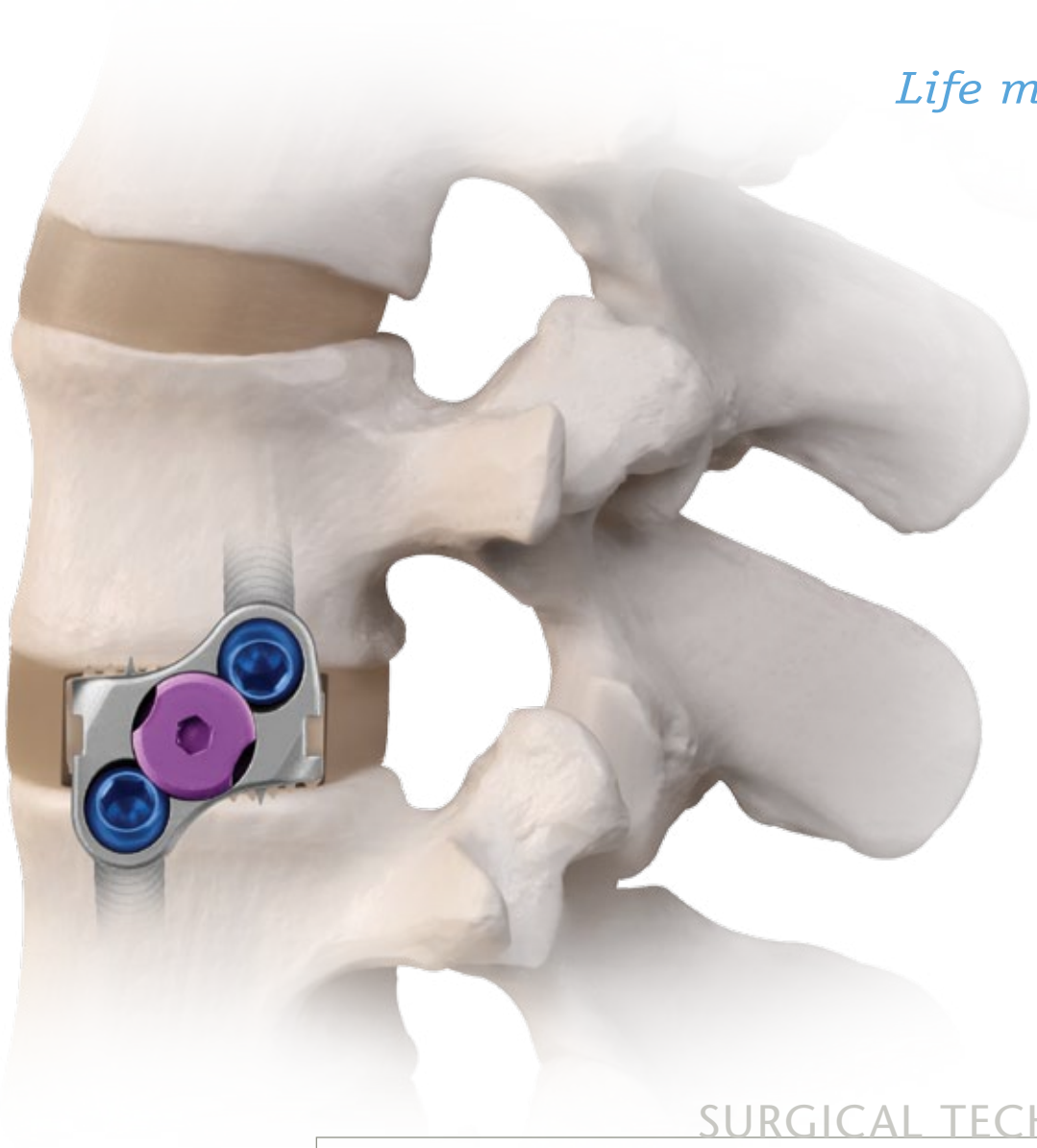
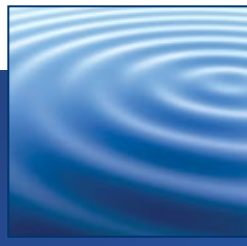
Life moves us



SURGICAL TECHNIQUE



InterContinental®

LLIF Plate-Spacer System

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.

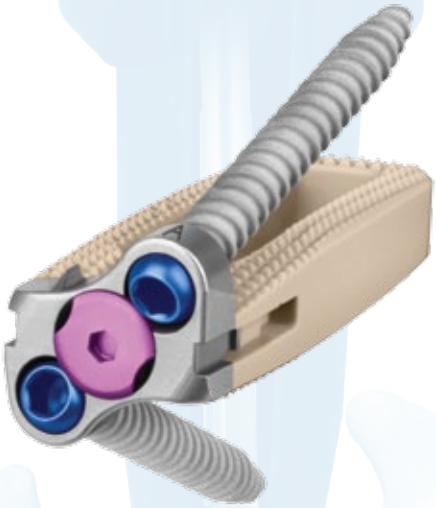
The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

GLOBUS
MEDICAL

www.globusmedical.com

InterContinental®

LLIF Plate-Spacer System



The InterContinental® Plate-Spacer is the next generation in minimally invasive lateral fixation.

The plate and spacer are positioned at the disc space, minimizing disruption to patient anatomy. The optimized screw design compressively loads the graft to help promote fusion.

The InterContinental® Plate-Spacer system offers a wide variety of footprints in order to meet different patient anatomy and to ensure optimal endplate contact.

InterContinental®
LLIF PLATE-SPACER SYSTEM

Stability

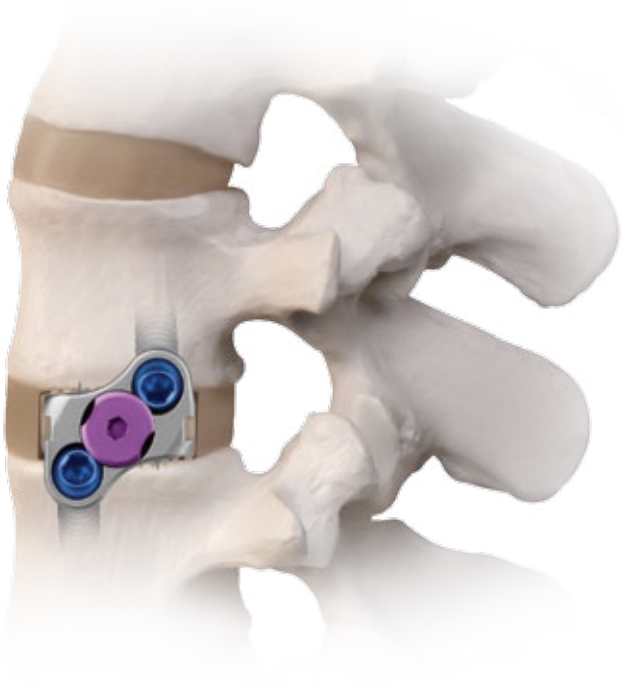
Enhanced stability through a lateral approach

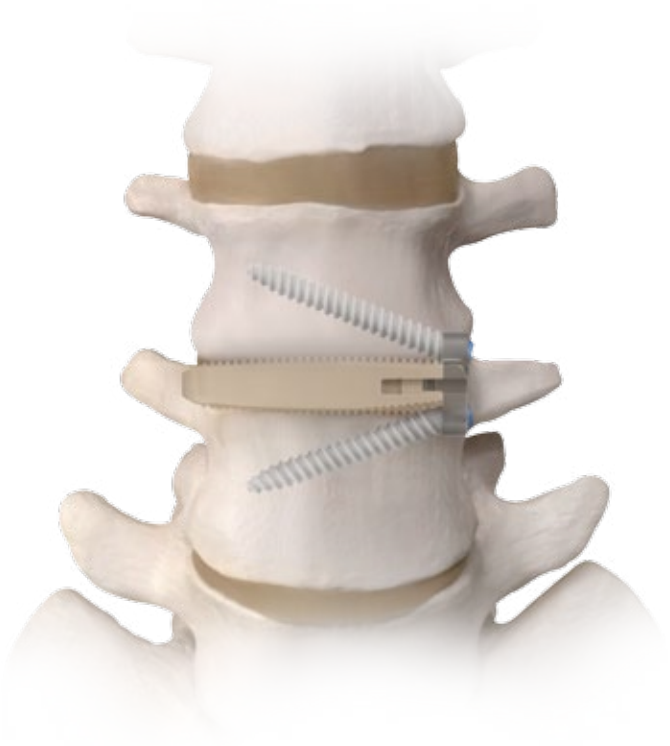
Ease

Integrated plate and spacer positioned at the disc space, eliminating additional retraction

Fusion

Hydroxyapatite (HA) coated lag screws compressively load spacer graft chamber to help promote fusion





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

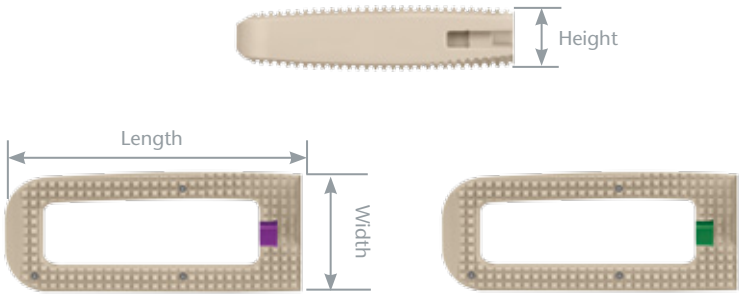
The TransContinental® M Spacer System and InterContinental® Plate are provided as two separate products that are intraoperatively assembled before positioned at the disc space. When assembled the spacer and plate are together referred to as the ***InterContinental® Plate-Spacer****.*

TransContinental® M Spacer System

- Indicated for interbody fusion
- 6 heights: 8, 9, 11, 13, and 15mm (17mm additionally available)
- Used alone or in conjunction with plate
- 2 sagittal profiles: 0° and 6° lordotic
- 6 lengths: 35–55mm in 5mm increments (60mm additionally available)
- Width: 20mm

Height: 8–17mm

0° or 6° Lordotic



6° Lordotic

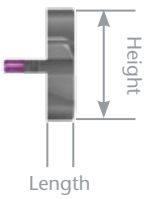
0°

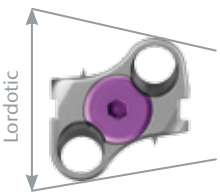
TransContinental® M Spacers	
Length	**Width**
35mm	20mm
40mm	20mm
45mm	20mm
50mm	20mm
55mm	20mm
60mm	20mm

InterContinental® Plate

- Indicated for use only in conjunction with TransContinental® M Spacer
- 6 heights: 8, 9, 11, 13, and 15mm (17mm additionally available)
- 2 sagittal profiles: 0° and 6° lordotic
- Length: 5mm
- Width: 20mm

0°





6° Lordotic

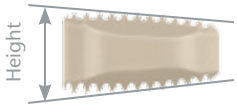
Items highlighted in gray are additionally available.

IMPLANT OVERVIEW

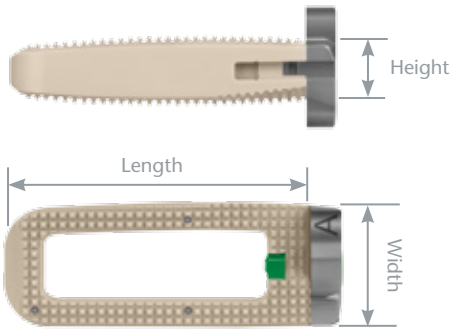
InterContinental® Plate-Spacer

- Intraoperatively assembled using the TransContinental® M Spacer and the InterContinental® Plate
- 6 heights: 8, 9, 11, 13, and 15 (17mm additionally available)
- 2 sagittal profiles: 0° and 6° lordotic
- 6 lengths: 40–60mm in 5mm increments (65mm additionally available)
- Width: 20mm

Height: 8–17mm



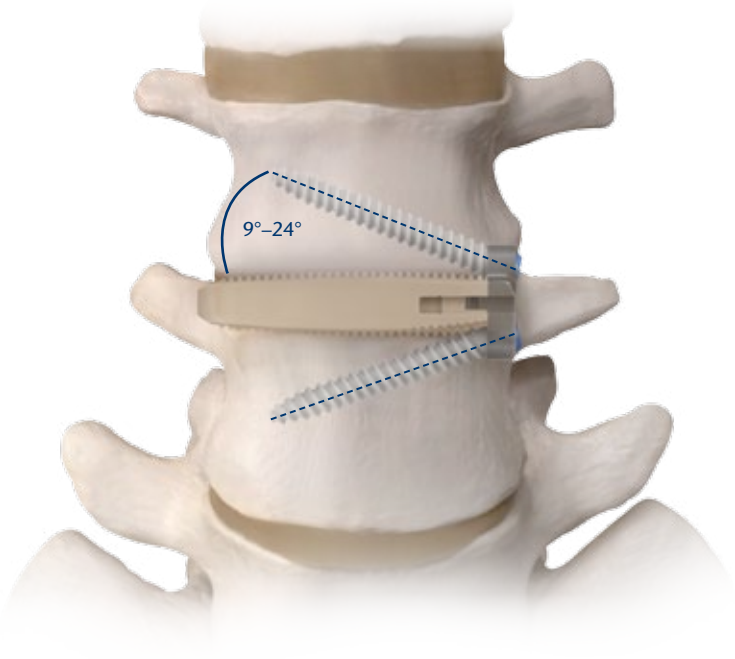
0° or 6° Lordotic



InterContinental® Plate-Spacer	
Length	**Width**
40mm	20mm
45mm	20mm
50mm	20mm
55mm	20mm
60mm	20mm
65mm	20mm

Screws

- Hydroxyapatite (HA) coated
- Variable angle (9°–24°)
- Fixed angle (18°)
- 5.5mm diameter
- Lengths from 30–55mm in 5mm increments (60mm additionally available)
- Self-tapping



Items highlighted in gray are additionally available.

