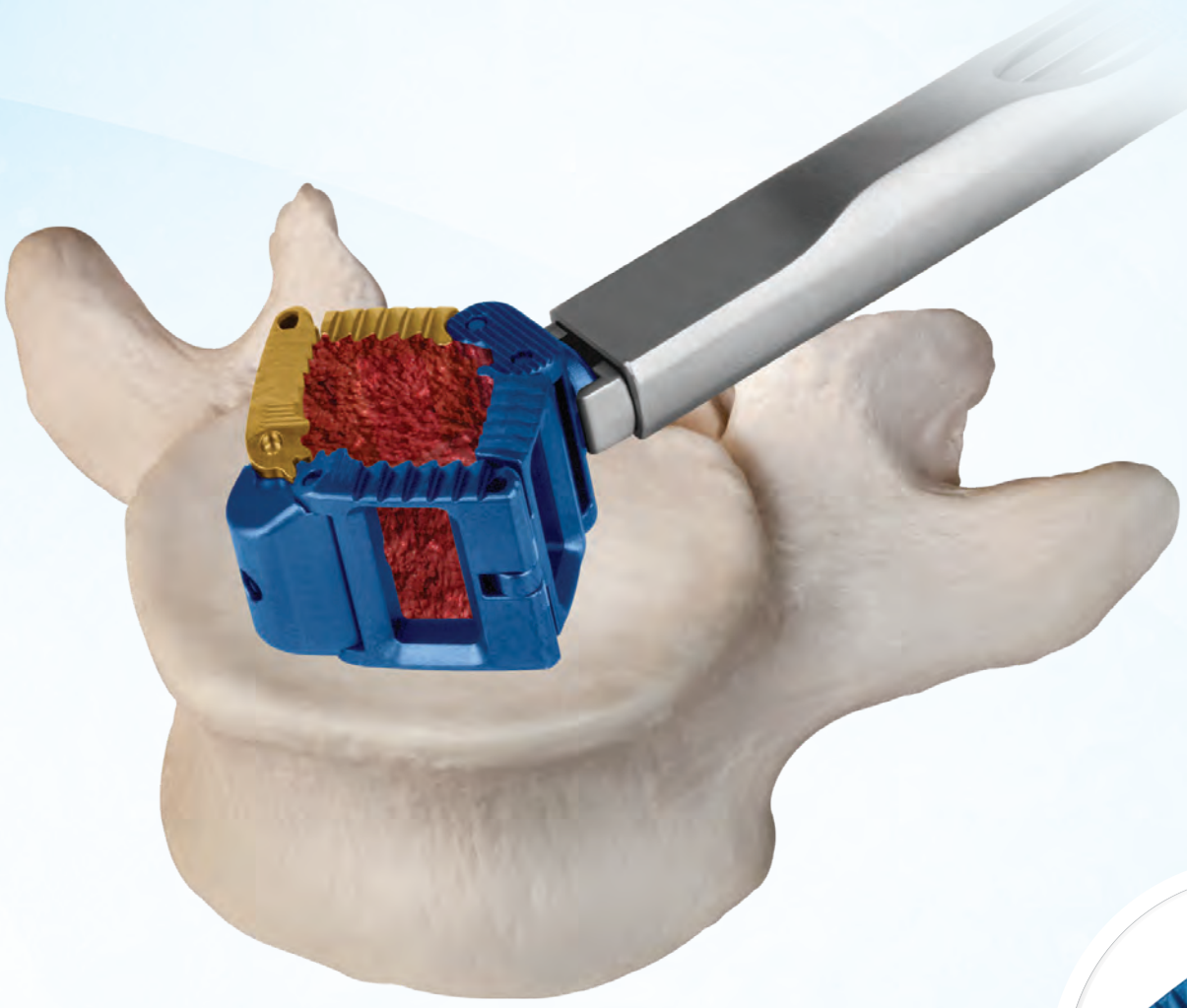
GLOBUS MEDICAL



LATIS®

The TLIF Spacer with an ALIF Footprint

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.

Life moves us

SURGICAL TECHNIQUE GUIDE

LATIS®

LATIS®

The TLIF Spacer with an ALIF Footprint

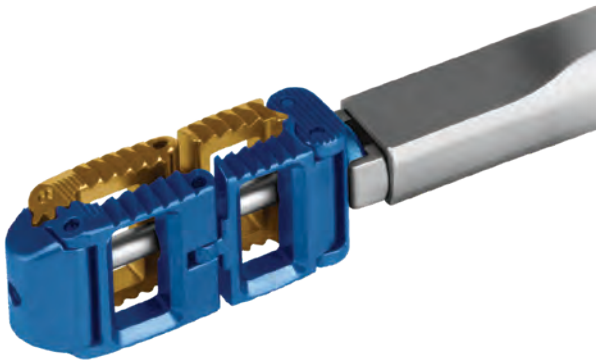
LATIS® is an innovative expandable lumbar interbody fusion spacer designed to maximize the footprint, surface area and graft volume from a transforaminal approach.

The ability to expand and lock at various intervals, combined with a variety of implant footprint heights and lordotic options, allows surgeons to provide a more customized patient fit.

When fully expanded, LATIS® creates the largest single graft chamber of any TLIF implant on the market, allowing for a distinctively large fusion mass.

Contracted

Fully Expanded



MIS Approach, Maximized Footprint

LATIS® expands laterally *in situ,* optimizing apophyseal ring engagement to potentially reduce subsidence.

Maximized Fusion Bed

Once expanded, LATIS® creates a substantial single graft chamber allowing for a distinctively large fusion mass.

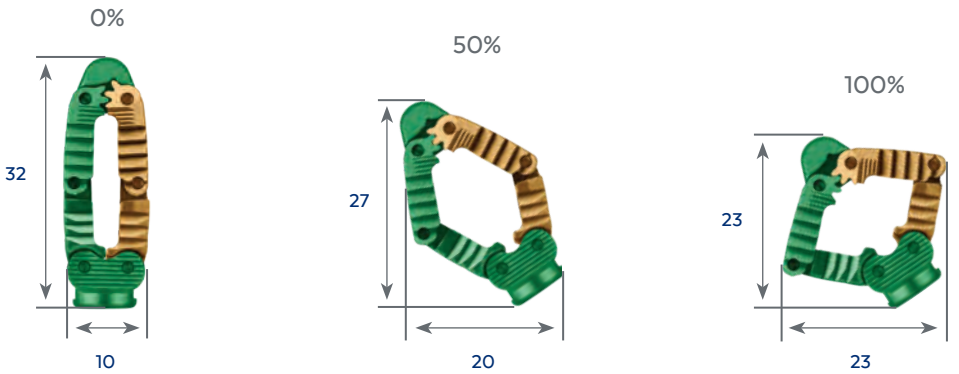
Migration Resistance

The expanded implant geometry and slotted tooth pattern are designed to help resist implant migration.

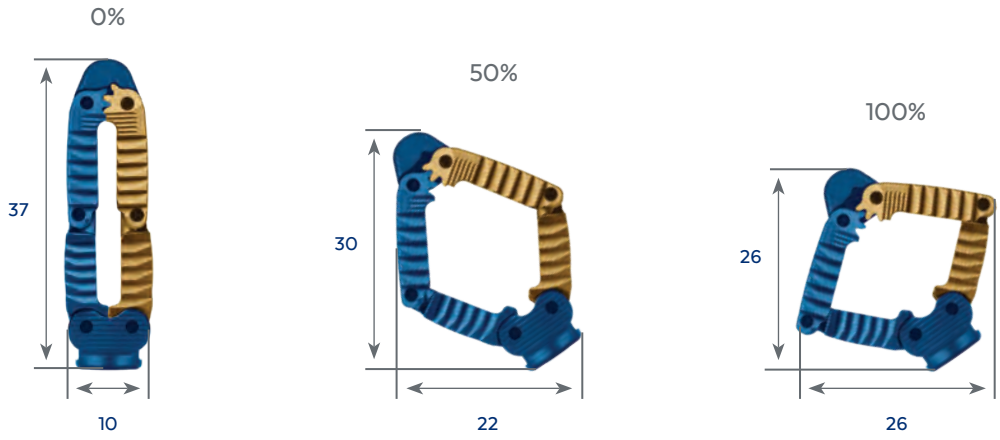
IMPLANT OVERVIEW

- Low-profile design for minimally invasive surgery (MIS) applications
- Bullet-nosed leading edge eases impaction into the disc space
- *In situ* graft delivery maximizes packing of bone graft into the implant
- Large axial graft chamber
- Implant interference links retain implant shape, while the set screw provides secure locking at any expansion range
- Single instrument for insertion, expansion, locking and bone graft delivery

Small Footprint



Medium Footprint



Heights	7–15mm (1mm increments), 17mm
Lordotic Option	Available in heights ≥ 9mm

**Additionally available*

INSTRUMENT OVERVIEW

SIZERS/SHAVERS

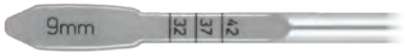
Sizer/Shaver

	Height	Part No.
	7mm	681.307
	8mm	681.308
	9mm	681.309
	10mm	681.310
	11mm	681.311
	12mm	681.312
	13mm	681.313
	14mm	681.314
	15mm	681.315
	17mm	681.317

INSTRUMENT OVERVIEW

PADDLE DISTRACTORS

Paddle Distractor

	Height	Part No.
	7mm	681.407
	8mm	681.408
	9mm	681.409
	10mm	681.410
	11mm	681.411
	12mm	681.412
	13mm	681.413
	14mm	681.414
	15mm	681.415
	17mm	681.417

Additionally Availble Paddle Distractors: 5mm (681.405) and 6mm (681.406)

INSTRUMENT OVERVIEW

IMPLANT INSERTER COMPONENTS

Inserter Body 681.850

Small T-Handle Actuator 681.853

Medium T-Handle Actuator 681.863

Inserter Sleeve 681.851

Small Threaded Shaft 681.852

Medium Threaded Shaft 681.862

Inserter Body 681.850
Small T-Handle Actuator 681.853
Inserter Sleeve 681.851
Small Threaded Shaft 681.852
(Assembled)

INSTRUMENT OVERVIEW

LOCKING INSTRUMENT

Torque-Limiting Locking Screwdriver 681.855

GRAFT INSERTION INSTRUMENTS

Bone Funnel Tube 681.854

Bone Funnel Pusher 681.856

Bone Funnel 681.013

TRIALING INSTRUMENTS

Counter-Torque 681.699

Adjustable Footprint Trial, Small 681.207

Adjustable Footprint Trial, Medium 681.507

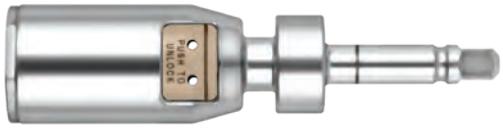
INSTRUMENT OVERVIEW

TRIALING INSTRUMENTS (CONT'D)

Torque-Limiting Palm Handle 694.002

Adjustable Trial 10x26mm, 7-14mm 693.212

MIS Handle 673.003



Removable Drive, Right Hand 694.218

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

INSTRUMENT OVERVIEW

REMOVAL INSTRUMENTS

Removal Tool 681.511

Slide Hammer 681.858

Compressor 681.857

SURGICAL TECHNIQUE

LATIS®

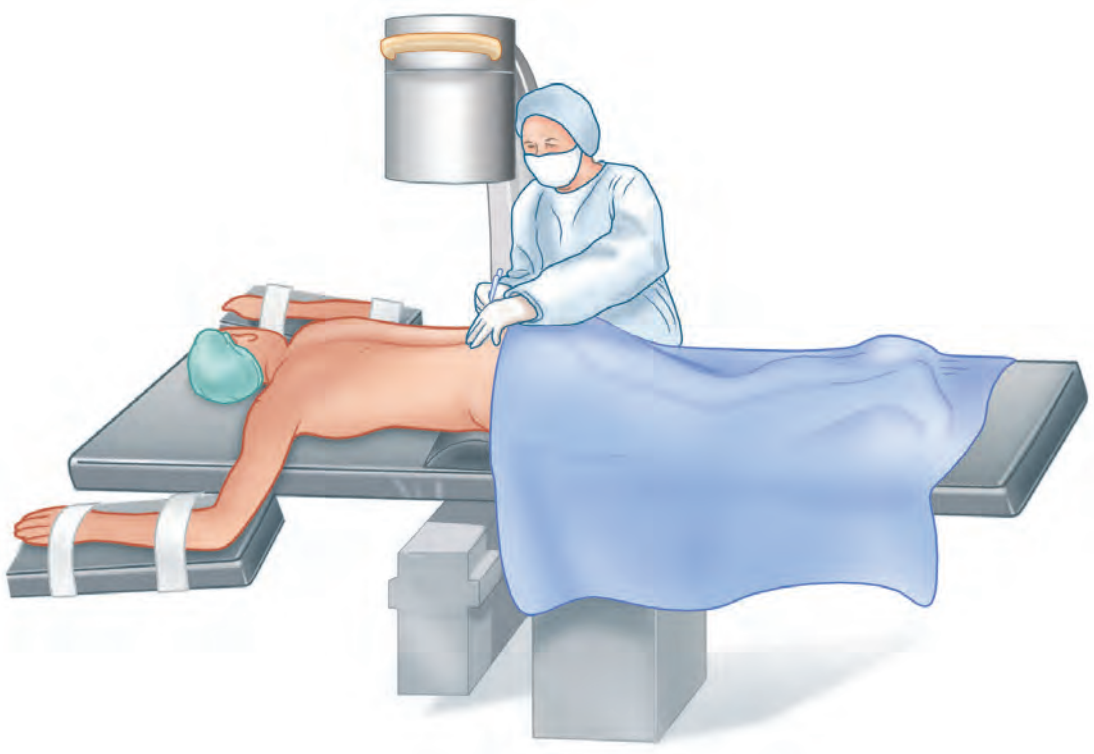
Please refer to the package insert, also printed at the back of this manual, for complete description, indications, contraindications, precautions and warnings.

