	TransContinental® Spacer, X-Large, 0°, 7mm	2
375.015	TransContinental® Spacer, Small, 0°, 15mm	2	375.609	TransContinental® Spacer, X-Large, 0°, 9mm	2
375.017	TransContinental® Spacer, Small, 0°, 17mm	1	375.611	TransContinental® Spacer, X-Large, 0°, 11mm	2
375.107	TransContinental® Spacer, Small, 6°, 7mm	2	375.613	TransContinental® Spacer, X-Large, 0°, 13mm	2
375.109	TransContinental® Spacer, Small, 6°, 9mm	2	375.615	TransContinental® Spacer, X-Large, 0°, 15mm	2
375.111	TransContinental® Spacer, Small, 6°, 11mm	2	375.617	TransContinental® Spacer, X-Large, 0°, 17mm	1
375.113	TransContinental® Spacer, Small, 6°, 13mm	2	375.707	TransContinental® Spacer, X-Large, 6°, 7mm	2
375.115	TransContinental® Spacer, Small, 6°, 15mm	2	375.709	TransContinental® Spacer, X-Large, 6°, 9mm	2
375.117	TransContinental® Spacer, Small, 6°, 17mm	1	375.711	TransContinental® Spacer, X-Large, 6°, 11mm	2
375.207	TransContinental® Spacer, Medium, 0°, 7mm	2	375.713	TransContinental® Spacer, X-Large, 6°, 13mm	2
375.209	TransContinental® Spacer, Medium, 0°, 9mm	2	375.715	TransContinental® Spacer, X-Large, 6°, 15mm	2
375.211	TransContinental® Spacer, Medium, 0°, 11mm	2	375.717	TransContinental® Spacer, X-Large, 6°, 17mm	1
375.213	TransContinental® Spacer, Medium, 0°, 13mm	2	375.807	TransContinental® Spacer, X-Small, 0°, 7mm	2
375.215	TransContinental® Spacer, Medium, 0°, 15mm	2	375.809	TransContinental® Spacer, X-Small, 0°, 9mm	2
375.217	TransContinental® Spacer, Medium, 0°, 17mm	1	375.811	TransContinental® Spacer, X-Small, 0°, 11mm	2
375.307	TransContinental® Spacer, Medium, 6°, 7mm	2	375.813	TransContinental® Spacer, X-Small, 0°, 13mm	2
375.309	TransContinental® Spacer, Medium, 6°, 9mm	2	375.815	TransContinental® Spacer, X-Small, 0°, 15mm	2
375.311	TransContinental® Spacer, Medium, 6°, 11mm	2	375.817	TransContinental® Spacer, X-Small, 0°, 17mm	1
375.313	TransContinental® Spacer, Medium, 6°, 13mm	2	375.907	TransContinental® Spacer, X-Small, 6°, 7mm	2
375.315	TransContinental® Spacer, Medium, 6°, 15mm	2	375.909	TransContinental® Spacer, X-Small, 6°, 9mm	2
375.317	TransContinental® Spacer, Medium, 6°, 17mm	1	375.911	TransContinental® Spacer, X-Small, 6°, 11mm	2
375.407	TransContinental® Spacer, Large, 0°, 7mm	2	375.913	TransContinental® Spacer, X-Small, 6°, 13mm	2
375.409	TransContinental® Spacer, Large, 0°, 9mm	2	375.915	TransContinental® Spacer, X-Small, 6°, 15mm	2
375.411	TransContinental® Spacer, Large, 0°, 11mm	2	375.917	TransContinental® Spacer, X-Small, 6°, 17mm	1
375.413	TransContinental® Spacer, Large, 0°, 13mm	2	975.011	TransContinental® Graphic Case – Implants	
375.415	TransContinental® Spacer, Large, 0°, 15mm	2			
375.417	TransContinental® Spacer, Large, 0°, 17mm	1			
375.507	TransContinental® Spacer, Large, 6°, 7mm	2			
375.509	TransContinental® Spacer, Large, 6°, 9mm	2			
375.511	TransContinental® Spacer, Large, 6°, 11mm	2			

MARS™ 3V RETRACTOR SET

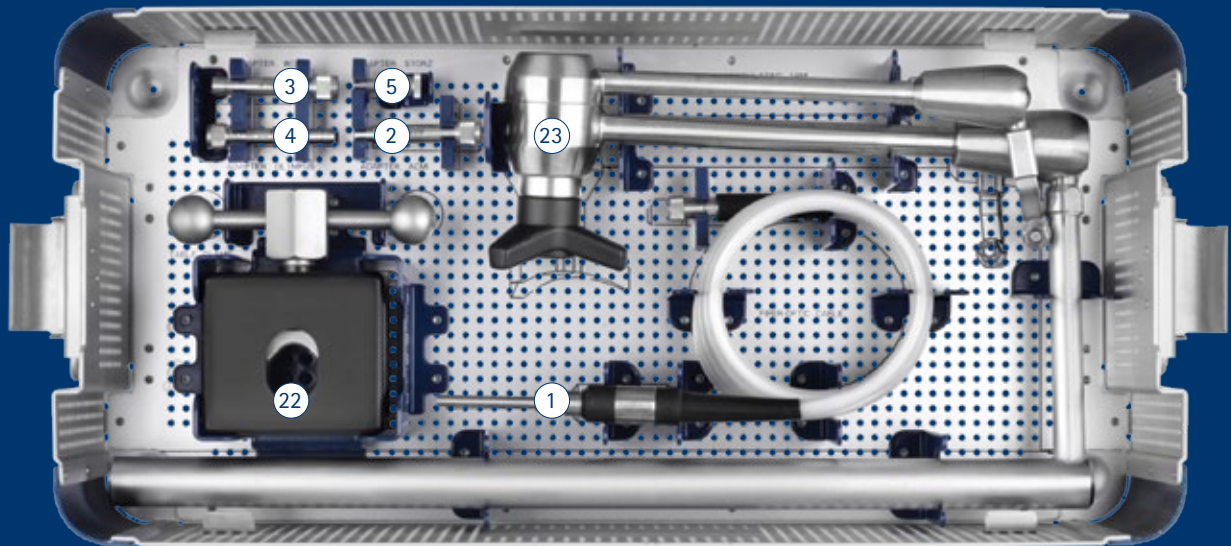
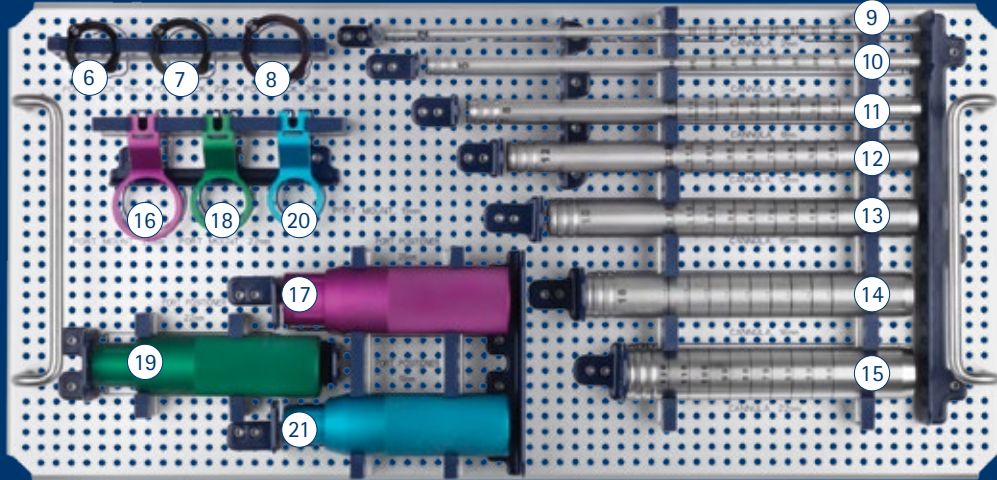


MARS™ 3V Retractor Set 998.901

Instruments			Qty	Retractor Blades		Qty
1	623.003	K-Wire Gripper	1	698.476	Blade, Posterior, 170mm	2
2	698.100	Retractor 3 Blade Frame	1	698.510	Blade, CC, 40mm	2
3	632.102	Retractor 2 Blade Frame	1	698.512	Blade, CC, 50mm	2
4	632.150	10mm Socket Driver	1	698.514	Blade, CC, 60mm	2
5	698.250	Hook and Latch Driver	1	698.516	Blade, CC, 70mm	2
6	675.403	Flouro Modulator	1	698.518	Blade, CC, 80mm	2
7	675.404	Incision Locator	1	698.520	Blade, CC, 90mm	2
8	675.513	8" Suction	1	698.522	Blade, CC, 100mm	2
9	675.800	Radiolucent Initial Dilator Holder	1	698.524	Blade, CC, 110mm	2
10	698.205	Cannula A	1	698.526	Blade, CC, 120mm	2
11	698.210	Cannula B	1	698.528	Blade, CC, 130mm	2
12	698.215	Cannula C	1	698.530	Blade, CC, 140mm	2
13	698.220	Cannula D	1	698.532	Blade, CC, 150mm	2
14	698.230	Frame Handle	1	698.534	Blade, CC, 160mm	2
15	698.240	Shim Tool, CC	1	698.536	Blade, CC, 170mm	2
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			
				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.