INSTRUMENT OVERVIEW

Disc Prep Instruments

Bayonetted 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 Prep Instruments (cont'd)

Disc Box Cutter 675.507

Thin Rasp, 12x20mm 675.510

Cobb, 10mm, 7° Up-angle 675.515

Cobb, 20mm, 7° Up-angle 675.516

Ring Curette, 10mm Straight 675.518

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

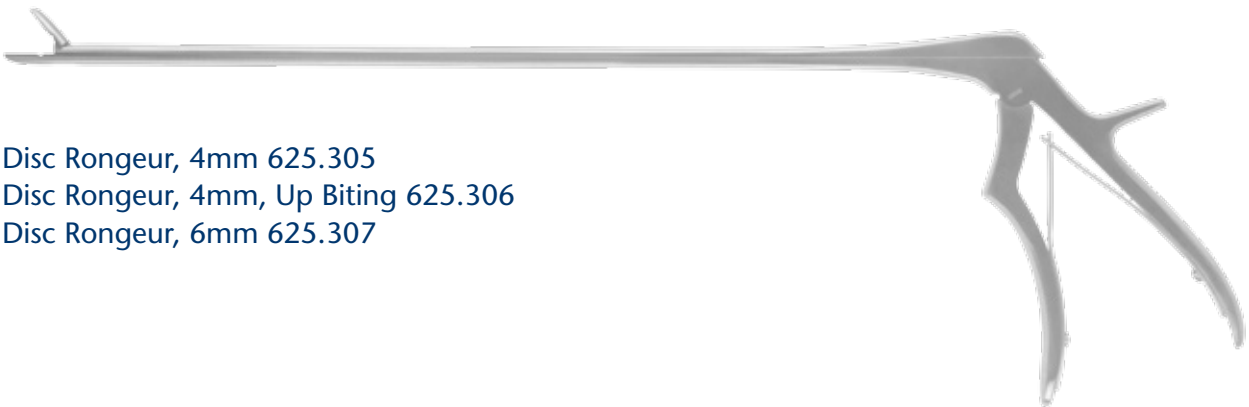
Disc Prep Instruments (cont'd)

Cup Curette, 6.5x9.5mm, Straight 675.525

Cup Curette, 6.5x9.5mm, 15°, Up-angle 675.526

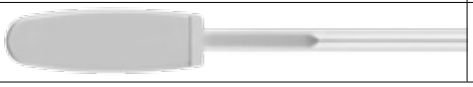
Cup Curette, 6.5x9.5mm, 90°, Down-angle 675.527

Kerrison, 4mm 625.202
Kerrison, 6mm 625.203

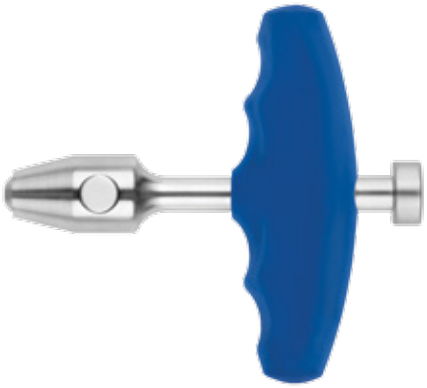


Disc Rongeur, 4mm 625.305
Disc Rongeur, 4mm, Up Biting 625.306
Disc Rongeur, 6mm 625.307

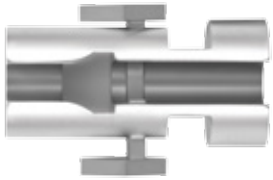
Scrapers

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

Additional Disc Prep Instruments



T-Handle with Impaction Cap 675.005



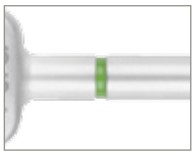
Slap Hammer Attachment 675.002

Quick Connect Guide 675.201

L-Handle with Impaction Cap 687.100

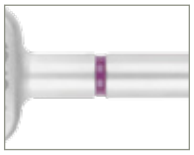
Insertion Instruments

Universal Holder 687.001



Trial, 0° Lordotic

Note: trials marked with a green ring on the shaft are 0° lordotic. Trials marked with a purple ring are 6° lordotic.



Trial, 6° Lordotic

Trials		
Height	**0° Lordotic**	**6° Lordotic**
8mm	687.008	687.058
9mm	687.009	687.059
11mm	687.011	687.061
13mm	687.013	687.063
15mm	687.015	687.065
17mm*	687.017	687.067

Straight Implant Holder 687.400

U-Joint 3.5mm Hex 687.529

Items highlighted in gray are additionally available.

Angled Holder Instruments

Quick Connect Swivel Handle 687.005

Ratchet Handle 687.105

3.5mm Angled Hex Driver 687.504

Angled Holder 687.505

Angled Holder Shaft 687.506

Angled Holder Nut 687.507

Spanner Wrench 687.509

Anti-Torque Holder 687.906

Angled Holder Instruments (cont'd)

Quick Connect Swivel Handle 687.005
3.5mm Angled Hex Driver 687.504
Anti-Torque Holder 687.906
(Assembled)

Quick Connect Swivel Handle 687.005
Short 3.5mm Hex Driver Tip 687.026
Angled Holder 687.505
Angled Holder Shaft 687.506
Angled Holder Nut 687.507
Anti-Torque Holder 687.906
(Assembled)

Tips

Short 3.5mm Hex Driver Tip 687.026

Short Counterbore Tip 687.514

Short 5.5mm Drill Tip 687.521

Short 5.5mm Tap Tip 687.721

Screw Hole Preparation Instruments

Angled Awl 687.511

Sleeveless Angled Awl 687.512

Straight Counterbore 687.516

Straight 5.5mm Drill 687.520

Straight Awl 687.524

Straight 5.5mm Tap 687.526

Straight Shaft 3.5mm Hex Driver 687.527

Additional Instruments

Long Throw Slide Hammer 675.004

3mm Removal Tool 687.300

Set Screw Driver, 2.5mm Hex 675.600

InterContinental®
SURGICAL TECHNIQUE

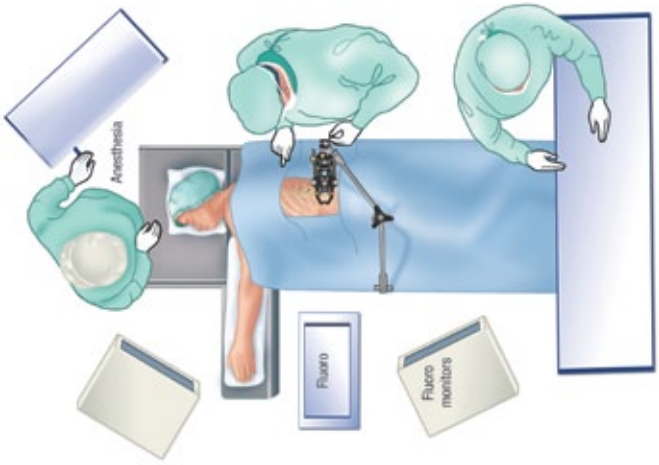
Step 1 Patient Preparation

Patient Positioning

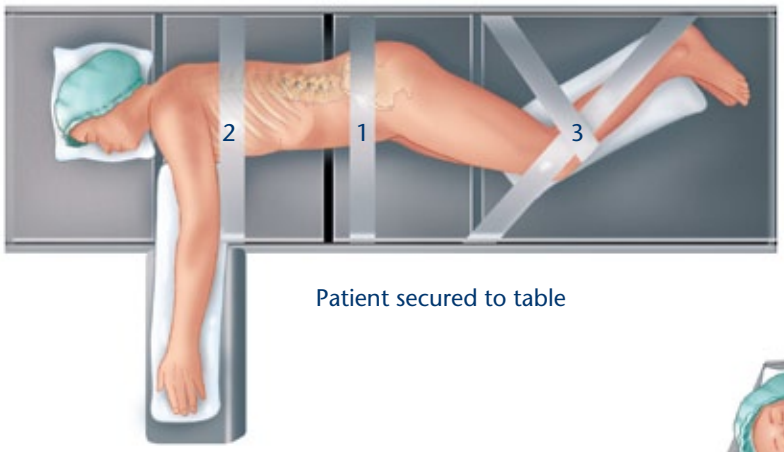
The patient is placed on a flexible surgical table in a straight 90° right lateral decubitus position so that the iliac crest is just over the table break, as shown below.

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

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



Patient positioning



Patient secured to table

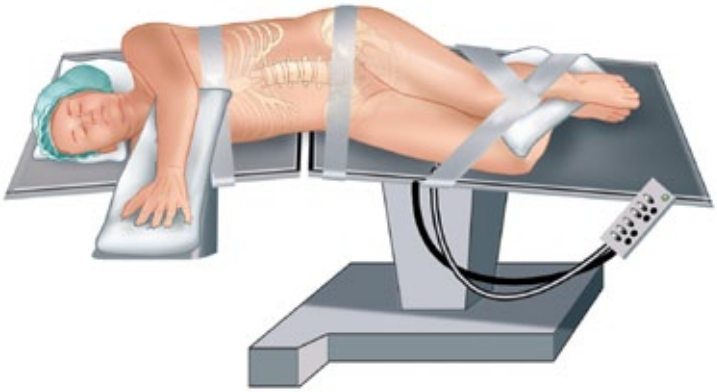
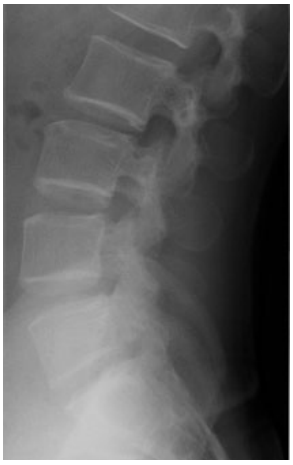


Table flexed

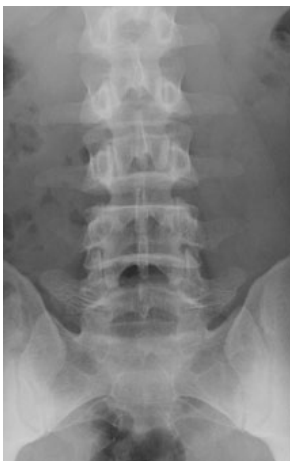
Patient Preparation (cont'd)

X-Ray Confirmation

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



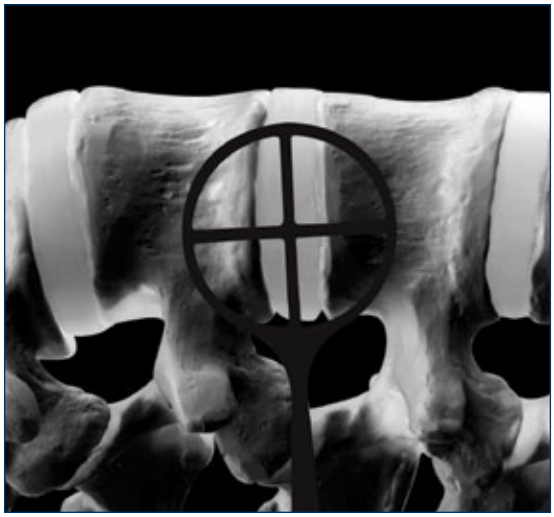
Lateral image



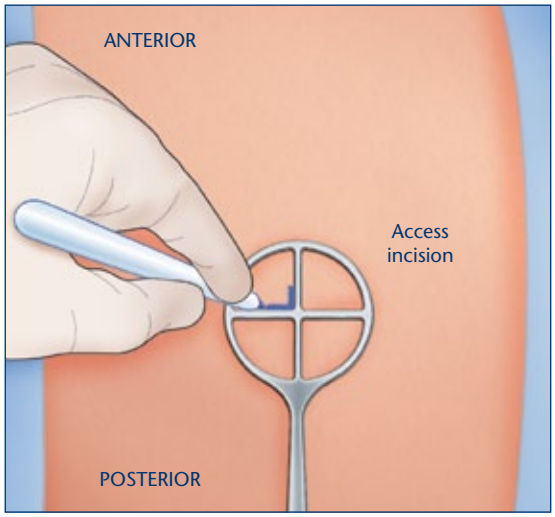
AP image

Incision Location

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



Using Incision Locator



Marking the incision locations

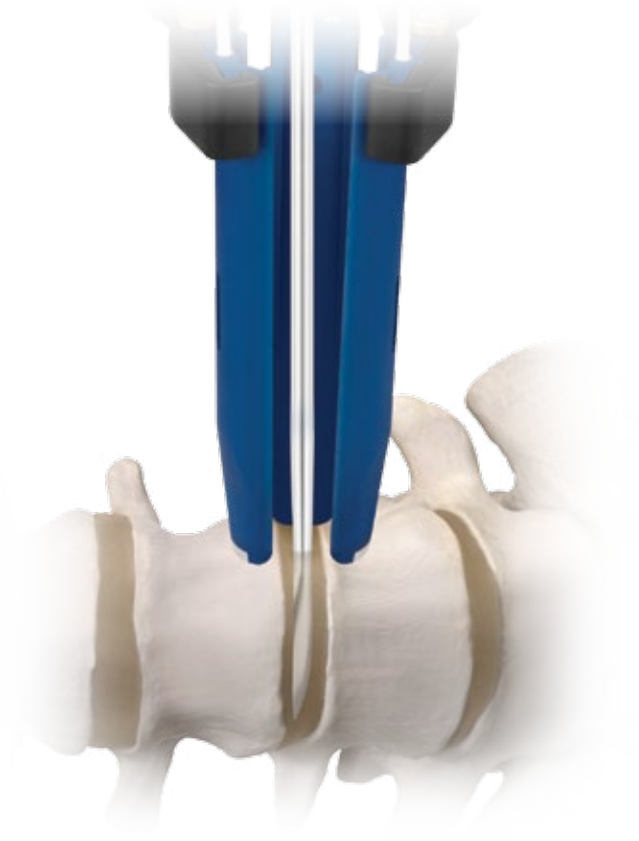
Step 2 Disc Preparation

Annulotomy

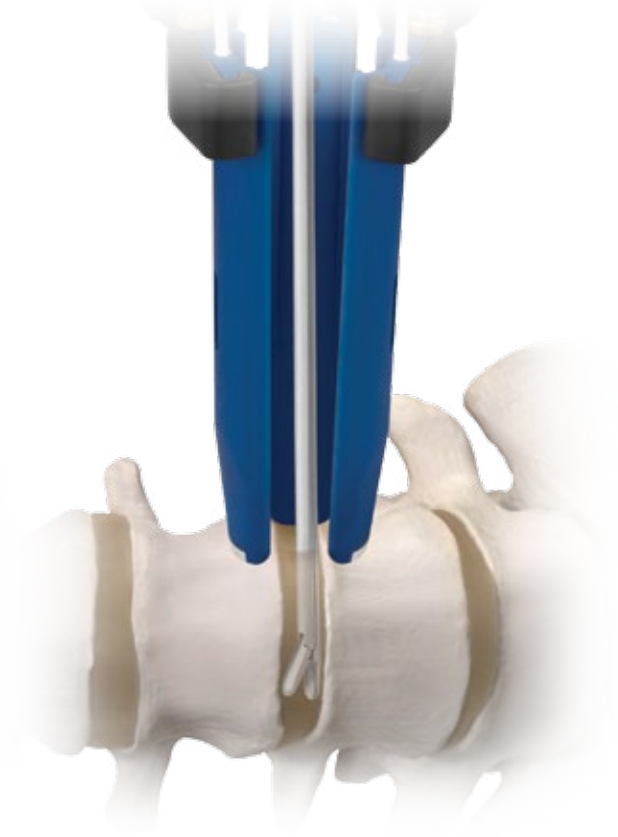
The **Bayonneted Annulotomy Knife** may be used to create a window centered in the anterior half of the annulus, large enough for graft insertion.

Contralateral Annulus Release

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



Using the Cobb Elevator



Using the Disc Rongeur

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 available for disc removal and endplate preparation, as shown at left.