STEP 1 TRANSFORAMINAL ACCESS AND APPROACH

Approach

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

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



STEP 2 USING THE RETRACTOR*

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

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

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

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

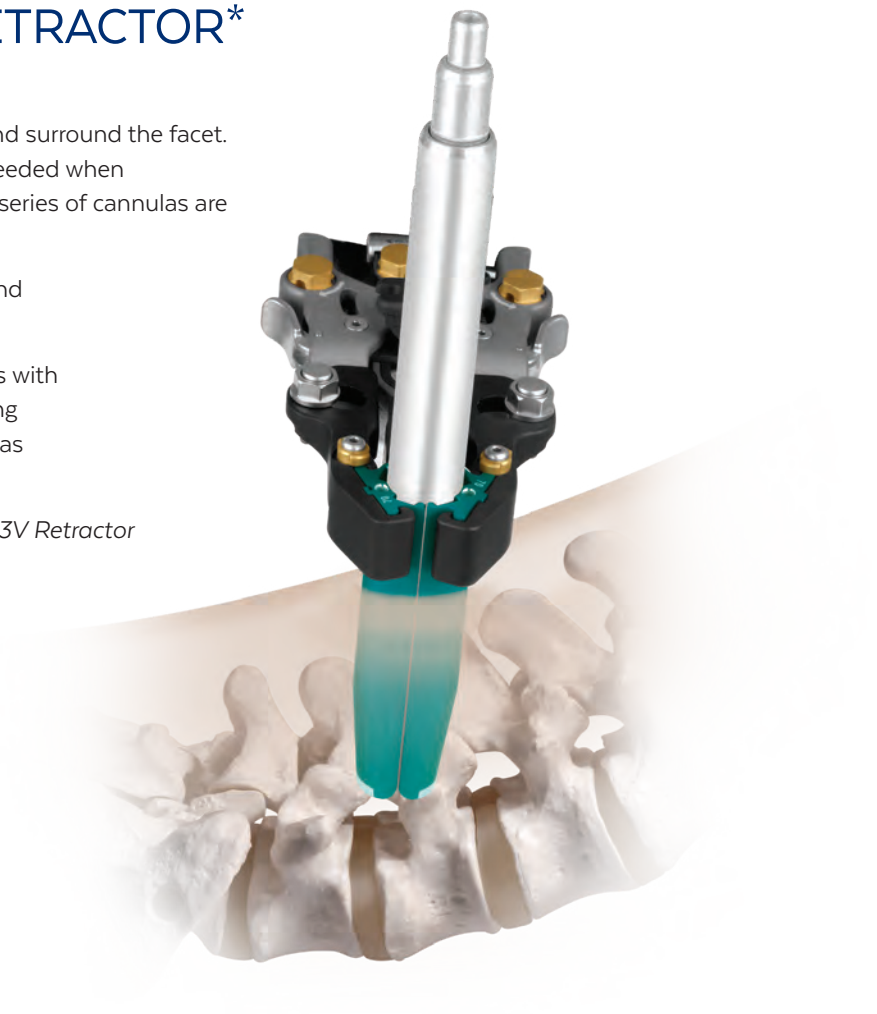


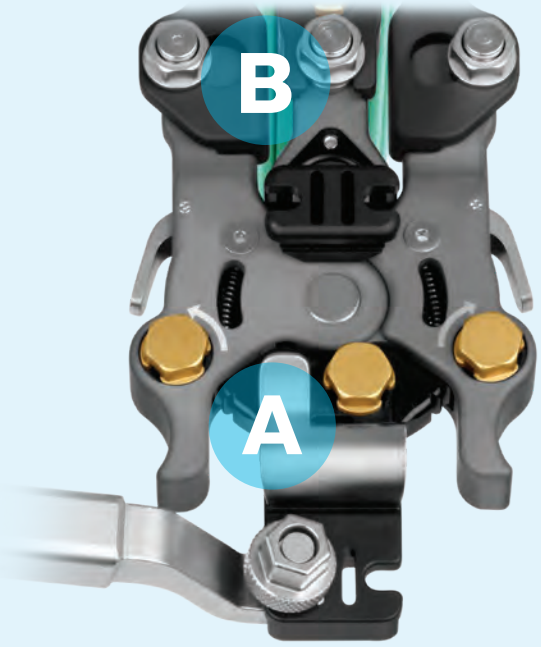
TABLE ARM ATTACHMENT

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

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

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

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

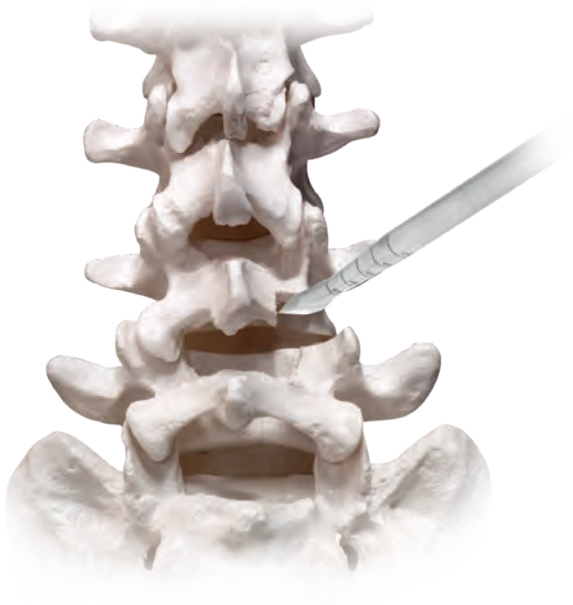


STEP 3 CREATING TRANSFORAMINAL ACCESS

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

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

Approach via MARS™ 3V Retractor system

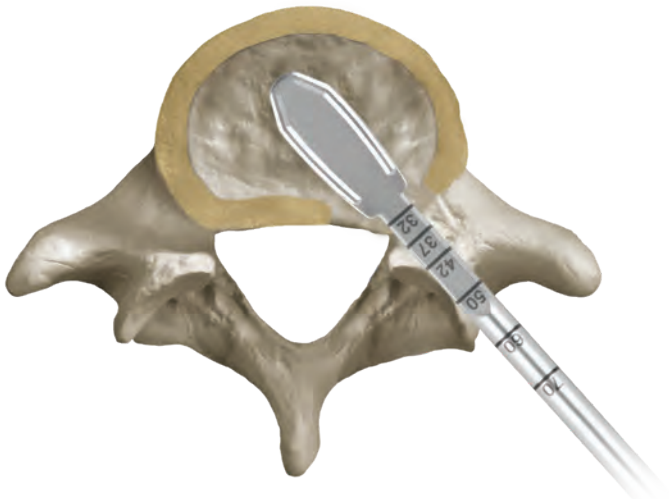


Creating transforaminal access

STEP 4 DISCECTOMY/ENDPLATE PREPARATION

After creating a sufficient annular window, remove disc material using rongeurs, rasps, curettes and other suitable preparation instruments.* **Sizers/Shavers** may be used to remove superficial layers of the cartilaginous endplates. As much of the annulus as possible should be preserved to provide peripheral support for the implant and bone graft. Insert the smallest shaver into the disc space for further disc removal and endplate preparation, moving to the larger shavers as needed. Use caution while using the shavers to avoid damage to the endplate. Careful disc removal and endplate preparation maximizes the potential for a successful fusion. A thorough discectomy must be performed to allow for lateral implant expansion.

**Available in the Posterior Disc Prep Instruments Set I (926.901)*

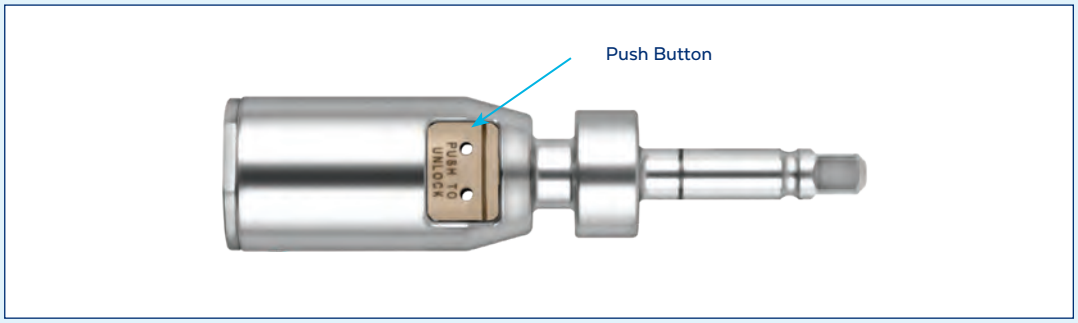


STEP 5 HEIGHT SIZING

Insert the **Paddle Distractors** or **Adjustable Trial** to determine which implant height best fits the prepared disc space.

ASSEMBLING THE ADJUSTABLE TRIAL ASSEMBLY

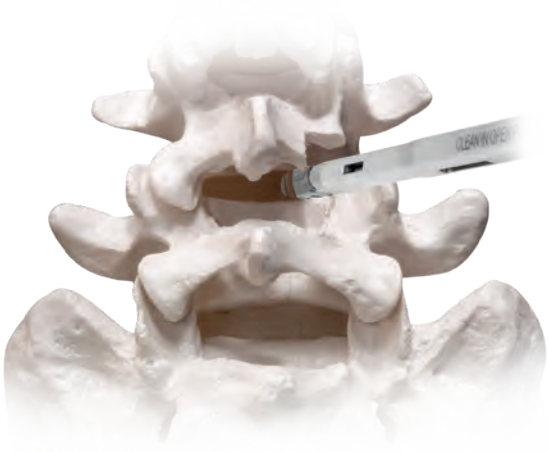
1. Ensure that the **Removable Drive, Right Hand** is in the unlocked position by verifying that the PEEK push button is protruding beyond the cylinder.



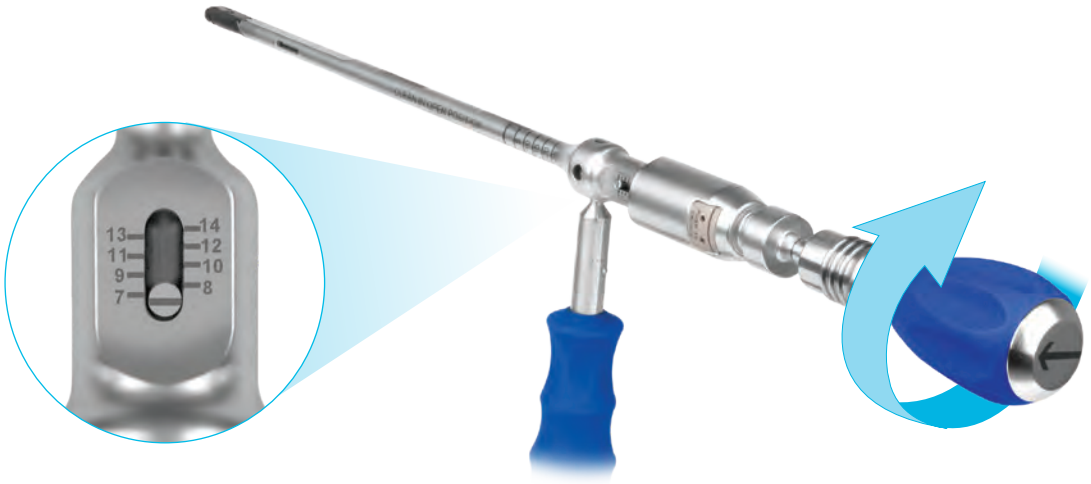
2. Hold the shaft of the trial while rotating the removable drive onto the threaded end until it stops and rotate back 1/8th of a turn to reduce tension. To lock, push the protruding push button until it is flush with the cylinder.

3. Thread the **MIS Handle** into the threaded hole.
4. Attach the **Torque-Limiting Palm Handle**.
5. The Adjustable Trial Assembly is now ready for use.

Gently insert the Adjustable Trial Assembly into the disc space at its contracted height. Expand gradually to the desired height by rotating the palm handle clockwise. Use fluoroscopy to identify which implant height best fits the disc space. Use caution while expanding to avoid excessive distraction and endplate damage.



