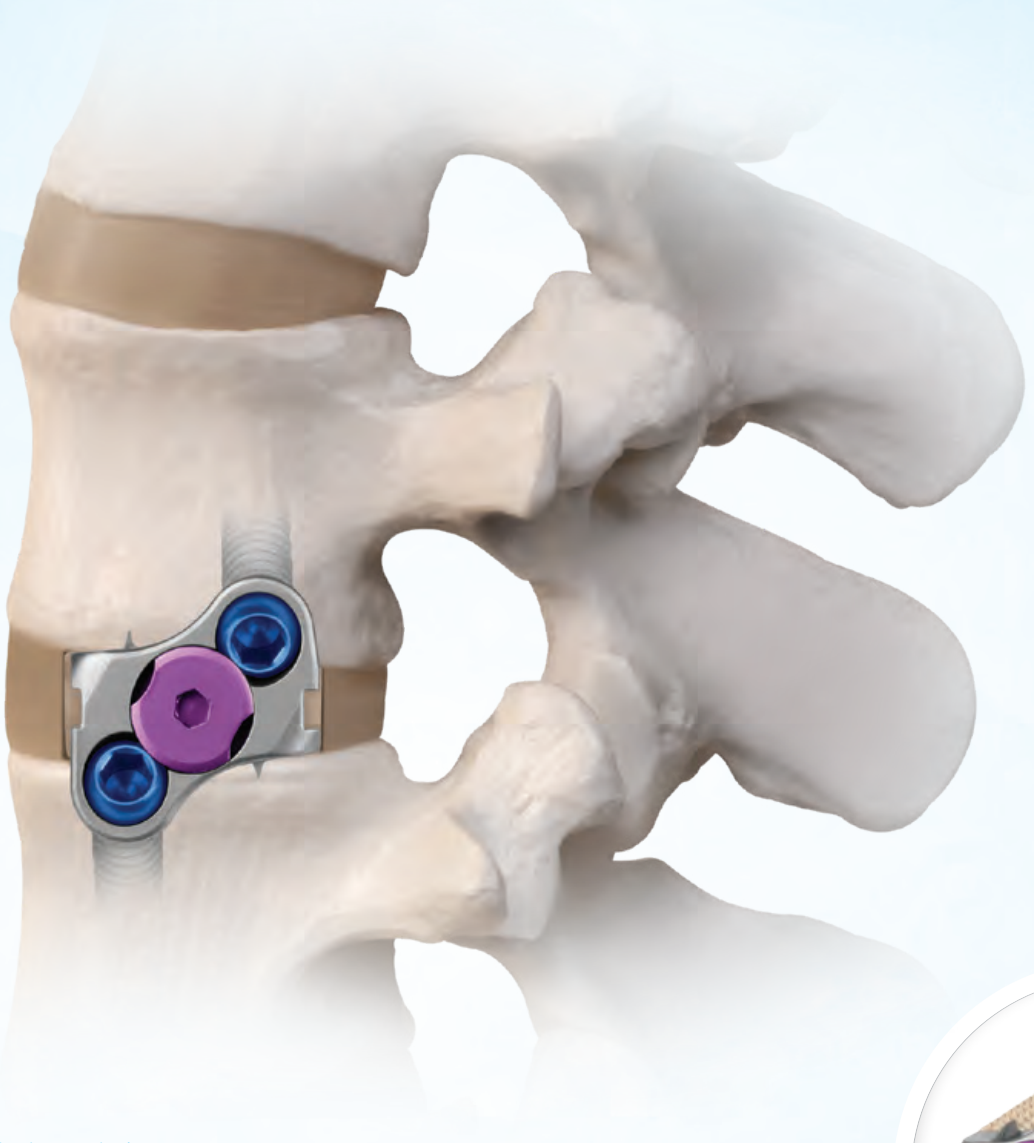

Supplemental fixation required.

InterContinental®

LLIF Plate-Spacer System

SURGICAL TECHNIQUE GUIDE

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

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SURGICAL TECHNIQUE GUIDE

InterContinental®

InterContinental®

LLIF Plate-Spacer System

The InterContinental® Plate-Spacer is an innovative system designed for achieving minimally invasive lateral fixation. The plate and spacer are assembled intraoperatively and positioned at the disc space, helping to minimize disruption to patient anatomy.

Two bone screws, two anchors, or a combination to secure the plate-spacer to the vertebral bodies and compressively load the spacer and graft chamber to help promote fusion.

The InterContinental® Plate-Spacer system contains a wide variety of footprints to accommodate different patient anatomy.

Minimized Retraction

Integrated plate and spacer is positioned at the disc space with less retraction

Enhanced Stability

Designed to add stability through a lateral approach

Optimized Fusion

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

Intraoperative Versatility

Compatible with anchors and screws, providing multiple options for securing the spacer to the vertebral body

Supplemental fixation required.

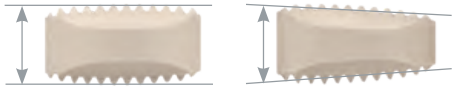
IMPLANT OVERVIEW

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

TransContinental® M Spacer System

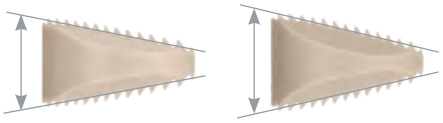
- Indicated for interbody fusion
- 4 sagittal profiles: 0°, 6°, 20°, and 25° lordotic
- Heights (0°, 6° lordosis): 8, 9, 11, 13, and 15mm (17mm additionally available)
- Heights (20°, 25° lordosis): 11, 13, 15, 17, 19, and 21mm
- 6 lengths: 35–60mm, in 5mm increments
- Width: 20mm

Heights: 8–17mm

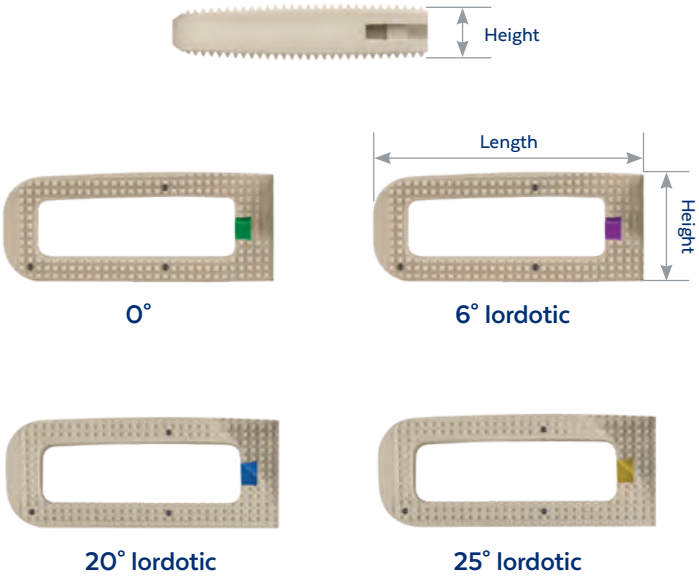


0° 6° lordotic

Heights: 11–21mm



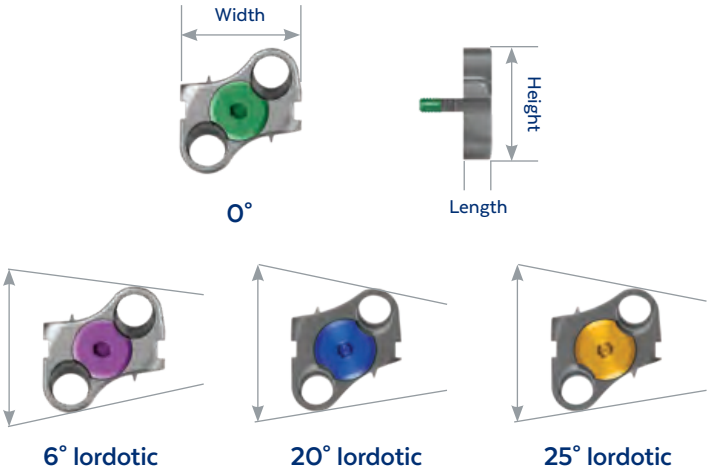
20° lordotic 25° lordotic



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

InterContinental® Plate

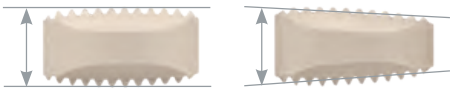
- Indicated for use only in conjunction with TransContinental® M Spacer
- 4 sagittal profiles: 0°, 6°, 20°, and 25° lordotic
- Heights (0°, 6° lordosis): 8, 9, 11, 13, and 15mm (17mm additionally available)
- Heights (20°, 25° lordosis): 11, 13, 15, 17, 19, and 21mm
- Length: 5mm
- Width: 20mm



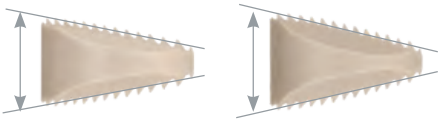
InterContinental® Plate-Spacer

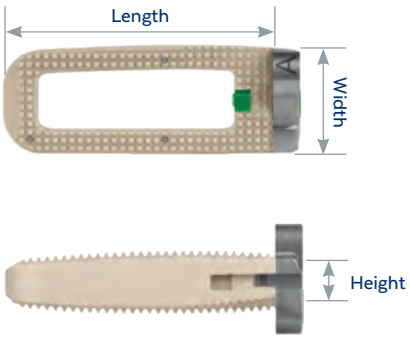
- Intraoperatively assembled using the TransContinental® M Spacer and the InterContinental® Plate
- 4 sagittal profiles: 0°, 6°, 20°, and 25° lordotic
- Heights (0°, 6° lordosis): 8, 9, 11, 13, and 15mm (17mm additionally available)
- Heights (20°, 25° lordosis): 11, 13, 15, 17, 19, and 21mm
- 6 lengths: 40–65mm, in 5mm increments
- Width: 20mm

Heights: 8–17mm



Heights: 11–21mm

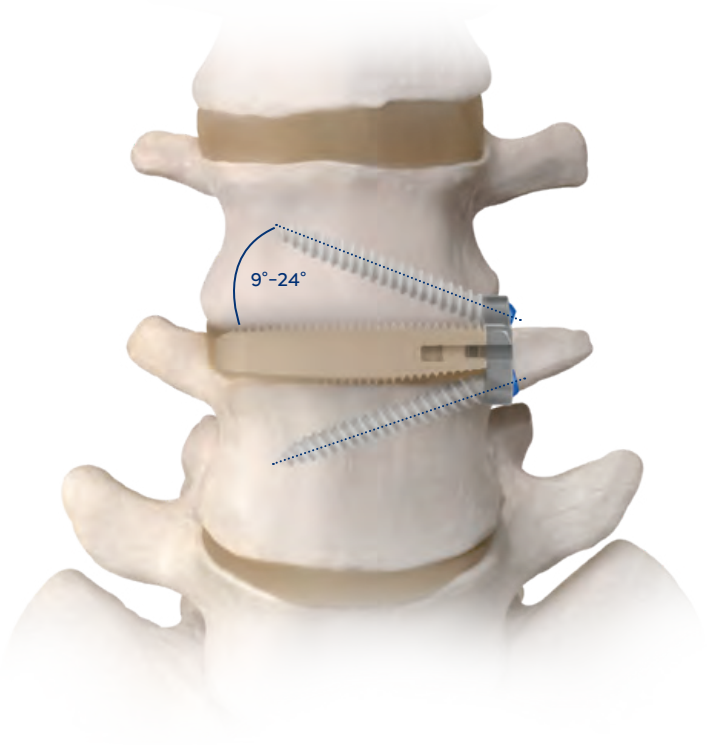




InterContinental® Plate-Spacer	
Length	**Width**
40mm	20mm
45mm	20mm
50mm	20mm
55mm	20mm
60mm	20mm
65mm	20mm

Screws

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



Anchors

- Titanium bone anchor
- Lengths: 22, 25, and 27mm
- Diameter: 5.5mm
- Variable angle (0°–22°)

INSTRUMENT OVERVIEW

DISC PREPARATION INSTRUMENTS

Bayonetted Annulotomy Knife 675.405S

Penfield, Bayonetted, Pull 675.173

Penfield #4, Pull, 190mm 675.174

Cobb Elevator, Straight, 20mm 675.503

Cobb Elevator, Straight, 10mm 675.504

Thin Rasp, 12x20mm 675.510

DISC PREPARATION INSTRUMENTS (CONT'D)

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

Double Rasp 675.520

Cup Curette, 6.5x9.5mm, Straight 675.525

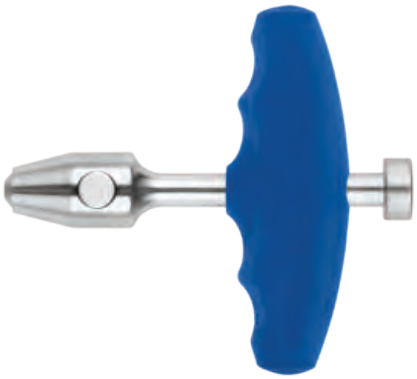
Cup Curette, 6.5x9.5mm, 15°, Up-Angle 675.526

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

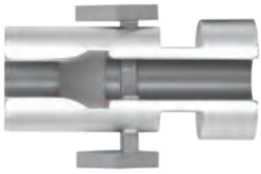
Kerrison, 4mm 625.202
Kerrison, 6mm 625.203

Disc Rongeur, 4mm 625.305
Disc Rongeur, 6mm 625.307

ADDITIONAL DISC PREP INSTRUMENTS



T-Handle with Impaction Cap 675.005



Slap Hammer Adapter 675.002

Quick-Connect Guide 675.201

SCRAPERS

	Height	Part No.
	5mm	675.605
	7mm	675.606
	9mm	675.609
	11mm	675.611
	13mm	675.613
	15mm	675.615
	17mm	675.617

PADDLE DISTRACTORS

	Height	Part No.
	5mm	675.855
	7mm	675.857
	9mm	675.859
	11mm	675.861
	13mm	675.863

BOX CUTTERS

	Height	Part No.
	5mm	675.533
	7mm	675.534
	9mm	675.535

INSERTION INSTRUMENTS

Note: Trials marked with a green ring on the shaft are 0° lordotic. Trials marked with a purple ring are 6° lordotic. Trials marked with a blue ring are 20° lordotic. Trials marked with a gold ring are 25° lordotic.

Universal Holder 687.001

Trial, 0° Lordotic

Trial, 6° Lordotic

Trial, 20° Lordotic

Trial, 25° Lordotic

Trials				
Height	**0° Lordotic**	**6° Lordotic**	**20° Lordotic**	**25° Lordotic**
8mm	687.008	687.058	-	-
9mm	687.009	687.059	687.800	-
11mm	687.011	687.061	687.801	687.811
13mm	687.013	687.063	687.803	687.813
15mm	687.015	687.065	687.805	687.815
17mm	687.017	687.067	687.807	687.817
19mm	-	-	687.809	687.819
21mm	-	-	-	687.821

**Items in gray are additionally available.*

INSERTION INSTRUMENTS (CONT'D)

Straight Implant Holder 687.400

U-Joint 3.5mm Hex 687.529

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

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 Awl 687.524

Straight 5.5mm Drill 687.520

Straight 5.5mm Tap 687.526

Straight Shaft 3.5mm Hex Driver 687.527

ADDITIONAL INSTRUMENTS

Single Anchor Inserter, Lateral 6219.1000

Long Throw Slide Hammer 675.004

3mm Removal Tool 687.300

Set Screw Driver, 2.5mm Hex 676.600

SURGICAL TECHNIQUE

InterContinental®

Refer to the package insert for information on the indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

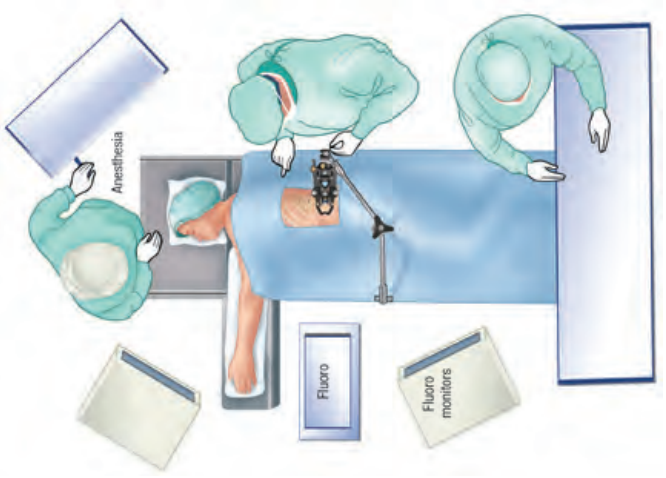
STEP 1 PATIENT PREPARATION

Patient Positioning

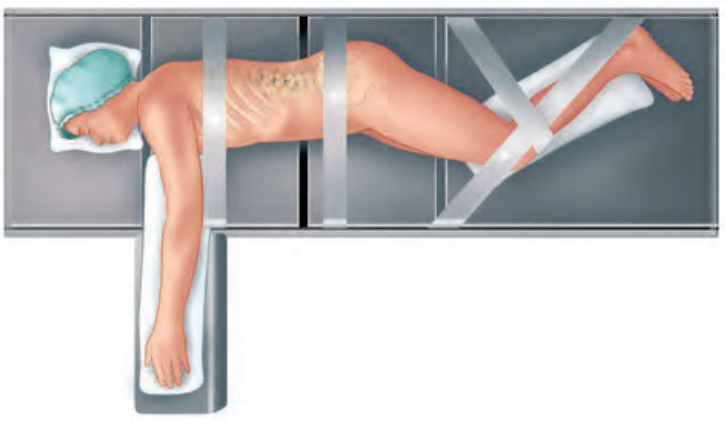
The patient is placed on a flexible surgical table in a straight 90° right lateral decubitus position so that the iliac crest is just over the table break, as shown below.