Step 3 Implant Insertion

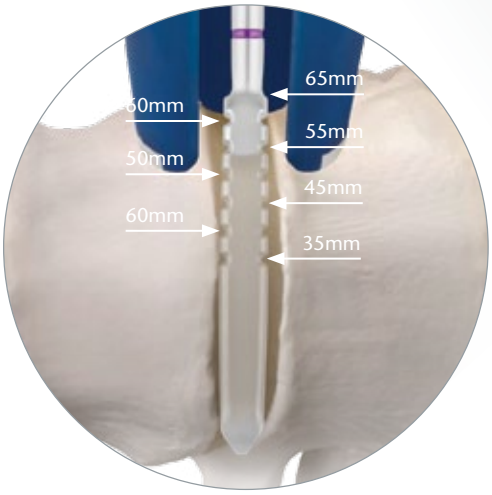
Implant Sizing

To determine the appropriate implant size for the desired segment, first insert the smallest **Trial, Parallel** or **Trial, 6° Lordotic** into the disc space, moving to larger trials as needed.

Note: Trials marked with a green ring on the shaft are 0° lordotic. Trials marked with a purple ring are 6° lordotic.

For correct orientation, insert the trial into the disc space with the side etched "Anterior" facing the patient's anterior side. Determine which trial best fits the prepared disc space. A secure fit is desirable to maintain disc height and stabilize the segment.

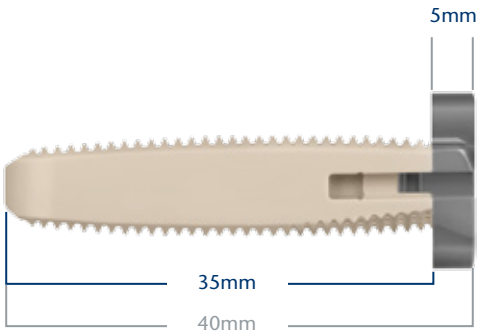
Ensure that the tapered end of the trial overhangs the contralateral edge to account for implant marker location. The trial length indicates the combined length of the spacer and plate.



Implant Sizing

If the trial reads 55mm in total length, a 50mm TransContinental® M implant is chosen. The plate will account for the remaining 5mm.

The InterContinental® Plate-Spacer System is intraoperatively assembled. Select the desired implant size that matches the trial.



35mm TransContinental® M Implant with InterContinental® Plate

Implant Assembly

Align the "A" etched on the plate with the anterior side of the implant and slide the plate into the spacer. Use the **Torque Limiting Driver** to thread the blocking set screw into the implant.

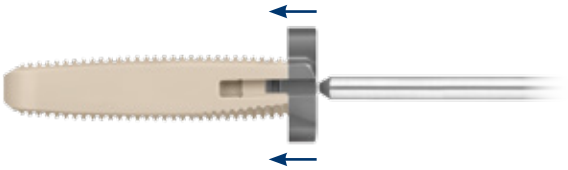
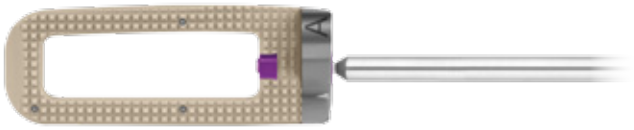


Plate placed onto the spacer



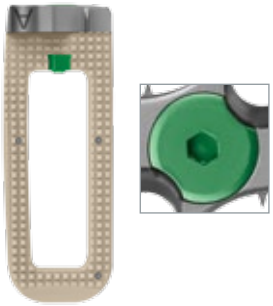
Blocking set screw threaded

Aligning Blocking Set Screw

Rotate the blocking set screw clockwise until the screw is finger tight. Then rotate the set screw counterclockwise approximately 30° until the notches on the set screw line up with the screw, as shown below. The implant is now ready to be loaded onto the holder.

Note: The 6° lordotic plates have a purple blocking set screw and are to be assembled with the 6° lordotic spacer with the purple titanium nut. The 0° lordotic plates having a green blocking set screw and are to be assembled with the 0° lordotic spacer with the green titanium nut.

6° lordotic plate
blocking set screw



0° lordotic plate
blocking set screw

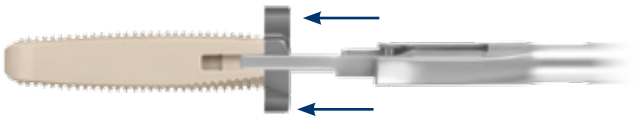
Positioning set screw
finger tight

Aligning the set screw
to allow for screws

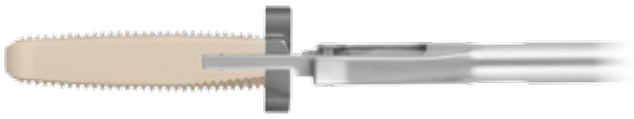
Implant Insertion (cont'd)

Attaching the Universal Implant Holder to the Implant

Place the **Universal Implant Holder** over the implant, ensuring that the tabs on the holder are seated within the side pockets on the spacer.



Positioning the holder on the implant

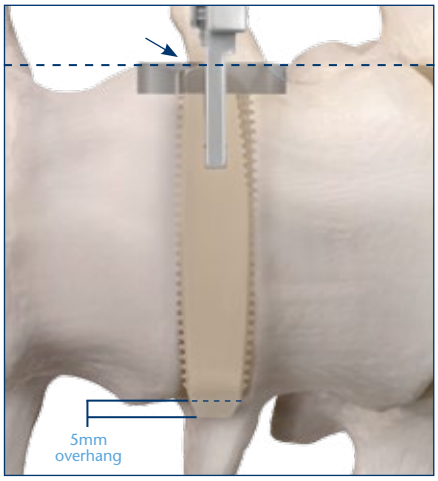


Holder properly positioned on the implant

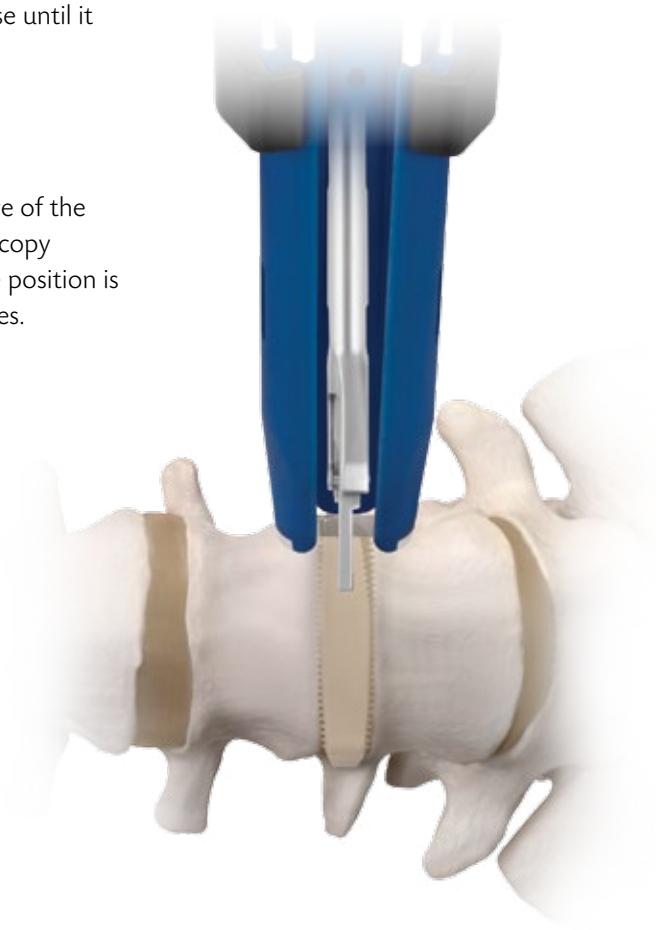
After placement of the holder, rotate the grooved knob clockwise until it stops to tighten the holder onto the implant.

Implant Positioning

Insert the implant into the intervertebral space until the top edge of the plate is flush with the lateral margin of the vertebrae. AP fluoroscopy should be used to facilitate proper implant placement. Once the position is confirmed, the implant is ready for preparation of the screw holes.



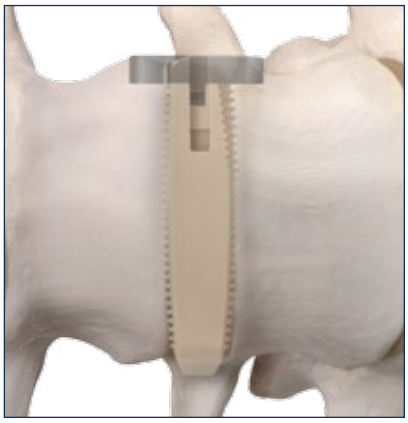
Implant Final Position

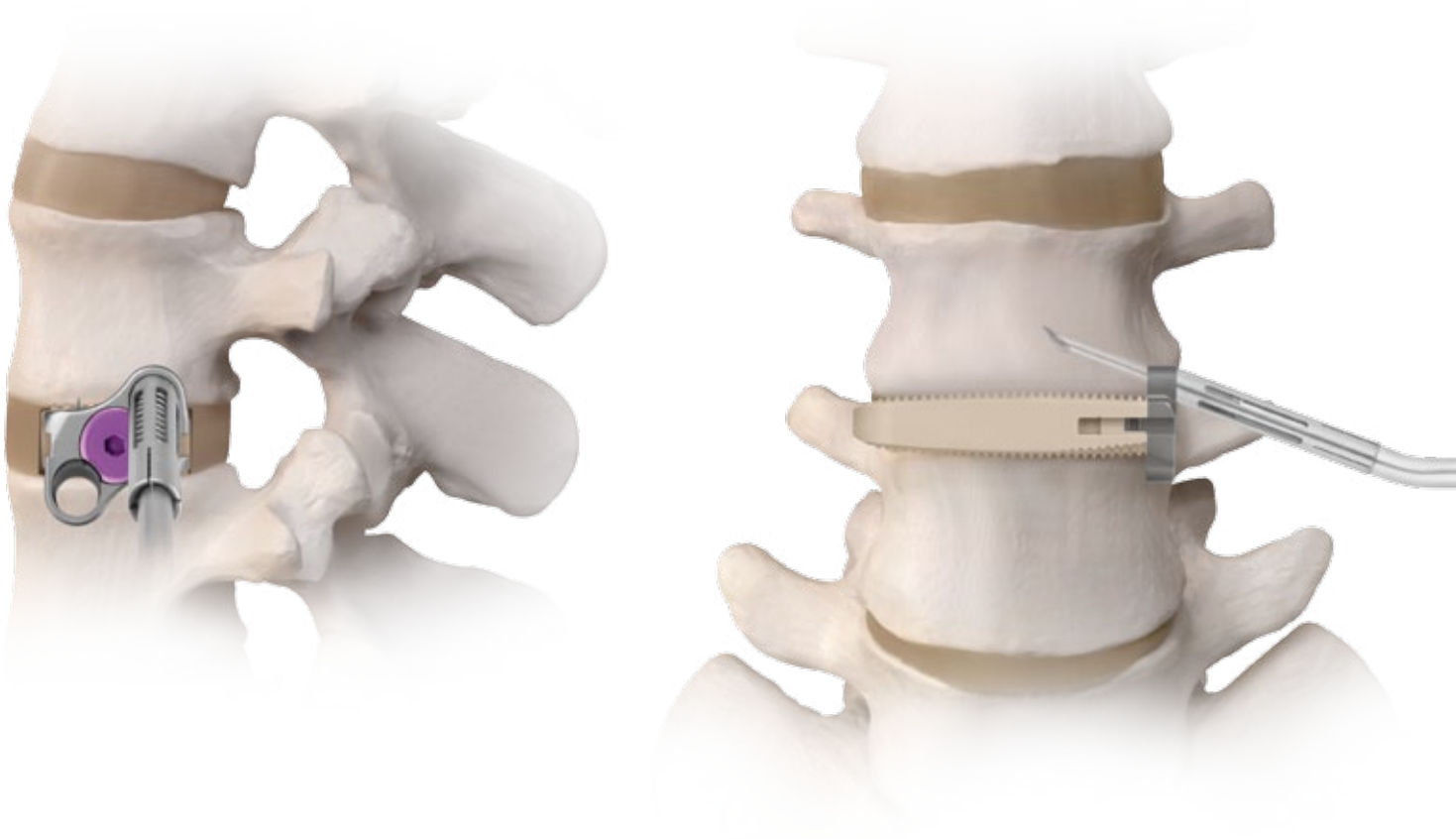


Implant insertion with the Implant Holder Assembly

Step 4 Screw Hole Preparation

Insert the **Angled Awl** through the screw hole to perforate the cortex. While inserting the Angled Awl ensure that the flat on the upper shaft faces the most proximal endplate. A drill and tap may also be used to further prepare the screw hole. When one of the screw holes is prepared, move to screw insertion (Step 5) before preparing the second screw hole.



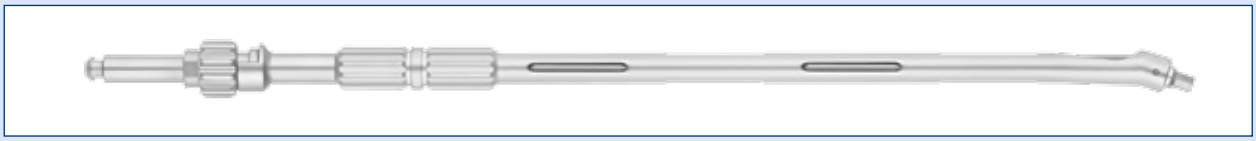


Angled Awl inserted through screw hole

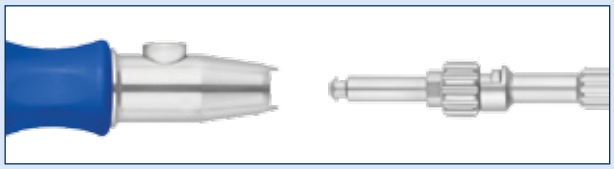
Step 5 Screw Insertion

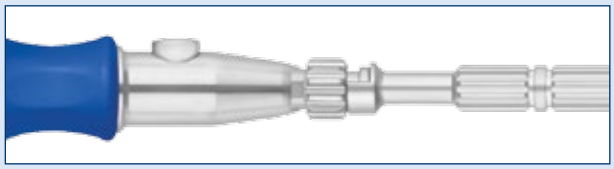
Angled Driver Assembly Using 3.5mm Angled Hex Driver

Step 1: Select the **3.5mm Angled Hex Driver**.