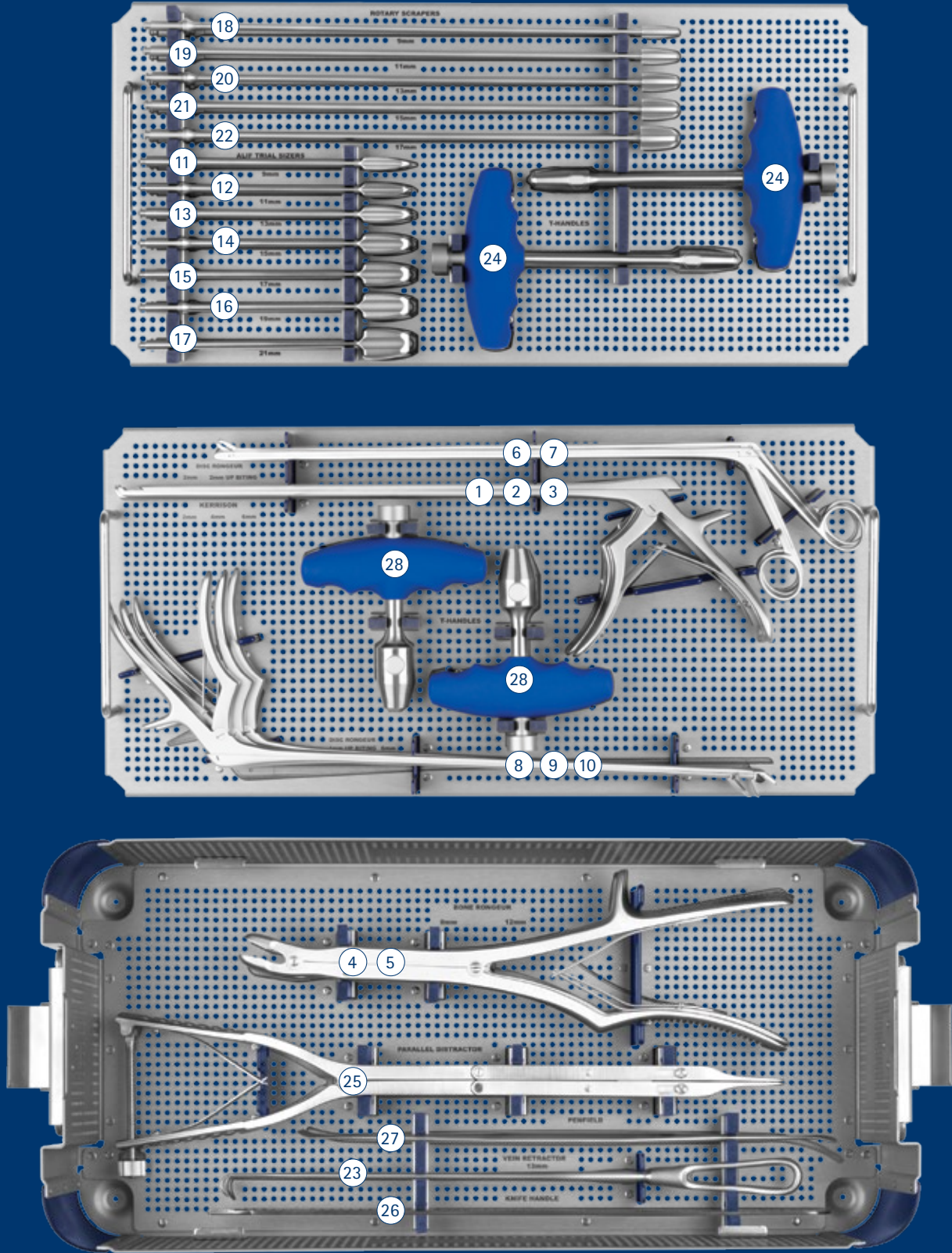
MARS™ INSTRUMENT II SET



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

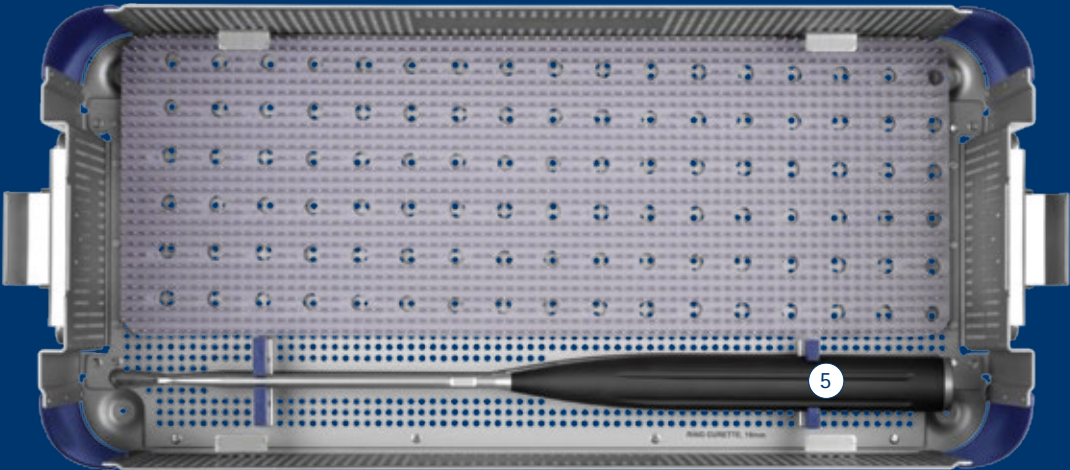
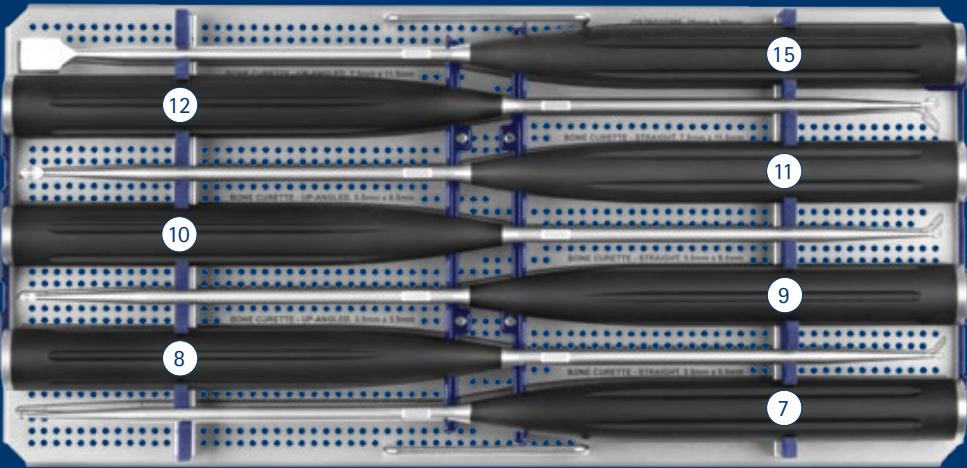
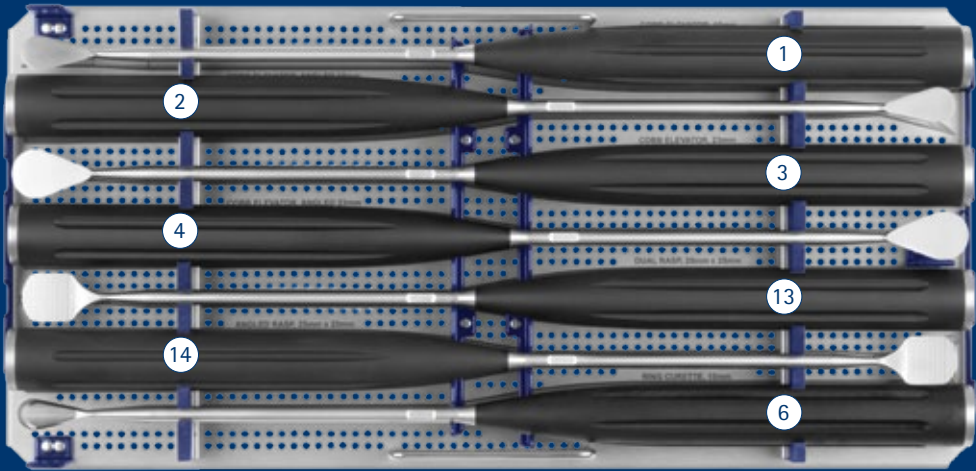
ANTERIOR DISC PREP I INSTRUMENT SET



Anterior Disc Prep I Instrument Set 925.901

	Instruments	Qty
1	625.201 Kerrison, 2mm	1
2	625.202 Kerrison, 4mm	1
3	625.203 Kerrison, 6mm	1
4	625.301 Bone Rongeur, Double Acting, 8mm	1
5	625.302 Bone Rongeur, Double Acting, 12mm	1
6	625.303 Disc Rongeur, 2mm	1
7	625.304 Disc Rongeur, 2mm, Up Biting	1
8	625.305 Disc Rongeur, 4mm	1
9	625.306 Disc Rongeur, 4mm, Up Biting	1
10	625.307 Disc Rongeur, 6mm	1
11	625.609 ALIF Trial Sizer, 9mm	1
12	625.611 ALIF Trial Sizer, 11mm	1
13	625.613 ALIF Trial Sizer, 13mm	1
14	625.615 ALIF Trial Sizer, 15mm	1
15	625.617 ALIF Trial Sizer, 17mm	1
16	625.619 ALIF Trial Sizer, 19mm	1
17	625.621 ALIF Trial Sizer, 21mm	1
18	625.709 Rotary Scraper, 9mm	1
19	625.711 Rotary Scraper, 11mm	1
20	625.713 Rotary Scraper, 13mm	1
21	625.715 Rotary Scraper, 15mm	1
22	625.717 Rotary Scraper, 17mm	1
23	625.801 Vein Retractor	1
24	625.804 T-Handle with Impaction Cap, Long	2
25	625.805 Parallel Distractor	1
26	625.806 Knife Handle	1
27	625.811 Long Penfield	1
28	675.005 T-Handle with Impaction Cap	2
	925.101 Graphic Case	