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

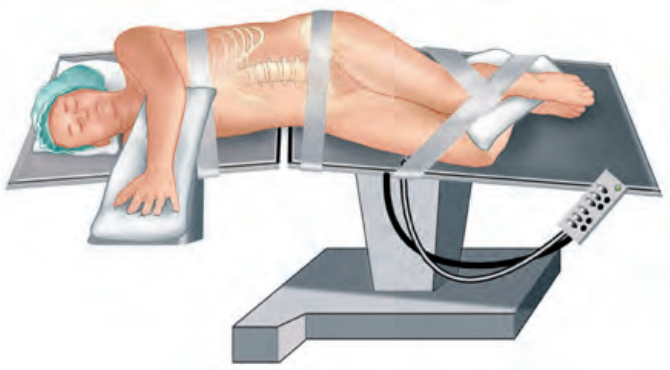


Table flexed

X-Ray Confirmation

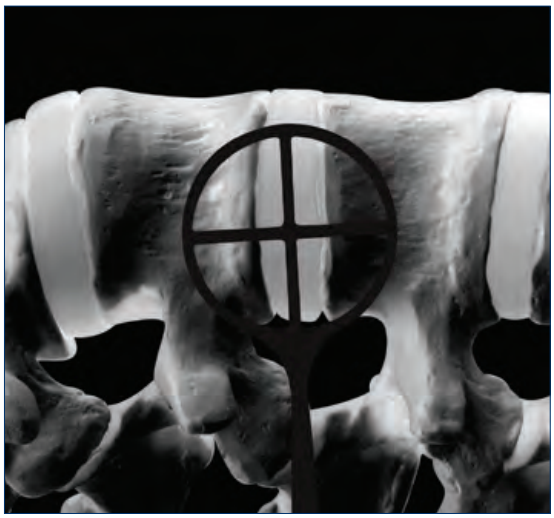
Fluoroscopy is used to ensure that the spine is oriented in a straight lateral position. The table should be adjusted so that the C-arm provides straight AP images when at 0° and straight lateral images at 90°.

Lateral image

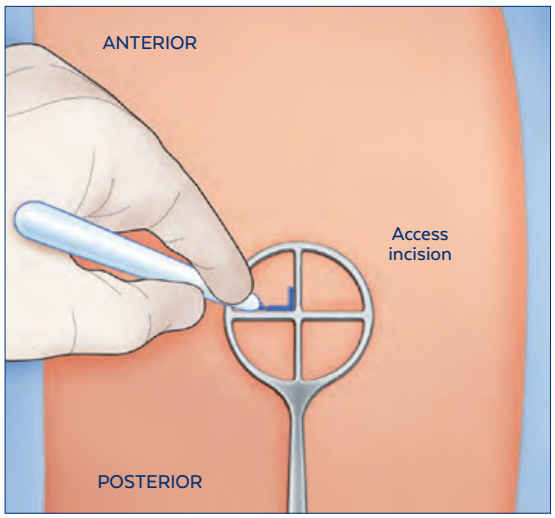
AP image

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

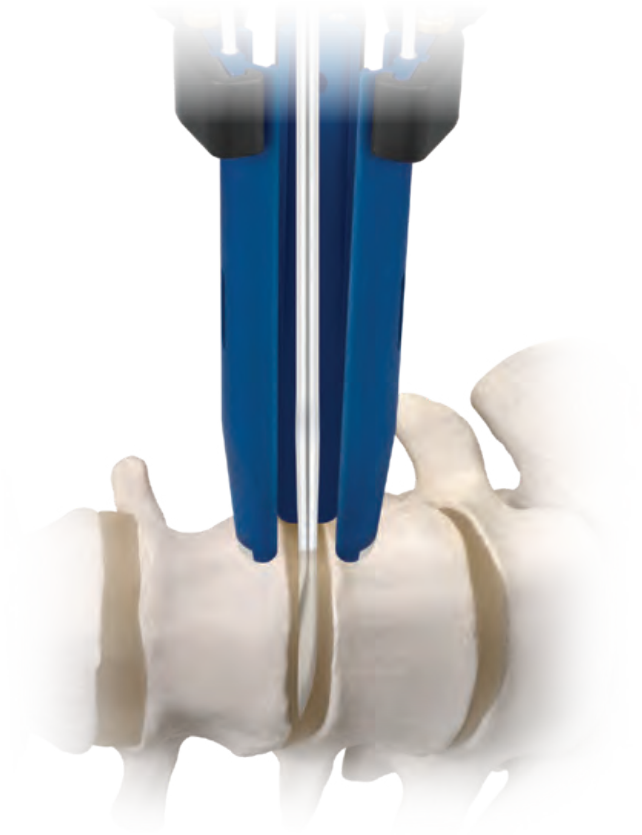
STEP 2 DISC PREPARATION

Annulotomy

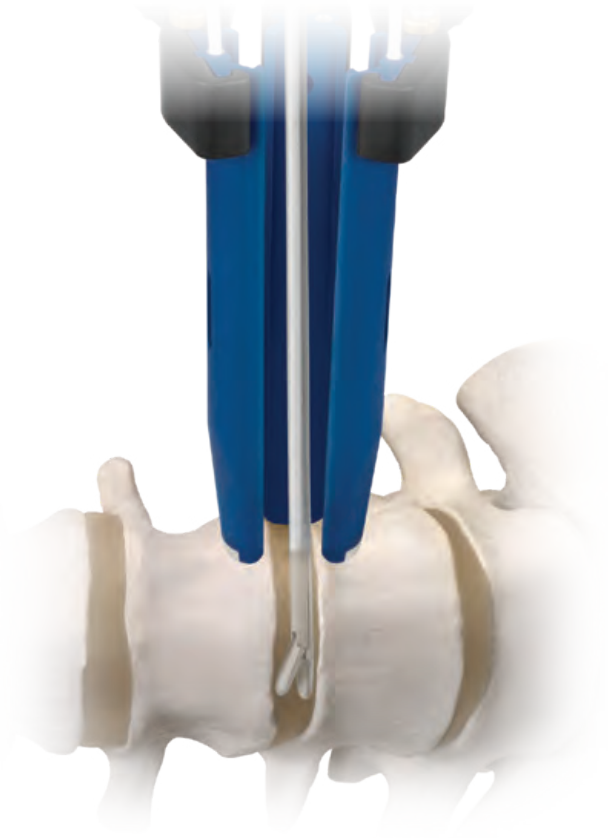
The **Bayonneted Annulotomy Knife** may be used to create a window centered in the anterior half of the annulus, large enough for graft insertion.

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 Cobb Elevator



Using Disc Rongeur

Disc Space Preparation

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

STEP 3 IMPLANT INSERTION

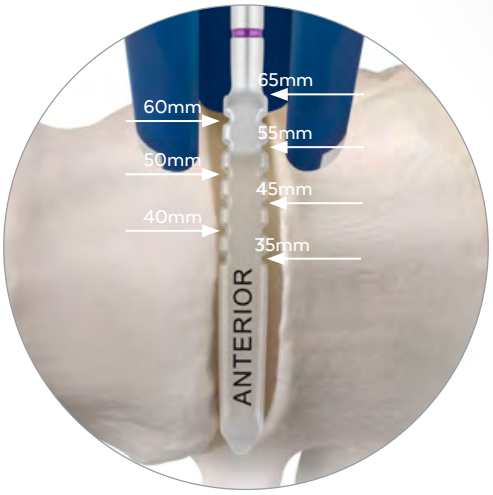
Implant Sizing

To determine the appropriate implant size for the desired segment, insert the smallest Trial, 0° 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. Trials marked with a blue ring are 20° lordotic. Trials marked with a gold ring are 25° lordotic.

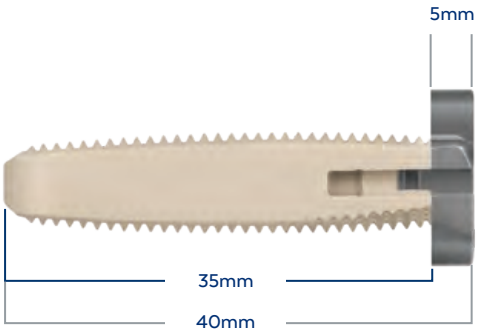
For correct orientation, insert the trial into the disc space with the side etched "Anterior" facing the patient's anterior side. Determine which trial best fits the prepared disc space. A secure fit is desirable to maintain disc height and stabilize the segment.

Ensure that the tapered end of the trial overhangs the contralateral edge to account for implant marker location.



Implant Sizing

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



35mm TransContinental® M Implant with InterContinental® Plate

IMPLANT INSERTION (CONT'D)

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.

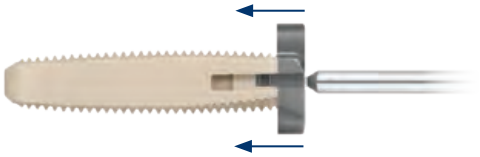
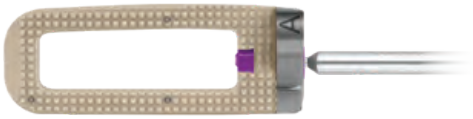


Plate placed onto spacer



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 have a green blocking set screw and are to be assembled with the 0° lordotic spacer with the green titanium nut. The 20° lordotic plates have a blue blocking set screw and are to be assembled with the 20° lordotic spacer with the blue titanium nut. The 25° lordotic plates have a gold blocking set screw and are to be assembled with the 25° lordotic spacer with the gold titanium nut.

0° lordotic plate blocking set screw

6° lordotic plate blocking set screw

20° lordotic plate blocking set screw

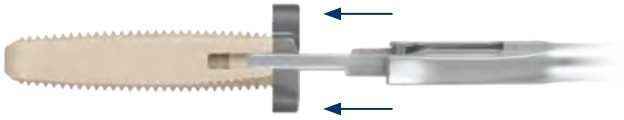
25° lordotic plate blocking set screw

Positioning set screw finger tight

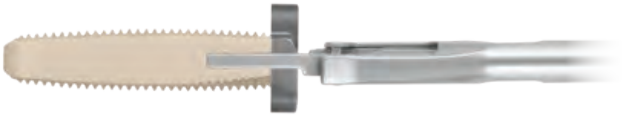
Aligning set screw to allow for screws

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 of the spacer.



Positioning holder on the implant

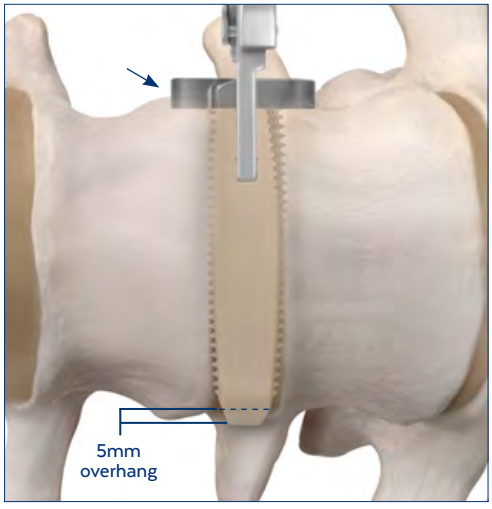


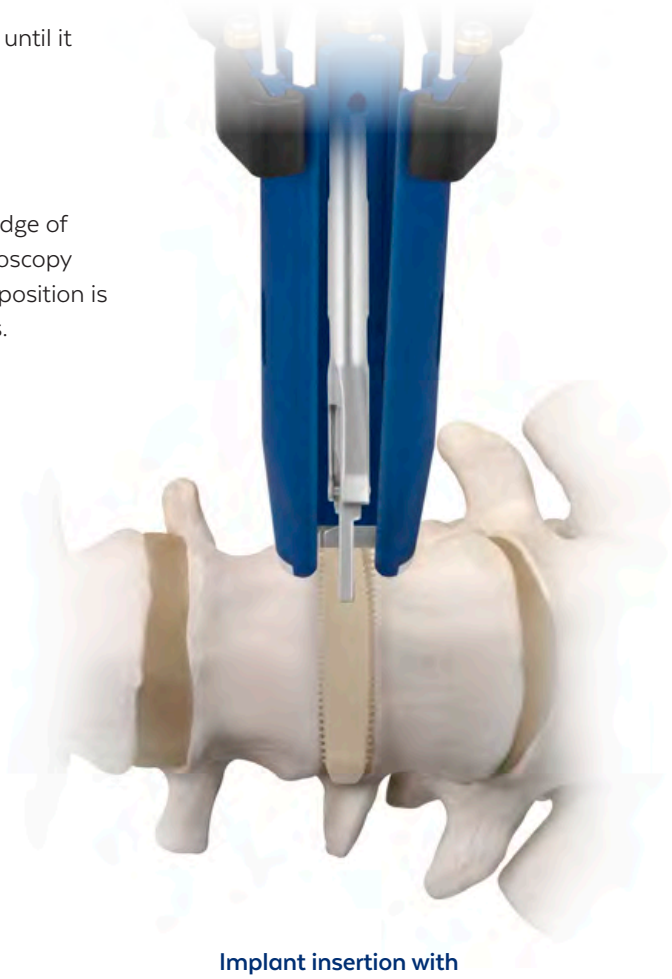
Holder properly positioned on implant

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 leading edge of the plate is seated at 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 insertion with
Universal Implant Holder

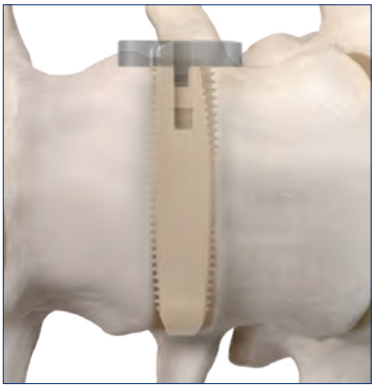
InterContinental® may be used with two screws, two anchors, or a combination of both screws and anchors.

- **Screw Fixation:** Follow steps 4-6 on pages 24-28.
- **Anchor Fixation:** Follow steps 4-6 on pages 29-32.
- **Hybrid Screw/Anchor Fixation:** For screw fixation follow steps 4-6 on pages 24-28. For anchor fixation follow steps 4-6 on pages 29-32.