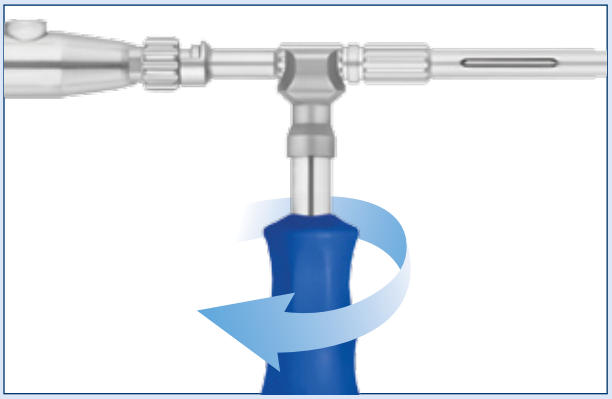


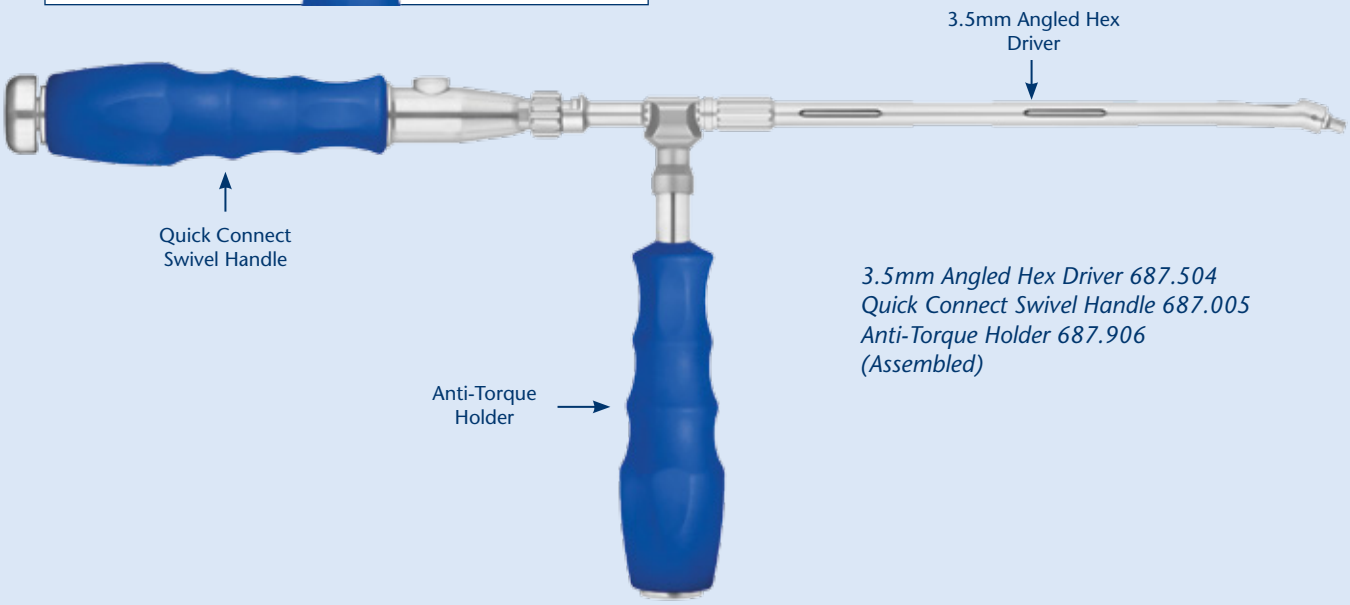
Step 2: Connect the **Quick Connect Swivel Handle** to the 3.5mm Angled Hex Driver.





Step 3: Slide the **Anti-Torque Holder** from the smooth portion of the angled hex driver to the knurled portion. Rotate the Anti-Torque Holder clockwise to tighten the Quick Connect Swivel Handle.



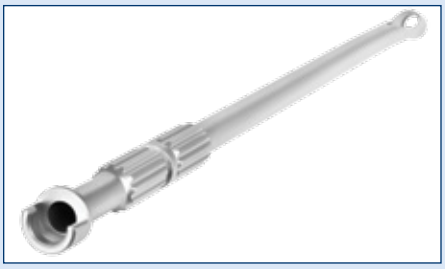


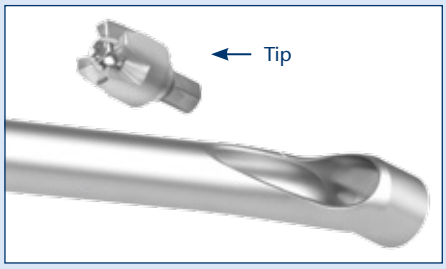
3.5mm Angled Hex Driver 687.504
Quick Connect Swivel Handle 687.005
Anti-Torque Holder 687.906
(Assembled)

Angled Driver Assembly Using Components

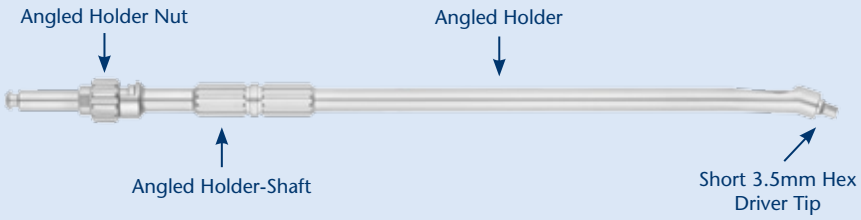
Step 1: Select the appropriate tip.

Step 2: Hold the **Angled Holder** pointed downwards with the cutout facing up as shown below. Insert the tip into the distal end of the holder.

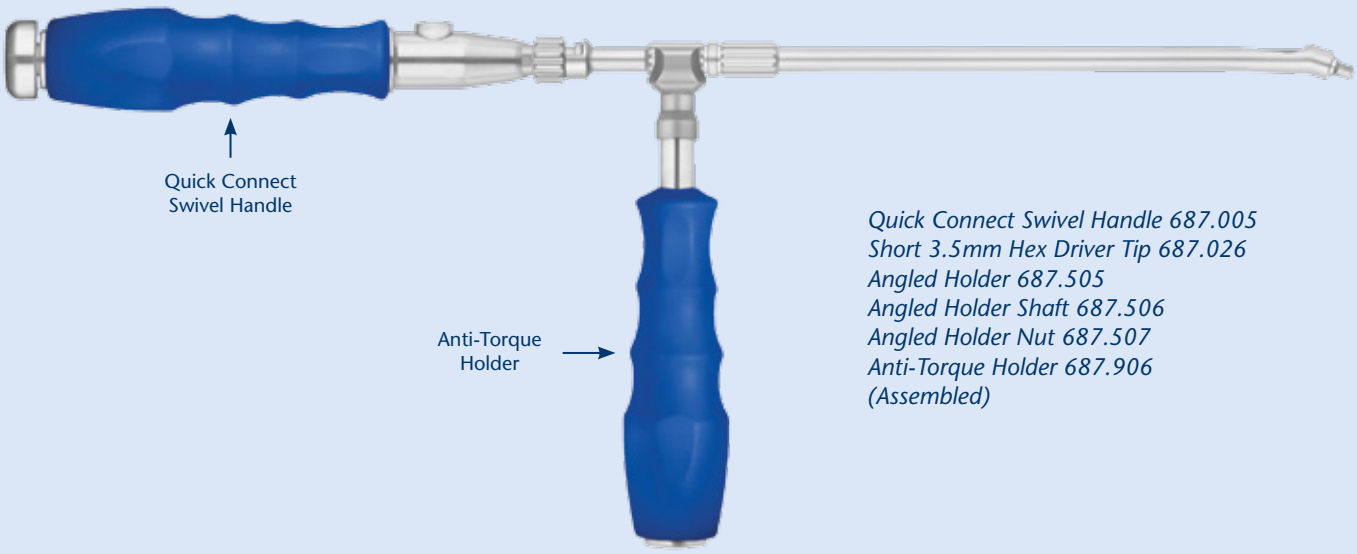




Step 3: Place the **Angled Holder Nut** into the notch at the proximal end of the Angled Holder. Insert the **Angled Holder-Shaft** through the nut and holder so that the gears of the shaft align with the gears on the tip. Attach the Quick Connect Swivel Handle to the shaft, rotate the nut counterclockwise until tight. Use the **Spanner Wrench** to tighten the nut.



Connect the swivel handle. Slide the Anti-Torque Holder from the smooth portion of the Angled Holder to the knurled portion. Rotate the Anti-Torque Holder clockwise to tighten the swivel handle.

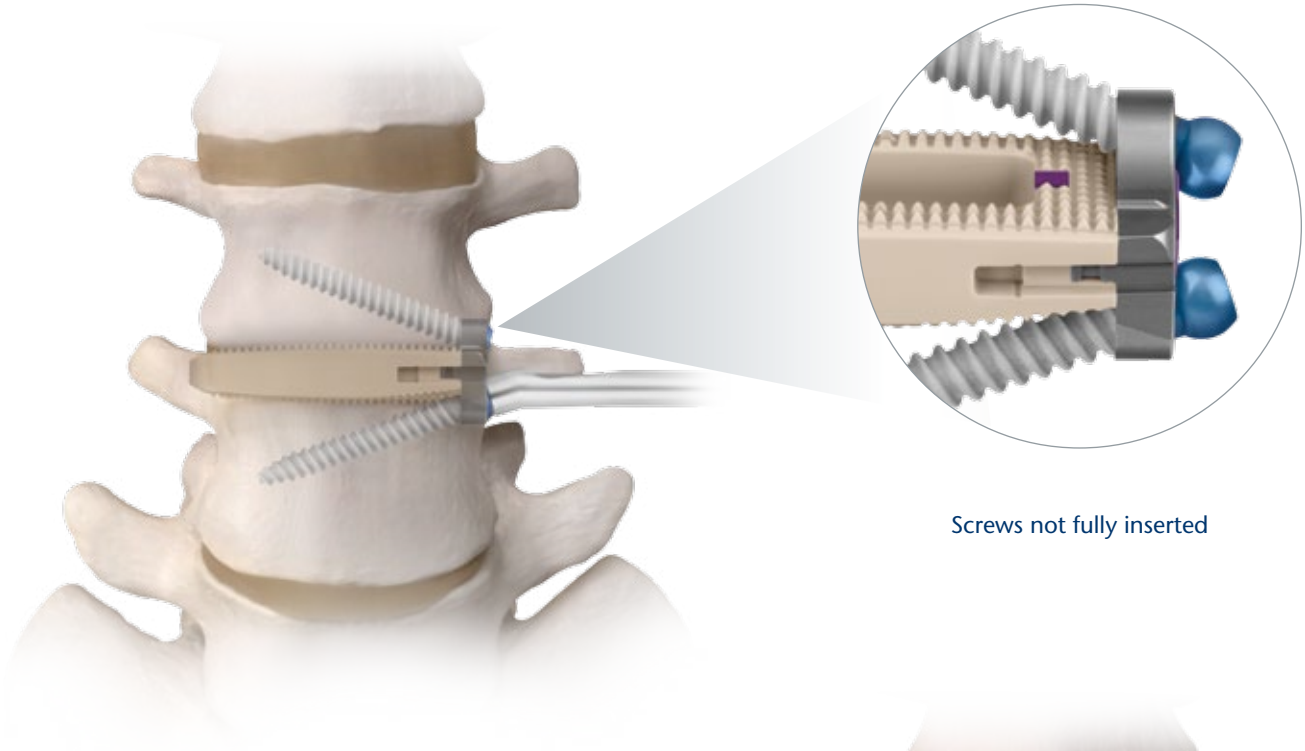


Quick Connect Swivel Handle 687.005
Short 3.5mm Hex Driver Tip 687.026
Angled Holder 687.505
Angled Holder Shaft 687.506
Angled Holder Nut 687.507
Anti-Torque Holder 687.906
(Assembled)

Screw Insertion (cont'd)

Insert the desired length screw with the Angled Driver Assembly. Insert the screw until the screw head contacts the plate. Ensure that the screws do not disrupt any adjacent structures outside the vertebrae.

Note: Do not final tighten at this time. Repeat screw hole preparation (Step 4) and screw insertion (Step 5) for the second screw hole.

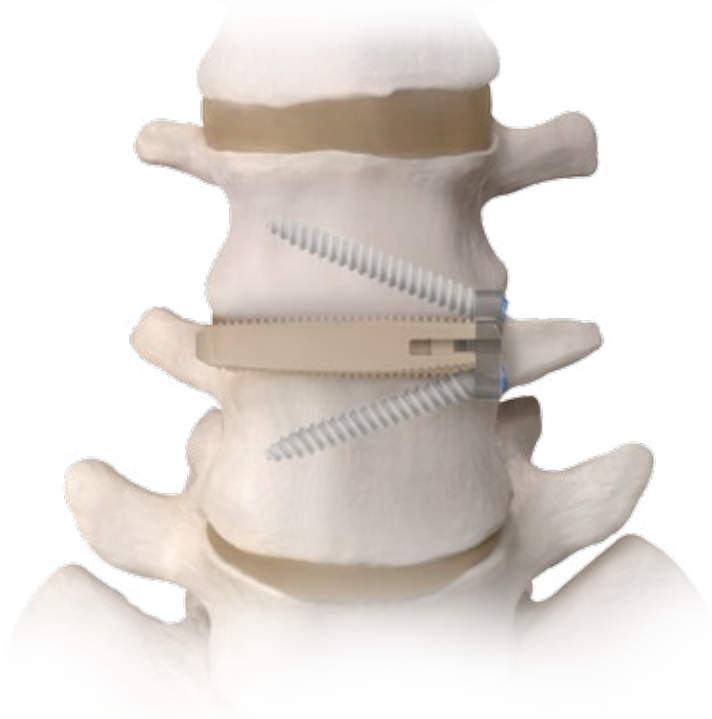


Screws not fully inserted

Screws inserted using
the Angled Driver Assembly

Final Screw Positioning

Once both screws are inserted and positioned, alternately final tighten each screw using the Angled Driver Assembly, until fully seated within the plate.