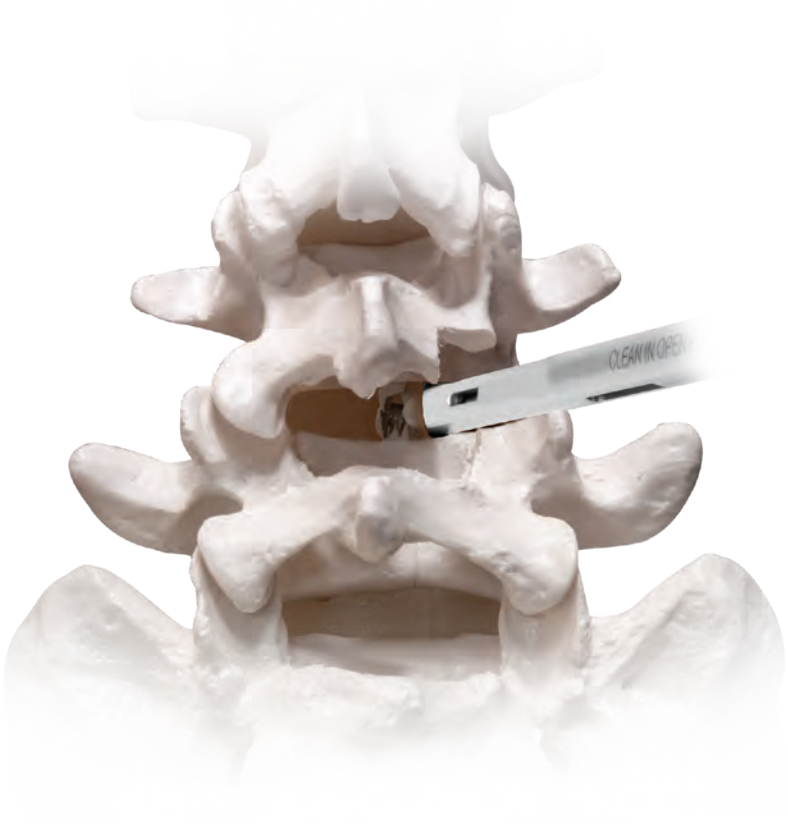
Inserting Adjustable Trial Assembly



Trial height shown on side of trial

Rotate clockwise to expand trial to desired height

Determine which height best fits the prepared disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment. The final implant height may be confirmed using fluoroscopy and tactile feel.



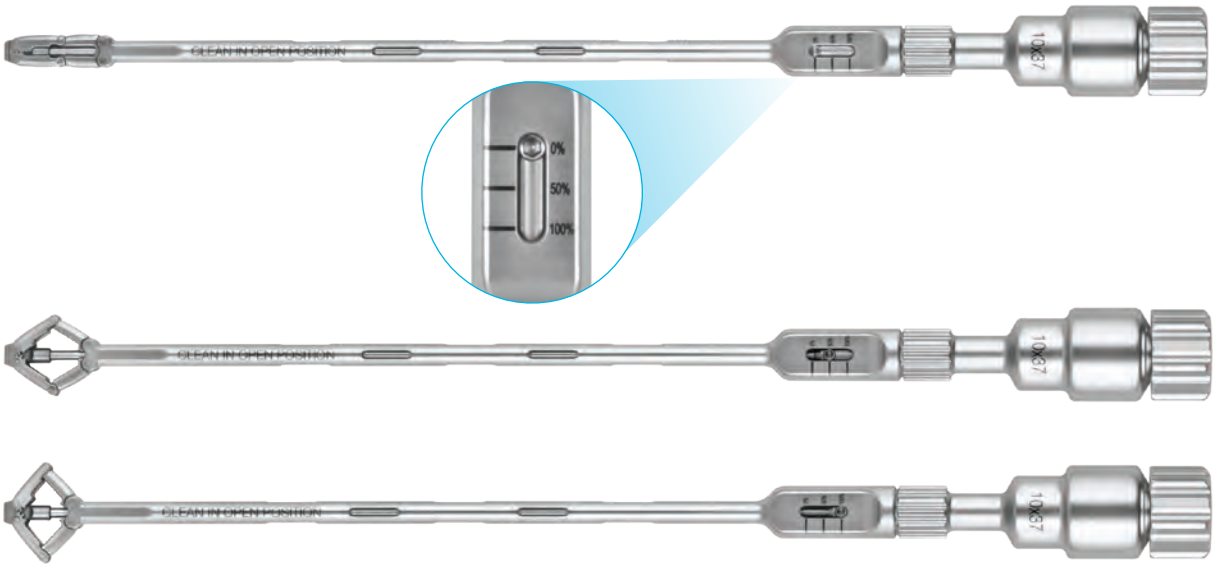
Note: Alternatively, the Sizers/Shavers may be used for distraction and to loosen the disc space. Begin with the smallest sizer and use larger sizes until the desired distraction is achieved. Use caution while using sizers to avoid damage to the endplate.

STEP 6 FOOTPRINT SIZING

After determining proper implant height and loosening the disc space, measure the prepared disc using the appropriate **Adjustable Footprint Trial**. Gently insert the collapsed trial into the disc space. Rotate the knurled knob clockwise to expand. Use fluoroscopy to identify which footprint and expanded position best fits the prepared disc space.

Using Adjustable Footprint Trial

Expansion intervals are indicated on the shaft of the trials. Rotate the knurled knob counterclockwise to collapse the trial before removing. A secure fit is desirable in order to stabilize the segment and can be confirmed using fluoroscopy and tactile feel.



Adjustable Footprint Trial Expansion

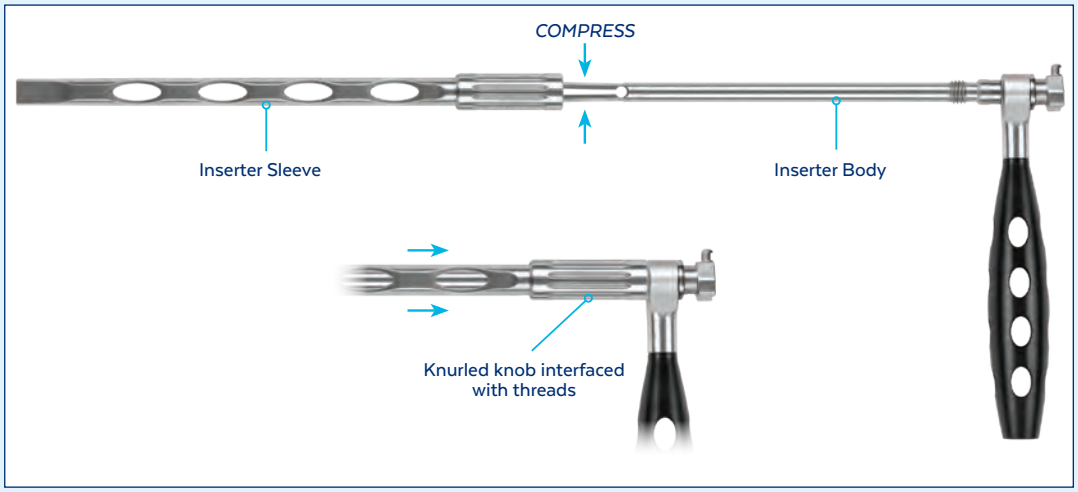
Note: Begin with the small trial and increase to the larger size until the desired width is achieved. Use caution while expanding trials.

STEP 7 IMPLANT INSERTION

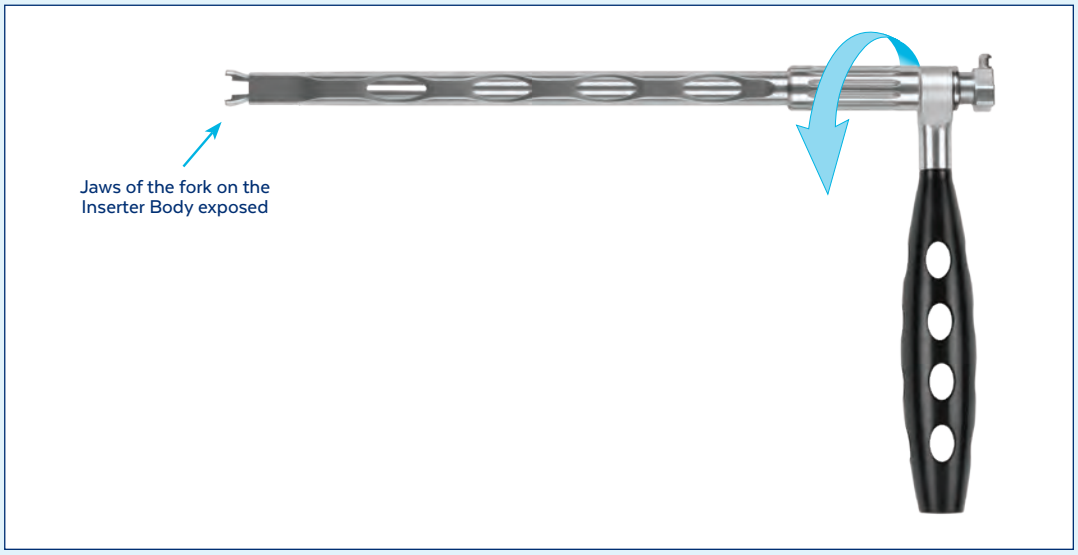
Assemble the inserter as described below.

ASSEMBLING THE IMPLANT INSERTER ASSEMBLY

1. Compress the jaws of the forks on the **Inserter Body** and place through the **Inserter Sleeve** until the knurled knob on the sleeve interfaces with the threads on the body.



2. Rotate the knurled knob on the sleeve counterclockwise until the jaws of the fork on the Inserter Body are exposed and open.

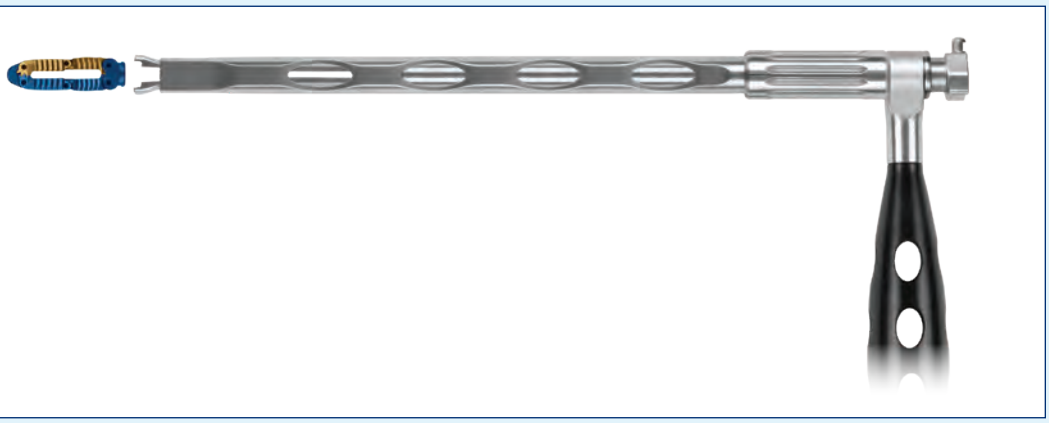


IMPLANT INSERTION (CONT'D)

Select the desired implant and attach to the Implant Inserter Assembly.

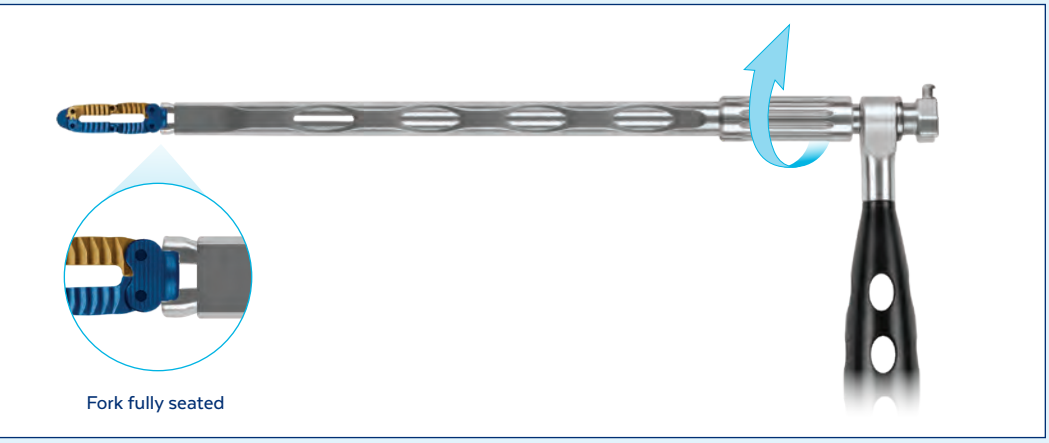
IMPLANT ATTACHMENT

1. Align the slots of the rear link of the LATIS® implant with the exposed jaws of the fork. When using lordotic (6°) implants, ensure that the gold link is facing the medial position. This ensures the correct orientation for lordosis.



2. Advance the sleeve over the jaws of the fork by rotating the knob clockwise, engaging the implant.

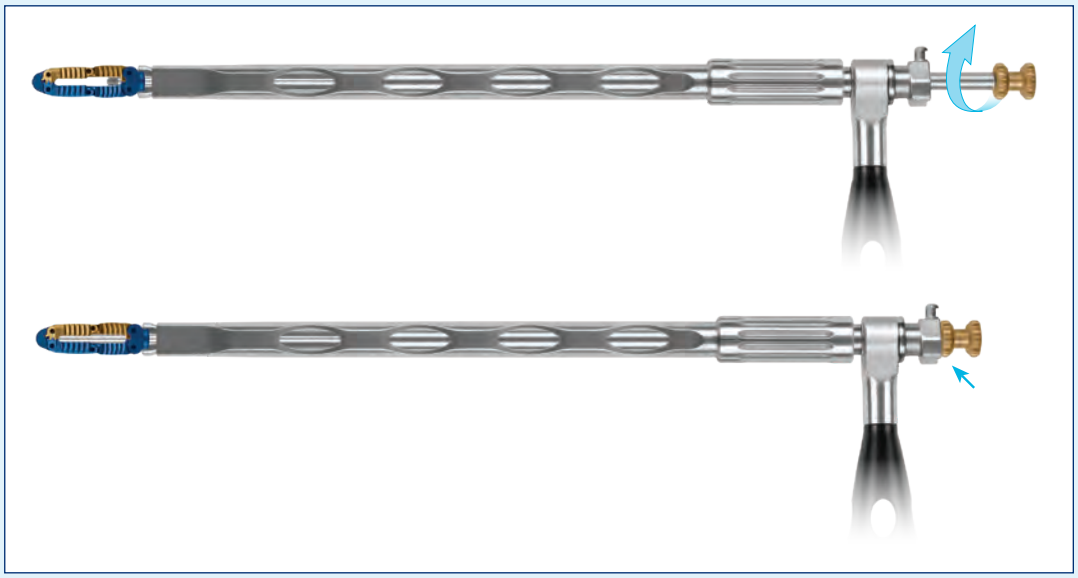
Note: Visually confirm that the fork is fully seated into the implant.