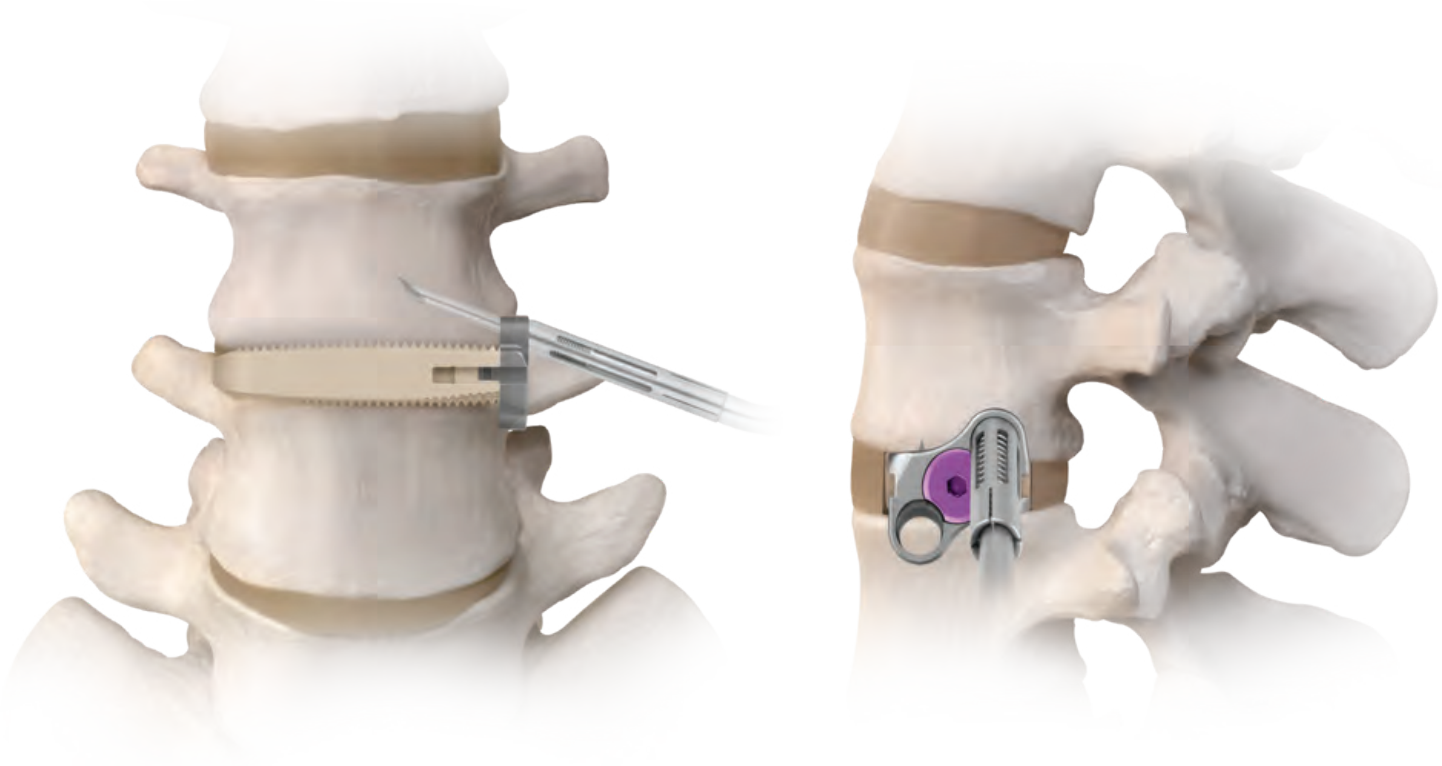
SCREW FIXATION

STEP 4 SCREW HOLE PREPARATION

Insert the **Angled Awl** through the screw hole to perforate the cortex. While inserting the 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.



Implant Final Position



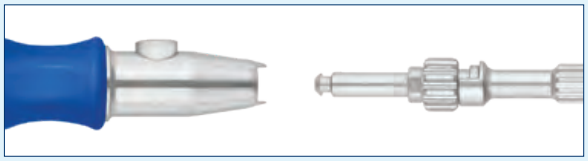
Angled Awl inserted through screw hole

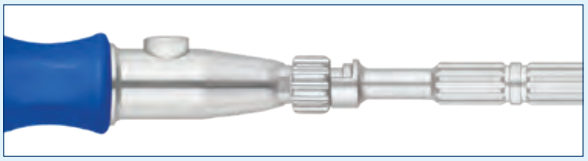
STEP 5 SCREW INSERTION

ANGLED DRIVER ASSEMBLY USING 3.5MM ANGLED HEX DRIVER

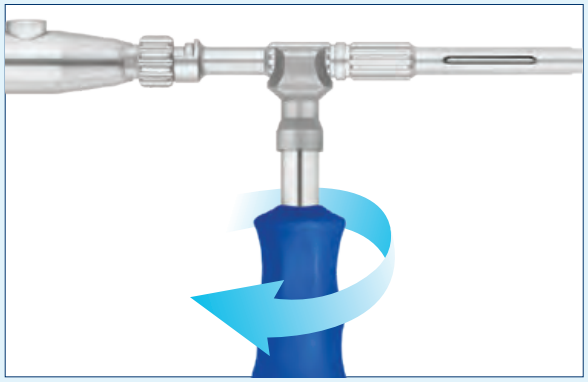
Select the **3.5mm Angled Hex Driver**.

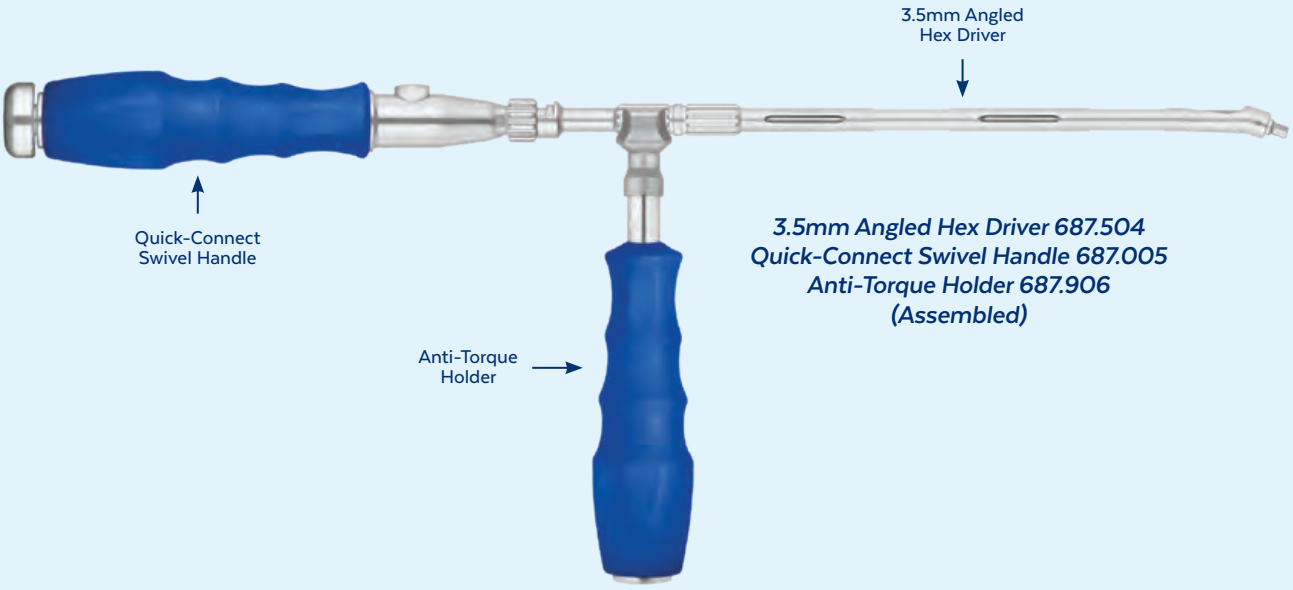
Connect the **Quick-Connect Swivel Handle** to the 3.5mm Angled Hex Driver.





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.



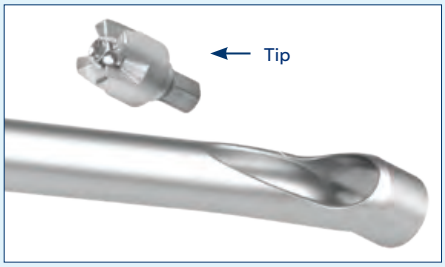


3.5mm Angled Hex Driver 687.504
Quick-Connect Swivel Handle 687.005
Anti-Torque Holder 687.906
(Assembled)

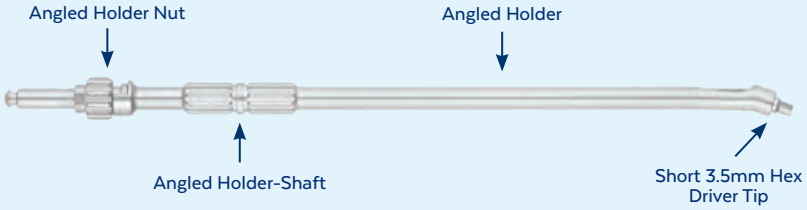
ANGLED DRIVER ASSEMBLY USING COMPONENTS

Select the appropriate tip.

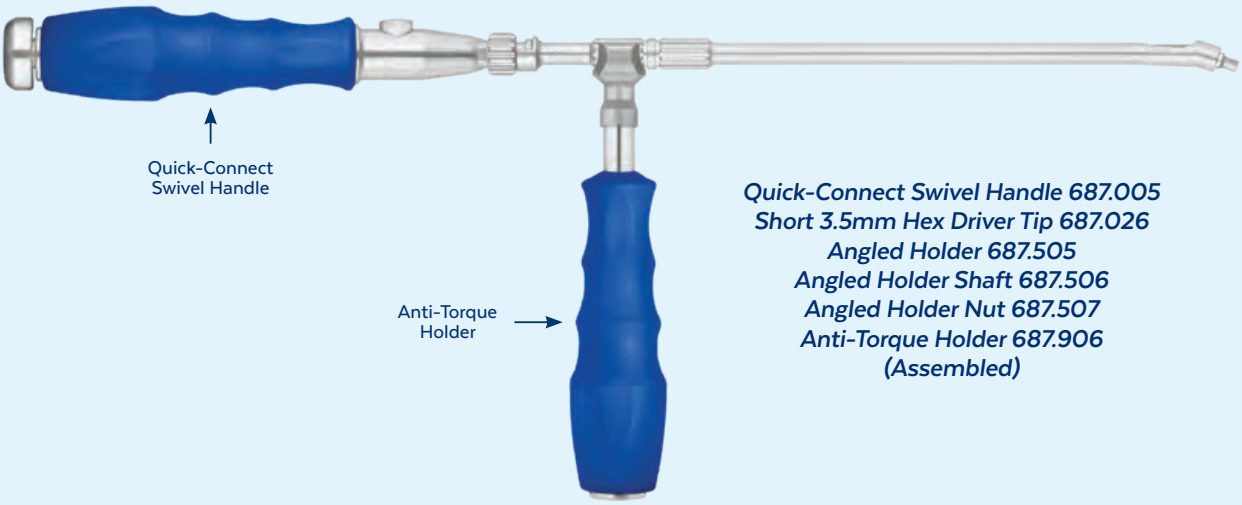
Hold the **Angled Holder** pointed downwards with the cutout facing up, as shown below. Insert the tip into the distal end of the holder.



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 and 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.

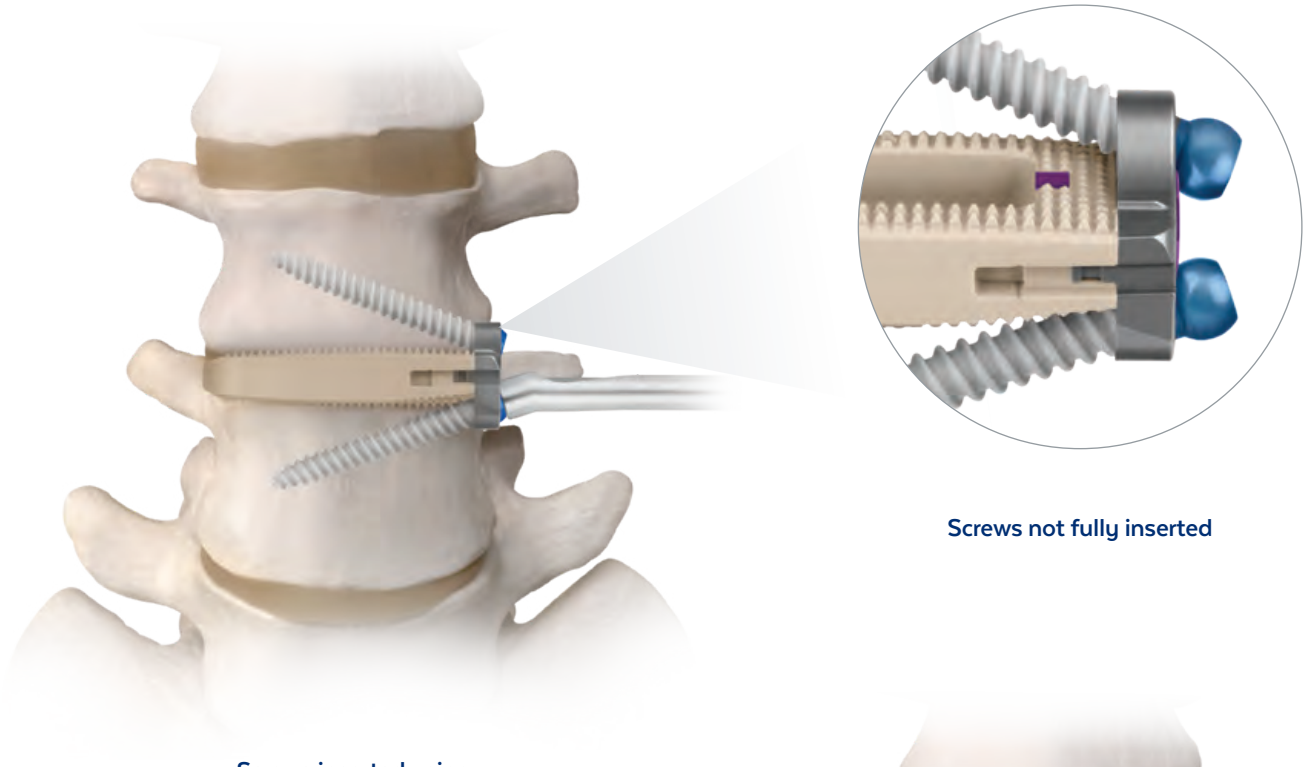


Quick-Connect Swivel Handle 687.005
Short 3.5mm Hex Driver Tip 687.026
Angled Holder 687.505
Angled Holder Shaft 687.506
Angled Holder Nut 687.507
Anti-Torque Holder 687.906
(Assembled)

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.

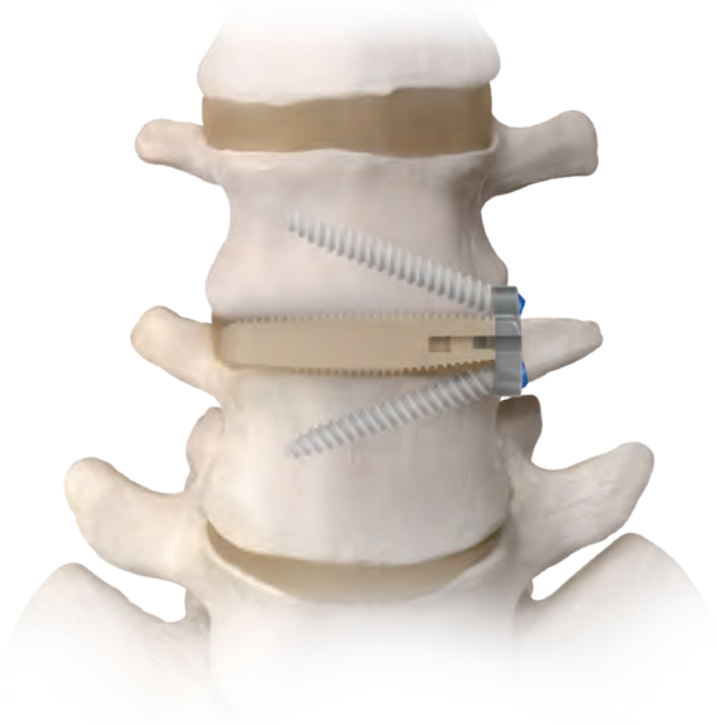


Screws not fully inserted

Screws inserted using
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.

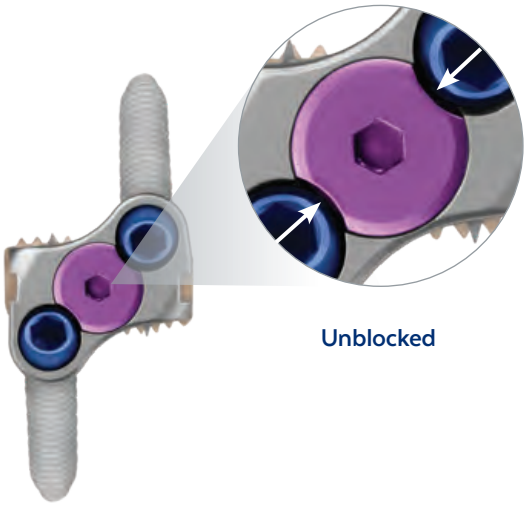


Final screw positioning

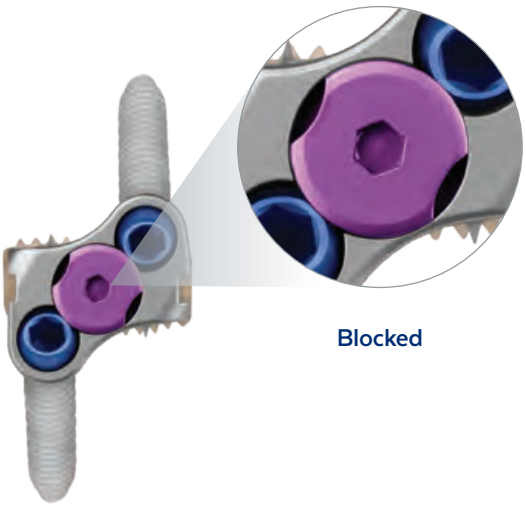
STEP 6 POSITIONING THE SET SCREW

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.