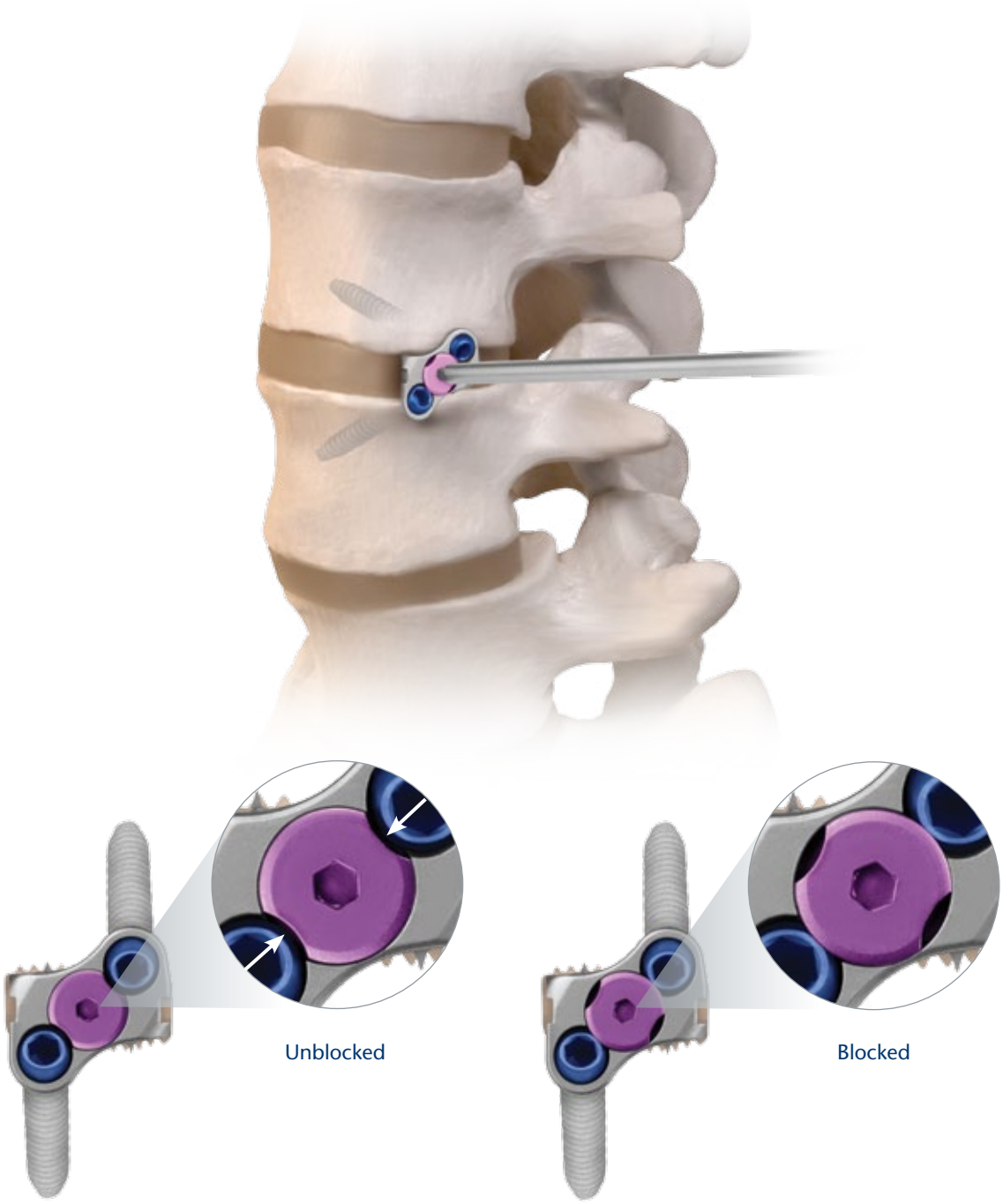


Final screw positioning

Step 6 Positioning the Set Screw

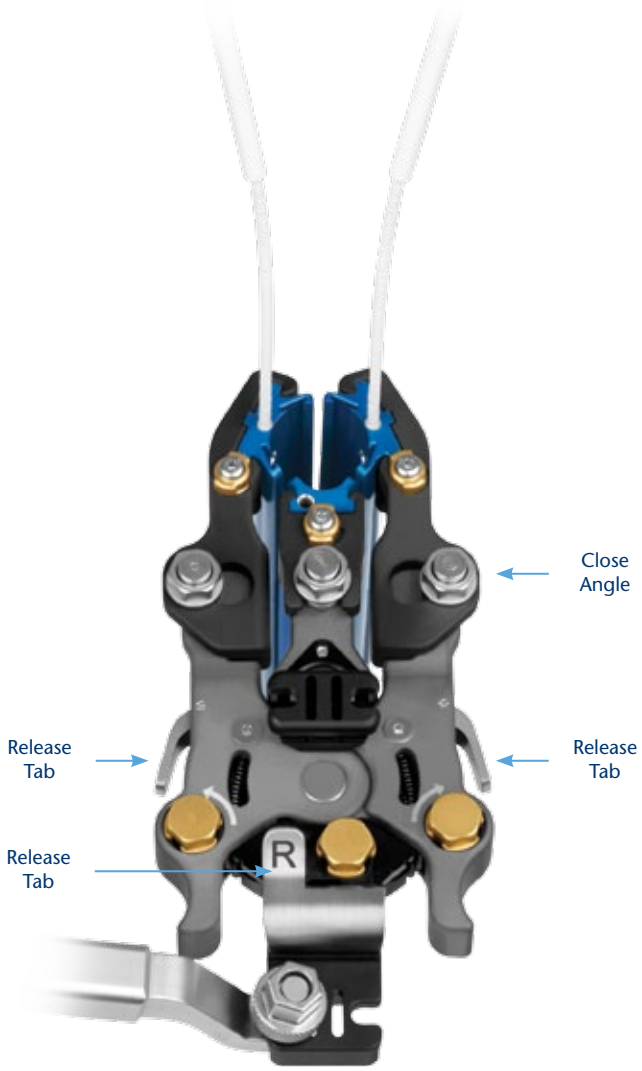
Use the **2.5mm Hex Set Screw Driver** to engage the blocking set screw and rotate it clockwise. An audible and tactile click occurs when the blocking set screw reaches its final position.

The InterContinental® Plate-Spacer is intended to be used with supplemental fixation. Posterior pedicle screw and rod fixation or anterior/lateral plating may be used for supplemental fixation.



Retractor Removal

Once the procedure is completed use the **10mm Socket Driver** to angle all retractor blades to the 0° starting position. Return all retractor blades to the original position by compressing the three release tabs on the back and sides of the retractor. Loosen the Articulating Arm Assembly and carefully remove the retractor.

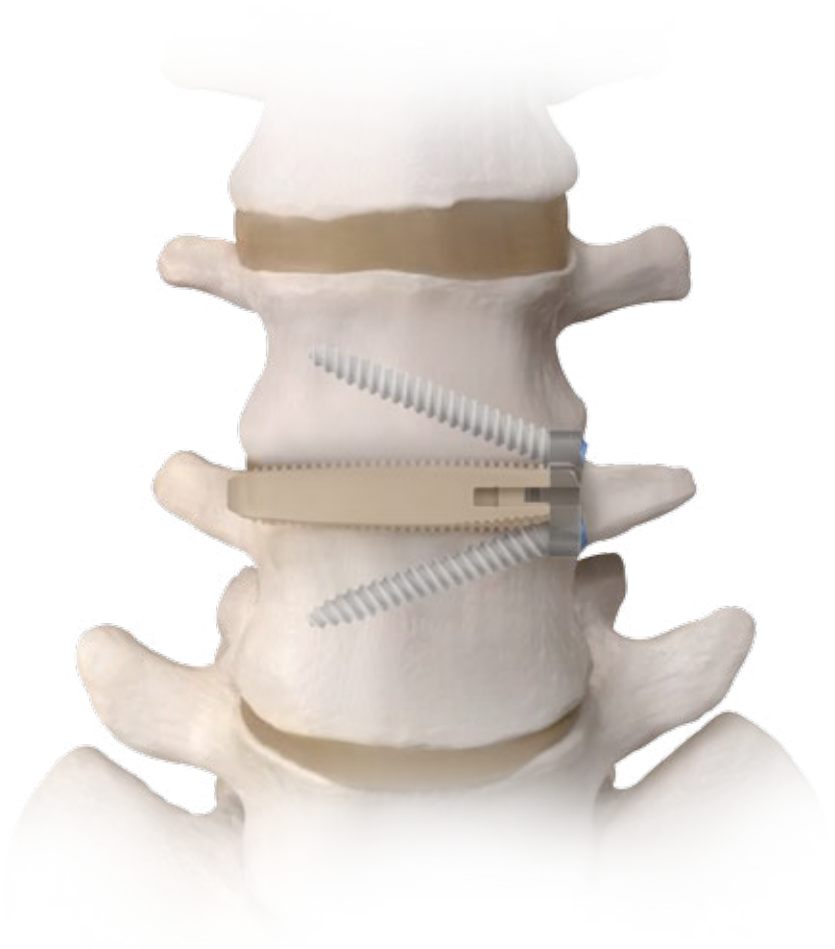


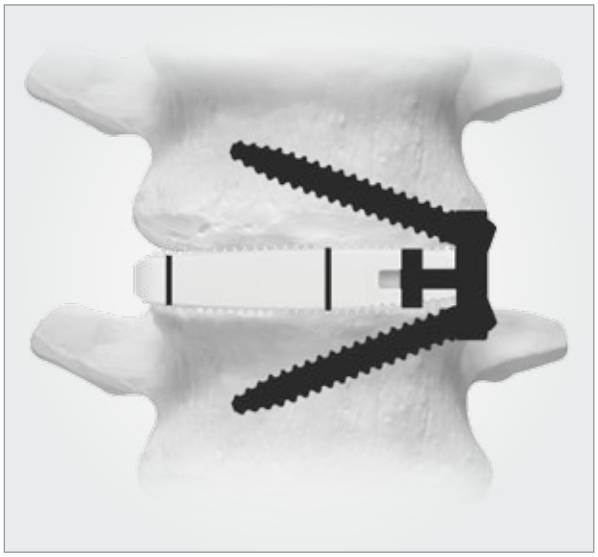
Optional: Implant Removal

For implant removal, unlock the blocking screw using the 2.5mm Hex Set Screw Driver and remove the bone screws using the Angled Driver Assembly. Implant removal may be performed using the Universal Implant Holder or other manual surgical instruments.

Note: Supplemental fixation may require removal prior to removal of the plate-spacer; refer to the specific system used for removal instructions.

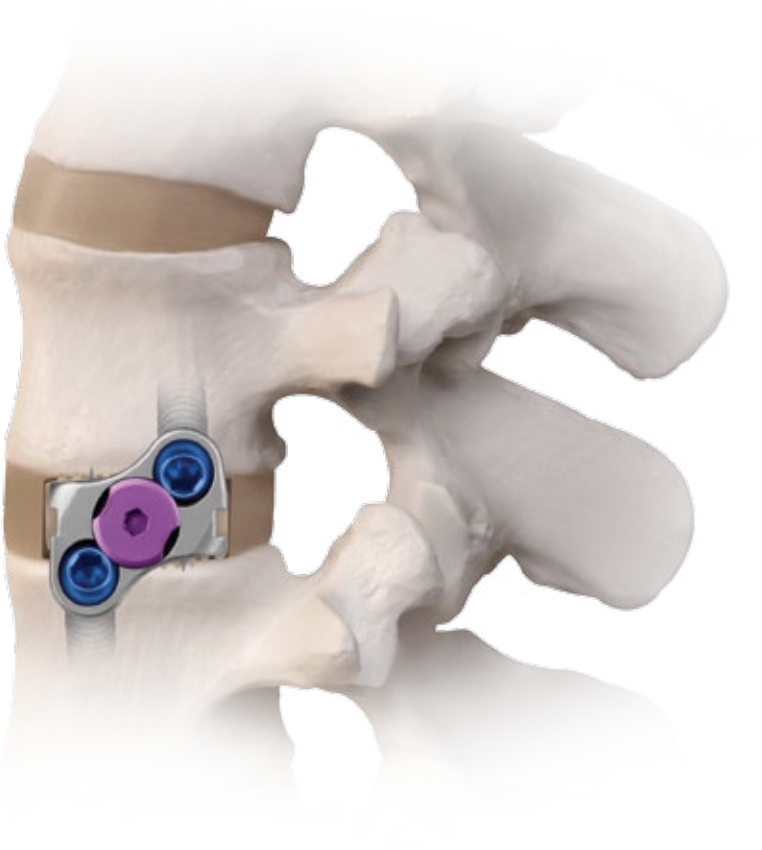
Final Position (AP View)

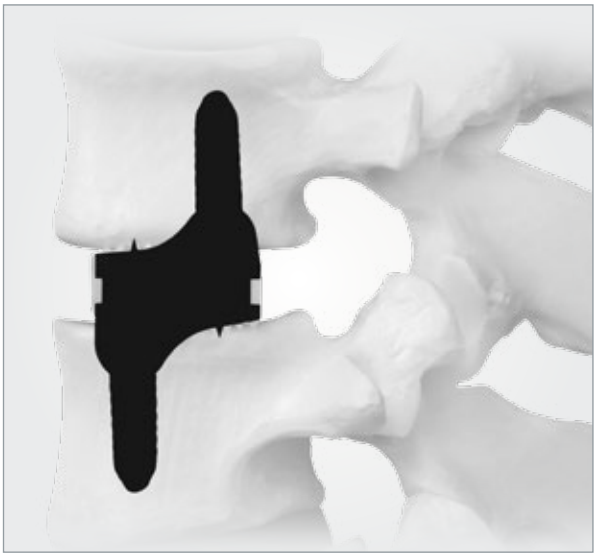




Radiographic AP view

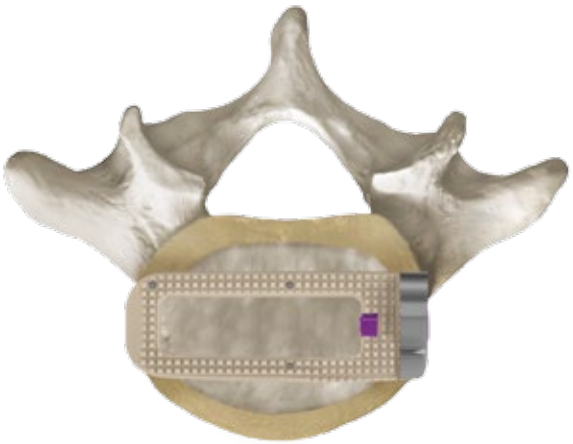
Final Position (Sagittal View)

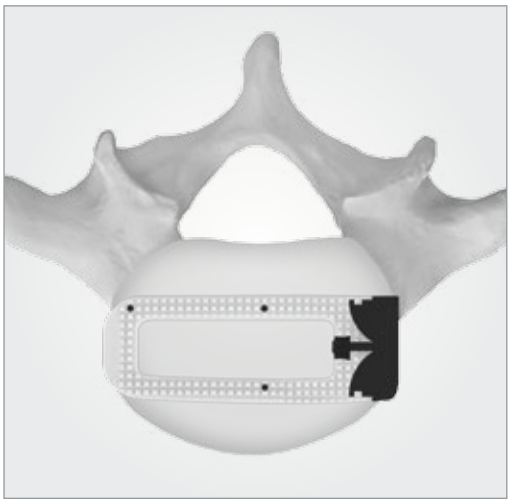




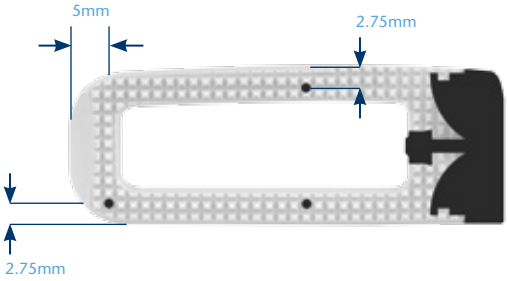
Radiographic sagittal view

Final Position (Axial View)