3. Select the **Threaded Shaft** corresponding to the implant size selected.

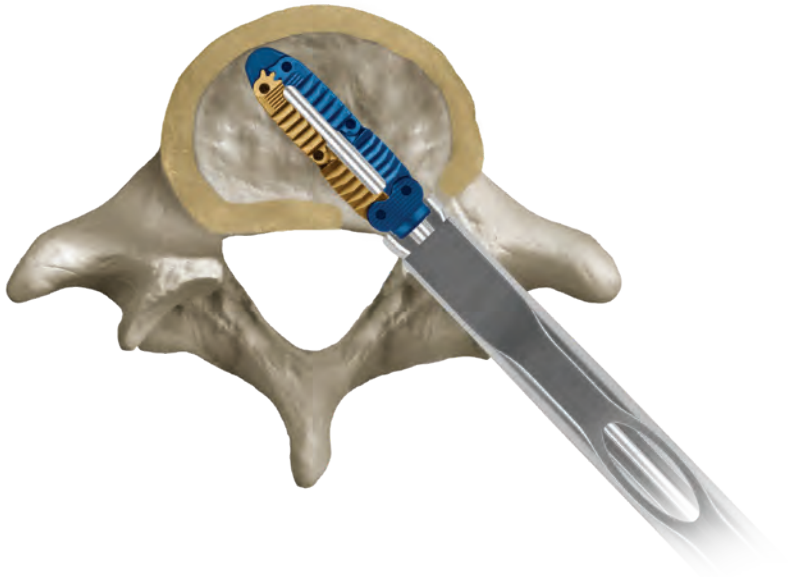
IMPLANT ATTACHMENT (CONT'D)

4. Insert the shaft through the Inserter Body. Attach to the implant by rotating the Threaded Shaft clockwise until "two finger tight."



Insert LATIS® into the disc space in the collapsed state. If needed, the knurled knob on the Threaded Shaft may be impacted for proper placement. Attach the T-Handle Actuator as shown on page 22.

CAUTION: Ensure that the implant is fully within the disc space prior to expansion, to avoid damage to the surrounding tissue.

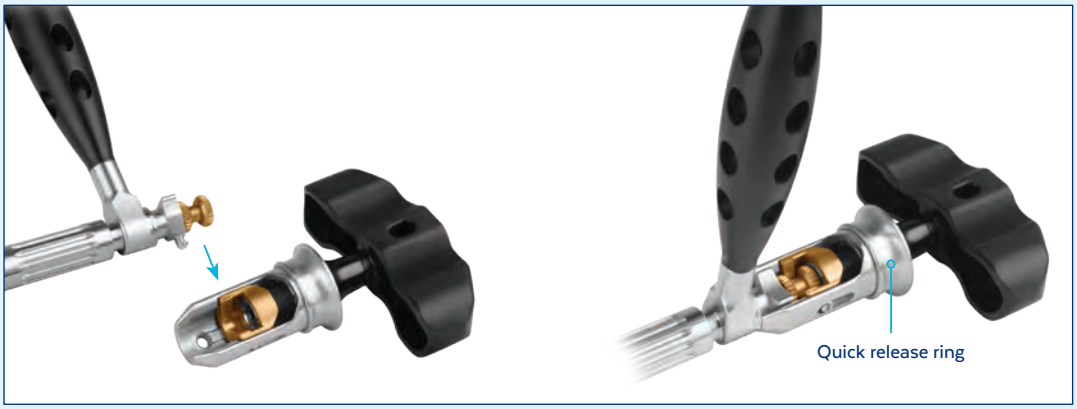


IMPLANT INSERTION (CONT'D)

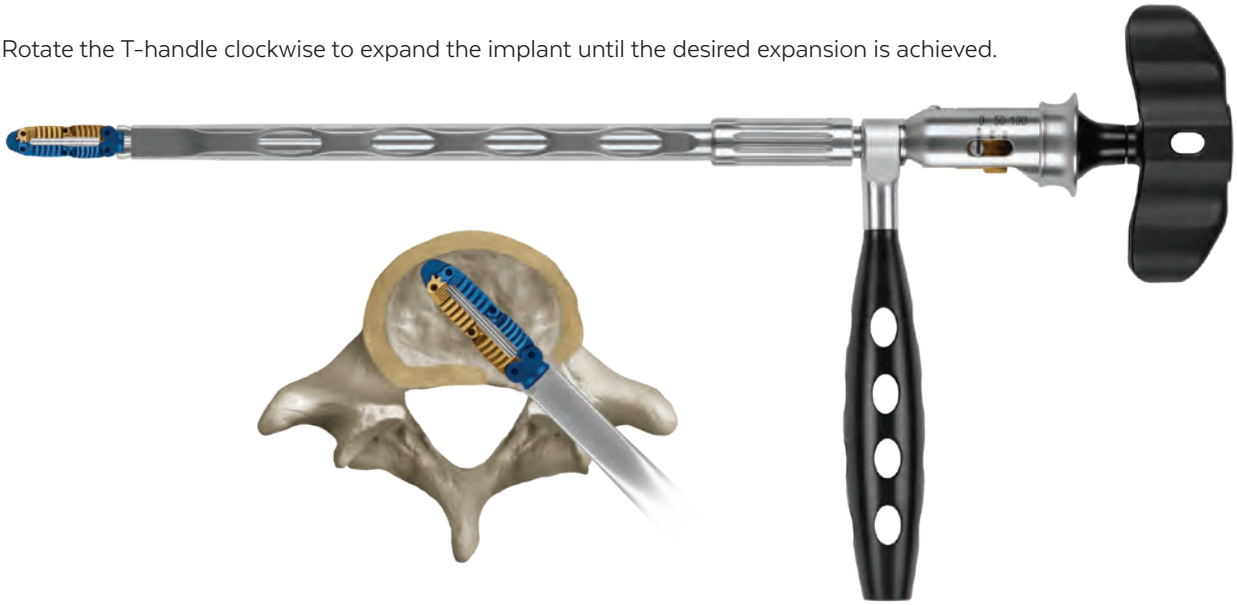
ATTACHING THE T-HANDLE ACTUATOR

Select the appropriate T-Handle Actuator corresponding to the implant and set to the starting position (0). This allows the gold carriage piece to align with the gold section of the Threaded Shaft.

Pull back on the quick release ring and engage the post on the Inserter Body with the hole on the distal end of the T-Handle. Release the quick release ring and ensure the handle is securely fastened to the inserter assembly.



Rotate the T-handle clockwise to expand the implant until the desired expansion is achieved.

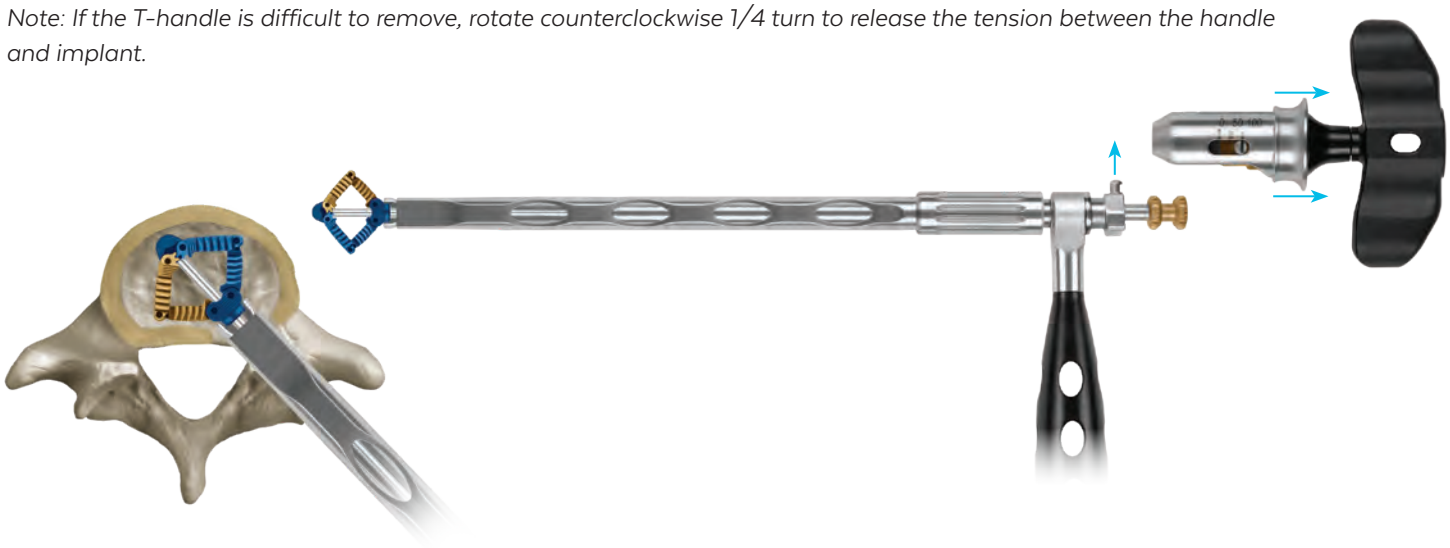


Fluoroscopy may be used to verify the implant position. Approximate expansion (0, 50, 100%) is indicated on the side window of the T-handle.

Note: If implant repositioning is required after the implant has been expanded, impact on the strike plate of the T-Handle Actuator to reposition the implant as needed.

Once the desired expansion is achieved, pull back on the quick release ring and slide the T-Handle Actuator off the post on the Inserter Body to remove the T-handle. Once removed, do not impact on the gold threaded shaft as this will cause the implant to close.

Note: If the T-handle is difficult to remove, rotate counterclockwise 1/4 turn to release the tension between the handle and implant.

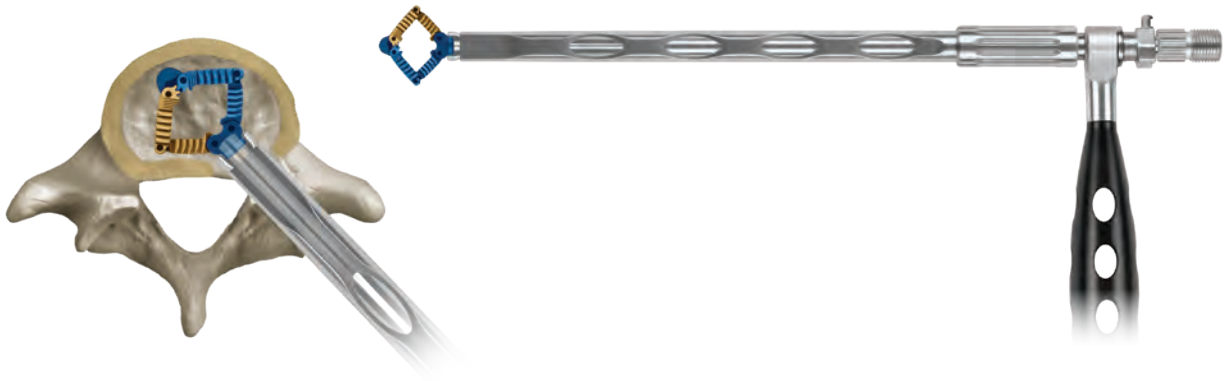


Disengage the Threaded Shaft from the implant by rotating counterclockwise. Remove from the assembly.

Insert the **Torque-Limiting Locking Screwdriver** into the assembly and advance it into the set screw of the implant. Rotate clockwise until it reaches the torque limit to lock the implant into the expanded position. Remove the driver from the assembly.

IMPLANT INSERTION (CONT'D)

The **Bone Funnel Tube** holds 4cc of bone graft and can be preloaded. Autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone should be morselized and advanced through the tube to confirm that the graft particulate size can be easily pushed through. After the implant is locked, insert the tube and thread it into the proximal end of the Inserter Body until two-finger tight.



If the tube is not preloaded, thread the **Bone Funnel** onto the tube and use the **Bone Funnel Pusher** to plunge finely milled bone graft through the tube into the implant.

*Note: If needed, the **Counter-Torque** can be used to aid in unthreading the Bone Funnel from the Funnel Tube.*

Insert the pusher through the tube to fill the implant with finely milled bone graft material through the central hole, tightly packing the device. Refer to the chart on page 25 for approximate graft volumes.

BONE GRAFT FILLING

The volume of bone graft required to fill a LATIS® spacer is dependent on the selected implant size and expansion. Track the volume used to determine when the implant is filled.

The table below shows the approximate graft volume for each implant configuration.