Supplemental fixation is required. See page 35 for details.



Unblocked

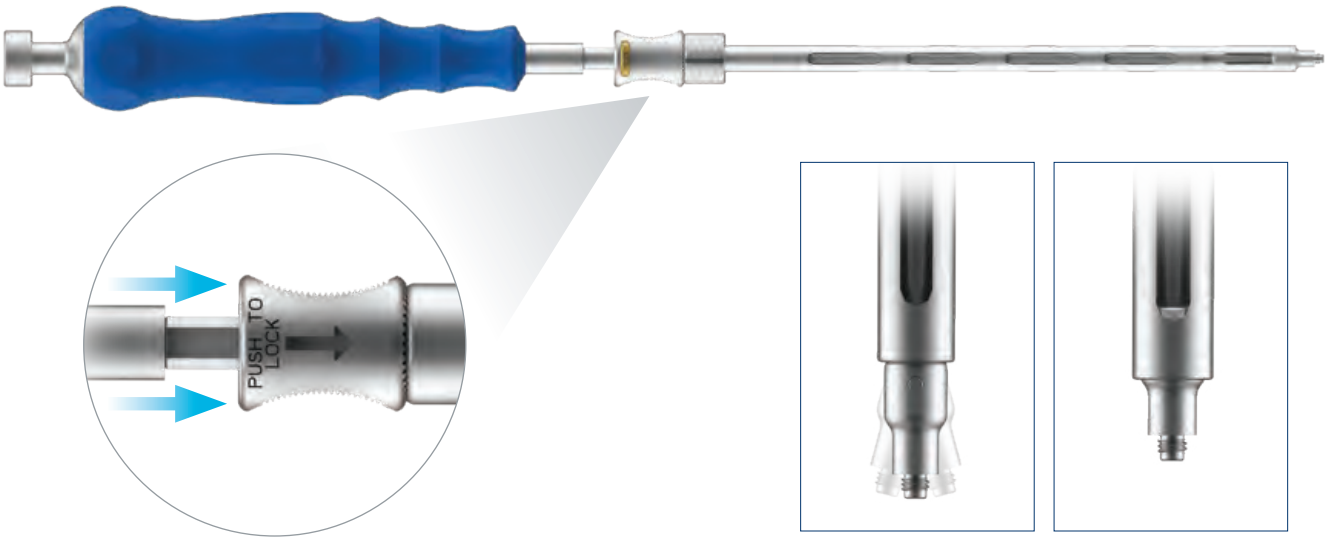


Blocked

ANCHOR FIXATION

STEP 4 ANCHOR INSERTION

Place the **Single Anchor Inserter, Lateral** in the locked position by sliding the lock assembly towards the distal end. To confirm that the inserter is locked, ensure that the outer sleeve is pushed forward and the tip does not angulate.



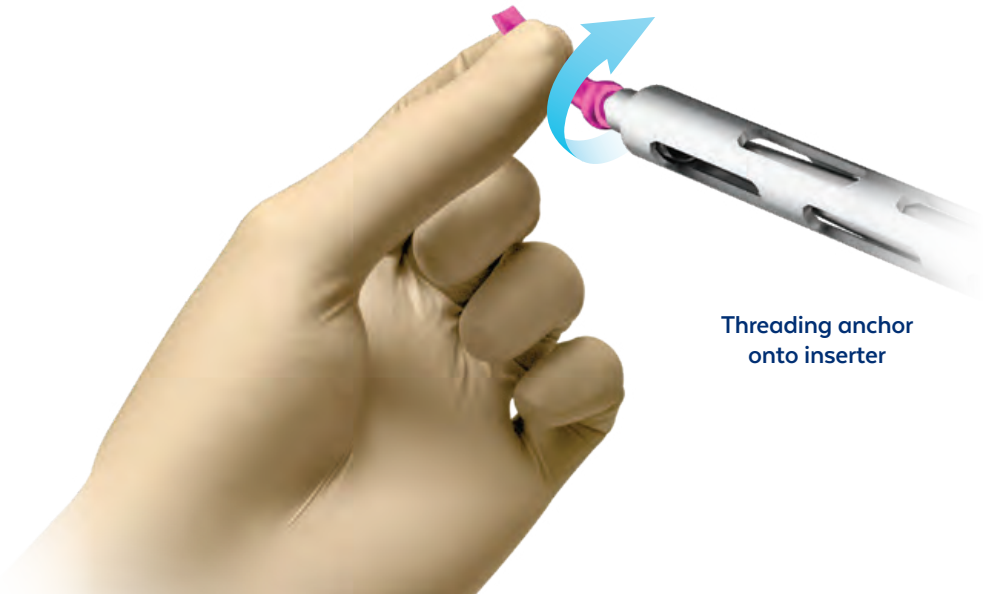
Placing instrument in locked position

Unlocked

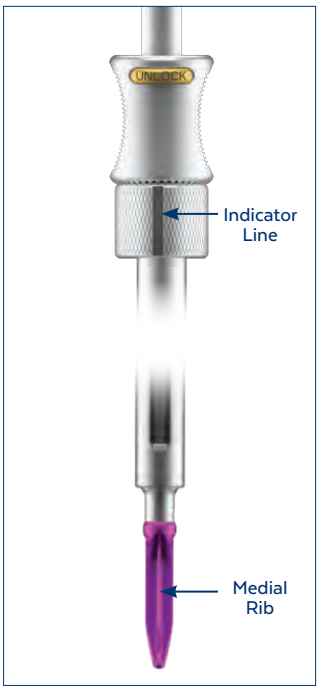
Locked

Confirm the implant is flush with the vertebral body, then select the appropriate anchor length. Thread the anchor onto the inserter by rotating the handle clockwise until finger tight. Ensure the anchor is flush against the inserter. Do not over-tighten the anchor, as this may damage the threads or make removal challenging. Use care when handling the anchor as the tip is sharp.

The directional indicator can be used to track the direction of the anchor after being introduced into the surgical corridor. To adjust the indicator, pull down distally and rotate to align the indicator line with the medial rib of the anchor.



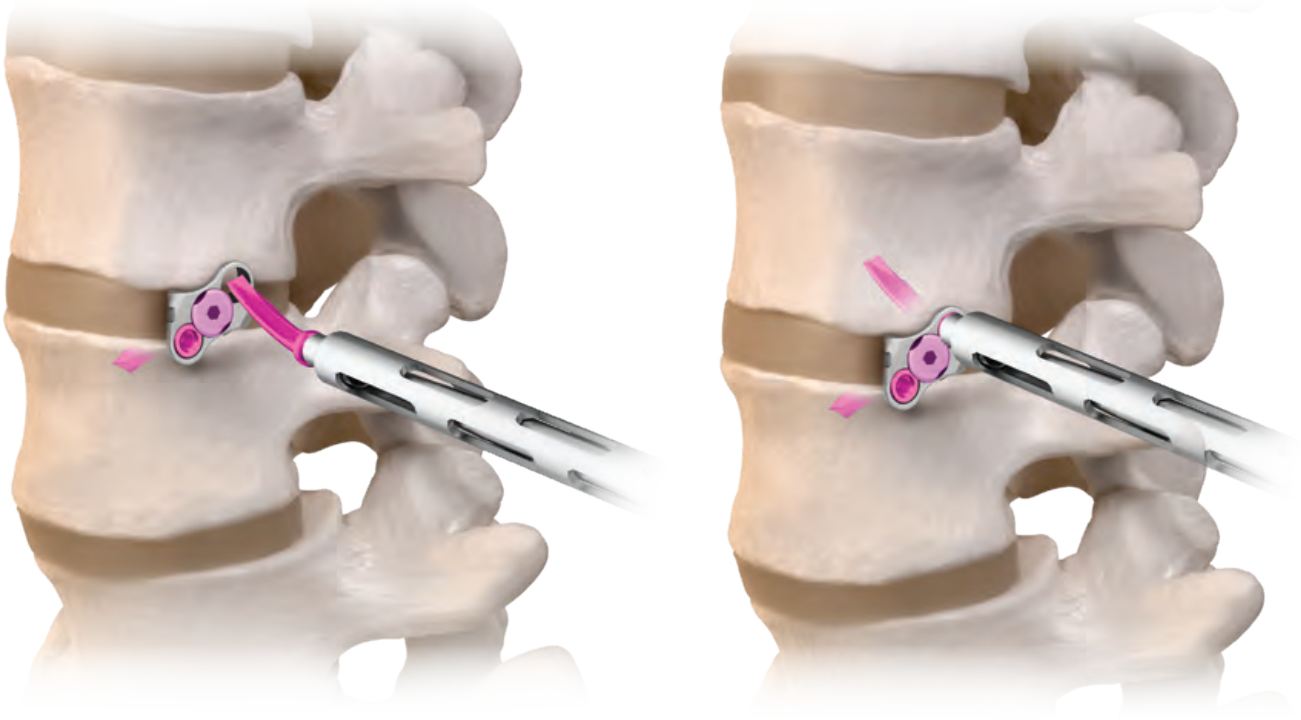
Threading anchor onto inserter



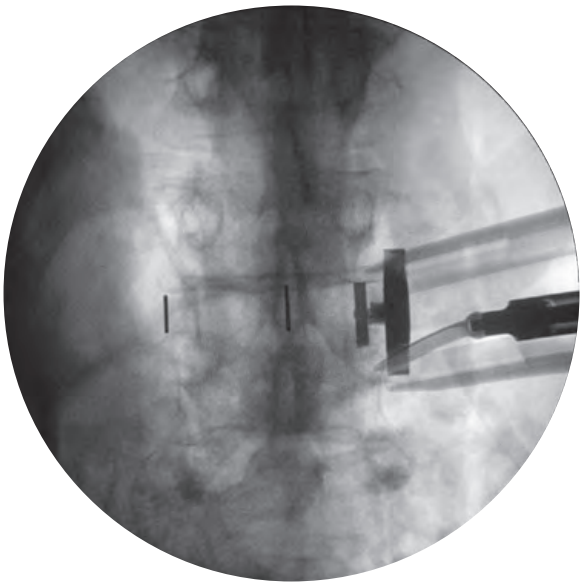
Directional indicator

ANCHOR INSERTION (CONT'D)

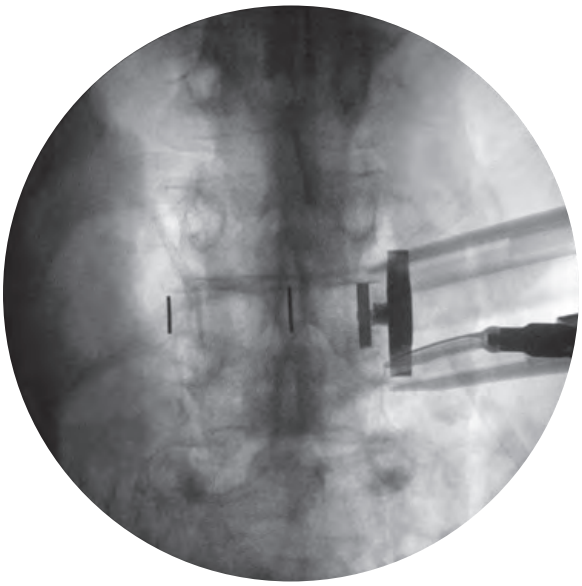
Carefully insert the anchor into the surgical corridor to seat the anchor tip into a fixation hole in the plate. Check the desired trajectory. Using a mallet, gently tamp the inserter to advance the anchor under AP fluoroscopy.



Inserting anchors using Anchor Inserter



Locked



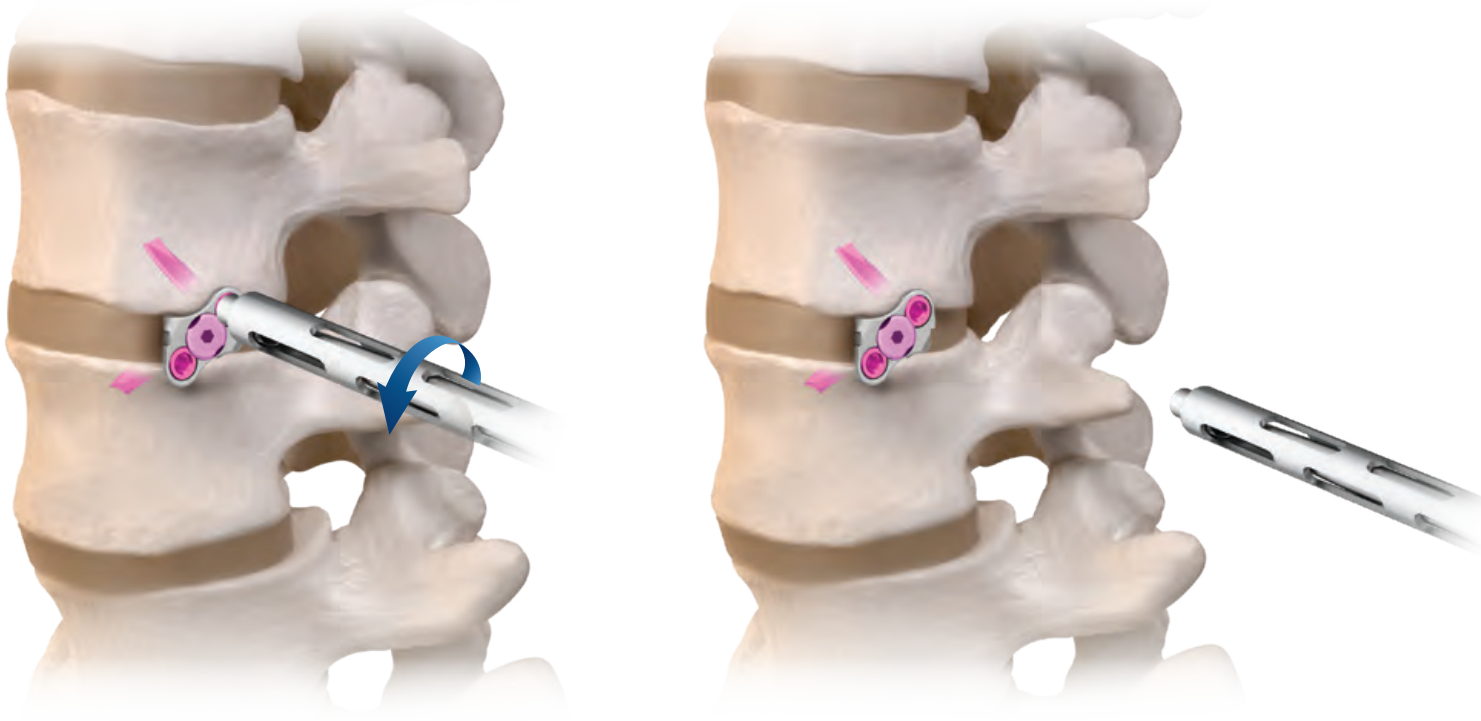
Unlocked

ANCHOR ANGULATION

The tip on the Anchor Inserter is designed to angulate for difficult trajectories. After placing the anchor into the fixation hole, begin impacting the inserter. If needed, press the gold button to release the slider to allow angulation. The anchor may be impacted while in the unlocked position.

STEP 5 INSERTER REMOVAL

Once the anchor is fully seated in the fixation hole, rotate the inserter counterclockwise to disengage the anchor. When the inserter is disconnected, it may be removed. Repeat steps 4 and 5 for the second anchor.

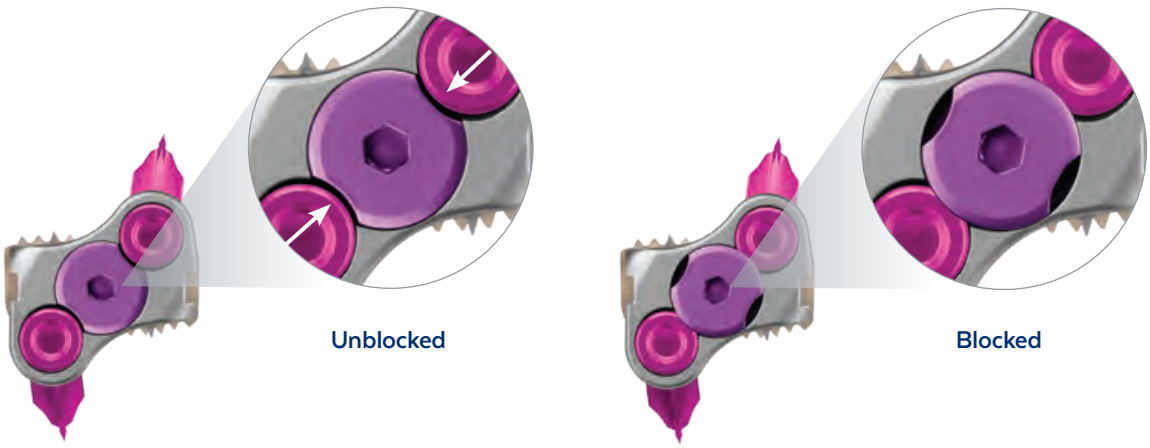


Disconnecting and removing inserter

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.