ANTERIOR DISC PREP II INSTRUMENT SET



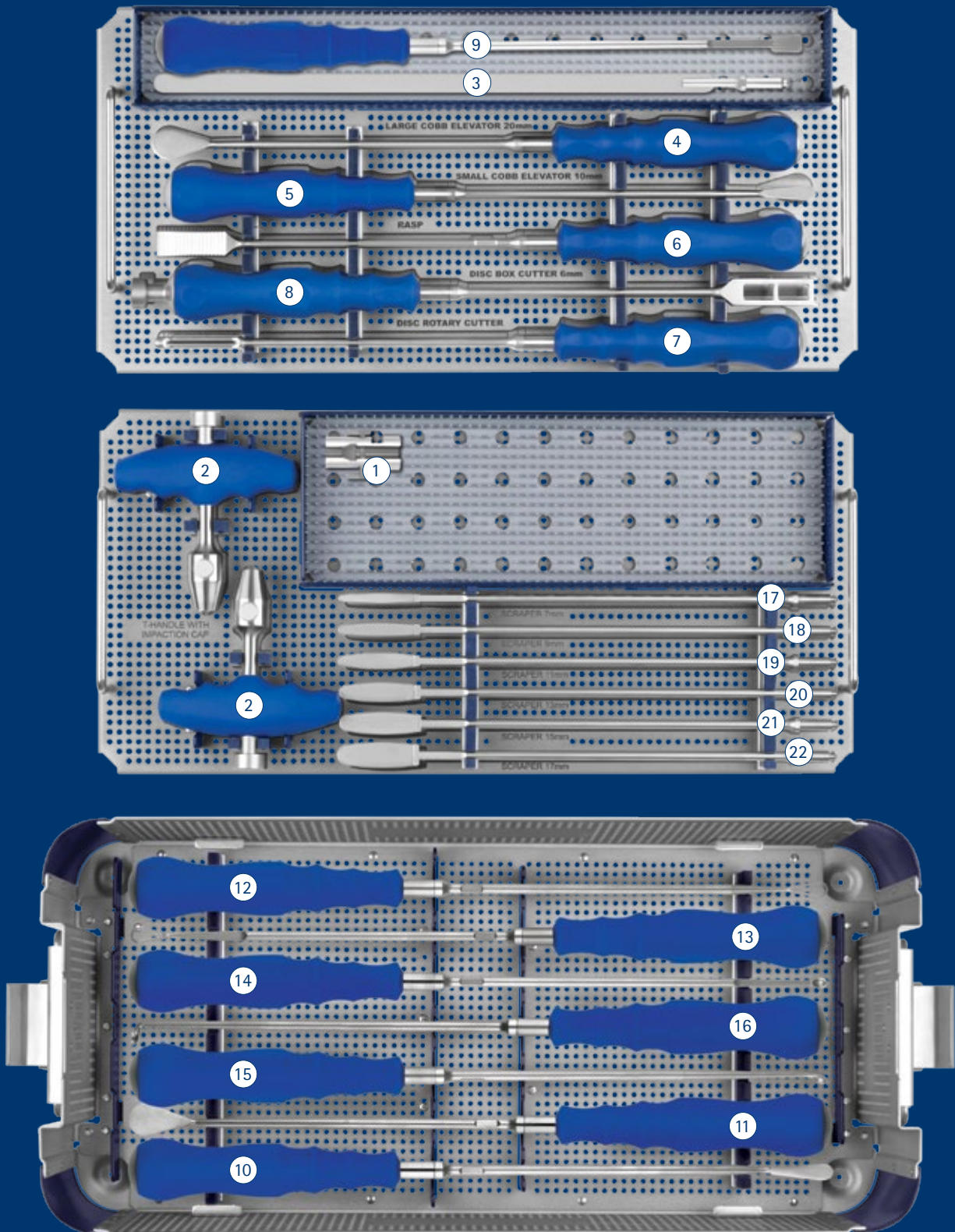
Anterior Disc Prep II Instrument Set 925.902

	Instruments	Qty
①	625.101 Cobb Elevator, 18mm	1
②	625.102 Cobb Elevator, Angled, 18mm	1
③	625.103 Cobb Elevator, 23mm	1
④	625.104 Cobb Elevator, Angled, 23mm	1
⑤	625.401 Ring Curette, 10mm	1
⑥	625.402 Ring Curette, 15mm	1
⑦	625.403 Bone Curette, 3.5mm x 5.5mm, Straight	1
⑧	625.404 Bone Curette, 3.5mm x 5.5mm, Up-Angled	1
⑨	625.405 Bone Curette, 5.5mm x 8.5mm, Straight	1
⑩	625.406 Bone Curette, 5.5mm x 8.5mm, Up-Angled	1
⑪	625.407 Bone Curette, 7.5mm x 11.5mm, Straight	1
⑫	625.408 Bone Curette, 7.5mm x 11.5mm, Up-Angled	1
⑬	625.501 Dual Rasp	1
⑭	625.502 Angled Rasp	1
⑮	625.803 Osteotome, 16mm x 20mm	1
	925.102 Graphic Case II	

Additionally Available

625.409	Bone Curette, 9.5mm x 14.5mm, Straight
625.410	Bone Curette, 9.5mm x 14.5mm, Up-Angled
625.411	Bone Curette, 11.5mm x 17.5mm, Straight
625.412	Bone Curette, 11.5mm x 17.5mm, Up-Angled
625.413	Bone Curette, 13.5mm x 20.5mm, Straight
625.414	Bone Curette, 13.5mm x 20.5mm, Up-Angled

LATERAL DISC PREP INSTRUMENT SET



Lateral Disc Prep Instrument Set 975.914

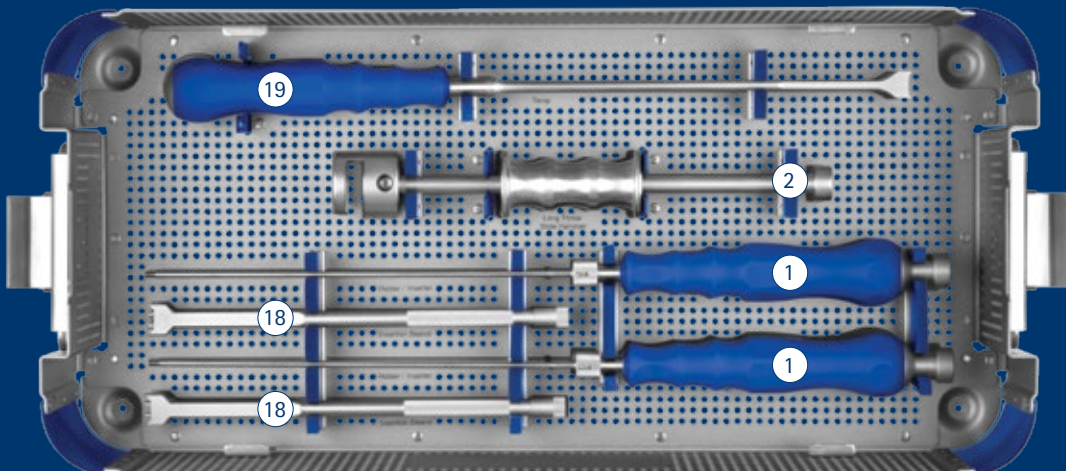
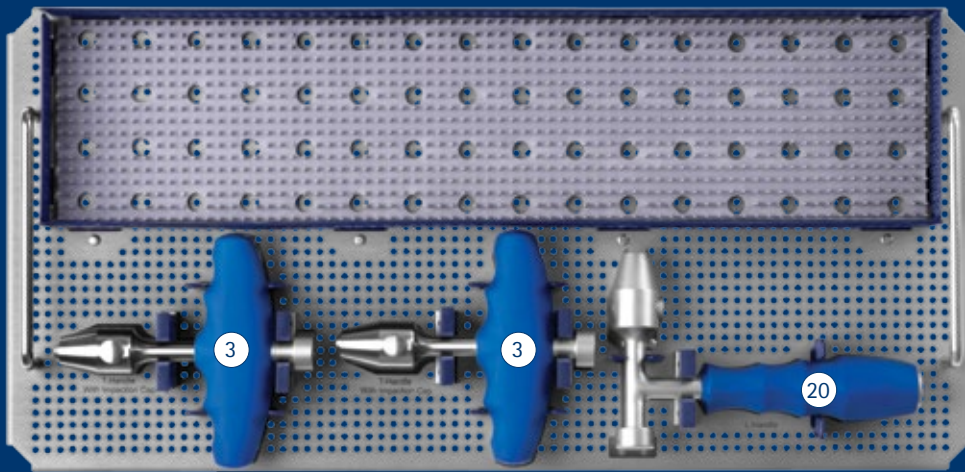
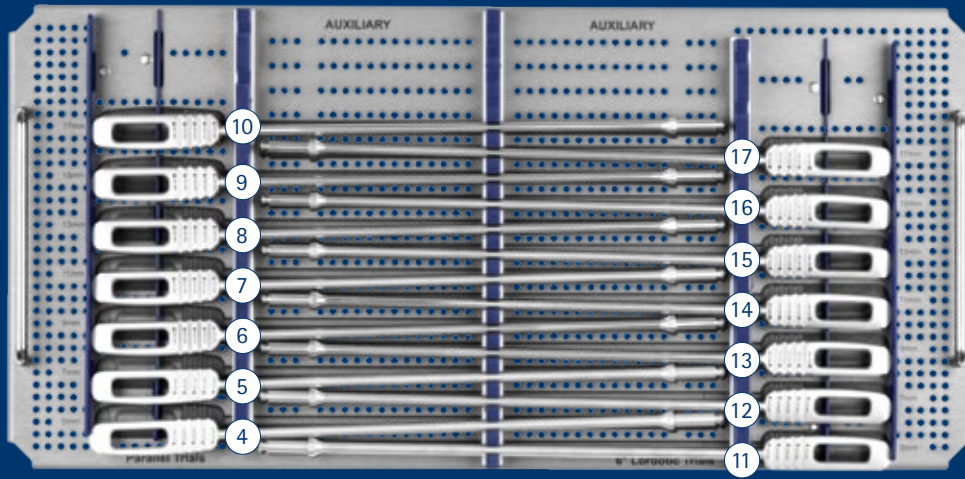
	Instruments	Qty
①	675.002 Slap Hammer Adaptor	1
②	675.005 T-Handle with Impaction Cap	2
③	675.201 Quick Connect Guide	2
④	675.503 Large Cobb Elevator	1
⑤	675.504 Small Cobb Elevator	1
⑥	675.505 Rasp	1
⑦	675.506 Disc Rotary Cutter	1
⑧	675.507 Box Cutter	1
⑨	675.510 Thin Rasp, 12x20mm	1
⑩	675.515 Cobb, 10mm, 7°, Up-Angle	1
⑪	675.516 Cobb, 20mm, 7°, Up-Angle	1
⑫	675.518 Ring Curette, 10mm, Straight	1
⑬	675.519 Ring Curette, 10mm, 7°, Up-angle Tip	1
⑭	675.525 Cup Curette, 6.5x9.5mm, Straight	1
⑮	675.526 Cup Curette, 6.5x9.5mm, 15°, Up-angle	1
⑯	675.527 Cup Curette, 6.5x9.5mm, 90°, Down-angle	1
⑰	675.607 Scaper, 7mm	1
⑱	675.609 Scaper, 9mm	1
⑲	675.611 Scaper, 11mm	1
⑳	675.613 Scaper, 13mm	1
㉑	675.615 Scaper, 15mm	1
㉒	675.617 Scaper, 17mm	1
	975.008 TransContinental® Disc Preparation Graphic Case	