Approximate Graft Volume

Size	Part No.	Height	Graft Volume 100% Expansion (cc)	Size	Part No.	Height	Graft Volume 100% Expansion (cc)
10x32mm	181.237	7mm	1.06	10x37mm	181.537	7mm	1.92
	181.238	8mm	1.21		181.538	8mm	2.02
	181.209	9mm	1.36		181.509	9mm	2.12
	181.210	10mm	1.51		181.510	10mm	2.32
	181.211	11mm	1.67		181.511	11mm	2.52
	181.212	12mm	1.82		181.512	12mm	2.64
	181.213	13mm	1.97		181.513	13mm	2.82
	181.215	15mm	2.27		181.515	15mm	3.12
	181.217	17mm	2.73		181.517	17mm	3.52

It is recommended to test the tube with graft particulate to ensure it can be easily placed through the tube. If graft particulate is too large the tabs could be blocked. The Bone Funnel Tube holds a maximum of 4cc of bone graft and should be pre-loaded on the back table prior to delivering *in situ*. A Bone Mill with a fine blade is recommended to ensure graft is finely morselized. Advance through the tube to confirm that the graft particulate size can be pushed through with ease.

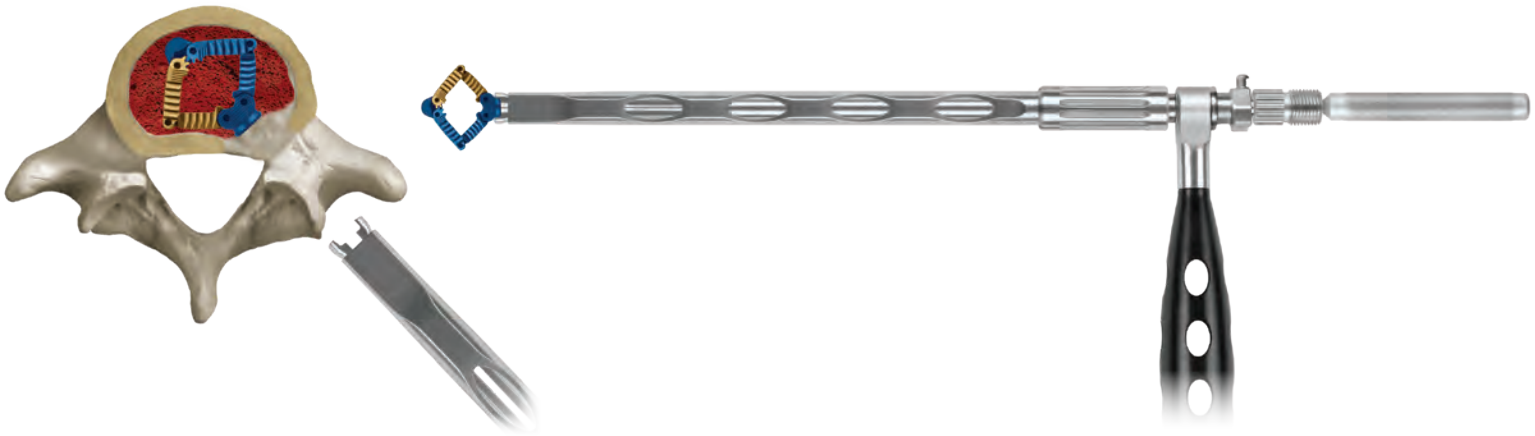
Thread the Bone Funnel onto the end of the tube and use the Bone Funnel Pusher to re-pack the tube. To determine the amount contained within the tube, advance the pusher into the tube until graft begins to exude from the tip. Continue to advance the pusher until the next mark disappears into the tube. The marks remaining outside the tube indicate the amount of cc's remaining in the tube. Fill the implant with the desired amount of bone graft, tightly packing the implant.

Note: If graft jams in the tube, empty half of the bone graft out of the tube, then re-insert the tube through the assembly and continue to deliver bone graft into the implant.

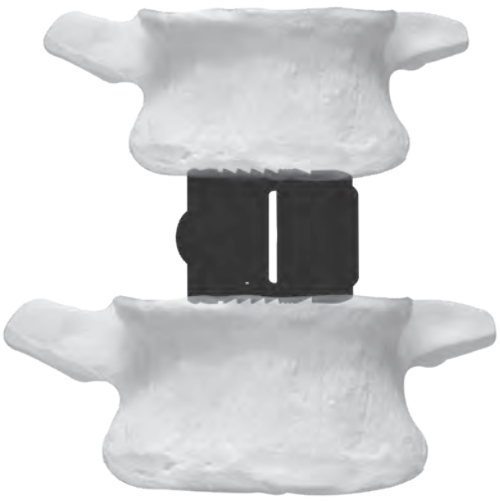
Caution: Do NOT strike with a mallet as this may result in unintended implant movement.

IMPLANT INSERTION (CONT'D)

Once the bone graft is placed, the assembly is removed from the implant by rotating the knob counterclockwise. Supplemental bone graft should also be packed around the implant.



STEP 8 RADIOGRAPHIC CONFIRMATION



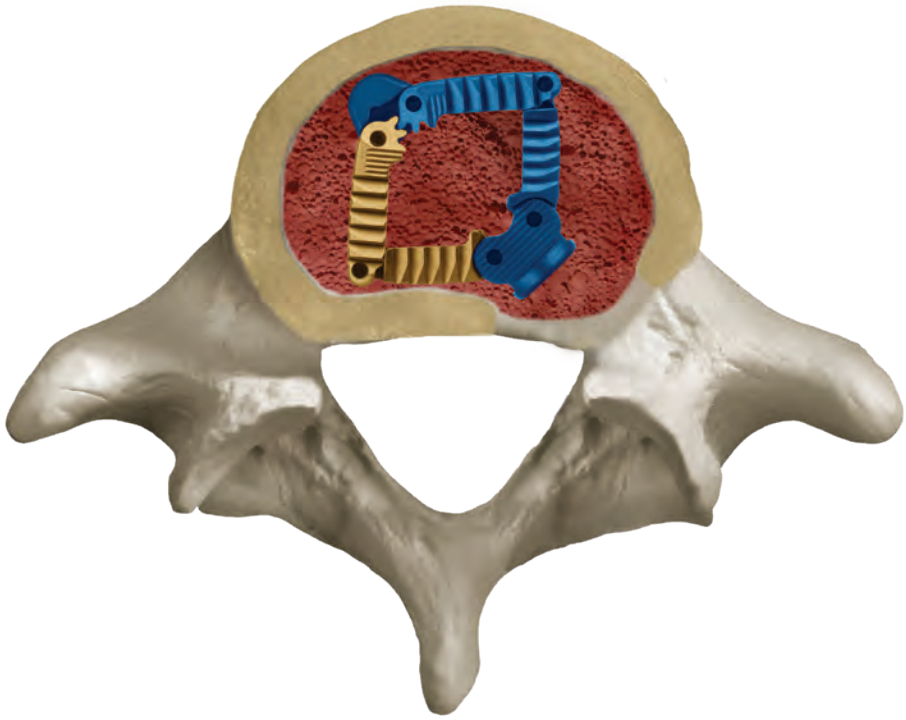
AP View

Lateral View

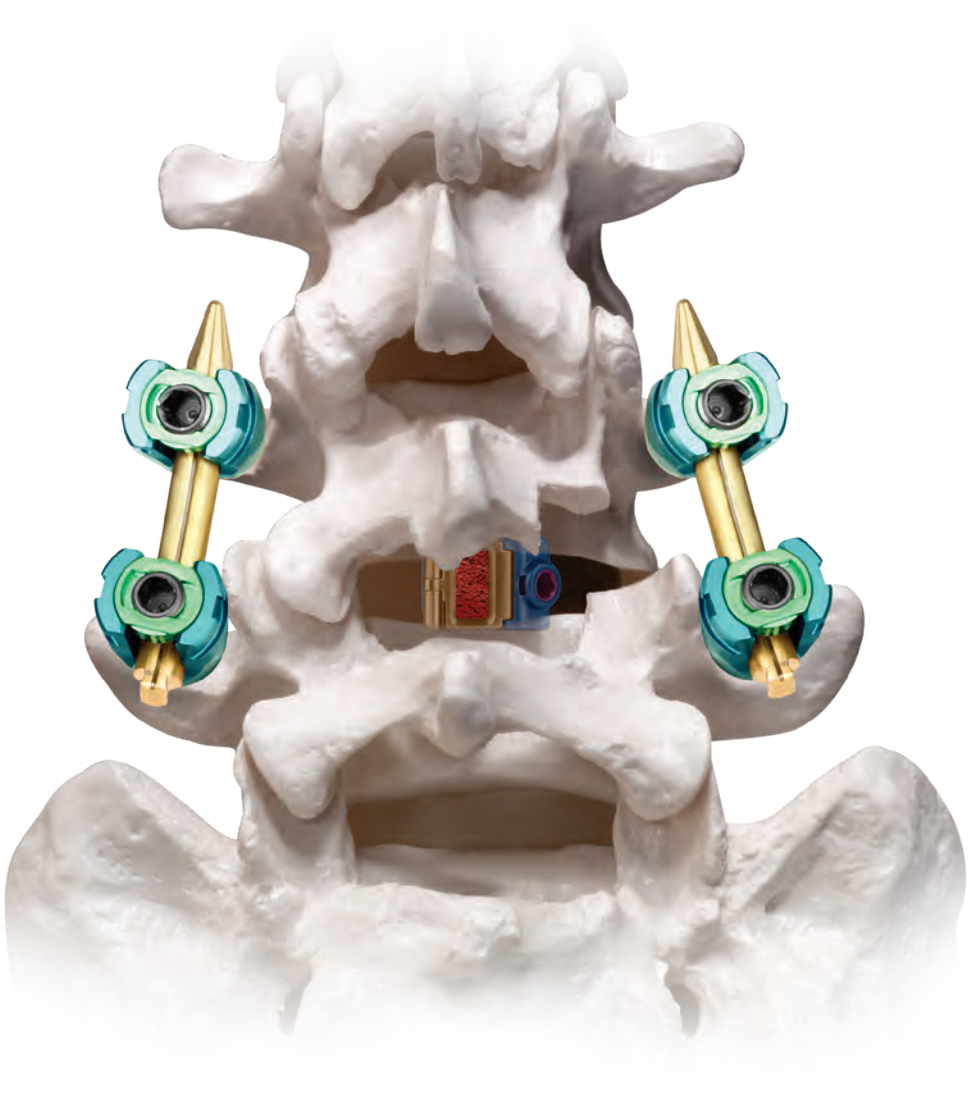
Using fluoroscopy, verify the final position of the implant before disengaging the Implant Inserter. Once the desired position is achieved, disengage the assembly by rotating the Inserter Knob counterclockwise and rock the inserter gently medial/lateral until the assembly no longer mates with the implant.

Note: This step should be completed prior to filling with bone graft material.

FINAL CONSTRUCT



FINAL CONSTRUCT (WITH SUPPLEMENTAL FIXATION)



Posterior View with
REVOLVE® Supplemental Fixation

OPTIONAL: IMPLANT REMOVAL

For implant removal, insert the Removal Tool through the rear link of the implant and thread it into the nose. Use the tool to guide the Inserter Body into the cutouts on the rear link of the implant. Advance the sleeve over the jaws by rotating the knob clockwise to engage the implant. Once the implant is attached to the inserter assembly, unthread the Removal Tool from the implant and remove from the assembly. Select the Threaded Shaft that corresponds with the implant to be removed. Insert the shaft through the assembly and rotate until two finger tight. Attach the **Compressor** to the proximal end of the inserter assembly and compress until the implant is fully collapsed. If needed, attach the **Slide Hammer** to the proximal end of the inserter assembly and remove the implant from the disc space.