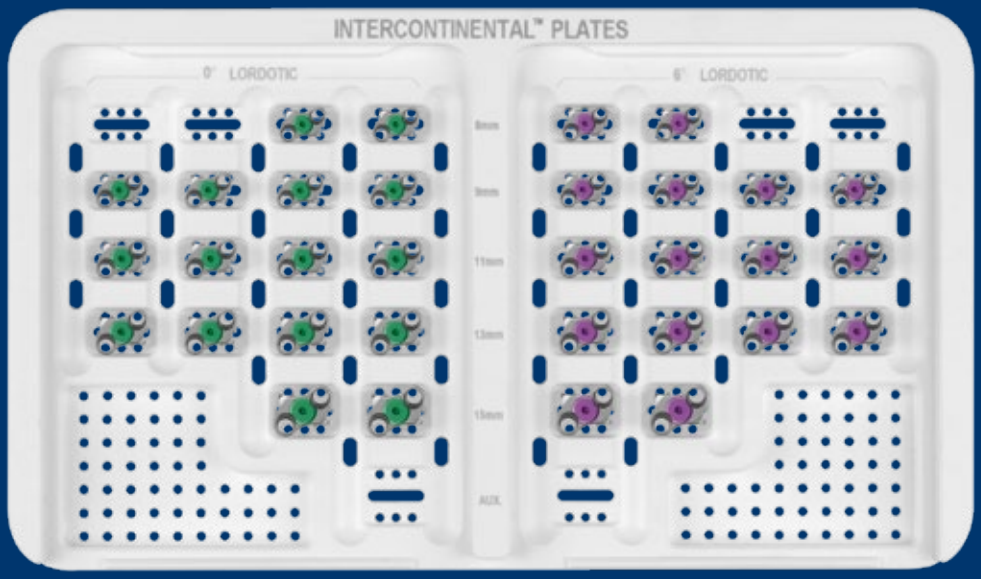


Radiographic axial view



Radiographic marker positions

InterContinental® IMPLANT SET



InterContinental® Implant Set 987.902

Parts No.	Description	Qty
187.008	InterContinental® Plate 0° 20x8mm	2
187.009	InterContinental® Plate 0° 20x9mm	4
187.011	InterContinental® Plate 0° 20x11mm	4
187.013	InterContinental® Plate 0° 20x13mm	4
187.015	InterContinental® Plate 0° 20x15mm	2
187.058	InterContinental® Plate 6° 20x8mm	2
187.059	InterContinental® Plate 6° 20x9mm	4
187.061	InterContinental® Plate 6° 20x11mm	4
187.063	InterContinental® Plate 6° 20x13mm	4
187.065	InterContinental® Plate 6° 20x15mm	2
987.002	InterContinental® Implant Graphic Case	

Additionally Available

187.017	InterContinental® Plate 0° 20x17mm
187.067	InterContinental® Plate 6° 20x17mm

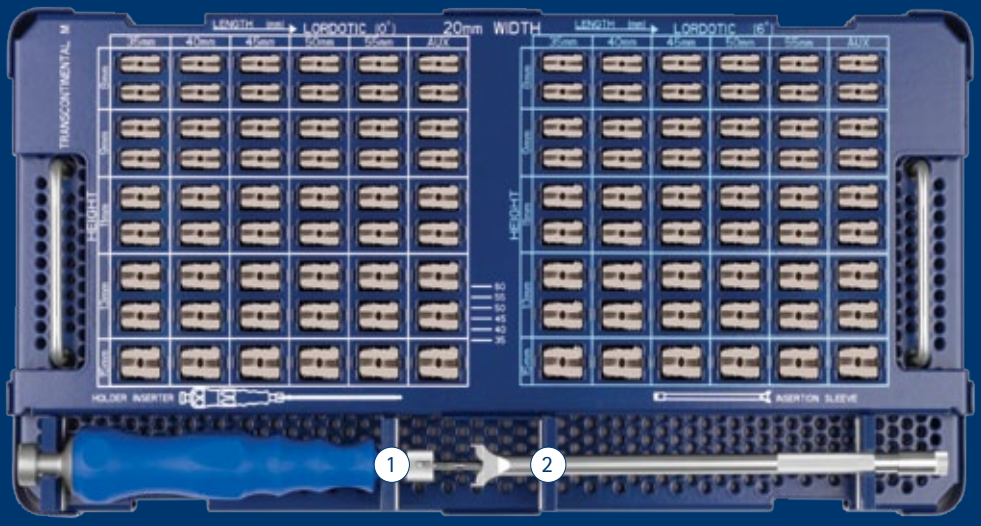
InterContinental® Implant Set 987.903

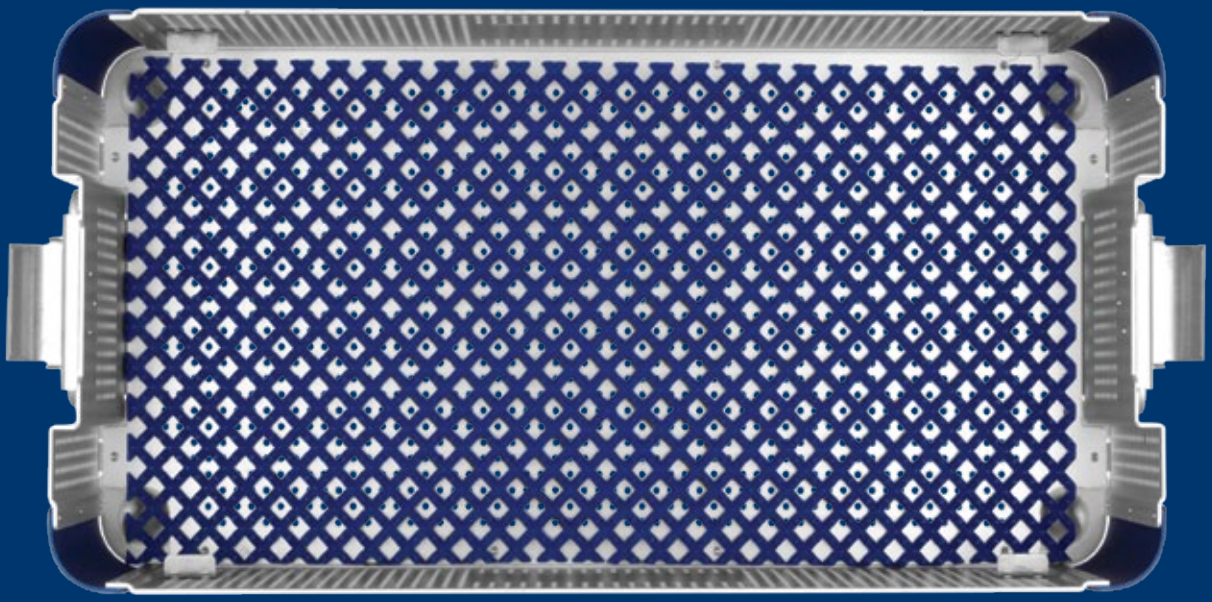
Parts No.	Description	Qty
187.230S	5.5mm HA-Coated Screw, Varaible Angle, 30mm	4
187.235S	5.5mm HA-Coated Screw, Variable Angle, 35mm	6
187.240S	5.5mm HA-Coated Screw, Variable Angle, 40mm	6
187.245S	5.5mm HA-Coated Screw, Variable Angle, 45mm	4
187.250S	5.5mm HA-Coated Screw, Variable Angle, 50mm	4
187.255S	5.5mm HA-Coated Screw, Variable Angle, 55mm	2
987.003	InterContinental® HA Coated Screw Soft Pack	

Additionally Available

187.130S	5.5mm HA-Coated Screw, Fixed Angle, 30mm
187.135S	5.5mm HA-Coated Screw, Fixed Angle, 35mm
187.140S	5.5mm HA-Coated Screw, Fixed Angle, 40mm
187.145S	5.5mm HA-Coated Screw, Fixed Angle, 45mm
187.150S	5.5mm HA-Coated Screw, Fixed Angle, 50mm
187.155S	5.5mm HA-Coated Screw, Fixed Angle, 55mm
187.160S	5.5mm HA-Coated Screw, Fixed Angle, 60mm
187.260S	5.5mm HA-Coated Screw, Variable Angle, 60mm

TransContinental® M IMPLANT SET





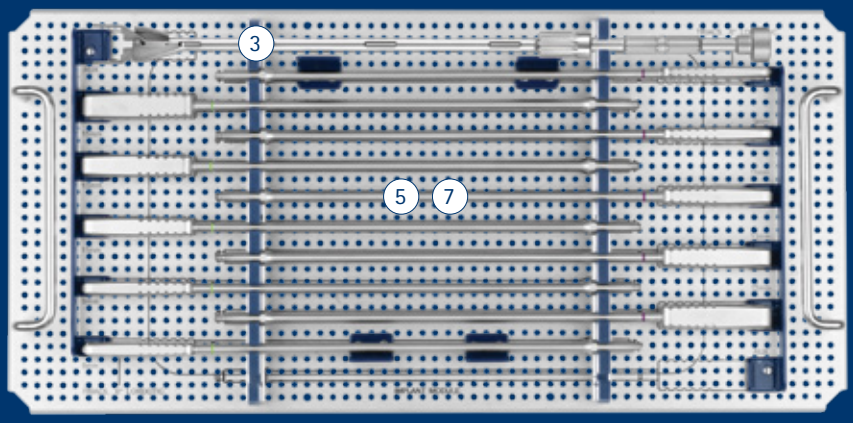
TransContinental® M Implant Set 975.951

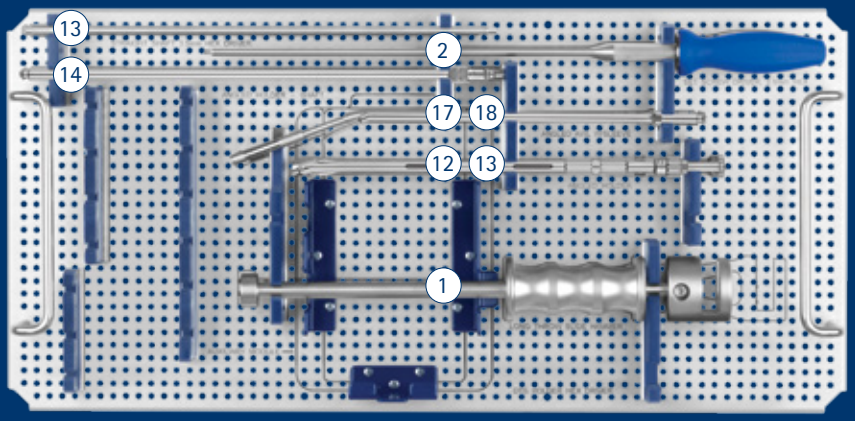
Part No.	Description	Qty
375.028	TransContinental® M Spacer, 20x35mm, 8mm	2
375.029	TransContinental® M Spacer, 20x35mm, 9mm	2
375.031	TransContinental® M Spacer, 20x35mm, 11mm	2
375.033	TransContinental® M Spacer, 20x35mm, 13mm	2
375.035	TransContinental® M Spacer, 20x35mm, 15mm	1
375.078	TransContinental® M Spacer, 6° 20x35mm, 8mm	2
375.079	TransContinental® M Spacer, 6° 20x35mm, 9mm	2
375.081	TransContinental® M Spacer, 6° 20x35mm, 11mm	2
375.083	TransContinental® M Spacer, 6° 20x35mm, 13mm	2
375.085	TransContinental® M Spacer, 6° 20x35mm, 15mm	1
375.128	TransContinental® M Spacer, 20x40mm, 8mm	2
375.129	TransContinental® M Spacer, 20x40mm, 9mm	2
375.131	TransContinental® M Spacer, 20x40mm, 11mm	2
375.133	TransContinental® M Spacer, 20x40mm, 13mm	2
375.135	TransContinental® M Spacer, 20x40mm, 15mm	1
375.178	TransContinental® M Spacer, 6° 20x40mm, 8mm	2
375.179	TransContinental® M Spacer, 6° 20x40mm, 9mm	2
375.181	TransContinental® M Spacer, 6° 20x40mm, 11mm	2
375.183	TransContinental® M Spacer, 6° 20x40mm, 13mm	2
375.185	TransContinental® M Spacer, 6° 20x40mm, 15mm	1
375.228	TransContinental® M Spacer, 20x45mm, 8mm	2
375.229	TransContinental® M Spacer, 20x45mm, 9mm	2
375.231	TransContinental® M Spacer, 20x45mm, 11mm	2
375.233	TransContinental® M Spacer, 20x45mm, 13mm	2
375.235	TransContinental® M Spacer, 20x45mm, 15mm	1
375.278	TransContinental® M Spacer, 6° 20x45mm, 8mm	2
375.279	TransContinental® M Spacer, 6° 20x45mm, 9mm	2
375.281	TransContinental® M Spacer, 6° 20x45mm, 11mm	2
375.283	TransContinental® M Spacer, 6° 20x45mm, 13mm	2
375.285	TransContinental® M Spacer, 6° 20x45mm, 15mm	1
375.328	TransContinental® M Spacer, 20x50mm, 8mm	2
375.329	TransContinental® M Spacer, 20x50mm, 9mm	2
375.331	TransContinental® M Spacer, 20x50mm, 11mm	2
375.333	TransContinental® M Spacer, 20x50mm, 13mm	2
375.335	TransContinental® M Spacer, 20x50mm, 15mm	1
375.378	TransContinental® M Spacer, 6° 20x50mm, 8mm	2
375.379	TransContinental® M Spacer, 6° 20x50mm, 9mm	2
375.381	TransContinental® M Spacer, 6° 20x50mm, 11mm	2
375.383	TransContinental® M Spacer, 6° 20x50mm, 13mm	2
375.385	TransContinental® M Spacer, 6° 20x50mm, 15mm	1
375.428	TransContinental® M Spacer, 20x55mm, 8mm	2
375.429	TransContinental® M Spacer, 20x55mm, 9mm	2
375.431	TransContinental® M Spacer, 20x55mm, 11mm	2
375.433	TransContinental® M Spacer, 20x55mm, 13mm	2
375.435	TransContinental® M Spacer, 20x55mm, 15mm	1
375.478	TransContinental® M Spacer, 6° 20x55mm, 8mm	2
375.479	TransContinental® M Spacer, 6° 20x55mm, 9mm	2
375.481	TransContinental® M Spacer, 6° 20x55mm, 11mm	2
375.483	TransContinental® M Spacer, 6° 20x55mm, 13mm	2
375.485	TransContinental® M Spacer, 6° 20x55mm, 15mm	1
(1) 675.940	Holder Inserter	1
(2) 675.950	Insertion Sleeve	1
975.051	TransContinental® M Graphic Case	