Additionally Available

675.170S Bipolar Forceps Bayonetted, Straight

675.171S Bipolar Forceps Bayonetted, Angled

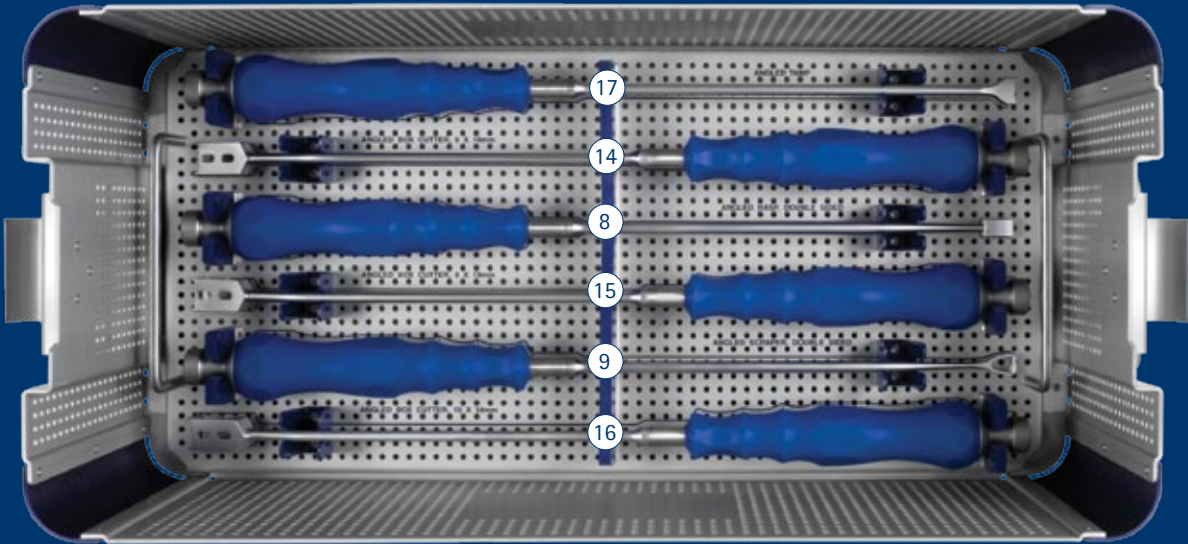
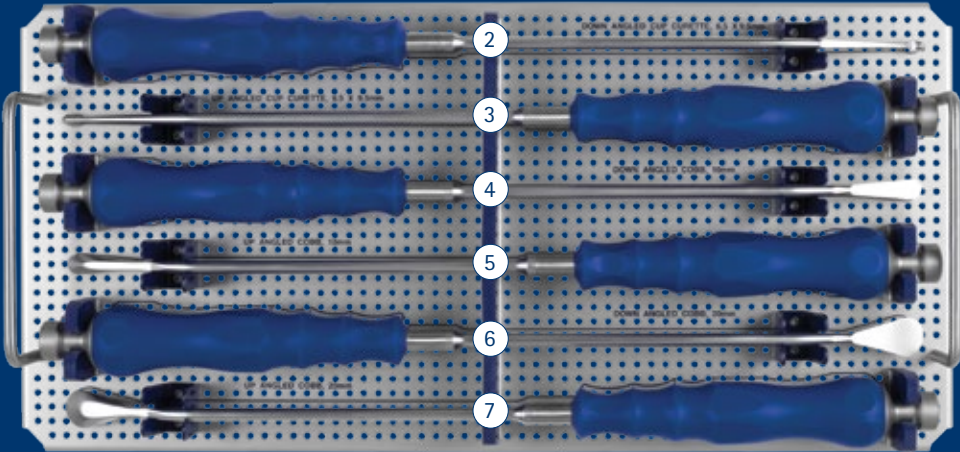
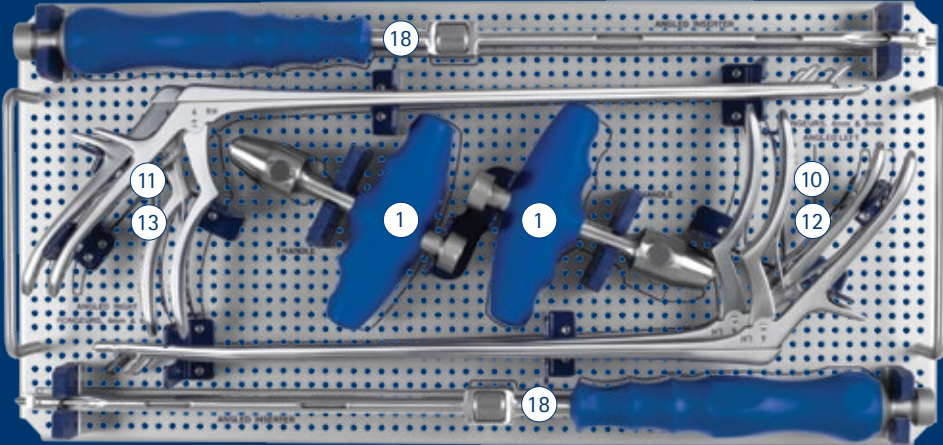
TransContinental® INSERTION INSTRUMENTS SET



TransContinental® Insertion Instruments Set 975.915

	Instruments	Qty
1	664.500 PATRIOT® CONTINENTAL® Holder/Inserter	2
2	675.004 Long Throw Slide Hammer	1
3	675.005 T-Handle with Impaction Cap	2
4	675.006 TransContinental® Trial, Parallel, 5mm	1
5	675.007 TransContinental® Trial, Parallel, 7mm	1
6	675.009 TransContinental® Trial, Parallel, 9mm	1
7	675.011 TransContinental® Trial, Parallel, 11mm	1
8	675.013 TransContinental® Trial, Parallel, 13mm	1
9	675.015 TransContinental® Trial, Parallel, 15mm	1
10	675.017 TransContinental® Trial, Parallel, 17mm	1
11	675.106 TransContinental® Trial, Lordotic, 5mm	1
12	675.107 TransContinental® Trial, Lordotic, 7mm	1
13	675.109 TransContinental® Trial, Lordotic, 9mm	1
14	675.111 TransContinental® Trial, Lordotic, 11mm	1
15	675.113 TransContinental® Trial, Lordotic, 13mm	1
16	675.115 TransContinental® Trial, Lordotic, 15mm	1
17	675.117 TransContinental® Trial, Lordotic, 17mm	1
18	675.501 Insertion Sleeve	2
19	675.502 Tamp	1
20	679.010 L-Handle	1
	975.007 TransContinental® Graphic Case – Insertion	

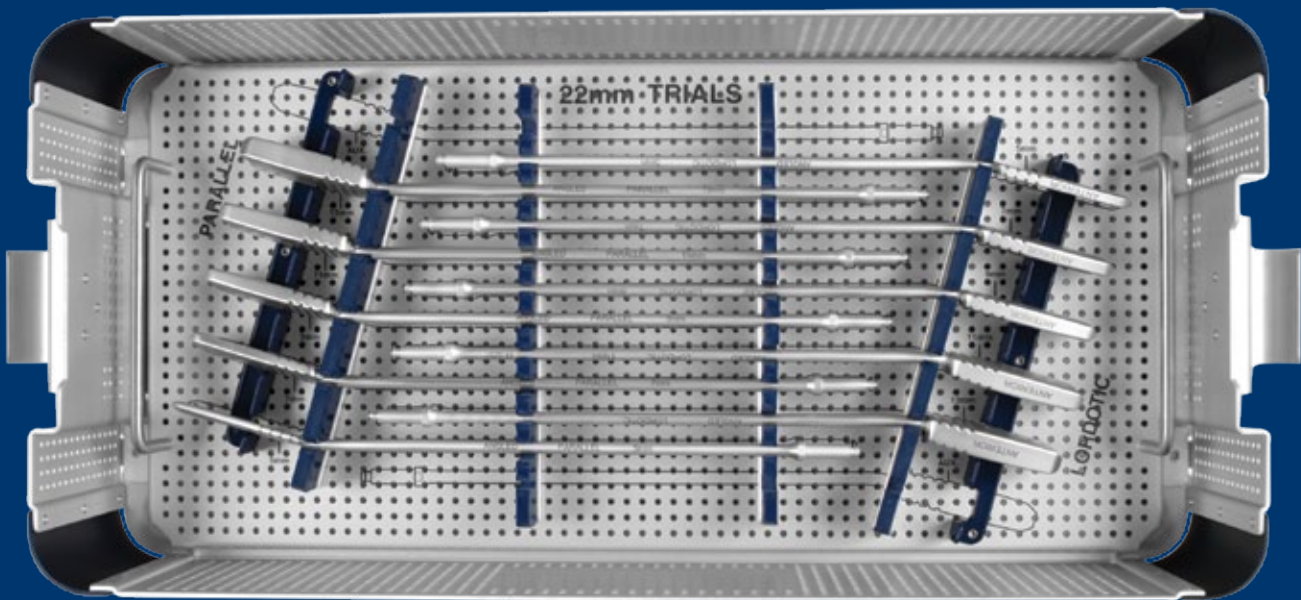
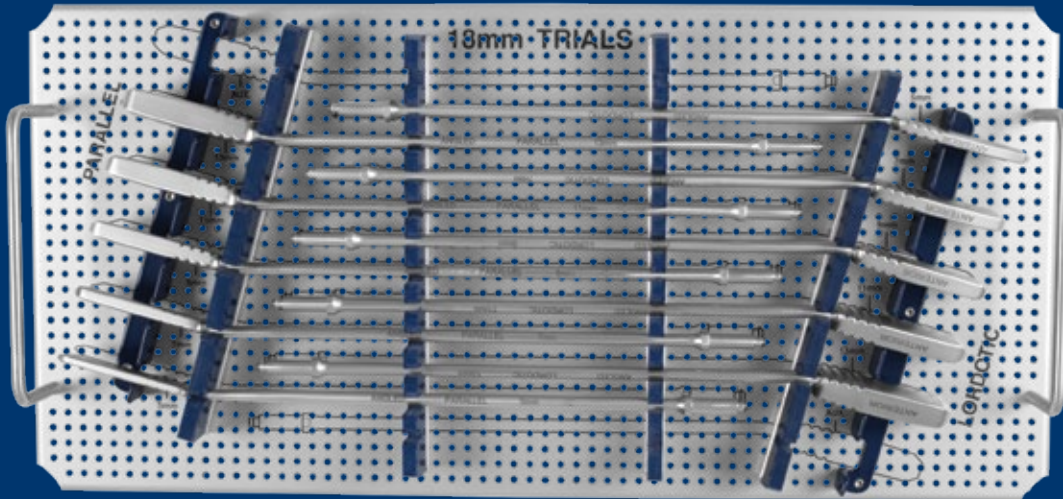
LATERAL ANGLED DISC PREP INSTRUMENT SET