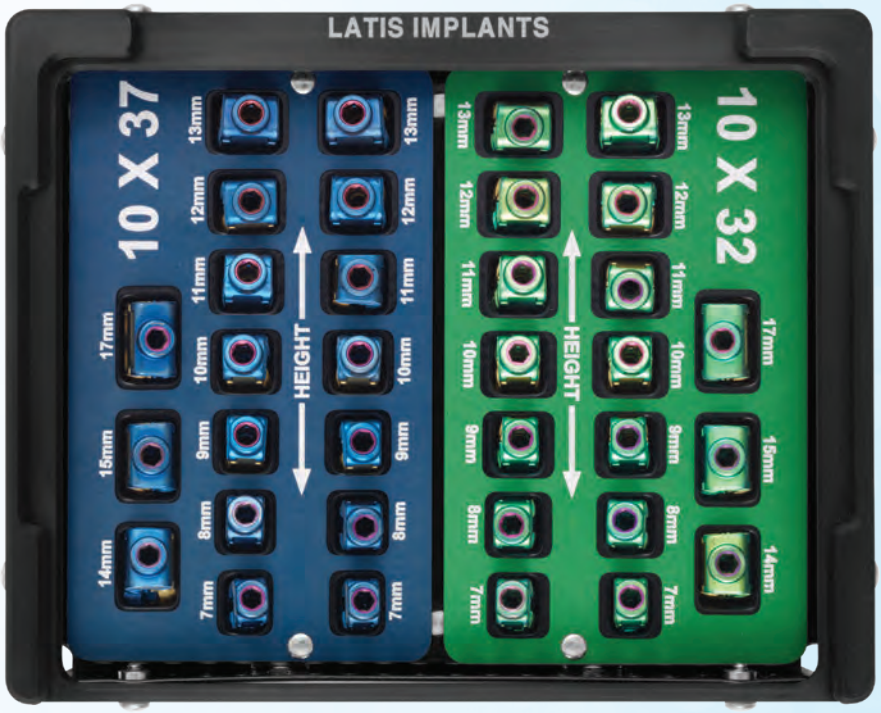
LATIS®
IMPLANT SET 981.901

Part No.	10x32mm Length	Qty
181.237	LATIS® 10x32mm; 7mm	2
181.238	LATIS® 10x32mm; 8mm	2
181.209	LATIS® 10x32mm; 9mm 6°	2
181.210	LATIS® 10x32mm; 10mm 6°	2
181.211	LATIS® 10x32mm; 11mm 6°	2
181.212	LATIS® 10x32mm; 12mm 6°	2
181.213	LATIS® 10x32mm; 13mm 6°	2
181.214	LATIS® 10x32mm; 14mm 6°	1
181.215	LATIS® 10x32mm; 15mm 6°	1
181.217	LATIS® 10x32mm; 17mm 6°	1

Part No.	10x37mm Length	Qty
181.537	LATIS® 10x37mm; 7mm	2
181.538	LATIS® 10x37mm; 8mm	2
181.509	LATIS® 10x37mm; 9mm 6°	2
181.510	LATIS® 10x37mm; 10mm 6°	2
181.511	LATIS® 10x37mm; 11mm 6°	2
181.512	LATIS® 10x37mm; 12mm 6°	2
181.513	LATIS® 10x37mm; 13mm 6°	2
181.514	LATIS® 10x37mm; 14mm 6°	1
181.515	LATIS® 10x37mm; 15mm 6°	1
181.517	LATIS® 10x37mm; 17mm 6°	1

981.004	LATIS® Implant Module

LATIS®
IMPLANT SET 981.901



LATIS®
INSTRUMENT SET 981.907

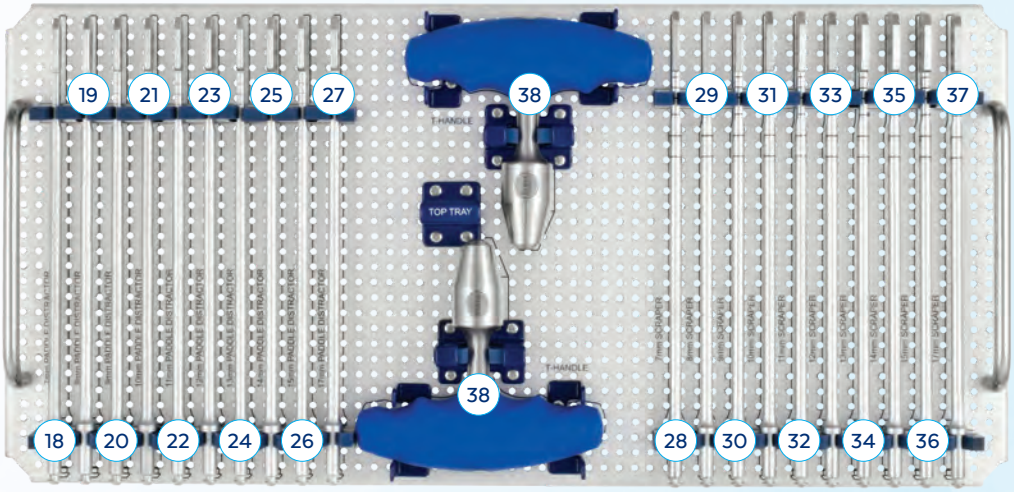
	Part No.	Description	Qty
1	681.207	Adjustable Footprint Trial - Small	1
2	681.507	Adjustable Footprint Trial - Medium	1
3	681.850	Inserter Body	2
4	681.851	Inserter Sleeve	2
5	681.852	Small Threaded Shaft	2
6	681.853	Small T-Handle Actuator	2
7	681.854	Bone Funnel Tube	2
8	681.855	Torque-Limiting Locking Screwdriver	1
9	681.856	Bone Funnel Pusher	2
10	681.857	Compressor	1
11	681.858	Slide Hammer	1
12	681.862	Medium Threaded Shaft	2
13	681.863	Medium T-Handle Actuator	2
14	694.002	Torque-Limiting Palm Handle	1
15	693.212	Adjustable Trial, 10x26, 7-14	1
16	694.218	Removable Drive, Right Hand	1
17	673.003	MIS Handle	1
18	681.407	Paddle Distractor, 7mm	1
19	681.408	Paddle Distractor, 8mm	1
20	681.409	Paddle Distractor, 9mm	1
21	681.410	Paddle Distractor, 10mm	1
22	681.411	Paddle Distractor, 11mm	1
23	681.412	Paddle Distractor, 12mm	1
24	681.413	Paddle Distractor, 13mm	1
25	681.414	Paddle Distractor, 14mm	1
26	681.415	Paddle Distractor, 15mm	1
27	681.417	Paddle Distractor, 17mm	1
28	681.307	Sizer/Shaver, 7mm	1
29	681.308	Sizer/Shaver, 8mm	1
30	681.309	Sizer/Shaver, 9mm	1
31	681.310	Sizer/Shaver, 10mm	1
32	681.311	Sizer/Shaver, 11mm	1
33	681.312	Sizer/Shaver, 12mm	1
34	681.313	Sizer/Shaver, 13mm	1
35	681.314	Sizer/Shaver, 14mm	1
36	681.315	Sizer/Shaver, 15mm	1
37	681.317	Sizer/Shaver, 17mm	1
38	601.800	T-Handle	1
39	681.511	Removal Tool	1
40	681.013	Bone Funnel	1
41	681.699	Counter-Torque	1

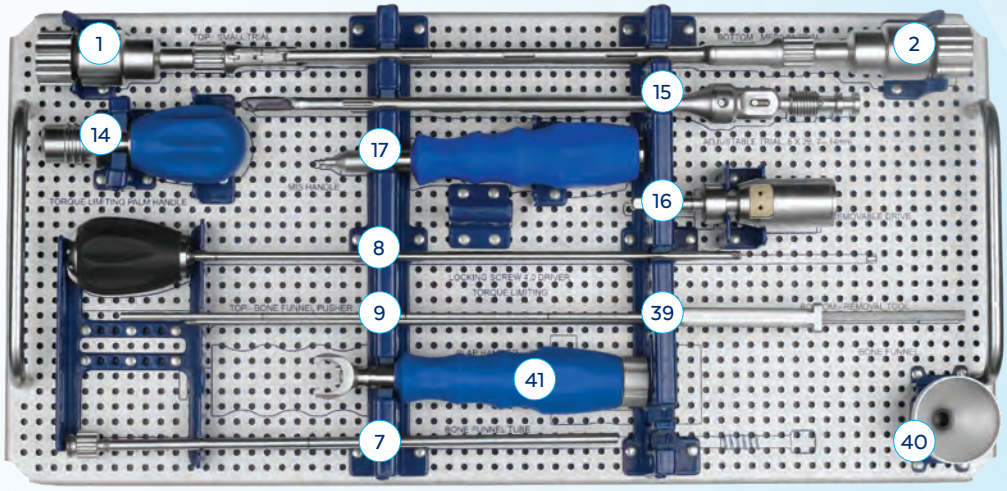
	981.003	LATIS® Graphic Case

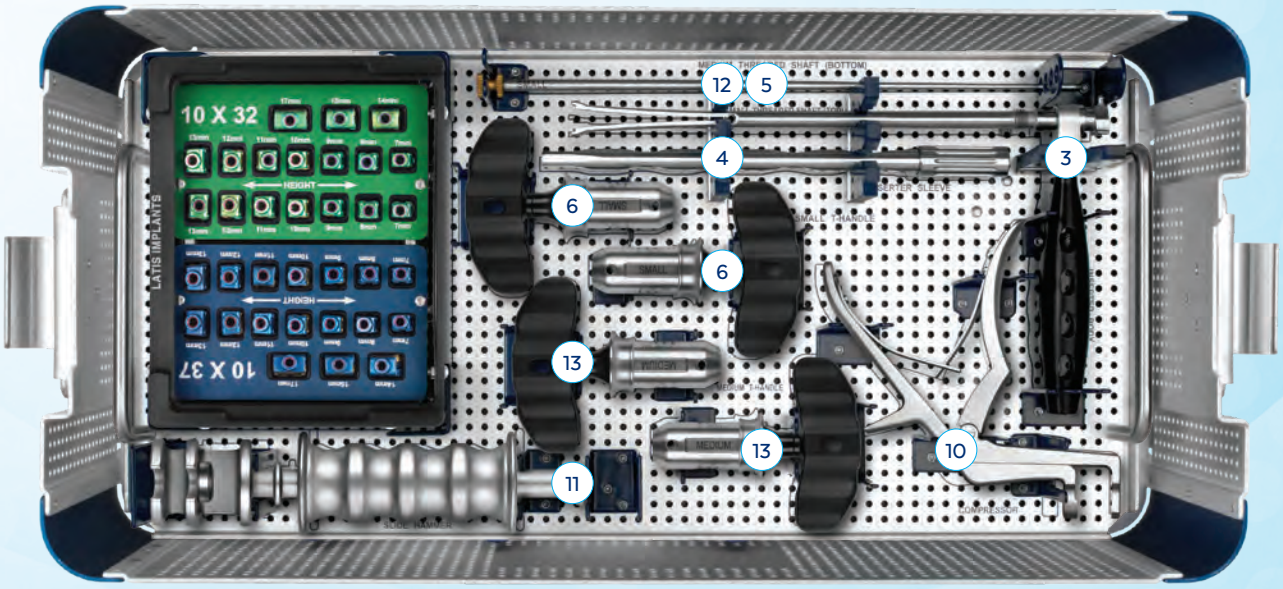
Additionally Available

681.405	Paddle Distractor, 5mm
681.406	Paddle Distractor, 6mm

LATIS®
INSTRUMENT SET 981.907



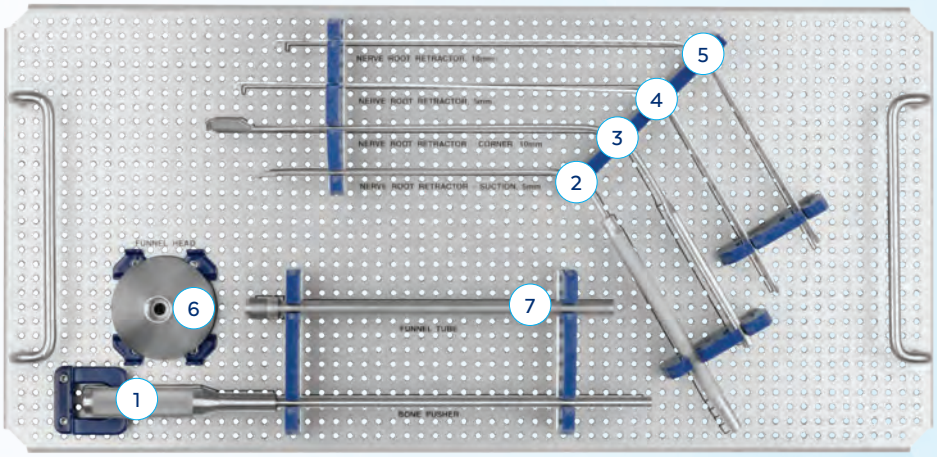


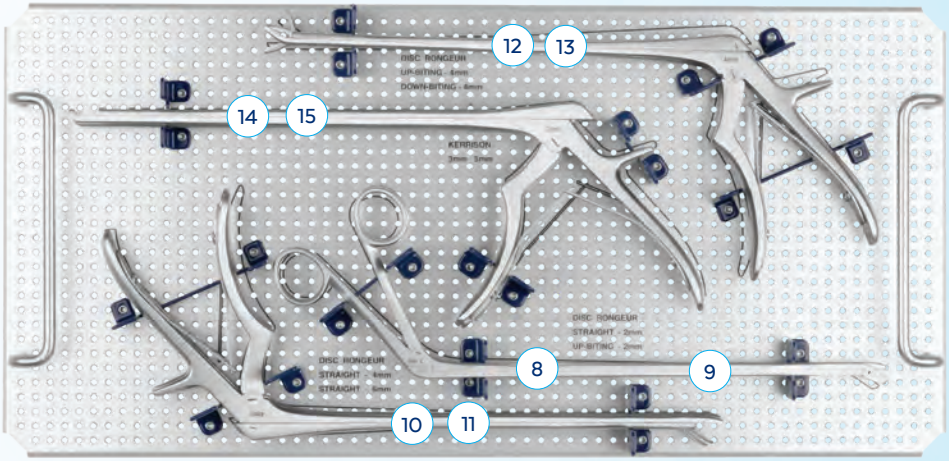


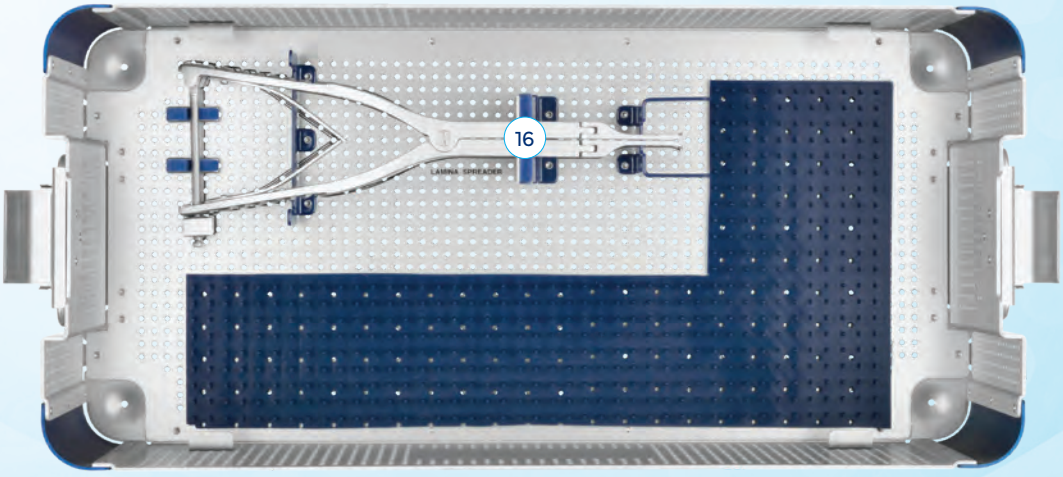
POSTERIOR DISC PREP
INSTRUMENTS I SET 926.901