Supplemental fixation is required. See page 35 for details.



HYBRID SCREW/ANCHOR FIXATION

If a hybrid screw/anchor construct is desired, follow steps 1-3 for disc prep, implant assembly, and implant insertion.

For screw fixation, follow steps 4-6 on pages 24-28.

For anchor fixation, follow steps 4-6 on pages 29-32.

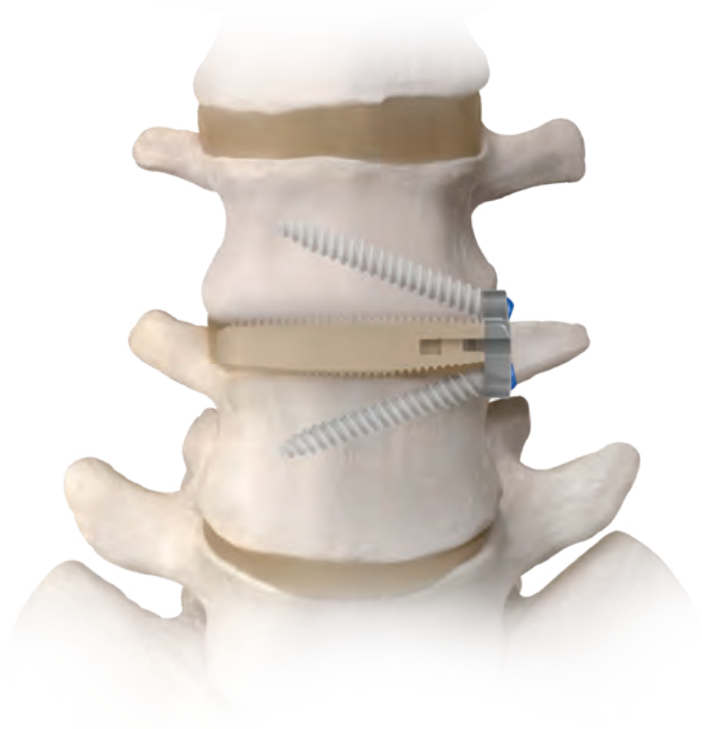
HYBRID FINAL POSITION

Supplemental fixation is required. See page 35 for details.

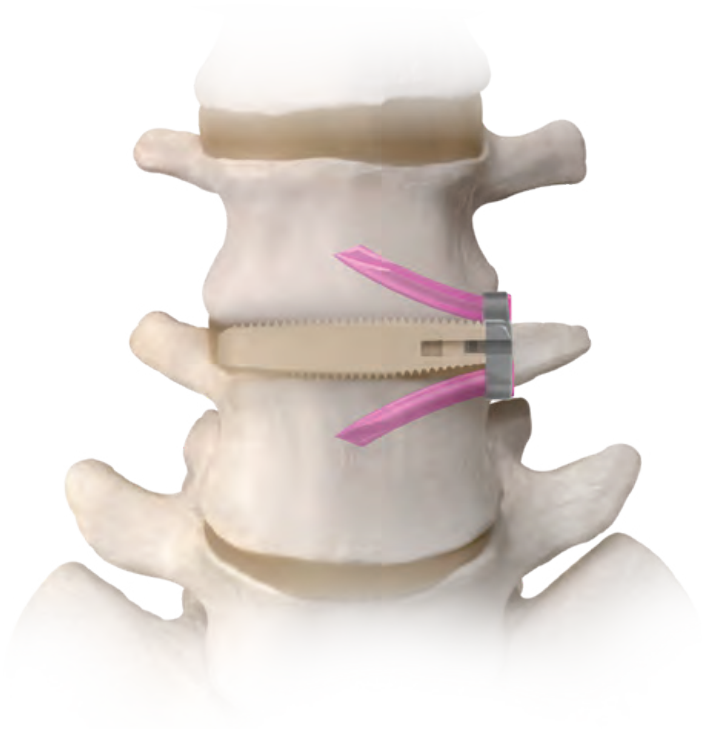
Hybrid final position

FINAL POSITION

Supplemental fixation is required. See page 35 for details.



Final position with screws - AP view



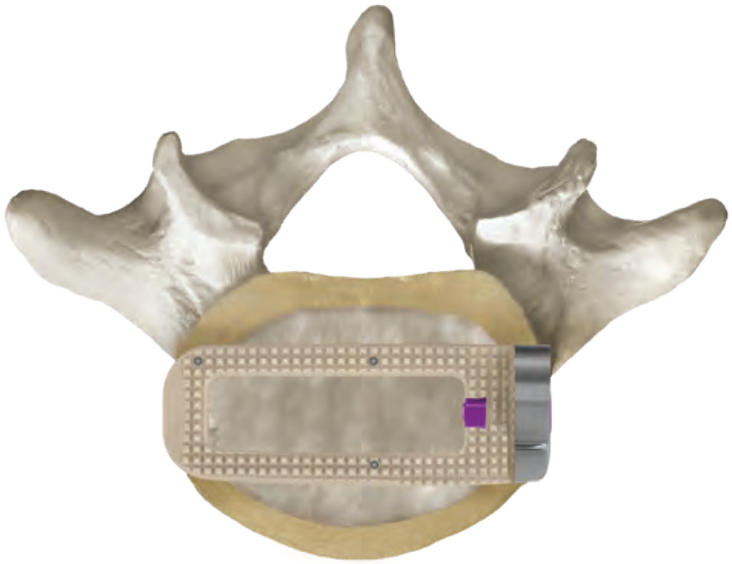
Final position with anchors - AP view

Final position with screws - sagittal view

Final position with anchors - sagittal view

FINAL POSITION

Supplemental fixation is required. See below for details.



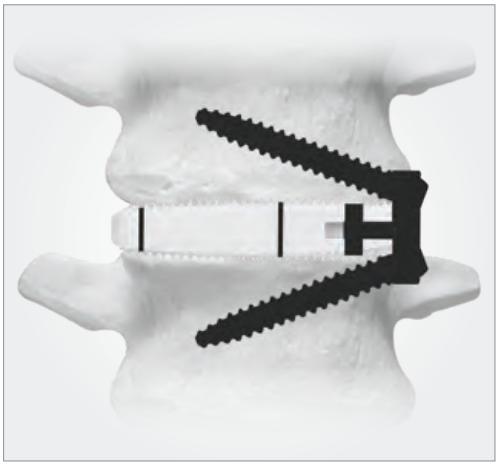
Axial view

SUPPLEMENTAL FIXATION

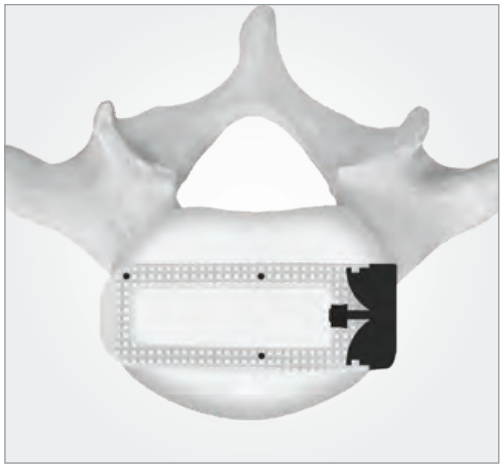
This device is intended to be used with supplemental fixation and may be used with or without the two integrated bone screws or anchors. Hyperlordotic (≥20°) devices must be used with two screws or anchors in addition to the supplemental fixation. Refer to the surgical technique manual for the desired supplemental fixation system for specific instructions.

RADIOGRAPHIC MARKERS

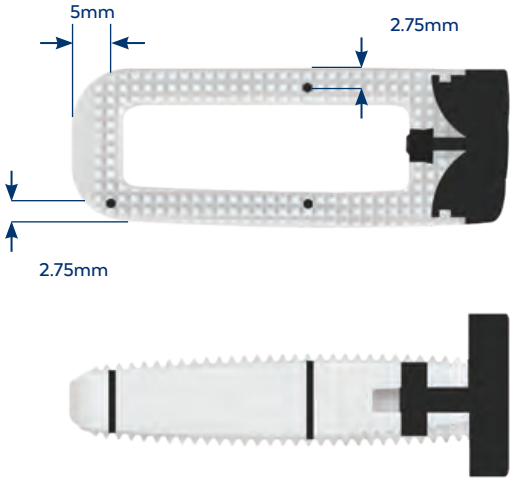
Radiographic sagittal view



Radiographic AP view



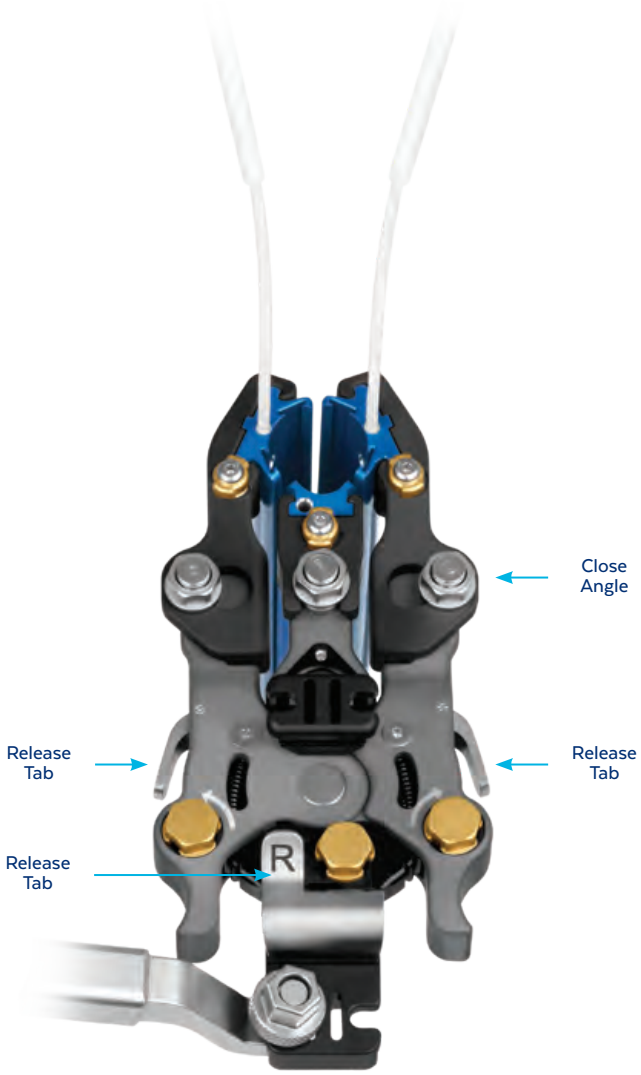
Radiographic axial view



Radiographic marker positions

Retractor Removal

To remove the retractor, 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, use a **Set Screw Driver, 2.5mm Hex** to unlock the blocking screw. Remove bone screws using a screwdriver. Remove anchors by reattaching the inserter and using a slap hammer.

Interbody removal may be performed using the Universal Implant Holder or other manual surgical instruments. Supplemental fixation may require removal before the implant is removed; refer to the corresponding surgical technique for removal instructions.

InterContinental®
IMPLANT SET

InterContinental® Plates Set 987.902

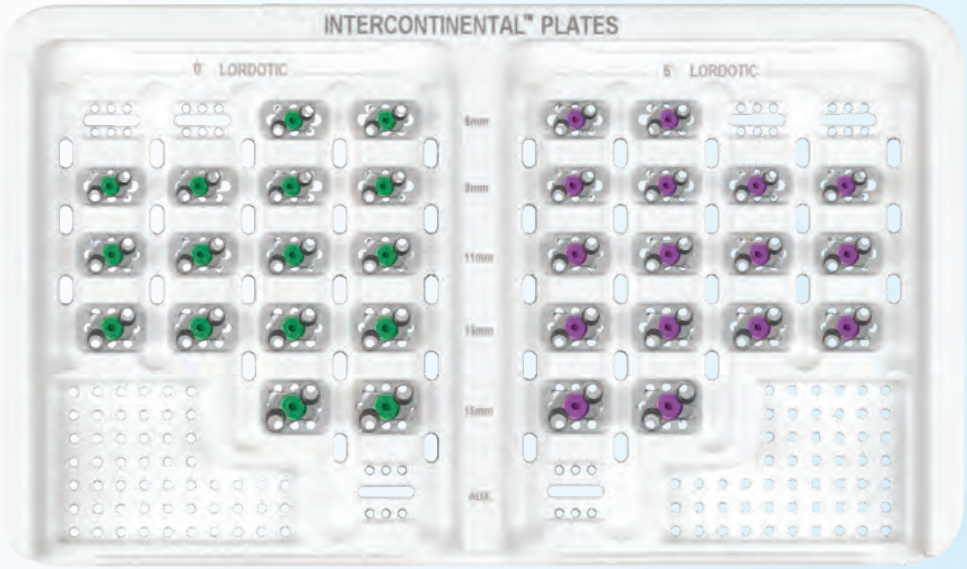
Part No.	Description	Qty
187.008	InterContinental® Plate 0° 20x8mm	2
187.009	InterContinental® Plate 0° 20x9mm	4
187.011	InterContinental® Plate 0° 20x11mm	4
187.013	InterContinental® Plate 0° 20x13mm	4
187.015	InterContinental® Plate 0° 20x15mm	2
187.058	InterContinental® Plate 6° 20x8mm	2
187.059	InterContinental® 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
187.017	InterContinental® Plate 0° 20x17mm	0
187.067	InterContinental® Plate 6° 20x17mm	0
987.002	InterContinental® Implant Graphic Case	

InterContinental® Screw Set 987.903

Part No.	Description	Qty
187.230S	5.5mm HA-Coated Screw, Variable 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
1187.245S	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
187.130S	5.5mm HA-Coated Screw, Fixed Angle, 30mm	0
187.135S	5.5mm HA-Coated Screw, Fixed Angle, 35mm	0
187.140S	5.5mm HA-Coated Screw, Fixed Angle, 40mm	0
187.145S	5.5mm HA-Coated Screw, Fixed Angle, 45mm	0
187.150S	5.5mm HA-Coated Screw, Fixed Angle, 50mm	0
187.155S	5.5mm HA-Coated Screw, Fixed Angle, 55mm	0
187.160S	5.5mm HA-Coated Screw, Fixed Angle, 60mm	0
187.260S	5.5mm HA-Coated Screw, Variable Angle, 60mm	0
987.003	InterContinental® HA Coated Screw Soft Pack	