Lateral Angled Disc Prep Instrument Set 975.940

	Instruments	Qty
①	675.005 T-Handle with Impaction Cap	2
②	675.330 Cup, Curette, Angled, 6.5x9.5mm, Down	1
③	675.331 Cup, Curette, Angled, 6.5x9.5mm, Up	1
④	675.334 Cobb, Angled, 10mm, Down	1
⑤	675.335 Cobb, Angled, 10mm, Up	1
⑥	675.336 Cobb, Angled, 20mm, Down	1
⑦	675.337 Cobb, Angled, 20mm, Up	1
⑧	675.338 Double Sided Rasp, Angled	1
⑨	675.339 Double Sided Scraper, Angled	1
⑩	675.340 Rongeur, Angled, Left, 4mm	1
⑪	675.341 Rongeur, Angled Right, 4mm	1
⑫	675.342 Rongeur, Angled Left, 6mm	1
⑬	675.343 Rongeur, Angled Right, 6mm	1
⑭	675.344 Box Cutter, Angled, 6x18mm	1
⑮	675.345 Box Cutter, Angled, 8x18mm	1
⑯	675.346 Box Cutter, Angled, 10x18mm	1
⑰	675.347 Tamp, Angled	1
⑱	675.980 Angled Inserter	2
	975.040 Lateral Angled Disc Prep Graphic Case	

TransContinental® Angled Trials Set



TransContinental® Angled Trials Set 975.941

Part No.	Description	Qty
675.273	18mm Trial, Angled, Parallel, 5mm	1
675.275	18mm Trial, Angled, Parallel, 7mm	1
675.277	18mm Trial, Angled, Parallel, 9mm	1
675.279	18mm Trial, Angled, Parallel, 11mm	1
675.281	18mm Trial, Angled, Parallel, 13mm	1
675.473	22mm Trial, Angled, Parallel, 5mm	1
675.475	22mm Trial, Angled, Parallel, 7mm	1
675.477	22mm Trial, Angled, Parallel, 9mm	1
675.479	22mm Trial, Angled, Parallel, 11mm	1
675.481	22mm Trial, Angled, Parallel, 13mm	1
675.543	18mm Trial, Angled, Lordotic, 5mm	1
675.545	18mm Trial, Angled, Lordotic, 7mm	1
675.547	18mm Trial, Angled, Lordotic, 9mm	1
675.549	18mm Trial, Angled, Lordotic, 11mm	1
675.551	18mm Trial, Angled, Lordotic, 13mm	1
675.573	22mm Trial, Angled, 6° Lordotic, 5mm	1
675.575	22mm Trial, Angled, 6° Lordotic, 7mm	1
675.577	22mm Trial, Angled, 6° Lordotic, 9mm	1
675.579	22mm Trial, Angled, 6° Lordotic, 11mm	1
675.581	22mm Trial, Angled, 6° Lordotic, 13mm	1
975.041	TransContinental® Angled Trials Graphic Case	

Additionally Available

675.083	18mm Trial, Angled, Right Lordotic, 5mm
675.085	18mm Trial, Angled, Right Lordotic, 7mm
675.087	18mm Trial, Angled, Right Lordotic, 9mm
675.089	18mm Trial, Angled, Right Lordotic, 11mm
675.091	18mm Trial, Angled, Right Lordotic, 13mm
675.673	22mm Trial, Angled, Right Lordotic, 5mm
675.675	22mm Trial, Angled, Right Lordotic, 7mm
675.677	22mm Trial, Angled, Right Lordotic, 9mm
675.679	22mm Trial, Angled, Right Lordotic, 11mm
675.681	22mm Trial, Angled, Right Lordotic, 13mm

TransContinental® 16mm Wide Implant Set 975.920

Part No.	Description	Qty
375.060	TransContinental® Spacer, 0°, 16x25mm, 7mm	2
375.061	TransContinental® Spacer, 0°, 16x25mm, 9mm	2
375.062	TransContinental® Spacer, 0°, 16x25mm, 11mm	2
375.063	TransContinental® Spacer, 0°, 16x25mm, 13mm	2
375.160	TransContinental® Spacer, 0°, 16x30mm, 7mm	2
375.161	TransContinental® Spacer, 0°, 16x30mm, 9mm	2
375.162	TransContinental® Spacer, 0°, 16x30mm, 11mm	2
375.163	TransContinental® Spacer, 0°, 16x30mm, 13mm	2
375.260	TransContinental® Spacer, 0°, 16x35mm, 7mm	2
375.261	TransContinental® Spacer, 0°, 16x35mm, 9mm	2
375.262	TransContinental® Spacer, 0°, 16x35mm, 11mm	2
375.263	TransContinental® Spacer, 0°, 16x35mm, 13mm	2
375.360	TransContinental® Spacer, 0°, 16x40mm, 7mm	2
375.361	TransContinental® Spacer, 0°, 16x40mm, 9mm	2
375.362	TransContinental® Spacer, 0°, 16x40mm, 11mm	2
375.363	TransContinental® Spacer, 0°, 16x40mm, 13mm	2
375.460	TransContinental® Spacer, 0°, 16x20mm, 7mm	2
375.461	TransContinental® Spacer, 0°, 16x20mm, 9mm	2
375.462	TransContinental® Spacer, 0°, 16x20mm, 11mm	2
375.463	TransContinental® Spacer, 0°, 16x20mm, 13mm	2
675.059	16mm Trial 0° Lordotic, 5mm	1
675.060	16mm Trial 0° Lordotic, 7mm	1
675.061	16mm Trial 0° Lordotic, 9mm	1
675.062	16mm Trial 0° Lordotic, 11mm	1
675.063	16mm Trial 0° Lordotic, 13mm	1
675.930	Insertion Sleeve	2
675.940	Holder Inserter	2
975.020	TransContinental® Graphic Case - Implant, 16mm Wide	

Bayonnetted Disc Prep Instrument Set 975.923

Instruments	Qty
675.128 Dual Convex Rasp, Bayonnetted	1
675.131 Bone Curette, Bayonnetted, Small	1
675.132 Bone Curette, Bayonnetted, Up-Angled, Small	1
675.133 Bone Curette, Bayonnetted, 90°, Small	1
675.139 Bone Curette, Bayonnetted, Large	1
675.140 Bone Curette, Bayonnetted, Up-Angled, Large	1
675.141 Bone Curette, Bayonnetted, 90°, Large	1
675.148 Ring Curette, Bayonnetted, Up Angled	1
675.151 Box Curette, Bayonnetted, Up Angled, Wide	1
675.154 Box Curette, Bayonnetted, Up Angled, Narrow	1
675.162 Nerve Retractor	1
675.172 Penfield, Bayonnetted, Push	1
675.173 Penfield, Bayonnetted, Pull	1
675.182 Thin Rasp, Bayonnetted, Straight	1
675.183 Thin Rasp, Bayonnetted, Angled	1
675.185 Rake, Bayonnetted	1
675.186 Nerve Hook, Bayonnetted	1
675.305 Kerrison, Bayonnetted, 3mm	1
675.306 Kerrison, Bayonnetted, 5mm	1
675.316 Disc Rongeur, Bayonnetted, 2mm, Straight	1
675.317 Disc Rongeur, Bayonnetted, 2mm, Up	1
675.318 Disc Rongeur, Bayo, 4mm, Straight	1
675.319 Disc Rongeur, Bayonnetted, 4mm, Up	1
675.320 Disc Rongeur, Bayonnetted, 6mm, Straight	1
675.321 Disc Rongeur, Bayonnetted, 6mm, Up	1
975.023 Bayonnetted Lateral Instruments Graphic Case	