	Part No.	Description	Qty
1	626.210	Push Rod Assembly, Bone Funnel	1
2	626.215	Nerve Retractor, 5mm, Suction	1
3	626.220	Nerve Retractor, Corner	1
4	603.061	Nerve Root Retractor, Fine, 5mm	1
5	603.062	Nerve Root Retractor, Medium, 10mm	1
6	679.015	Bone Funnel	1
7	679.015	Bone Funnel - Tube	1
8	626.235	Disc Rongeur, 250x2mm, Straight	1
9	626.236	Disc Rongeur, 250x2mm, Up Biting	1
10	626.240	Disc Rongeur, 250x4mm, Straight	1
11	626.241	Disc Rongeur, 250x6mm, Straight	1
12	626.242	Disc Rongeur, 250x4mm, Up Biting	1
13	626.243	Disc Rongeur, 250x4mm, Down Biting	1
14	626.250	Kerrison, 250 x 3mm, Straight	1
15	626.252	Kerrison, 250 x 5mm, Straight	1
16	626.260	Lamina Spreader, Hinged	1
	926.102	Graphic Case I	

POSTERIOR DISC PREP
INSTRUMENTS I SET 926.901



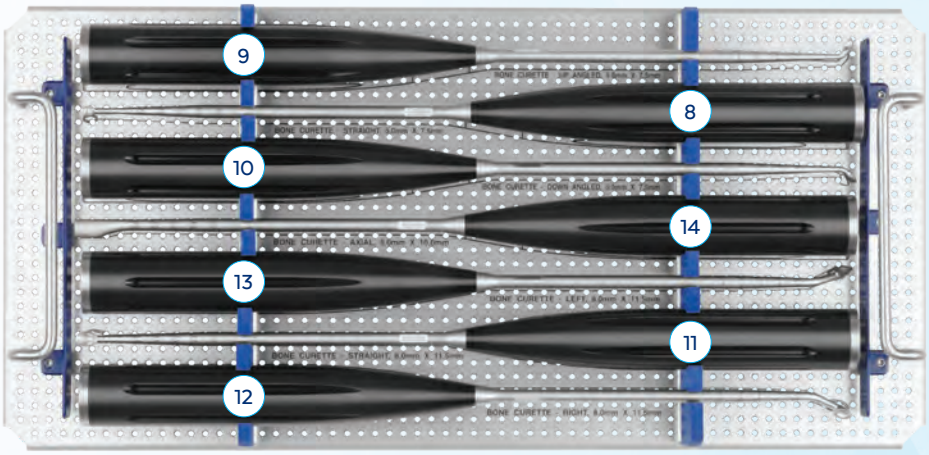


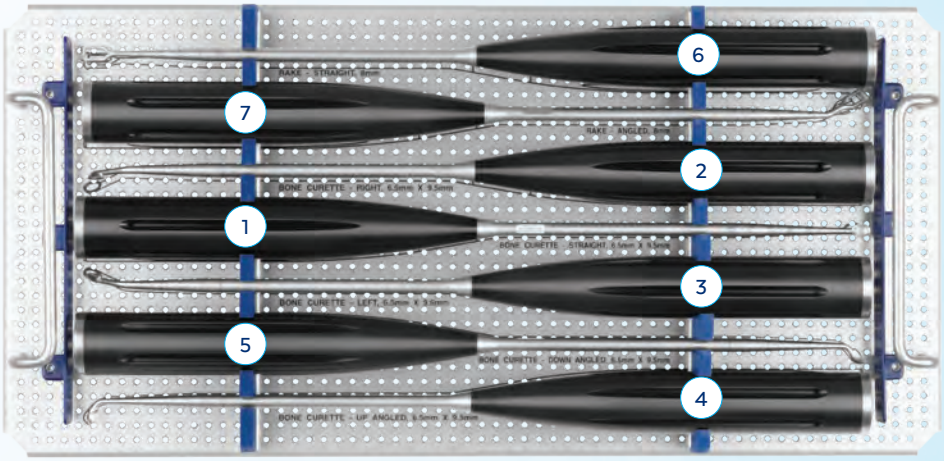


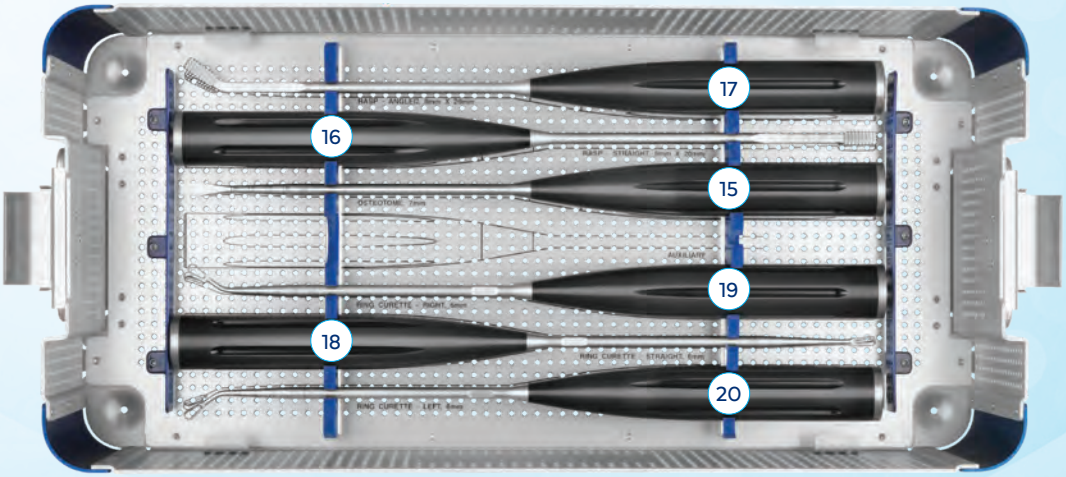
POSTERIOR DISC PREP
INSTRUMENTS II SET 926.902

	Part No.	Description	Qty
1	626.150	Bone Curette, 6.5x9.5mm, Straight	1
2	626.151	Bone Curette, 6.5x9.5mm, Right	1
3	626.152	Bone Curette, 6.5x9.5mm, Left	1
4	626.153	Bone Curette, 6.5x9.5mm, Up Pushing	1
5	626.154	Bone Curette, 6.5x9.5mm, Down Pushing	1
6	626.190	Rake, 8mm, Straight	1
7	626.191	Rake, 8mm, Angled	1
8	626.140	Bone Curette, 5.0x7.5mm, Straight	1
9	626.143	Bone Curette, 5.0x7.5mm, Up Pushing	1
10	626.144	Bone Curette, 5.0x7.5mm, Down Pushing	1
11	626.160	Bone Curette, 8.0x11.5mm, Straight	1
12	626.161	Bone Curette, 8.0x11.5mm, Right	1
13	626.162	Bone Curette, 8.0x11.5mm, Left	1
14	626.170	Bone Curette, 5.0x10mm, Axial	1
15	626.180	Osteotome, 7mm	1
16	626.185	Rasp, 8x20mm, Knurled, Straight	1
17	626.186	Rasp, 8x20mm, Knurled, Angled	1
18	626.200	Ring Curette, 6mm, Straight	1
19	626.201	Ring Curette, 6mm, Angled Right	1
20	626.202	Ring Curette, 6mm, Angled Left	1
	926.101	Graphic Case II	

POSTERIOR DISC PREP
INSTRUMENTS II SET 926.902







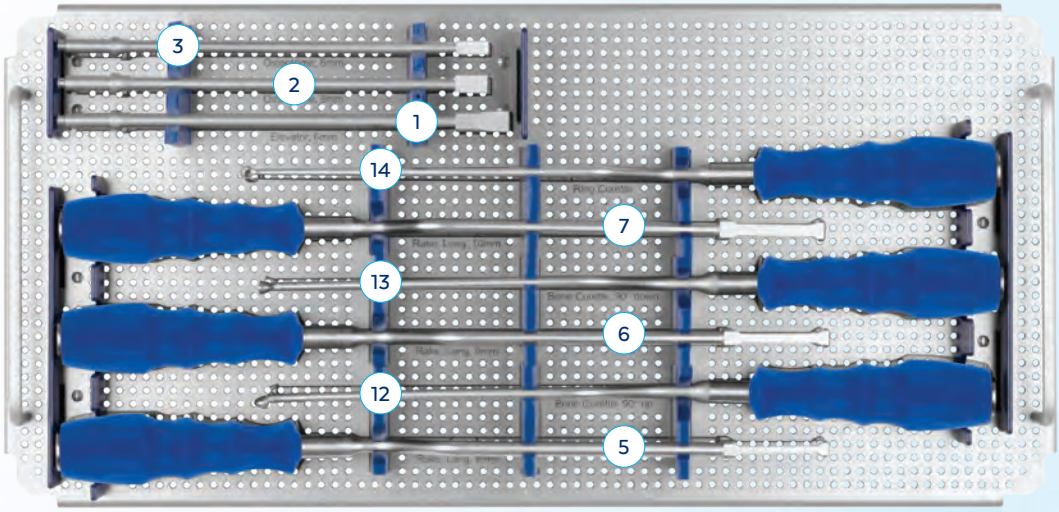
MIS LUMBAR DISCECTOMY
INSTRUMENT SET 979.901

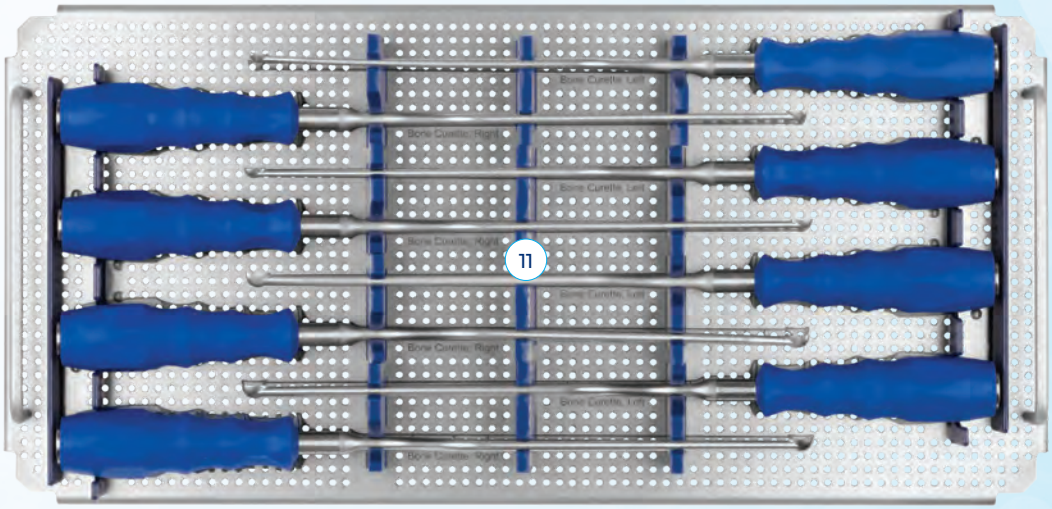
	Part No.	Description	Qty
1	679.005	Elevator 6mm	1
2	679.007	Osteotome, 8mm QR	1
3	679.008	Osteotome, 6mm QR	1
4	679.010	L-Handle	1
5	679.011	Rake, Long 8mm, Bayoneted	1
6	679.012	Rake, Long 9mm, Bayoneted	1
7	679.013	Rake, Long 10mm, Bayoneted	1
8	679.015	Bone Funnel	1
9	679.016	Bone Funnel Clamp	1
10	679.017	Bone Pusher Rod	1
11	679.025	Bone Curette, 10.0 Serrated Cup	1
	679.026	Bone Curette, Straight, 10.0 Serrated Cup	1
	679.027	Bone Curette, Angled, 10.0 Serrated Cup	1
	679.028	Bone Curette, Straight, 10.0 Serrated Cup	1
	679.031	Bone Curette, Angled, 12.0 Serrated Cup, Bayoneted, LH	1
	679.032	Bone Curette, Straight, 12.0 Serrated Cup, Bayoneted, LH	1
	679.033	Bone Curette, Angled, 12.0 Serrated Cup, Bayoneted, RH	1
	679.034	Bone Curette, Straight, 12.0 Serrated Cup, Bayoneted, RH	1
12	679.041	Bone Curette, 10.7 Serrated Cup, 90° Up	1
13	679.042	Bone Curette, 10.7 Serrated Cup, 90° Down	1
14	679.051	Ring Curette, 6mm	1
	979.001	MIS Discectomy Instruments Graphic Case	