**Items in gray are additionally available.*

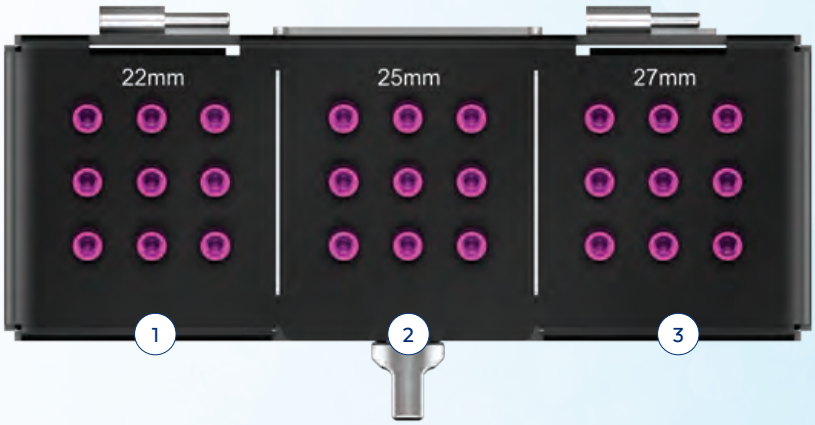
InterContinental®
IMPLANT SET

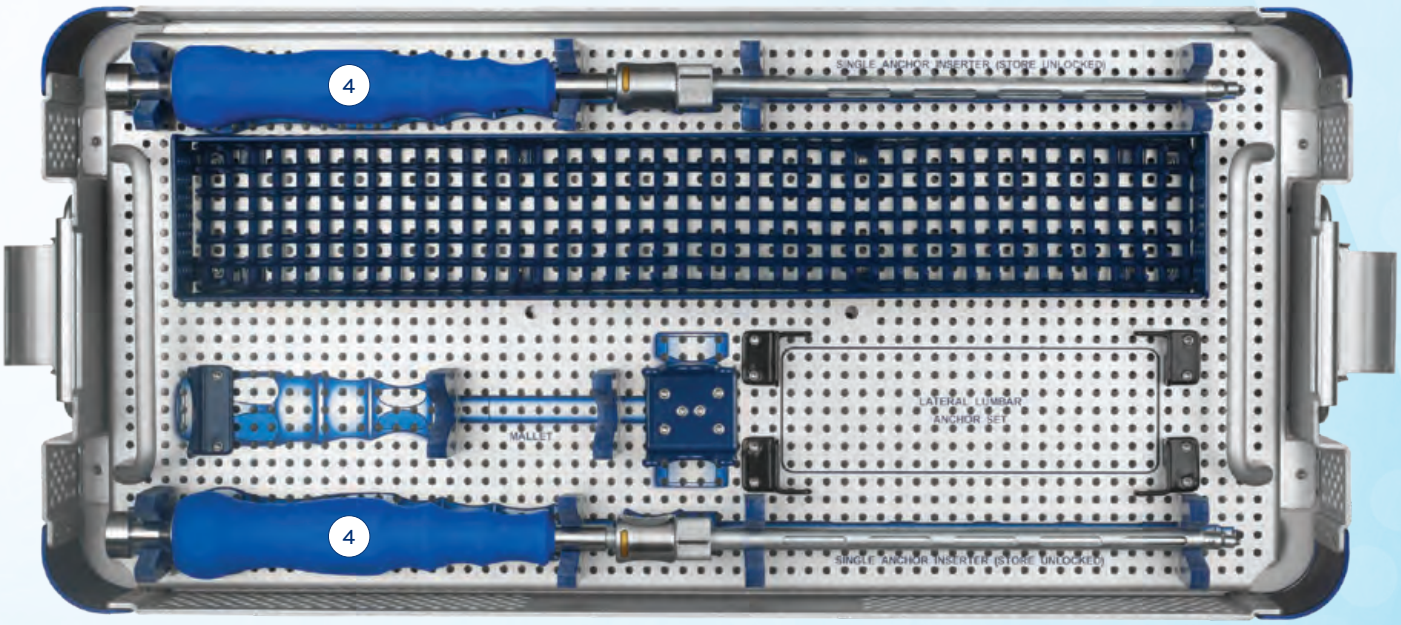


LATERAL MIS
IMPLANTS AND INSTRUMENTS SET 9219.9001

	Part No.	Description	Qty
	675.004	Long Throw Slide Hammer	1
1	1219.0022	Lateral Anchor 22mm	6
2	1219.0025	Lateral Anchor 25mm	6
3	1219.0027	Lateral Anchor 27mm	6
4	6219.1000	Single Anchor Inserter, Lateral	2
	9219.0001	Lateral MIS Anchor Module	
	9219.0002	Lateral MIS Graphic Case	

LATERAL MIS
IMPLANTS AND INSTRUMENTS SET 9219.9001





InterContinental® 20° and 25° Lordotic
IMPLANT SET 987.945

Part No.	Description	Qty
187.201	InterContinental® Plate - 20° Lordotic, 20x11mm	1
187.203	InterContinental® Plate - 20° Lordotic, 20x13mm	1
187.205	InterContinental® Plate - 20° Lordotic, 20x15mm	1
187.207	InterContinental® Plate - 20° Lordotic, 20x17mm	1
187.209	InterContinental® Plate - 20° Lordotic, 20x19mm	1
187.273	InterContinental® Plate - 25° Lordotic, 20x13mm	1
187.275	InterContinental® Plate - 25° Lordotic, 20x15mm	1
187.277	InterContinental® Plate - 25° Lordotic, 20x17mm	1
187.279	InterContinental® Plate - 25° Lordotic, 20x19mm	1
187.281	InterContinental® Plate - 25° Lordotic, 20x21mm	1
987.045	InterContinental® 20° and 25° Lordotic Module	

InterContinental® 20° and 25° Lordotic
IMPLANT SET 987.945

TransContinental® M
IMPLANT SET 975.951

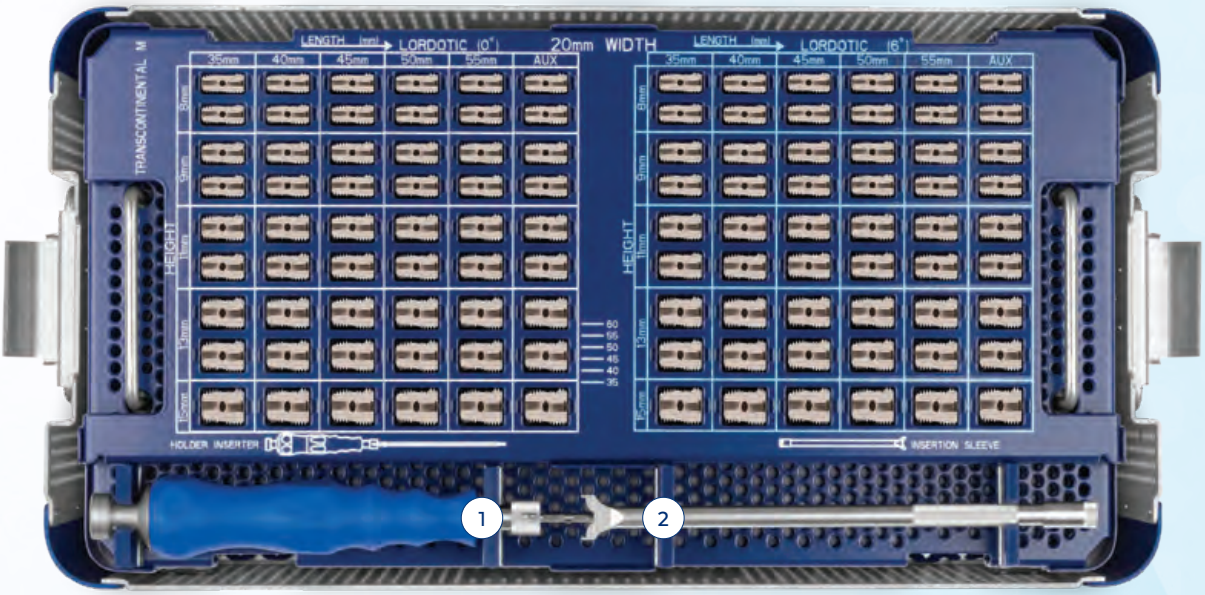
Part No.	Description	Qty
375.028	TransContinental® M Spacer, 20x35mm, 8mm	2
375.029	TransContinental® M Spacer, 20x35mm, 9mm	2
375.031	TransContinental® M Spacer, 20x35mm, 11mm	2
375.033	TransContinental® M Spacer, 20x35mm, 13mm	2
375.035	TransContinental® M Spacer, 20x35mm, 15mm	1
375.078	TransContinental® 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
375.528	TransContinental® M Spacer, 20x60mm, 8mm	1
375.529	TransContinental® M Spacer, 20x60mm, 9mm	1
375.531	TransContinental® M Spacer, 20x60mm, 11mm	1
375.533	TransContinental® M Spacer, 20x60mm, 13mm	1
375.535	TransContinental® M Spacer, 20x60mm, 15mm	1
375.578	TransContinental® M Spacer, 6° 20x60mm, 8mm	1
375.579	TransContinental® M Spacer, 6° 20x60mm, 9mm	1
375.581	TransContinental® M Spacer, 6° 20x60mm, 11mm	1
375.583	TransContinental® M Spacer, 6° 20x60mm, 13mm	1
375.585	TransContinental® M Spacer, 6° 20x60mm, 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
375.537	TransContinental® M Spacer, 20x60mm, 17mm
375.587	TransContinental® M Spacer, 6° 20x60mm, 17mm

**Items in gray are additionally available.*

TransContinental® M
IMPLANT SET 975.951



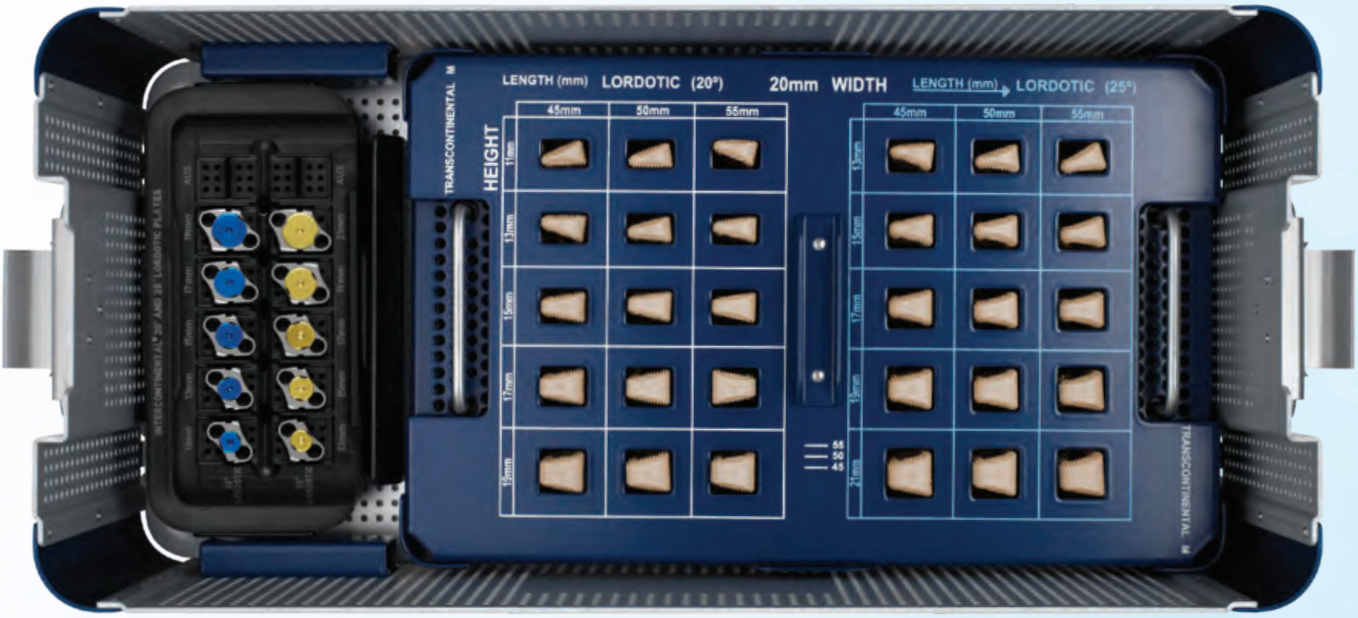
TransContinental® M 20° AND 25°
LORDOTIC SET 975.945

Part No.	Description	Qty
3375.722	TransContinental® M Spacer 20°, 20x45mm, 11mm	1
375.724	TransContinental® M Spacer 20°, 20x45mm, 13mm	1
375.726	TransContinental® M Spacer 20°, 20x45mm, 15mm	1
375.728	TransContinental® M Spacer 20°, 20x45mm, 17mm	1
375.730	TransContinental® M Spacer 20°, 20x45mm, 19mm	1
375.732	TransContinental® M Spacer 20°, 20x50mm, 11mm	1
375.734	TransContinental® M Spacer 20°, 20x50mm, 13mm	1
375.736	TransContinental® M Spacer 20°, 20x50mm, 15mm	1
375.738	TransContinental® M Spacer 20°, 20x50mm, 17mm	1
375.740	TransContinental® M Spacer 20°, 20x50mm, 19mm	1
375.822	TransContinental® M Spacer 20°, 20x55mm, 11mm	1
375.824	TransContinental® M Spacer 20°, 20x55mm, 13mm	1
375.826	TransContinental® M Spacer 20°, 20x55mm, 15mm	1
375.828	TransContinental® M Spacer 20°, 20x55mm, 17mm	1
375.830	TransContinental® M Spacer 20°, 20x55mm, 19mm	1
375.844	TransContinental® M Spacer 25°, 20x45mm, 13mm	1
375.859	TransContinental® M Spacer 25°, 20x45mm, 15mm	1
375.861	TransContinental® M Spacer 25°, 20x45mm, 17mm	1
375.863	TransContinental® M Spacer 25°, 20x45mm, 19mm	1
375.865	TransContinental® M Spacer 25°, 20x45mm, 21mm	1
375.922	TransContinental® M Spacer 25°, 20x50mm, 13mm	1
375.924	TransContinental® M Spacer 25°, 20x50mm, 15mm	1
375.926	TransContinental® M Spacer 25°, 20x50mm, 17mm	1
375.928	TransContinental® M Spacer 25°, 20x50mm, 19mm	1
375.930	TransContinental® M Spacer 25°, 20x50mm, 21mm	1
375.932	TransContinental® M Spacer 25°, 20x55mm, 13mm	1
375.934	TransContinental® M Spacer 25°, 20x55mm, 15mm	1
375.936	TransContinental® M Spacer 25°, 20x55mm, 17mm	1
375.938	TransContinental® M Spacer 25°, 20x55mm, 19mm	1
375.940	TransContinental® M Spacer 25°, 20x55mm, 21mm	1

Additionally Available	
375.622	TransContinental® M Spacer 20°, 20x35mm, 11mm
375.624	TransContinental® M Spacer 20°, 20x35mm, 13mm
375.626	TransContinental® M Spacer 20°, 20x35mm, 15mm
375.628	TransContinental® M Spacer 20°, 20x35mm, 17mm
375.630	TransContinental® M Spacer 20°, 20x35mm, 19mm
375.632	TransContinental® M Spacer 20°, 20x40mm, 11mm
375.634	TransContinental® M Spacer 20°, 20x40mm, 13mm
375.636	TransContinental® M Spacer 20°, 20x40mm, 15mm
375.638	TransContinental® M Spacer 20°, 20x40mm, 17mm
375.640	TransContinental® M Spacer 20°, 20x40mm, 19mm
375.644	TransContinental® M Spacer 25°, 20x35mm, 13mm
375.659	TransContinental® M Spacer 25°, 20x35mm, 15mm
375.661	TransContinental® M Spacer 25°, 20x35mm, 17mm
375.663	TransContinental® M Spacer 25°, 20x35mm, 19mm
375.665	TransContinental® M Spacer 25°, 20x35mm, 21mm
375.744	TransContinental® M Spacer 25°, 20x40mm, 13mm
375.759	TransContinental® M Spacer 25°, 20x40mm, 15mm
375.761	TransContinental® M Spacer 25°, 20x40mm, 17mm
375.763	TransContinental® M Spacer 25°, 20x40mm, 19mm
375.765	TransContinental® M Spacer 25°, 20x40mm, 21mm

*Items in gray are additionally available.