TransContinental® 22mm Implant Set 975.922

Part No.	Description	Qty	Part No.	Description	Qty
375.045	TransContinental® Spacer, 22mm Wide, Small, 0°, 7mm	1	375.357	TransContinental® Spacer, 22mm Wide, Medium, 6°, 17mm	1
375.049	TransContinental® Spacer, 22mm Wide, Small, 0°, 9mm	2	375.445	TransContinental® Spacer, 22mm Wide, Large, 0°, 7mm	1
375.051	TransContinental® Spacer, 22mm Wide, Small, 0°, 11mm	2	375.449	TransContinental® Spacer, 22mm Wide, Large, 0°, 9mm	2
375.053	TransContinental® Spacer, 22mm Wide, Small, 0°, 13mm	2	375.451	TransContinental® Spacer, 22mm Wide, Large, 0°, 11mm	2
375.055	TransContinental® Spacer, 22mm Wide, Small, 0°, 15mm	2	375.453	TransContinental® Spacer, 22mm Wide, Large, 0°, 13mm	2
375.057	TransContinental® Spacer, 22mm Wide, Small, 0°, 17mm	1	375.455	TransContinental® Spacer, 22mm Wide, Large, 0°, 15mm	2
375.145	TransContinental® Spacer, 22mm Wide, Small, 6°, 7mm	1	375.457	TransContinental® Spacer, 22mm Wide, Large, 0°, 17mm	1
375.149	TransContinental® Spacer, 22mm Wide, Small, 6°, 9mm	2	375.545	TransContinental® Spacer, 22mm Wide, Large, 6°, 7mm	1
375.151	TransContinental® Spacer, 22mm Wide, Small, 6°, 11mm	2	375.549	TransContinental® Spacer, 22mm Wide, Large, 6°, 9mm	2
375.153	TransContinental® Spacer, 22mm Wide, Small, 6°, 13mm	2	375.551	TransContinental® Spacer, 22mm Wide, Large, 6°, 11mm	2
375.155	TransContinental® Spacer, 22mm Wide, Small, 6°, 15mm	2	375.553	TransContinental® Spacer, 22mm Wide, Large, 6°, 13mm	2
375.157	TransContinental® Spacer, 22mm Wide, Small, 6°, 17mm	1	375.555	TransContinental® Spacer, 22mm Wide, Large, 6°, 15mm	2
375.245	TransContinental® Spacer, 22mm Wide, Medium, 0°, 7mm	1	375.557	TransContinental® Spacer, 22mm Wide, Large, 6°, 17mm	1
375.249	TransContinental® Spacer, 22mm Wide, Medium, 0°, 9mm	2	375.645	TransContinental® Spacer, 22mm Wide, X-Large, 0°, 7mm	1
375.251	TransContinental® Spacer, 22mm Wide, Medium, 0°, 11mm	2	375.649	TransContinental® Spacer, 22mm Wide, X-Large, 0°, 9mm	2
375.253	TransContinental® Spacer, 22mm Wide, Medium, 0°, 13mm	2	375.651	TransContinental® Spacer, 22mm Wide, X-Large, 0°, 11mm	2
375.255	TransContinental® Spacer, 22mm Wide, Medium, 0°, 15mm	2	375.653	TransContinental® Spacer, 22mm Wide, X-Large, 0°, 13mm	2
375.257	TransContinental® Spacer, 22mm Wide, Medium, deg, 17mm	1	375.655	TransContinental® Spacer, 22mm Wide, X-Large, 0°, 15mm	2
375.345	TransContinental® Spacer, 22mm Wide, Medium, 6°, 7mm	1	375.657	TransContinental® Spacer, 22mm Wide, X-Large, 0°, 17mm	1
375.349	TransContinental® Spacer, 22mm Wide, Medium, 6°, 9mm	2	375.745	TransContinental® Spacer, 22mm Wide, X-Large, 6°, 7mm	1
375.351	TransContinental® Spacer, 22mm Wide, Medium, 6°, 11mm	2	375.749	TransContinental® Spacer, 22mm Wide, X-Large, 6°, 9mm	2
375.353	TransContinental® Spacer, 22mm Wide, Medium, 6°, 13mm	2	375.751	TransContinental® Spacer, 22mm Wide, X-Large, 6°, 11mm	2
375.355	TransContinental® Spacer, 22mm Wide, Medium, 6°, 15mm	2	375.753	TransContinental® Spacer, 22mm Wide, X-Large, 6°, 13mm	2

TransContinental® 22mm Implant Set 975.922 (cont'd)

Part No.	Description	Qty	Part No.	Description	Qty
375.755	TransContinental® Spacer, 22mm Wide, X-Large, 6°, 15mm	2	675.453	TransContinental® 22mm Trial, 6°, Lordotic, 13mm	1
375.757	TransContinental® Spacer, 22mm Wide, X-Large, 6°, 17mm	1	675.455	TransContinental® 22mm Trial, 6°, Lordotic, 15mm	1
375.845	TransContinental® Spacer, 22mm Wide, X-Small, 0°, 7mm	1	675.457	TransContinental® 22mm Trial, 6°, Lordotic, 17mm	1
375.849	TransContinental® Spacer, 22mm Wide, X-Small, 0°, 9mm	1	675.522	Insertion Sleeve, 22mm	2
375.851	TransContinental® Spacer, 22mm Wide, X-Small, 0°, 11mm	1	975.022	TransContinental® 22mm Wide Implant Graphic Case	
375.853	TransContinental® Spacer, 22mm Wide, X-Small, 0°, 13mm	1	Additionally Available		
375.855	TransContinental® Spacer, 22mm Wide, X-Small, 0°, 15mm	1	375.857	TransContinental® Spacer, 22mm Wide, X-Small, 0°, 17mm	
375.945	TransContinental® Spacer, 22mm Wide, X-Small, 6°, 7mm	1	375.957	TransContinental® Spacer, 22mm Wide, X-Small, 6°, 17mm	
375.949	TransContinental® Spacer, 22mm Wide, X-Small, 6°, 9mm	1			
375.951	TransContinental® Spacer, 22mm Wide, X-Small, 6°, 11mm	1			
375.953	TransContinental® Spacer, 22mm Wide, X-Small, 6°, 13mm	1			
375.955	TransContinental® Spacer, 22mm Wide, X-Small, 6°, 15mm	1			
675.043	TransContinental® 22mm Trial, Parallel, 5mm	1			
675.045	TransContinental® 22mm Trial, Parallel, 7mm	1			
675.049	TransContinental® 22mm Trial, Parallel, 9mm	1			
675.051	TransContinental® 22mm Trial, Parallel, 11mm	1			
675.053	TransContinental® 22mm Trial, Parallel, 13mm	1			
675.055	TransContinental® 22mm Trial, Parallel, 15mm	1			
675.057	TransContinental® 22mm Trial, Parallel, 17mm	1			
675.443	TransContinental® 22mm Trial, 6° Lordotic, 5mm	1			
675.445	TransContinental® 22mm Trial, 6° Lordotic, 7mm	1			
675.449	TransContinental® 22mm Trial, 6° Lordotic, 9mm	1			
675.451	TransContinental® 22mm Trial, 6° Lordotic, 11mm	1			

TransContinental® 10° Lordotic Implant Set 975.924

Part No.	Description	Qty	Part No.	Description	Qty
375.067	TransContinental® Spacer, 18mm Wide, Small, 10°, 7mm	2	375.377	TransContinental® Spacer, 22mm Wide, Medium, 10°, 17mm	1
375.069	TransContinental® Spacer, 18mm Wide, Small, 10°, 9mm	2	375.467	TransContinental® Spacer, 18mm Wide, Large, 10°, 7mm	2
375.071	TransContinental® Spacer, 18mm Wide, Small, 10°, 11mm	2	375.469	TransContinental® Spacer, 18mm Wide, Large, 10°, 9mm	2
375.073	TransContinental® Spacer, 18mm Wide, Small, 10°, 13mm	2	375.471	TransContinental® Spacer, 18mm Wide, Large, 10°, 11mm	2
375.075	TransContinental® Spacer, 18mm Wide, Small, 10°, 15mm	2	375.473	TransContinental® Spacer, 18mm Wide, Large, 10°, 13mm	2
375.077	TransContinental® Spacer, 18mm Wide, Small, 10°, 17mm	1	375.475	TransContinental Spacer, 18mm Wide, Large, 10°, 15mm	2
375.167	TransContinental® Spacer, 22mm Wide, Small, 10°, 7mm	2	375.477	TransContinental® Spacer, 18mm Wide, Large, 10°, 17mm	1
375.169	TransContinental® Spacer, 22mm Wide, Small, 10°, 9mm	2	375.567	TransContinental® Spacer, 22mm Wide, Large, 10°, 7mm	2
375.171	TransContinental® Spacer, 22mm Wide, Small, 10°, 11mm	2	375.569	TransContinental® Spacer, 22mm Wide, Large, 10°, 9mm	2
375.173	TransContinental® Spacer, 22mm Wide, Small, 10°, 13mm	2	375.571	TransContinental® Spacer, 22mm Wide, Large, 10°, 11mm	2
375.175	TransContinental® Spacer, 22mm Wide, Small, 10°, 15mm	2	375.573	TransContinental® Spacer, 22mm Wide, Large, 10°, 13mm	2
375.177	TransContinental® Spacer, 22mm Wide, Small, 10°, 17mm	1	375.575	TransContinental® Spacer, 22mm Wide, Large, 10°, 15mm	2
375.267	TransContinental® Spacer, 18mm Wide, Medium, 10°, 7mm	2	375.577	TransContinental® Spacer, 22mm Wide, Large, 10°, 17mm	1
375.269	TransContinental® Spacer, 18mm Wide, Medium, 10°, 9mm	2	375.667	TransContinental® Spacer, 18mm Wide, X-Large, 10°, 7mm	2
375.271	TransContinental® Spacer, 18mm Wide, Medium, 10°, 11mm	2	375.669	TransContinental® Spacer, 18mm Wide, X-Large, 10°, 9mm	2
375.273	TransContinental® Spacer, 18mm Wide, Medium, 10°, 13mm	2	375.671	TransContinental® Spacer, 18mm Wide, X-Large, 10°, 11mm	2
375.275	TransContinental® Spacer, 18mm Wide, Medium, 10°, 15mm	2	375.673	TransContinental® Spacer, 18mm Wide, X-Large, 10°, 13mm	2
375.277	TransContinental® Spacer, 18mm Wide, Medium, 10°, 17mm	1	375.675	TransContinental® Spacer, 18mm Wide, X-Large, 10°, 15mm	2
375.367	TransContinental® Spacer, 22mm Wide, Medium, 10, 7mm	2	375.677	TransContinental® Spacer, 18mm Wide, X-Large, 10°, 17mm	1
375.369	TransContinental® Spacer, 22mm Wide, Medium, 10°, 9mm	2	375.767	TransContinental® Spacer, 22mm Wide, X-Large, 10°, 7mm	2
375.371	TransContinental® Spacer, 22mm Wide, Medium, 10°, 11mm	2	375.769	TransContinental® Spacer, 22mm Wide, X-Large, 10°, 9mm	2
375.373	TransContinental® Spacer, 22mm Wide, Medium, 10°, 13mm	2	375.771	TransContinental® Spacer, 22mm Wide, X-Large, 10°, 11mm	2
375.375	TransContinental® Spacer, 22mm Wide, Medium, 10°, 15mm	2	375.773	TransContinental® Spacer, 22mm Wide, X-Large, 10°, 13mm	2