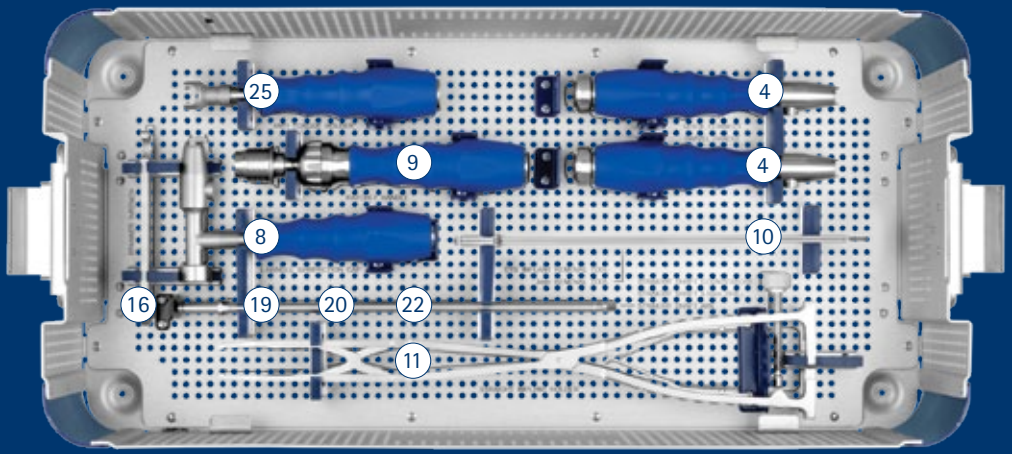
Additionally Available

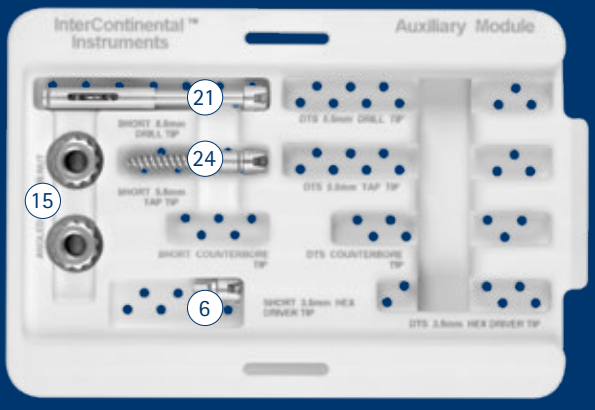
375.037	TransContinental® M Spacer, 20x35mm, 17mm
375.087	TransContinental® M Spacer, 6° 20x35mm, 17mm
375.137	TransContinental® M Spacer, 20x40mm, 17mm
375.187	TransContinental® M Spacer, 6° 20x40mm, 17mm
375.237	TransContinental® M Spacer, 20x45mm, 17mm
375.287	TransContinental® M Spacer, 6° 20x45mm, 17mm
375.337	TransContinental® M Spacer, 20x50mm, 17mm
375.387	TransContinental® M Spacer, 6° 20x50mm, 17mm
375.437	TransContinental® M Spacer, 20x55mm, 17mm
375.487	TransContinental® M Spacer, 6° 20x55mm, 17mm
375.528	TransContinental® M Spacer, 20x60mm, 8mm
375.529	TransContinental® M Spacer, 20x60mm, 9mm
375.531	TransContinental® M Spacer, 20x60mm, 11mm
375.533	TransContinental® M Spacer, 20x60mm, 13mm
375.535	TransContinental® M Spacer, 20x60mm, 15mm
375.537	TransContinental® M Spacer, 20x60mm, 17mm
375.578	TransContinental® M Spacer, 6° 20x60mm, 8mm
375.579	TransContinental® M Spacer, 6° 20x60mm, 9mm
375.581	TransContinental® M Spacer, 6° 20x60mm, 11mm
375.583	TransContinental® M Spacer, 6° 20x60mm, 13mm
375.585	TransContinental® M Spacer, 6° 20x60mm, 15mm
375.587	TransContinental® M Spacer, 6° 20x60mm, 17mm

InterContinental® INSTRUMENT SET









InterContinental® Instrument Set 987.901

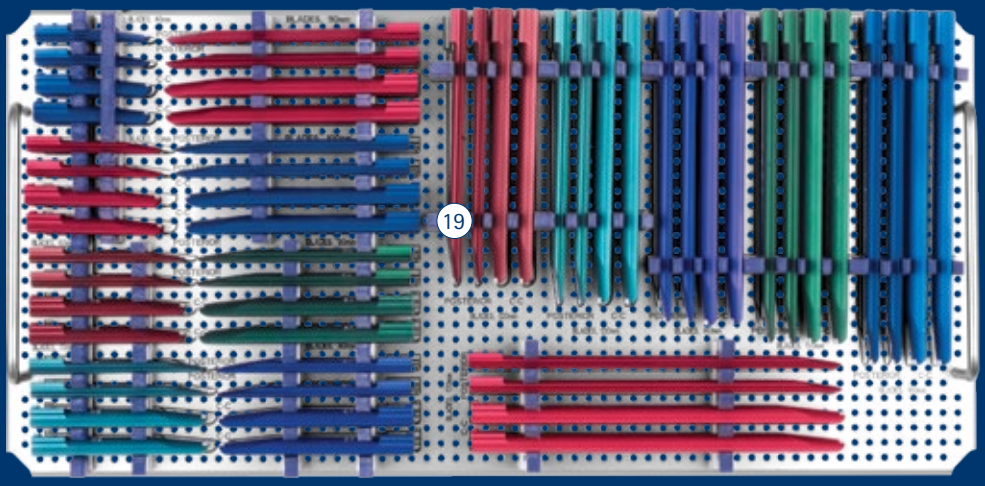
	Instruments		Qty
1	675.004	Long Throw Slide Hammer	1
2	676.600	Set Screw Driver, 2.5mm Hex	1
3	687.001	Universal Implant Holder	1
4	687.005	Quick Connect Swivel Handle	2
5	687.008	Trial, 0° Lordotic, 8mm	1
	687.009	Trial, 0° Lordotic, 9mm	1
	687.011	Trial, 0° Lordotic, 11mm	1
	687.013	Trial, 0° Lordotic, 13mm	1
	687.015	Trial, 0° Lordotic, 15mm	1
6	687.026	Short 3.5mm Hex Driver Tip	2
7	687.058	Trial, 6° Lordotic, 8mm	1
	687.059	Trial, 6° Lordotic, 9mm	1
	687.061	Trial, 6° Lordotic, 11mm	1
	687.063	Trial, 6° Lordotic, 13mm	1
	687.065	Trial, 6° Lordotic, 15mm	1
8	687.100	L-Handle with Impaction Cap	1
9	687.105	Ratchet Handle	1
10	687.300	3mm Removal Tool	1
11	687.400	Straight Implant Holder	1
12	687.504	3.5mm Angled Hex Driver	1
13	687.505	Angled Holder	1
14	687.506	Angled Holder Shaft	1
15	687.507	Angled Holder Nut	1
16	687.509	Spanner Wrench	1
17	687.511	Angled Awl	1
18	687.512	Sleeveless Angled Awl	1
19	687.516	Straight Shaft Counterbore	1
20	687.520	Straight Shaft 5.5mm Drill	1

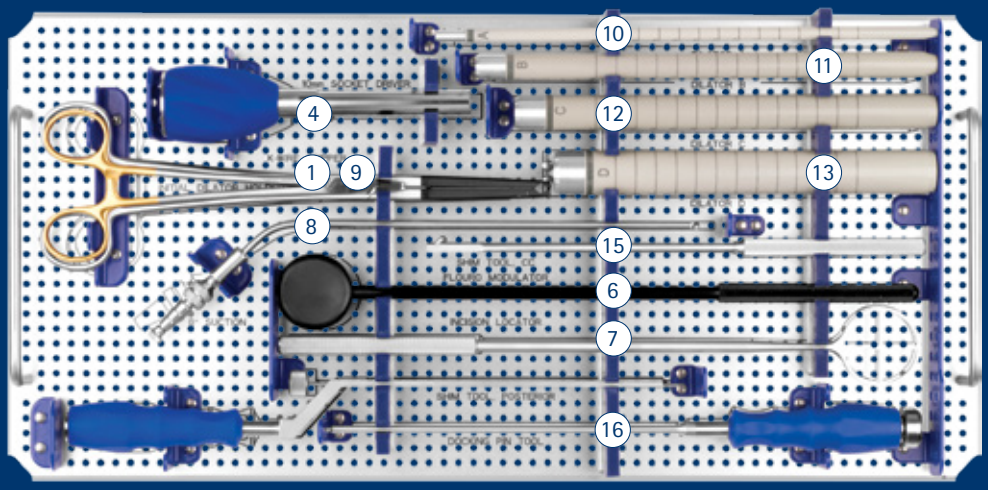
	Instruments		Qty
21	687.521	Short 5.5mm Drill Tip	1
22	687.524	Straight Shaft Awl	1
23	687.527	Straight Shaft 3.5mm Hex Driver	1
24	687.721	Short 5.5mm Tap Tip	1
25	687.906	Anti-Torque Holder	1
	987.001	Instrument Graphic Case	

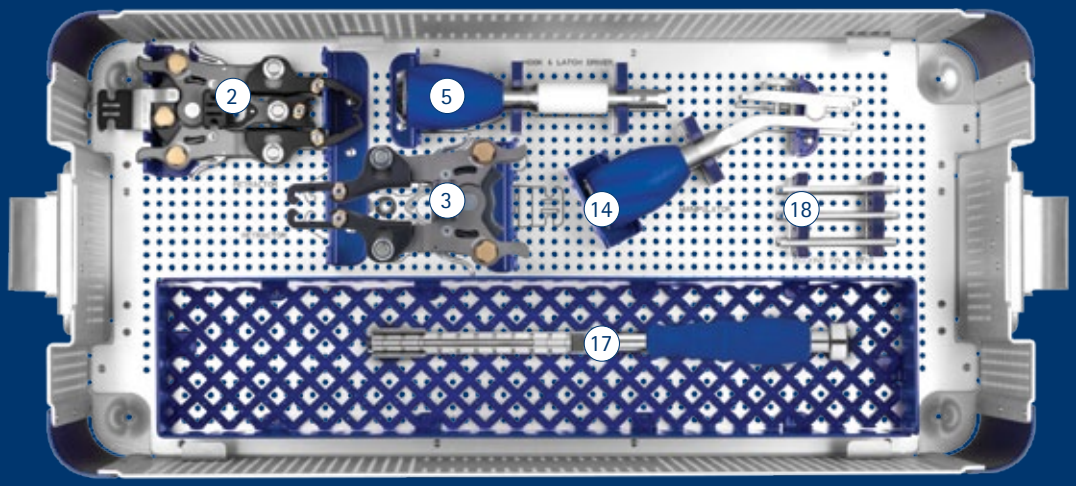
Additionally Available

687.017	Trial, 0° Lordotic, 17mm	
687.067	Trial, 6° Lordotic, 17mm	
687.514	Short Counterbore Tip	
687.526	Straight Shaft 5.5mm Tap	

MARS™ 3V RETRACTOR SET







MARS™3V Retractor Set 998.901

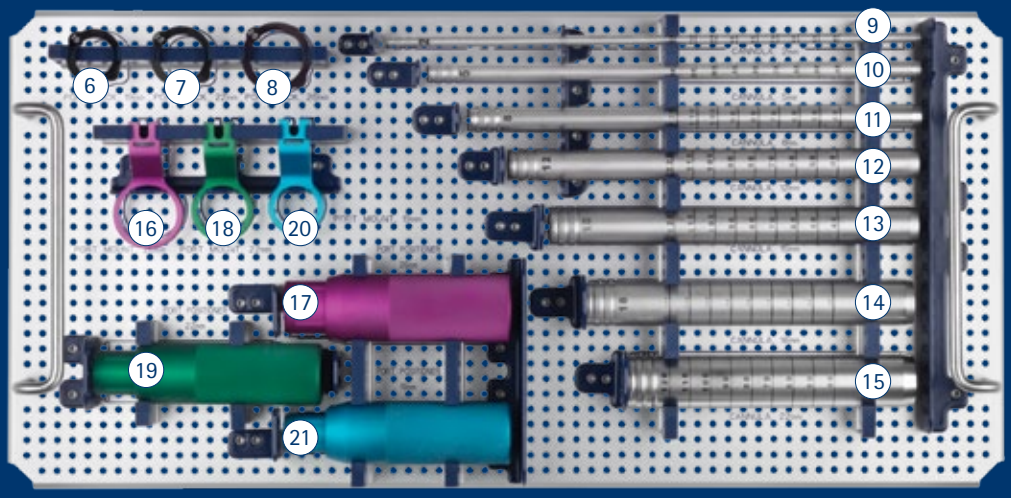
	Instruments		Qty
1	623.003	K-Wire Gripper	1
2	698.100	Retractor 3 Blade Frame	1
3	632.102	Retractor 2 Blade Frame	1
4	632.150	10mm Socket Driver	1
5	698.250	Hook and Latch Driver	1
6	675.403	Flouro Modulator	1
7	675.404	Incision Locator	1
8	675.513	8" Suction	1
9	675.800	Radiolucent Initial Dilator Holder	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

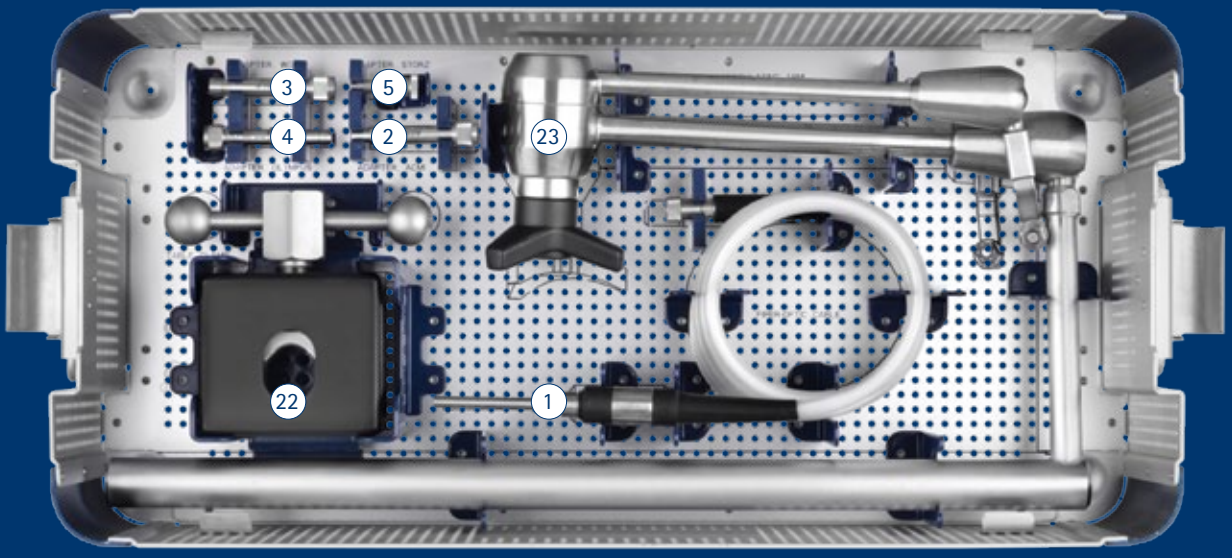
Retractor Blades		Qty
698.476	Blade, Posterior, 170mm	2
698.510	Blade, CC, 40mm	2
698.512	Blade, CC, 50mm	2
698.514	Blade, CC, 60mm	2
698.516	Blade, CC, 70mm	2
698.518	Blade, CC, 80mm	2
698.520	Blade, CC, 90mm	2
698.522	Blade, CC, 100mm	2
698.524	Blade, CC, 110mm	2
698.526	Blade, CC, 120mm	2
698.528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