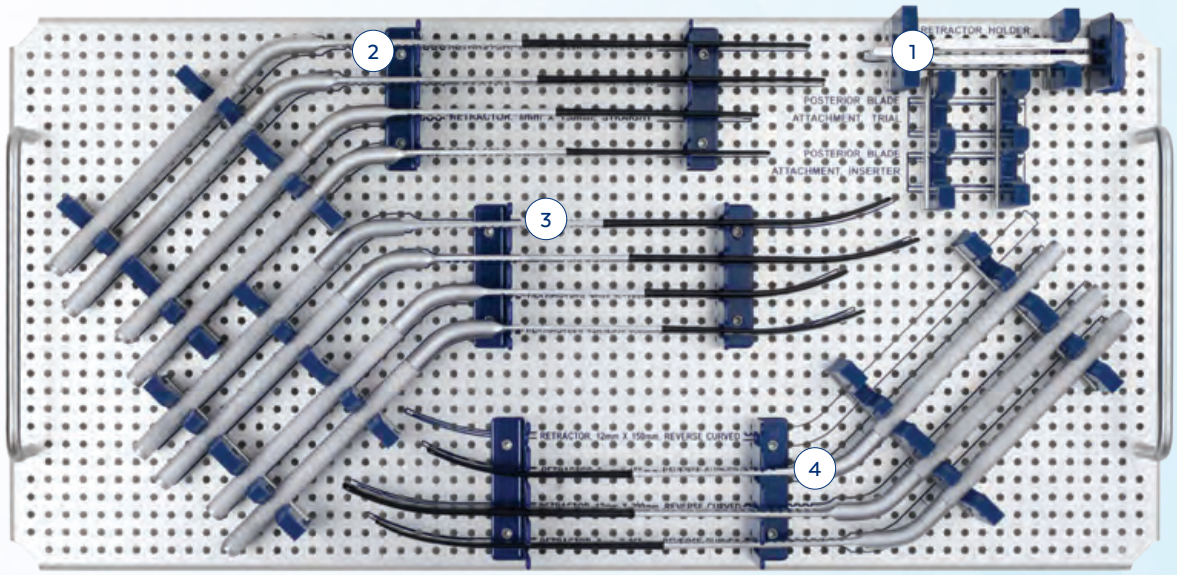
TransContinental® M 20° AND 25°
LORDOTIC SET 975.945

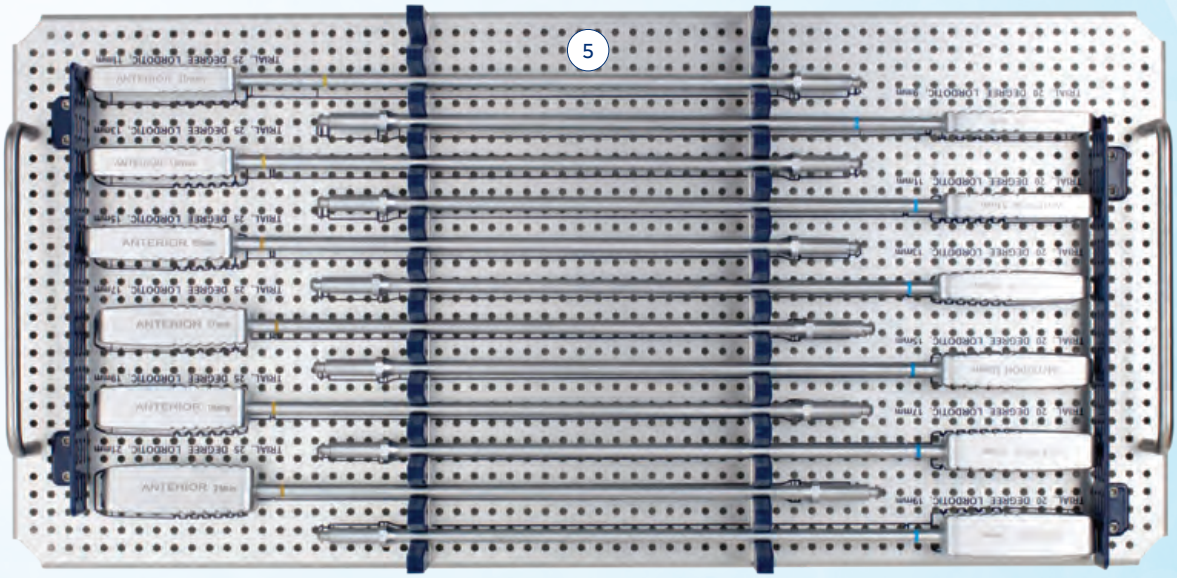


TransContinental® M 20° AND 25° LORDOTIC SET 975.945

	Part No.	Description	Qty
1	687.150	Retractor Holder	1
2	687.151	Retractor, 8x150mm, Straight	1
	687.152	Retractor, 8x200mm, Straight	1
	687.153	Retractor, 12x150mm, Straight	1
	687.154	Retractor, 12x200mm, Straight	1
3	687.157	Retractor, 8x150mm, Curved	1
	687.158	Retractor, 8x200mm, Curved	1
	687.159	Retractor, 12x150mm, Curved	1
	687.160	Retractor, 12x200mm, Curved	1
4	687.163	Retractor, 8x150mm, Reverse Curved	1
	687.164	Retractor, 8x200mm, Reverse Curved	1
	687.165	Retractor, 12x150mm, Reverse Curved	1
	687.166	Retractor, 12x200mm, Reverse Curved	1
5	687.800	Trial, 20° Lordotic, 9mm	1
	687.801	Trial, 20° Lordotic, 11mm	1
	687.803	Trial, 20° Lordotic, 13mm	1
	687.805	Trial, 20° Lordotic, 15mm	1
	687.807	Trial, 20° Lordotic, 17mm	1
	687.809	Trial, 20° Lordotic, 19mm	1
	687.811	Trial, 25° Lordotic, 11mm	1
	687.813	Trial, 25° Lordotic, 13mm	1
	687.815	Trial, 25° Lordotic, 15mm	1
	687.817	Trial, 25° Lordotic, 17mm	1
	687.819	Trial, 25° Lordotic, 19mm	1
	687.821	Trial, 25° Lordotic, 21mm	1
	975.045	TransContinental® M 20° and 25° Graphic Case	

TransContinental® M 20° AND 25°
LORDOTIC SET 975.945





InterContinental®
INSTRUMENT SET 987.901

	Part No.	Description	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

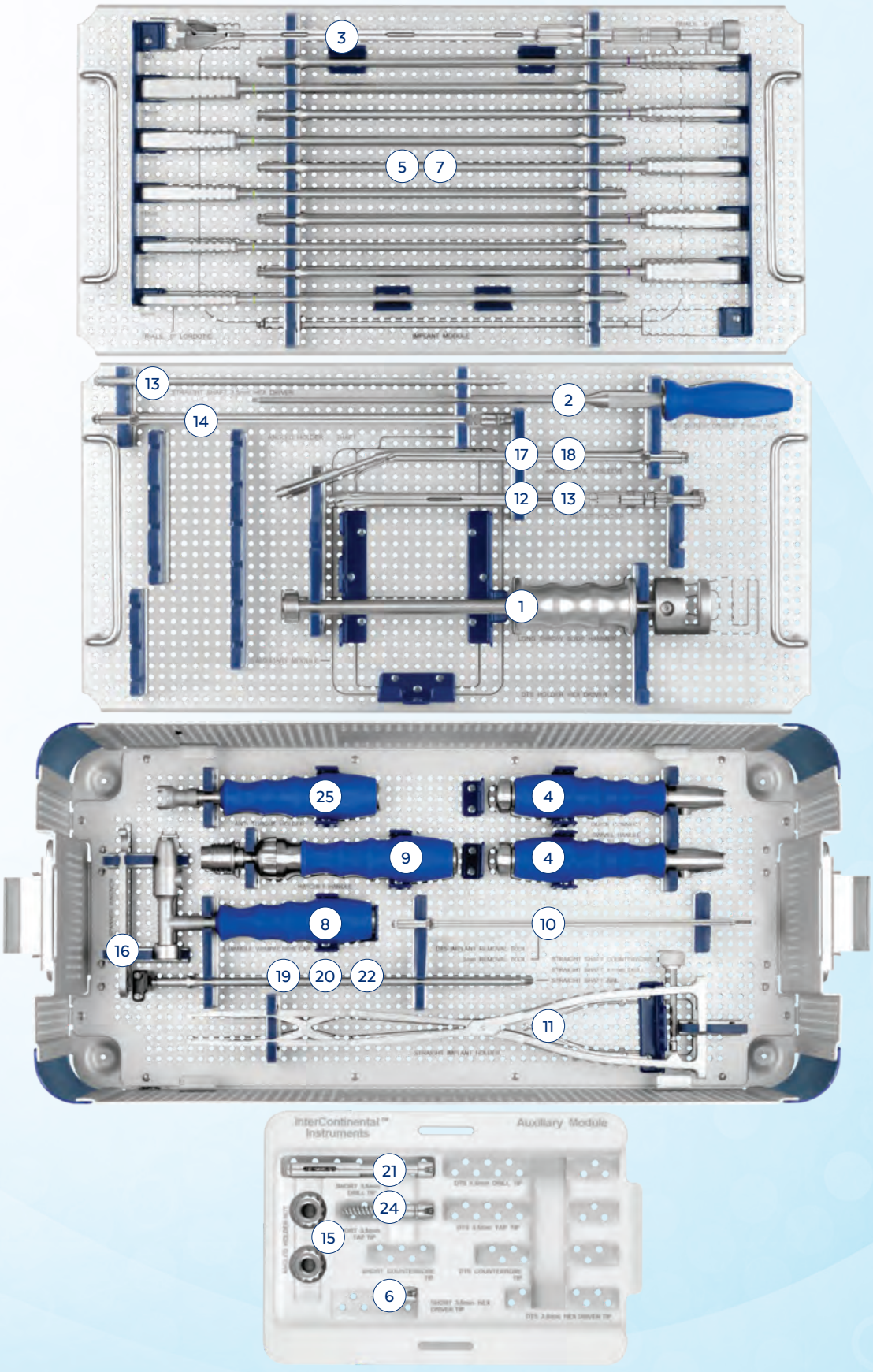
	Part No.	Description	Qty
21	687.521	Short 5.5mm Drill Tip	1
22	687.524	Straight Shaft Awl	1
23	687.527	Straight Shaft 3.5mm Hex Driver	1
24	687.721	Short 5.5mm Tap Tip	1
25	687.906	Anti-Torque Holder	1
	987.001	Instrument Graphic Case	

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

**Items in gray are additionally available.*

InterContinental®
INSTRUMENT SET 987.901



MARS™3V
RETRACTOR SET 998.901

	Part No.	Description	Qty
1	623.003	K-Wire Gripper	1
2	698.100	Retractor 3 Blade Frame	1
3	632.102	R etractor 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
	698.476	Blade, Posterior, 170mm	2
	698.510	Blade, CC, 40mm	2
	698.512	Blade, CC, 50mm	2

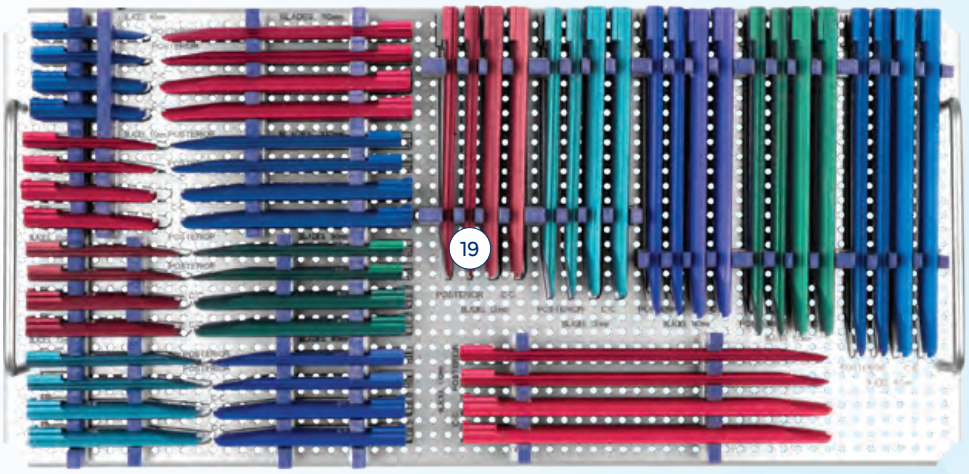
Retractor Blades		Qty
698.514	Blade, CC, 60mm	2
698.516	Blade, CC, 70mm	2
698.518	Blade, CC, 80mm	2
698.520	Blade, CC, 90mm	2
698.522	Blade, CC, 100mm	2
698.524	Blade, CC, 110mm	2
698.526	Blade, CC, 120mm	2
698.528	Blade, CC, 130mm	2
698.530	Blade, CC, 140mm	2
698.532	Blade, CC, 150mm	2
698.534	Blade, CC, 160mm	2
698.536	Blade, CC, 170mm	2

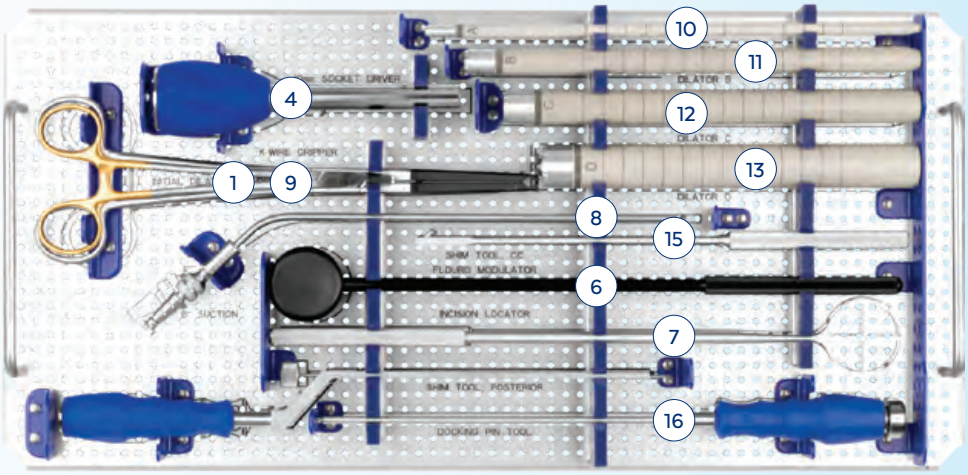
Disposables

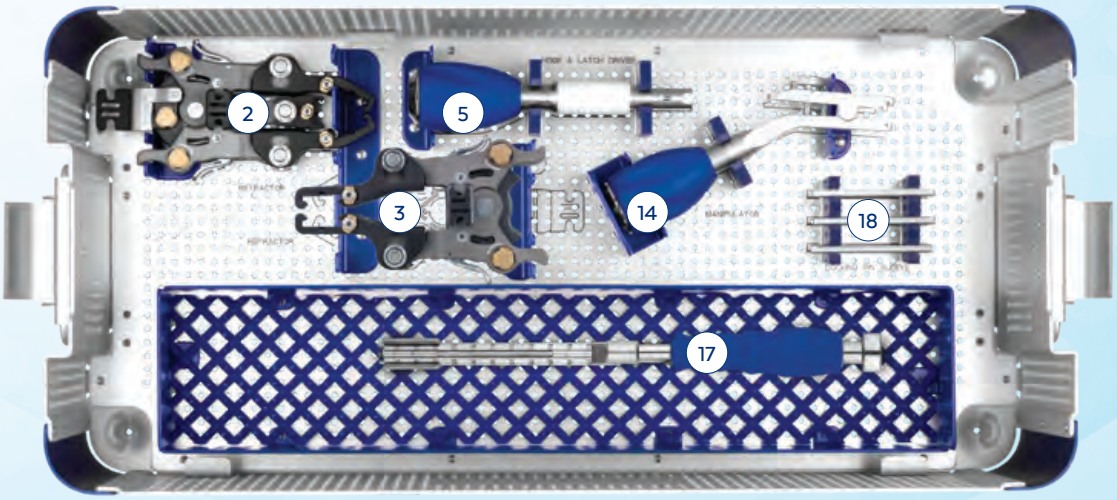
632.678S	Bipolar Forceps, 10” Bayo, 1.0mm Tip	1
698.600S	MARS™3V Disposable Kit	1
698.300S	Lengthening Shim	2
698.305S	Widening Shim	2
698.310S	Docking Pin, 10mm	2
698.315S	Docking Pin, 20mm	2
698.325S	Disc Shim, Aluminum	1
698.326S	Disc Shim, Stainless Steel	0