TransContinental® 10° Lordotic Implant Set 975.924 (cont'd)

Part No.	Description	Qty	Part No.	Description	Qty
375.775	TransContinental® Spacer, 22mm Wide, X-Large, 10°, 15mm	2	675.369	TransContinental® 22mm Trial, 10° Lordotic, 9mm	1
375.777	TransContinental® Spacer, 22mm Wide, X-Large, 10°, 17mm	1	675.371	TransContinental® 22mm Trial, 10° Lordotic, 11mm	1
375.867	TransContinental® Spacer, 18mm Wide, X-Small, 10°, 7mm	2	675.373	TransContinental® 22mm Trial, 10° Lordotic, 13mm	1
375.869	TransContinental® Spacer, 18mm Wide, X-Small, 10°, 9mm	2	675.375	TransContinental® 22mm Trial, 10° Lordotic, 15mm	1
375.871	TransContinental® Spacer, 18mm Wide, X-Small, 10°, 11mm	2	675.377	TransContinental® 22mm Trial, 10° Lordotic, 17mm	1
375.873	TransContinental® Spacer, 18mm Wide, X-Small, 10° 13mm	2	675.501	Insertion Sleeve	1
375.875	TransContinental® Spacer, 18mm Wide, X-Small, 10°, 15mm	2	675.522	Insertion Sleeve, 22mm	1
375.877	TransContinental® Spacer, 18mm Wide, X-Small, 10°, 17mm	1	975.024	TransContinental® 10° Lordotic Implant Graphic Case	
375.967	TransContinental® Spacer, 22mm Wide, X-Small, 10°, 7mm	2			
375.969	TransContinental® Spacer, 22mm Wide, X-Small, 10°, 9mm	2			
375.971	TransContinental® Spacer, 22mm Wide, X-Small, 10°, 11mm	2			
375.973	TransContinental® Spacer, 22mm Wide, X-Small, 10°, 13mm	2			
375.975	TransContinental® Spacer, 22mm Wide, X-Small, 10°, 15mm	2			
375.977	TransContinental® Spacer, 22mm Wide, X-Small, 10°, 17mm	1			
675.065	TransContinental® 18mm Trial, 10° Lordotic, 5mm	1			
675.067	TransContinental® 18mm Trial, 10° Lordotic, 7mm	1			
675.069	TransContinental® 18mm Trial, 10° Lordotic, 9mm	1			
675.071	TransContinental® 18mm Trial, 10° Lordotic, 11mm	1			
675.073	TransContinental® 18mm Trial, 10° Lordotic, 13mm	1			
675.075	TransContinental® 18mm Trial, 10° Lordotic, 15mm	1			
675.077	TransContinental® 18mm Trial, 10° Lordotic, 17mm	1			
675.365	TransContinental® 22mm Trial, 10° Lordotic, 5mm	1			
675.367	TransContinental® 22mm Trial, 10° Lordotic, 7mm	1			

TransContinental® Coronal Tapered Implant Set 975.925

Part No.	Description	Qty	Part No.	Description	Qty
375.092	TransContinental® Coronal Spacer, 0°, 18x30mm, 9mm	2	375.496	TransContinental® Coronal Spacer, 0°, 18x40mm, 17mm	1
375.093	TransContinental® Coronal Spacer, 0°, 18x30mm, 11mm	2	375.592	TransContinental® Coronal Spacer, 10°, 18x40mm, 9mm	2
375.094	TransContinental® Coronal Spacer, 0°, 18x30mm, 13mm	2	375.593	TransContinental® Coronal Spacer, 10°, 18x40mm, 11mm	2
375.095	TransContinental® Coronal Spacer, 0°, 18x30mm, 15mm	2	375.594	TransContinental® Coronal Spacer, 10°, 18x40mm, 13mm	2
375.096	TransContinental® Coronal Spacer, 0°, 18x30mm, 17mm	1	375.595	TransContinental® Coronal Spacer, 10°, 18x40mm, 15mm	2
375.192	TransContinental® Coronal Spacer, 10°, 18x30mm, 9mm	2	375.596	TransContinental® Coronal Spacer, 10°, 18x40mm, 17mm	1
375.193	TransContinental® Coronal Spacer, 10°, 18x30mm, 11mm	2	375.682	TransContinental® Coronal Spacer, 0°, 18x45mm, 9mm	2
375.194	TransContinental® Coronal Spacer, 10°, 18x30mm, 13mm	2	375.683	TransContinental® Coronal Spacer, 0°, 18x45mm, 11mm	2
375.195	TransContinental® Coronal Spacer, 10°, 18x30mm, 15mm	2	375.684	TransContinental® Coronal Spacer, 0°, 18x45mm, 13mm	2
375.196	TransContinental® Coronal Spacer, 10°, 18x30mm, 17mm	1	375.685	TransContinental® Coronal Spacer, 0°, 18x45mm, 15mm	2
375.292	TransContinental® Coronal Spacer, 0°, 18x35mm, 9mm	2	375.686	TransContinental® Coronal Spacer, 0°, 18x45mm, 17mm	1
375.293	TransContinental® Coronal Spacer, 0°, 18x35mm, 11mm	2	375.692	TransContinental® Coronal Spacer, 0°, 18x50mm, 9mm	2
375.294	TransContinental® Coronal Spacer, 0°, 18x35mm, 13mm	2	375.693	TransContinental® Coronal Spacer, 0°, 18x50mm, 11mm	2
375.295	TransContinental® Coronal Spacer, 0°, 18x35mm, 15mm	2	375.694	TransContinental® Coronal Spacer, 0°, 18x50mm, 13mm	2
375.296	TransContinental® Coronal Spacer, 0°, 18x35mm, 17mm	1	375.695	TransContinental® Coronal Spacer, 0°, 18x50mm, 15mm	2
375.392	TransContinental® Coronal Spacer, 10°, 18x35mm, 9mm	2	375.696	TransContinental® Coronal Spacer, 0°, 18x50mm, 17mm	1
375.393	TransContinental® Coronal Spacer, 10°, 18x35mm, 11mm	2	375.782	TransContinental® Coronal Spacer, 10°, 18x45mm, 9mm	2
375.394	TransContinental® Coronal Spacer, 10°, 18x35mm, 13mm	2	375.783	TransContinental® Coronal Spacer, 10°, 18x45mm, 11mm	2
375.395	TransContinental® Coronal Spacer, 10°, 18x35mm, 15mm	2	375.784	TransContinental® Coronal Spacer, 10°, 18x45mm, 13mm	2
375.396	TransContinental® Coronal Spacer, 10°, 18x35mm, 17mm	1	375.785	TransContinental® Coronal Spacer, 10°, 18x45mm, 15mm	2
375.492	TransContinental® Coronal Spacer, 0°, 18x40mm, 9mm	2	375.786	TransContinental® Coronal Spacer, 10°, 18x45mm, 17mm	1
375.493	TransContinental® Coronal Spacer, 0°, 18x40mm, 11mm	2	375.792	TransContinental® Coronal Spacer, 10°, 18x50mm, 9mm	2
375.494	TransContinental® Coronal Spacer, 0°, 18x40mm, 13mm	2	375.793	TransContinental® Coronal Spacer, 10°, 18x50mm, 11mm	2
375.495	TransContinental® Coronal Spacer, 0°, 18x40mm, 15mm	2	375.794	TransContinental® Coronal Spacer, 10°, 18x50mm, 13mm	2

TransContinental® Coronal Tapered Implant Set 975.925 (cont'd)

Part No.	Description	Qty	Part No.	Description	Qty
375.795	TransContinental® Coronal Spacer, 10°, 18x50mm, 15mm	2	675.031	Trial Leading – 4° Coronal x 0° Lordotic, 11mm	1
375.796	TransContinental® Coronal Spacer, 10°, 18x50mm, 17mm	1	675.033	Trial Leading – 4° Coronal x 0° Lordotic, 13mm	1
375.882	TransContinental® Coronal Spacer, 0°, 18x55mm, 9mm	2	675.035	Trial Leading – 4° Coronal x 0° Lordotic, 15mm	1
375.883	TransContinental® Coronal Spacer, 0°, 18x55mm, 11mm	2	675.037	Trial Leading – 4° Coronal x 0° Lordotic, 17mm	1
375.884	TransContinental® Coronal Spacer, 0°, 18x55mm, 13mm	2	675.227	Trial Trailing – 4° Coronal x 0° Lordotic, 7mm	1
375.885	TransContinental® Coronal Spacer, 0°, 18x55mm, 15mm	2	675.229	Trial Trailing – 4° Coronal x 0° Lordotic, 9mm	1
375.886	TransContinental® Coronal Spacer, 0°, 18x55mm, 17mm	1	675.231	Trial Trailing – 4° Coronal x 0° Lordotic, 11mm	1
375.892	TransContinental® Coronal Spacer, 0°, 18x60mm, 9mm	2	675.233	Trial Trailing – 4° Coronal x 0° Lordotic, 13mm	1
375.893	TransContinental® Coronal Spacer, 0°, 18x60mm, 11mm	2	675.235	Trial Trailing - 4° Coronal x 0° Lordotic, 15mm	1
375.894	TransContinental® Coronal Spacer, 0°, 18x60mm, 13mm	2	675.237	Trial Trailing - 4° Coronal x 0° Lordotic, 17mm	1
375.895	TransContinental® Coronal Spacer, 0°, 18x60mm, 15mm	2	675.427	Trial Leading – 4° Coronal x 10° Lordotic, 7mm	1
375.896	TransContinental® Coronal Spacer, 0°, 18x60mm, 17mm	1	675.429	Trial Leading – 4° Coronal x 10° Lordotic, 9mm	1
375.982	TransContinental® Coronal Spacer, 10°, 18x55mm, 9mm	2	675.431	Trial Leading – 4° Coronal x 10° Lordotic, 11mm	1
375.983	TransContinental® Coronal Spacer, 10°, 18x55mm, 11mm	2	675.433	Trial Leading – 4° Coronal x 10° Lordotic, 13mm	1
375.984	TransContinental® Coronal Spacer, 10°, 18x55mm, 13mm	2	675.435	Trial Leading – 4° Coronal x 10° Lordotic, 15mm	1
375.985	TransContinental® Coronal Spacer, 10°, 18x55mm, 15mm	2	675.437	Trial Leading – 4° Coronal x 10° Lordotic, 17mm	1
375.986	TransContinental® Coronal Spacer, 10°, 18x55mm, 17mm	1	675.827	Trial Trailing – 4° Coronal x 10° Lordotic, 7mm	1
375.992	TransContinental® Coronal Spacer, 10°, 18x60mm, 9mm	2	675.829	Trial Trailing – 4° Coronal x 10° Lordotic, 9mm	1
375.993	TransContinental® Coronal Spacer, 10°, 18x60mm, 11mm	2	675.831	Trial Trailing – 4° Coronal x 10° Lordotic, 11mm	1
375.994	TransContinental® Coronal Spacer, 10°, 18x60mm, 13mm	2	675.833	Trial Trailing – 4° Coronal x 10° Lordotic, 13mm	1
375.995	TransContinental® Coronal Spacer, 10°, 18x60mm, 15mm	2	675.835	Trial Trailing – 4° Coronal x 10° Lordotic, 15mm	1
375.996	TransContinental® Coronal Spacer, 10°, 18x60mm, 17mm	1	675.837	Trial Trailing – 4° Coronal x 10° Lordotic, 17mm	1
675.027	Trial Leading – 4° Coronal x 0° Lordotic, 7mm	1	675.940	Holder Insertor	2
675.029	Trial Leading – 4° Coronal x 0° Lordotic, 9mm	1	675.960	Coronal Insertion Sleeve, 18mm	2
			975.025	TransContinental® Coronal Tapered Implant Graphic Case	