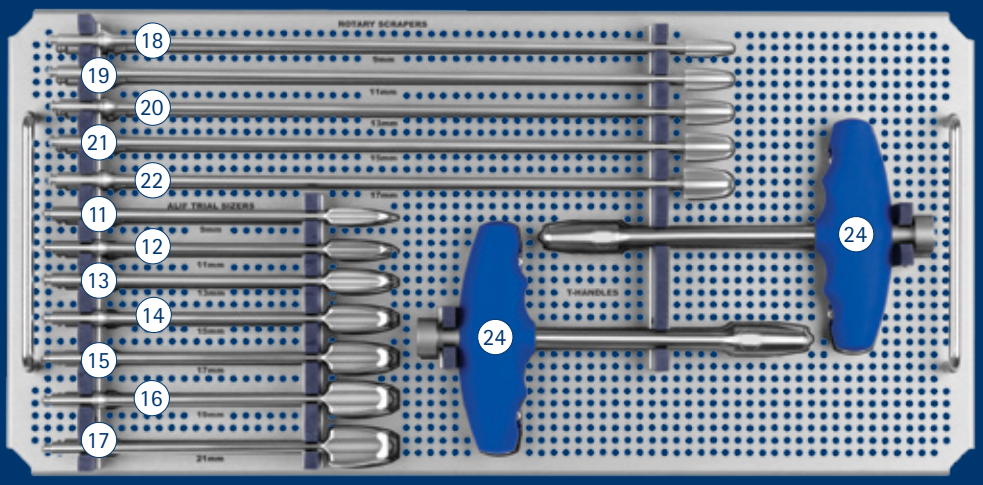


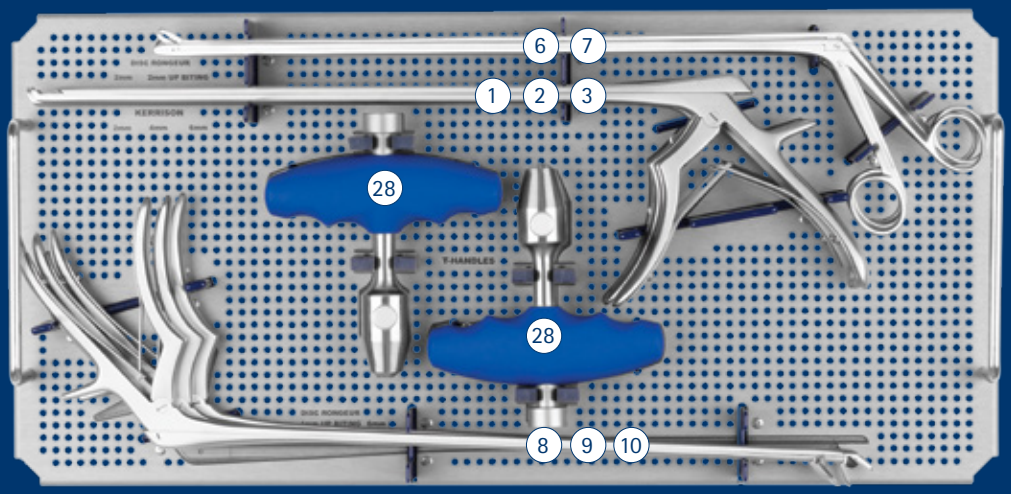
MARS™ Instrument II Set 932.902

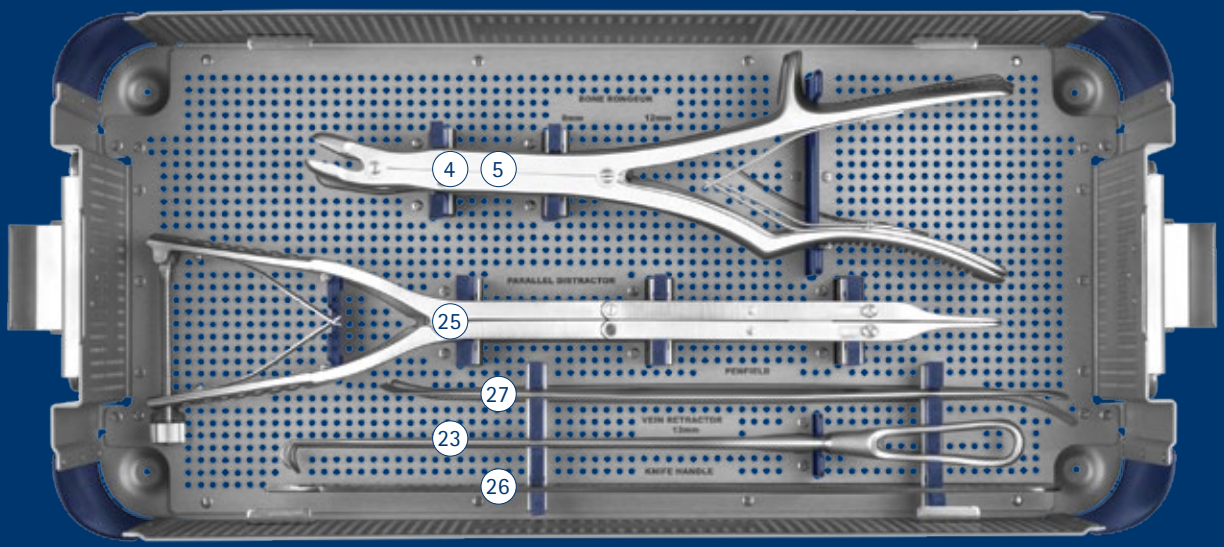
	Instruments		Qty
1	632.300	Fiber-Optic Cord	1
2	632.305	Adapter, ACMI	1
3	632.306	Adapter, Wolf	1
4	632.307	Adapter, Olympus	1
5	632.308	Adapter, Storz	1
6	632.390	Port Lock, 19mm	1
7	632.391	Port Lock, 22mm	1
8	632.392	Port Lock, 26mm	1
9	632.401	2mm Cannula	1
10	632.402	5mm Cannula	1
11	632.403	8mm 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
	632.310S	Light Cable	
	932.002	MARS™ Instrument II Graphic Case	

Items highlighted in gray are additionally available.

ANTERIOR DISC PREP I INSTRUMENT SET



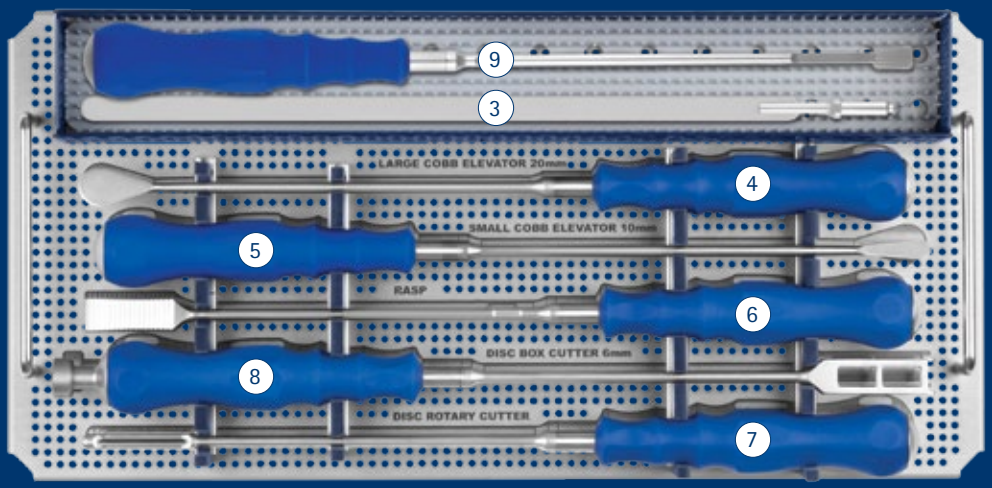


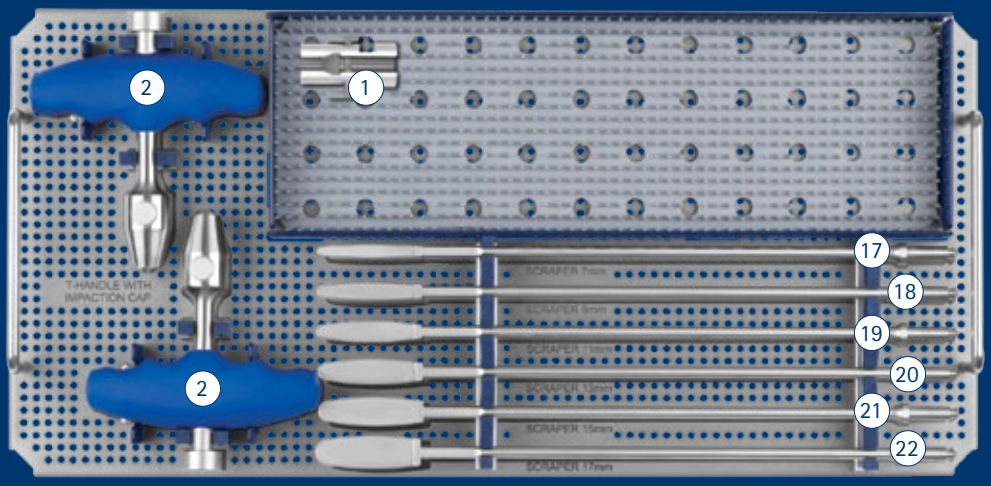


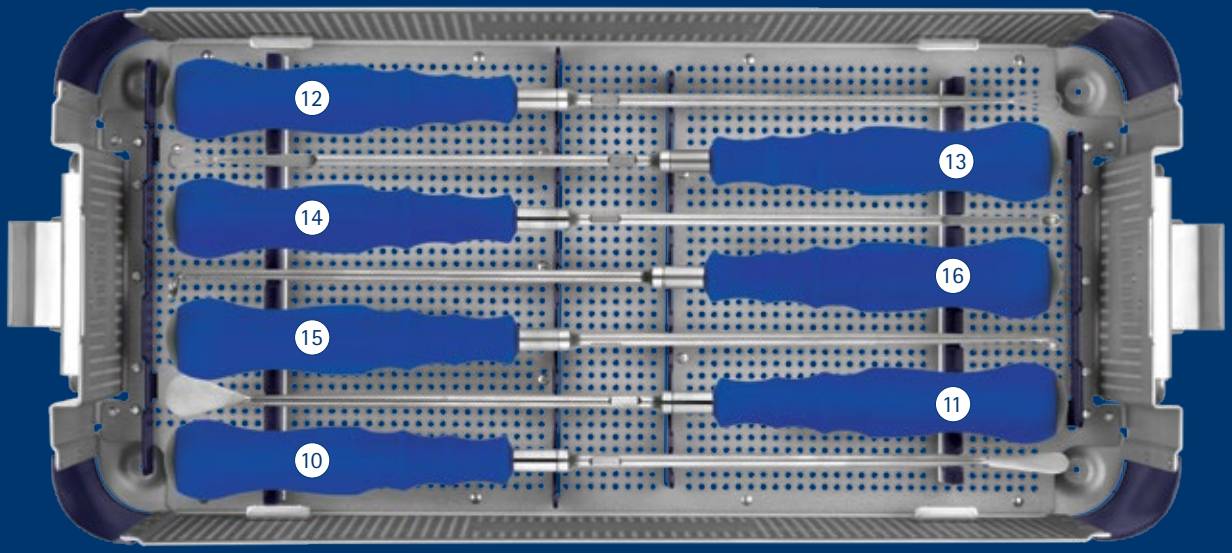
Anterior Disc Prep I Instrument Set 925.901

	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, Doube 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	

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

IMPORTANT INFORMATION ON THE InterContinental® PLATE-SPACER

DESCRIPTION

The InterContinental® Plate-Spacer is a lateral lumbar interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy. InterContinental® is available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces grip the endplates of the adjacent vertebrae to aid in expulsion resistance. InterContinental® is to be filled with autogenous bone graft material, and is to be used with titanium alloy bone screws, with or without hydroxyapatite coating. Bone screws are used to attach to the lateral portion of the adjacent vertebral bodies for bony fixation.

The spacers in the InterContinental® Plate-Spacer are manufactured from radiolucent polymer, with titanium alloy or tantalum markers, as specified in ASTM F136, F560, F1295, and F2026. The plates in the InterContinental® Plate-Spacer are manufactured from titanium alloy, as specified in ASTM F136 and F1295. The screws in the InterContinental® Plate-Spacer are manufactured from titanium alloy, as specified in ASTM F136 and F1295, and are available with or without hydroxyapatite (HA) coating, as specified in ASTM F1185.

INDICATIONS

The InterContinental® Plate-Spacer is a lateral lumbar 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 InterContinental® Plate-Spacer is to be filled with autogenous bone graft material, and is to be used with two titanium alloy screws which accompany the implant. These devices are intended to be used with supplemental fixation in addition to the integrated screws.

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 longterm 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.

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 InterContinental® Plate-Spacer has not been evaluated for safety and compatibility in the MR environment. The InterContinental® Plate-Spacer has not been tested for heating or migration in the MR environment.

Based on fatigue testing, when using the InterContinental® Plate-Spacer, the physician/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 InterContinental® Plate-Spacer is contraindicated in patients with the following conditions:

- 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.
- Prior fusion at the level(s) to be treated.
- Severe osteoporosis, which may prevent adequate fixation.
- 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.
- 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.
- 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

InterContinental® Plate-Spacer implants are provided non-sterile, with the exception of HA coated screws which are only available sterile. HA coated screws are sterilized by gamma radiation to ensure a Sterility Assurance Level (SAL) of 10^{-6}. The expiration date is provided on the package label. Do not use if expired. These implants are considered sterile unless the packaging has been opened or damaged.

IMPORTANT INFORMATION ON THE InterContinental® PLATE-SPACER

Non-sterile InterContinental® Plate-Spacer implants and instruments have been validated to assure a Sterility Assurance Level (SAL) of 10^{-6}. The use of 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 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	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 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.

REV A

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 inquires to Globus Medical.

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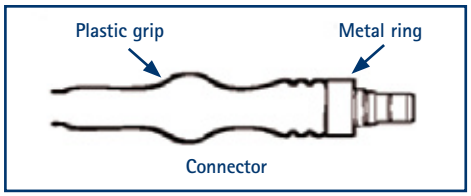

REV E

Notes

Notes

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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