**Items in gray are additionally available.*

MARS™3V
RETRACTOR SET 998.901





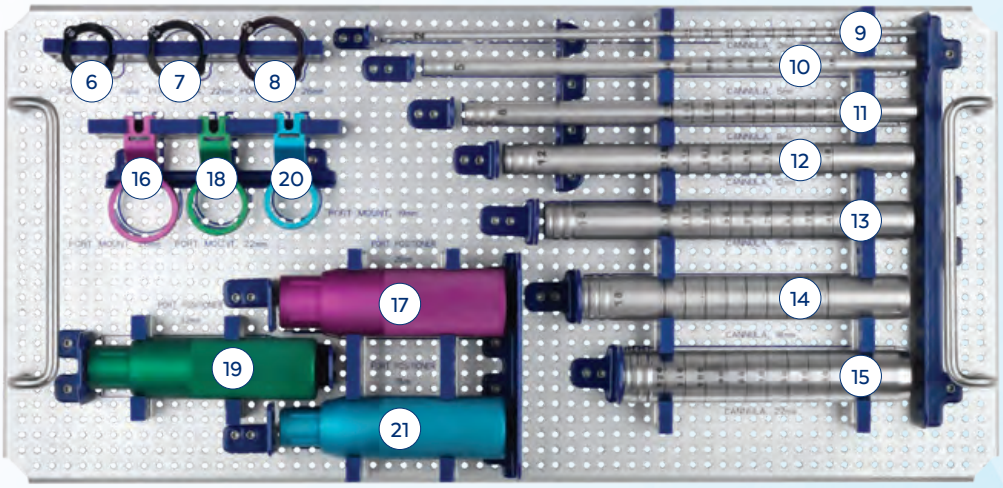


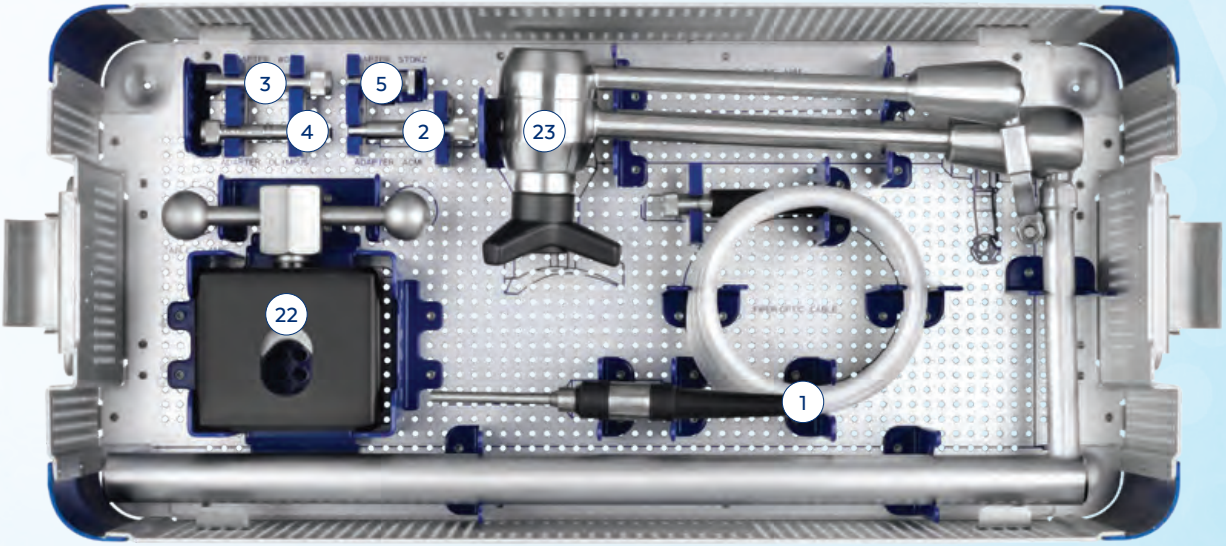
MARS™
INSTRUMENT II SET 932.902

	Part No.	Description	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	0
	932.002	MARS™ Instrument II Graphic Case	

**Items in gray are additionally available.*

MARS™
INSTRUMENT II SET 932.902





LATERAL DISC PREP
INSTRUMENT SET 975.914

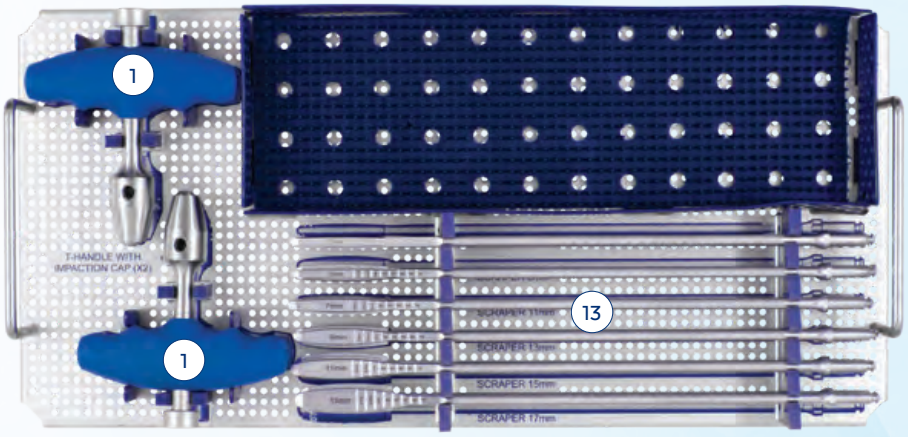
	Part No.	Description	Qty
1	6675.005	T-Handle with Impaction Cap	2
2	675.503	Large Cobb Elevator	1
3	675.504	Small Cobb Elevator	1
4	675.510	Thin Rasp, 12x20mm	1
5	675.515	Cobb, 10mm, 7° Up-Angled	1
6	675.516	Cobb, 20mm, 7° Up-Angled	1
7	675.518	Ring Curette, 10mm, Straight	1
8	675.519	Ring Curette, 10mm, 7° Up-Angle Tip	1
9	675.520	Double Rasp	1
10	675.525	Cup Curette, 6.5x9.5mm, Straight	1
11	675.526	Cup Curette, 6.5x9.5mm, 15° Up-Angle	1
12	675.527	Cup Curette, 6.5x9.5mm, 90° Down-Angle	1
13	675.605	Scraper, 5mm	1
	675.607	Scraper, 7mm	1
	675.609	Scraper, 9mm	1
	675.611	Scraper, 11mm	1
	675.613	Scraper, 13mm	1
	675.615	Scraper, 15mm	1
	675.617	Scraper, 17mm	1
	675.855	Paddle Distractor, 5mm	1
	675.857	Paddle Distractor, 7mm	1
	675.859	Paddle Distractor, 9mm	1
	675.861	Paddle Distractor, 11mm	1
	675.863	Paddle Distractor, 13mm	1
	975.008	TransContinental® Graphic Case - Disc Prep	

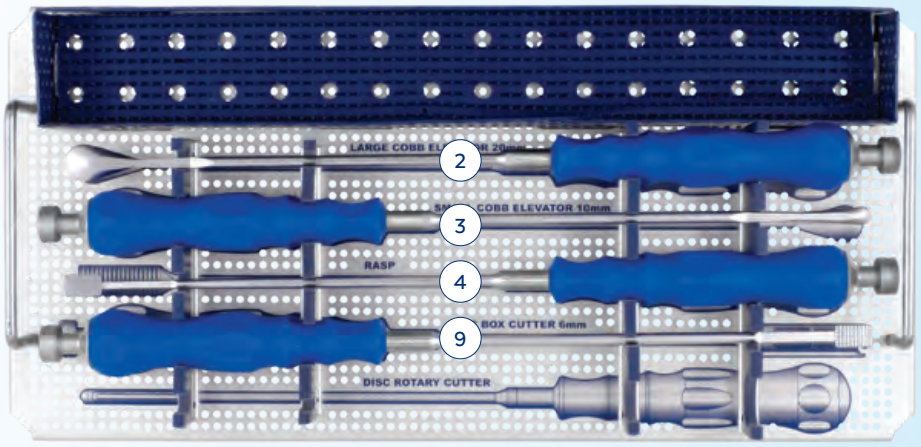
Additionally Available

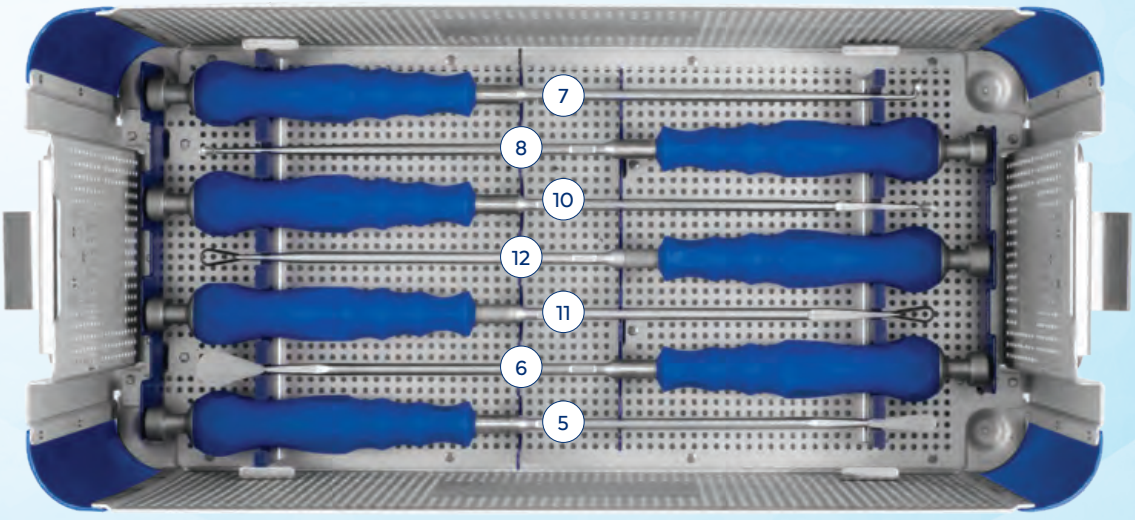
675.170S	Bipolar Forceps Bayonetted, Straight
675.171S	Bipolar Forceps Bayonetted, Angled

**Items in gray are additionally available.*

LATERAL DISC PREP
INSTRUMENT SET 975.914



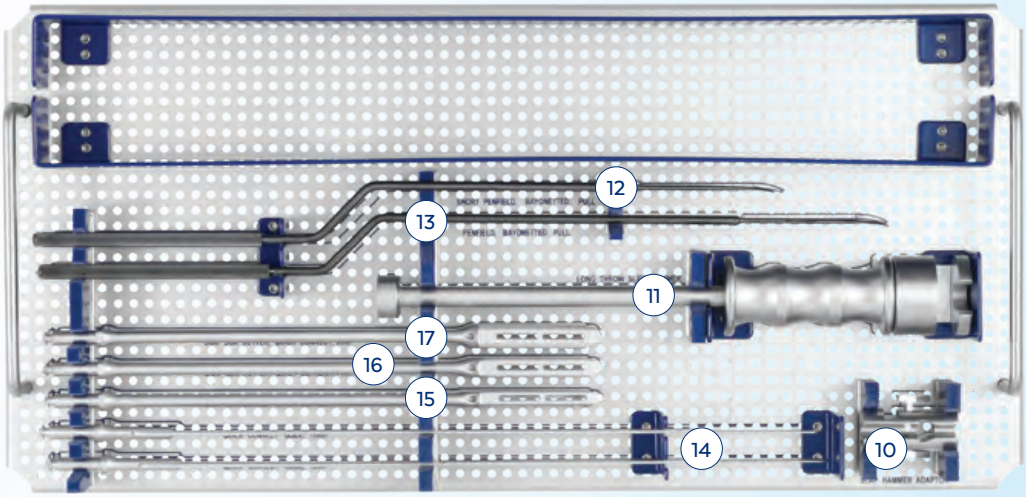


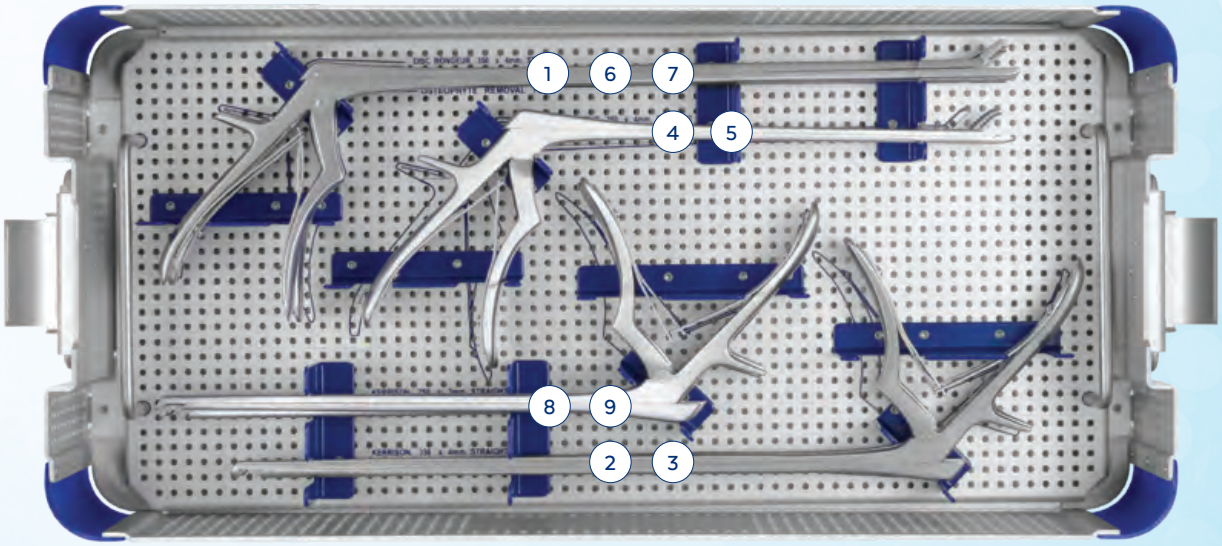


LATERAL DISC PREP II
INSTRUMENT SET 975.917

	Part No.	Description	Qty
1	66105.2016	Osteophyte Removal Tool	1
2	625.202	Kerrison, 4mm	1
3	625.203	Kerrison, 6mm	1
4	625.305	Disc Rongeur, 4mm	1
5	625.307	Disc Rongeur, 6mm	1
6	626.240	Disc Rongeur, 250x4mm, Straight	1
7	626.241	Disc Rongeur, 250x6mm, Straight	1
8	626.250	Kerrison, 250x3mm, Straight	1
9	626.252	Kerrison, 250x5mm, Straight	1
10	675.002	Slap Hammer Adaptor	1
11	675.004	Long Throw Slide Hammer	1
12	675.173	Penfield, Bayonetted, Pull	1
13	675.174	Penfield #4, Pull, 190mm	1
14	675.201	Quick-Connect Guide, 12mm	2
15	675.533	Disc Box Cutter, 5mm	1
16	675.534	Disc Box Cutter, 7mm	1
17	675.535	Disc Box Cutter, 9mm	1
	975.017	LLIF Disc Prep II Graphic Case	

LATERAL DISC PREP II
INSTRUMENT SET 975.917





Important Information on the InterContinental® Plate-Spacer

DESCRIPTION

InterContinental® Plate-Spacers are lateral lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. InterContinental® Plate-Spacers are 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® Plate-Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone, and are to be used with 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-Spacers are manufactured from radiolucent PEEK polymer, with titanium alloy or tantalum markers, as specified in ASTM F136, F560, F1295, and F2026. The plates in the InterContinental® Plate-Spacers are manufactured from titanium alloy, as specified in ASTM F136 and F1295. The screws and anchors in the InterContinental® Plate-Spacers 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. Locking screws are manufactured from cobalt chromium alloy, as specified in ASTM F1537. InterContinental® TPS Plate-Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

INDICATIONS

InterContinental® Plate-Spacers are lateral lumbar interbody fusion devices indicated for use at one or more levels of the lumbosacral spine (L1-S1), as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. All InterContinental® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

InterContinental® Plate-Spacers are intended to be used with or without two screws and/or anchors which accompany the implants. These devices are intended for use with supplemental fixation (e.g. facet screws or posterior fixation). InterContinental® Plate-Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone.

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.

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 involved 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, commercially pure titanium, and tantalum. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

These warnings do not include all adverse effects that could occur with surgery in general, but are important considerations particular to orthopedic implants. General surgical risks should be explained to the patient prior to surgery.

Use this device as supplied and in accordance with the handling and use information provided below.

PRECAUTIONS

The implantation of intervertebral fusion devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

Surgical implants must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

For optimal implant performance, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

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.

MRI SAFETY INFORMATION

The InterContinental® Plate-Spacer is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scan conditions defined above, the InterContinental® Plate-Spacer is expected to produce a maximum temperature rise of less than or equal to 3.9°C after 15 minutes of continuous scanning.

The image artifact caused by the device is not expected to extend beyond 35mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

CONTRAINDICATIONS

Use of these devices 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 a suspected or documented allergy, foreign body sensitivity, or known intolerance to any of the implant materials.
2. Signs of local inflammation.
3. Prior fusion at the level(s) to be treated.
4. Severe osteoporosis, which may prevent adequate fixation.
5. 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 risk versus the benefits to the patient.
6. 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.
7. Any patient not willing to cooperate with postoperative instructions.
8. Any condition not described in the indications for use.
9. Fever or leukocytosis.
10. Morbid obesity
11. Pregnancy.
12. Mental illness.
13. Any other condition that would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevations of the white blood count (WBC), or a marked left shift in the WBC differential count.
14. Suspected or documented allergy or intolerance to composite materials.
15. Any case not needing a fusion.

Important Information on the InterContinental® LLIF Plate-Spacer

16. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
17. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
18. Spondylolisthesis unable to be reduced to Grade 1.
19. Any case where the implant components selected for used would be too large or too small to achieve a successful result.
20. Any case that requires the mixing of metals from two different components or systems.
21. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
22. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS

Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential need for additional surgery to correct these effects:

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

PACKAGING

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

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

HANDLING AND USE

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

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

CLEANING

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

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

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

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

CONTACT INFORMATION

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

STERILIZATION

These implants and instruments may be available sterile or nonsterile. HA-coated implants are only available sterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, double pouch or container/pouch. The

expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below. Sterile implants meet pyrogen limit specifications.

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

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

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

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

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

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

CAUTION: Federal (U.S.A.) Law restricts this Device to Sale by or on the Order of a Physician.

REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

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NOTES

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