IMPORTANT INFORMATION ON MARS™ (Minimal Access Retractor System)

DESCRIPTION

MARS™ (Minimal Access Retractor System) is a comprehensive retractor, ports and instrument system that provides efficient access to posterior lumbar spine. MARS™ and MARS™3V consists of a retractor frame, blades, disposable ports, silicone sleeves, light cables and associated manual surgical instruments. The blades and ports are available in several designs to accommodate individual patient anatomy.

The MARS™ and MARS™3V instruments are made from aluminum and stainless steel as specified in ASTM B221-02 and F899-02. The ports are made from radiolucent polymer (PEEK) as specified in ASTM F2026.

CLEANING

Cleaning instructions by hand, when properly carried out, causes less damage than mechanical cleaning. When cleaning instruments by hand, the following should be observed:

1. Clear any corners or recesses of all debris. (Note: extra care should be taken to clean out any cannulated areas by using an appropriate cleaning stylet and rinsing immediately.)
2. Remove all traces of blood and other such residues immediately. Do not allow these to dry.
3. The instruments should be submerged (if applicable) and cleaned with a commercially available manual cleaner (i.e. Instraclean from Calgon or Medline High Suds Detergent) prepared according to the manufacturer's recommendation.
4. A soft nylon bristled brush is then used to manually clean the devices while immersed in the cleaning solution. Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
5. The instruments should be thoroughly rinsed after cleaning. Distilled water should be used.
6. Dry instruments immediately after cleaning.

Implants:

These devices are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132°C (270°F)	25 Minutes	45 Minutes
Steam	Pre-vacuum (Wrapped)	132°C (270°F)	15 Minutes	30 Minutes

Cycles should be performed on tray with devices opened for maximum steam penetration.

These parameters are validated to sterilize only these instruments. 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 autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

The following information is provided by LumitexMD, Inc. for MARS™ Light cable distributed by Globus Medical, Inc.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

INFORMATION FOR USE FOR THE MARS™ LIGHT CABLE

DESCRIPTION

The MARS™ Light Cable is a sterile, single use, latex free, plastic fiber optic device intended to bring cool area lighting into deep surgical sites. The MARS™ Light Cable is intended for use with a 300 watt xenon illuminator, using a 4mm fiber optic cable with a female ACMI connector. For best results use a Globus cable by LumitexMD.

INDICATIONS FOR USE

The MARS™ Light Cable is intended for the illumination of surgical procedures, particularly where deep cavities or adjacent tissues limit outside light in the surgical field. It is designed for use in less invasive spinal surgery.

CONTRAINDICATIONS

The MARS™ Light Cable presents no contraindication. However, the user should be familiar with the use of light sources and cables and should take precautions accordingly.

WARNINGS

The MARS™ Light Cable is designed for use with 300 watt xenon illuminators, using a 4mm fiber optic cable. Do not use light sources rated higher than 300 watts, or cables with fiber optic bundles of more than 4mm diameter. Use of higher watt sources or larger diameter cables could result in overheating; causing product failure and patient injury.

Should the MARS™ Light Cable become cut, collect fluid inside, appear broken or damaged in any manner, it should be replaced to minimize risk to the patient.

Do not operate the light source and cable without the MARS™ Light Cable attached. Without the MARS™ Light Cable, the output from the fiberoptic cable is extremely bright, hot and may cause burns, ignite drapes/gowns, or temporarily blind vision.

PRECAUTIONS

Light sources vary widely in emission of visible and infrared energy. As a precautionary measure, we recommend occasionally monitoring connector temperature during first time use with a new light source or lamp; thereafter if needed. As is common with fiber optic equipment, metal portion of connector can become hot to the touch. Use plastic grip as handle. Do not place the metal ring portion of connector directly on the patient's skin.

Because light energy can be absorbed as heat, the entire lit portion (distal end) of the MARS™ Light Cable should not be continuously embedded (i.e. lit surface should not be completely buried) in tissue and held fixed for more than a few minutes at one time.

Each MARS™ Light Cable package contains one MARS™ Light Cable assembly with an integrated adhesive strip and two double-sided adhesive strips. Each adhesive strip includes two paper release liners. Prior to closing the surgical site, all components must be accounted for.

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

IMPORTANT INFORMATION ON MARS™ (Minimal Access Retractor System)

DIRECTIONS FOR USE

Attach the MARS™ Light Cable to the Globus Medical MARS™ retractor using the integrated stainless steel clip located on the back of each MARS™ Light Cable.

The MARS™ Light Cable connects to a light source used for head lamps or endoscopes. A fiber optic cable attaches the light source and MARS™ Light Cable. Make sure the MARS™ Light Cable connector is securely attached to the cable. The cable should be in good repair with clean optics. Dirty optics or cables in need of repair can cause excessive heat at the connectors.

Turning down overhead lighting may improve visualization within the surgical site.

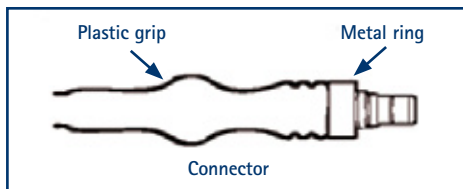
Body fluids or debris collecting on the surface of the MARS™ Light Cable may be irrigated or wiped away.

Sterile unless package is opened or damaged. Do not use if package is opened or damaged.

LIMITED WARRANTY

LumitexMD warrants the material conformity of the MARS™ Light Cable to specifications in the product labeling until the earlier of 12 months from shipment to customer or the expiration date of the product, and will repair or replace at LumitexMD option and expense any LumitexMD product that does not meet specifications in all material respects. LUMITEXMD LIABILITY TO CUSTOMER, USER, OR PATIENT IS EXPRESSLY LIMITED TO REPAIR OR REPLACEMENT. LumitexMD expressly disclaims all other warranties, express or implied, including, without limitation, merchantability or fitness for a particular purpose. Please direct any inquiries to Globus Medical.

Distributed by: Globus Medical, Inc. Valley Forge Business Center 2560 General Armisted Avenue Audubon, PA 19403 Tel: 610-415-9000 Fax: 610-415-9144	Manufactured by: LumitexMD, Inc. 8443 Dow Circle Strongsville, OH 44136 USA Tel: 800-969-5483 www.lumitexmd.com medical@lumitex.com	Authorized EC Representative: Medical Device Safety Service GmbH Schiffgraben 41 D-30175 Hannover, Germany
---	--	--



IMPORTANT INFORMATION ON THE PATRIOT® LUMBAR SPACER SYSTEM

DESCRIPTION

The PATRIOT® Spacers (CONSTITUTION® PLIF, SIGNATURE® TLIF, CONTINENTAL® ALIF, TransContinental® and TransContinental® M Spacers) are lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. Each of the PATRIOT® spacers provides a different shape to accommodate various surgical approaches to the lumbar spine. The CONSTITUTION® PLIF Spacer is inserted using a posterior approach. The SIGNATURE® TLIF Spacer is inserted using a transforaminal approach. The CONTINENTAL® ALIF Spacer is inserted using an anterior approach. The TransContinental® and TransContinental® M Spacer are inserted using an anterior or lateral approach. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. These spacers are 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.

PATRIOT® Spacers are made from PEEK radiolucent polymer, with titanium alloy or tantalum markers, as specified in ASTM F2026, F136, F1295, and F560. The TransContinental® M Spacer also includes an integrated titanium alloy nut, as specified in ASTM F136, F1295.

INDICATIONS

PATRIOT® Spacers (CONSTITUTION® PLIF, SIGNATURE® TLIF, CONTINENTAL® ALIF, TransContinental® and TransContinental® M Spacers) are interbody fusion devices 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).

PATRIOT® Spacers are 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,
- 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.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

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

The components of this system are manufactured from PEEK radiolucent polymer, titanium alloy, and tantalum. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

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.

The PATRIOT® Spacers have not been evaluated for safety and compatibility in the MR environment. The PATRIOT® Spacers have not been tested for heating or migration in the MR environment.

For optimal implant performance, when using the PATRIOT® Spacers, the physicians/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

CONTRAINDICATIONS

Use of PATRIOT® Spacer(s) 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.

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

The PATRIOT® Spacer implants and instruments have been validated to assure a Sterility Assurance Level (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*.

Implants:

These devices are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132°C (270°F)	10 minutes	15 minutes
Steam	Pre-vacuum (Wrapped)	132°C (270°F)	4 minutes	15 minutes

Instruments:

These instruments are supplied NONSTERILE. Sterilization is recommended as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132°C (270°F)	25 minutes	15 minutes
Steam	Pre-vacuum (Wrapped)	132°C (270°F)	15 minutes	20 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 autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

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



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)