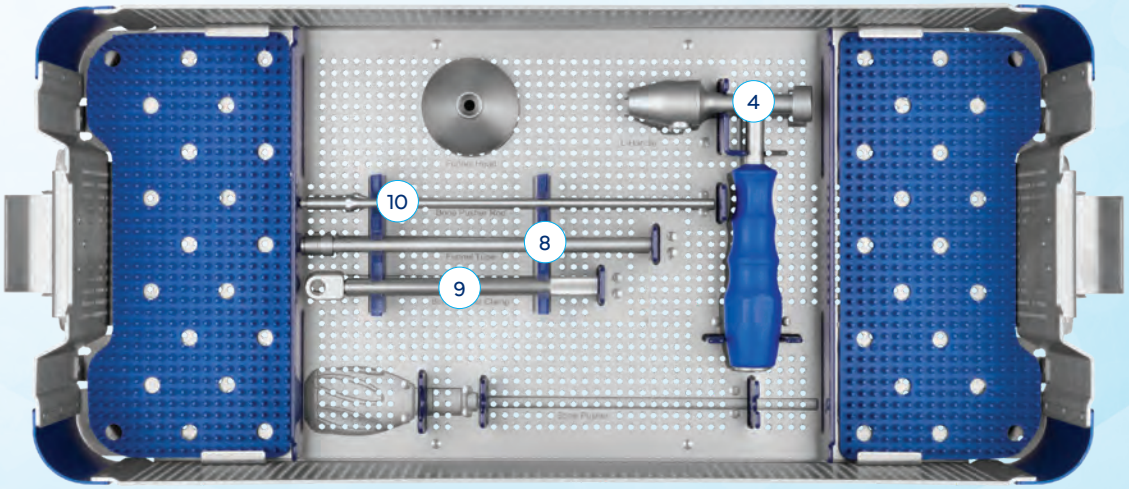
Additionally Available

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

MIS LUMBAR DISCECTOMY
INSTRUMENT SET 979.901



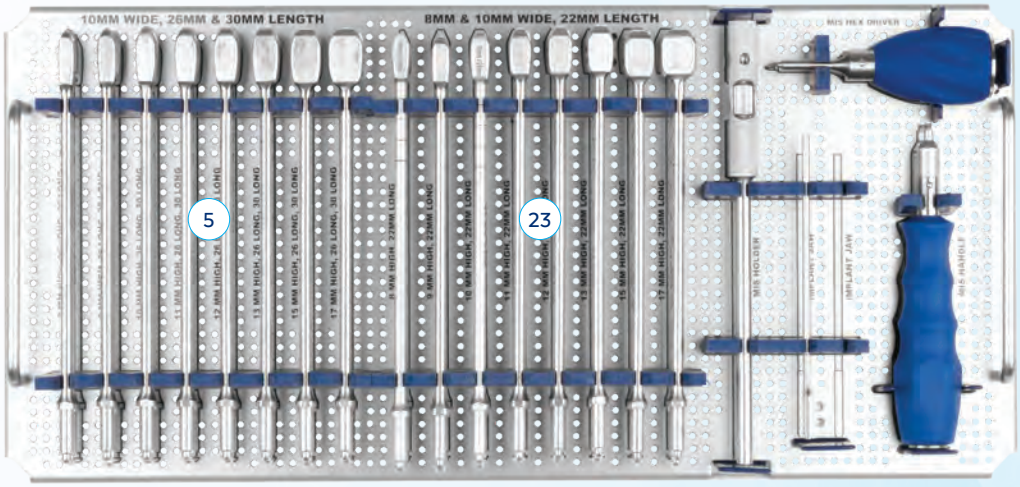


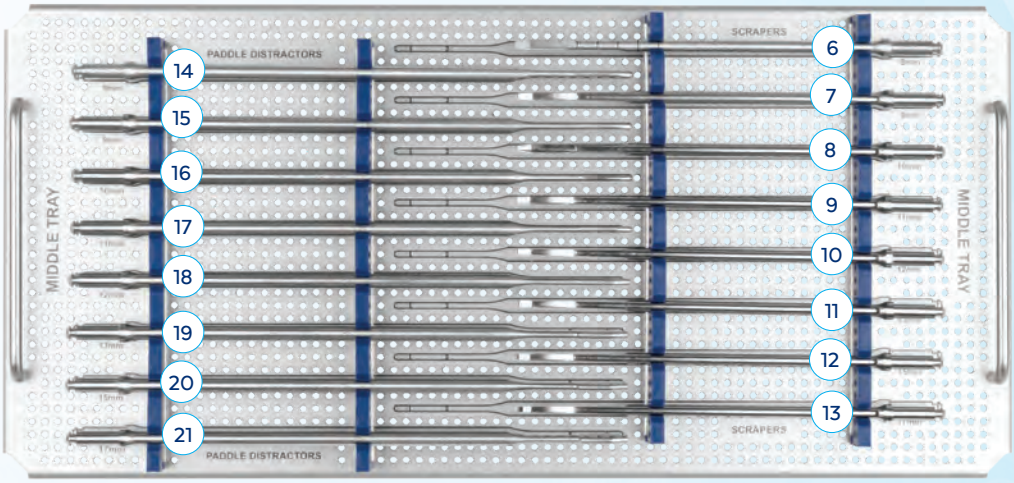


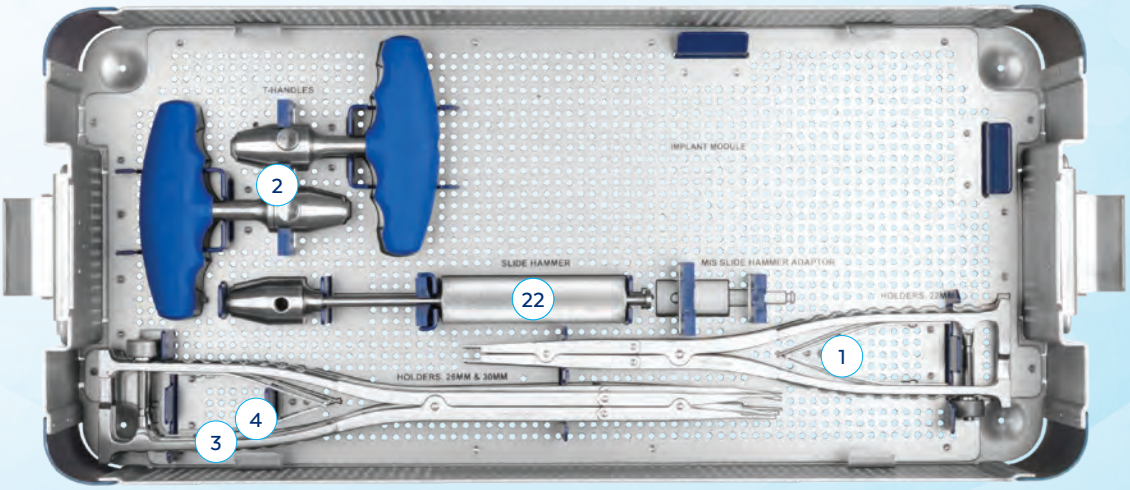
PRESERVE® POSTERIOR UNI-LATERAL INSTRUMENT SET 904.907

	Part No.	Description	Qty
1	601.001	Implant Holder	1
2	601.800	T-Handle	2
3	604.001	Holder, Straight	1
4	604.002	Holder, Angled	1
5	604.108	Trial, SUSTAIN®-R Oblique, 26mm length, 8mm	1
	604.109	Trial, SUSTAIN®-R Oblique, 26mm length, 9mm	1
	604.110	Trial, SUSTAIN®-R Oblique, 26mm length, 10mm	1
	604.111	Trial, SUSTAIN®-R Oblique, 26mm length, 11mm	1
	604.112	Trial, SUSTAIN®-R Oblique, 26mm length, 12mm	1
	604.113	Trial, SUSTAIN®-R Oblique, 26mm length, 13mm	1
	604.115	Trial, SUSTAIN®-R Oblique, 26mm length, 15mm	1
	604.117	Trial, SUSTAIN®-R Oblique, 26mm length, 17mm	1
	604.208	Trial, SUSTAIN®-R Oblique, 30mm length, 8mm	1
	604.209	Trial, SUSTAIN®-R Oblique, 30mm length, 9mm	1
	604.210	Trial, SUSTAIN®-R Oblique, 30mm length, 10mm	1
	604.211	Trial, SUSTAIN®-R Oblique, 30mm length, 11mm	1
	604.212	Trial, SUSTAIN®-R Oblique, 30mm length, 12mm	1
	604.213	Trial, SUSTAIN®-R Oblique, 30mm length, 13mm	1
	604.215	Trial, SUSTAIN®-R Oblique, 30mm length, 15mm	1
	604.217	Trial, SUSTAIN®-R Oblique, 30mm length, 17mm	1
6	604.308	Scraper, Oblique, 8mm	1
7	604.309	Scraper, Oblique, 9mm	1
8	604.310	Scraper, Oblique, 10mm	1
9	604.311	Scraper, Oblique, 11mm	1
10	604.312	Scraper, Oblique, 12mm	1
11	604.313	Scraper, Oblique, 13mm	1
12	604.315	Scraper, Oblique, 15mm	1
13	604.317	Scraper, Oblique, 17mm	1
14	604.808	Paddle Distractor, 8mm	1
15	604.809	Paddle Distractor, 9mm	1
16	604.810	Paddle Distractor, 10mm	1
17	604.811	Paddle Distractor, 11mm	1
18	604.812	Paddle Distractor, 12mm	1
19	604.813	Paddle Distractor, 13mm	1
20	604.815	Paddle Distractor, 15mm	1
21	604.817	Paddle Distractor, 17mm	1
22	673.017	Slide Hammer, Quick Disconnect	1
23	673.108	Trial Shaft, 8mm x 22mm wide, 8mm, SUSTAIN® Oblique, Small	1
	673.109	Trial Shaft, 8mm wide, 9mm, SUSTAIN® Oblique, Small	1
	673.110	Trial Shaft, 8mm wide, 10mm, SUSTAIN® Oblique, Small	1
	673.111	Trial Shaft, 8mm x 22mm wide, 11mm, SUSTAIN® Oblique, Small	1
	673.112	Trial Shaft, 8mm x 22mm wide, 12mm, SUSTAIN® Oblique, Small	1
	673.113	Trial Shaft, 8mm x 22mm wide, 13mm, SUSTAIN® Oblique, Small	1
	673.115	Trial Shaft, 8mm x 22mm wide, 15mm, SUSTAIN® Oblique, Small	1
	673.117	Trial Shaft, 8mm x 22mm wide, 17mm, SUSTAIN® Oblique, Small	1
	673.208	Trial Shaft, 10mm x 22mm wide, 8mm, SUSTAIN® Oblique, Small	1
	673.209	Trial Shaft, 10mm x 22mm wide, 9mm, SUSTAIN® Oblique, Small	1
	673.210	Trial Shaft, 10mm x 22mm wide, 10mm, SUSTAIN® Oblique, Small	1
	673.211	Trial Shaft, 10mm x 22mm wide, 11mm, SUSTAIN® Oblique, Small	1
	673.212	Trial Shaft, 10mm x 22mm wide, 12mm, SUSTAIN® Oblique, Small	1
	673.213	Trial Shaft, 10mm x 22mm wide, 13mm, SUSTAIN® Oblique, Small	1
	673.215	Trial Shaft, 10mm x 22mm wide, 15mm, SUSTAIN® Oblique, Small	1
	673.217	Trial Shaft, 10mm x 22mm wide, 17mm, SUSTAIN® Oblique, Small	1
	904.009	PRESERVE® Posterior Uni-Lateral Instruments	

PRESERVE® POSTERIOR UNI-LATERAL
INSTRUMENT SET 904.907







IMPORTANT INFORMATION ON LATIS®

DESCRIPTION

LATIS® Spacers are lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. LATIS® Spacers are provided in a shape that accommodates a posterior, transforaminal, or lateral approach to the lumbar spine; after insertion the implant can be transformed to the desired footprint. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. These spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

LATIS® Spacers are manufactured from titanium alloy per ASTM F136 and F1295.

INDICATIONS

LATIS® Spacers are interbody fusion devices intended for use at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment.

LATIS® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

WARNINGS

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:
- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

Interbody fusion devices for the treatment of degenerative conditions are designed to withstand both full load bearing and the loads associated with long-term use which could result from the presence of non-union or delayed union.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture.

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

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

The components of this system are manufactured from titanium alloy. 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.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

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

MRI SAFETY INFORMATION

The LATIS® Spacers are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:
- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg Under the scan conditions defined above, the LATIS® Spacers are expected to produce a maximum temperature rise of less than or equal to 3.9°C after 15 minutes of continuous scanning.

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

CONTRAINDICATIONS

Use of LATIS® Spacer(s) is contraindicated in patients with the following conditions:
1. Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials
2. Prior fusion at the level(s) to be treated
3. Severe osteoporosis, which may prevent adequate fixation
4. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
5. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
6. Any condition not described in the indications for use
7. Signs of local inflammation
8. Fever or leukocytosis
9. Morbid obesity
10. Pregnancy
11. Mental illness
12. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count
13. Suspected or documented allergy or intolerance to composite materials
14. Any case not needing a fusion
15. Any patient not willing to cooperate with postoperative instruction
16. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery
17. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth
18. Spondylolisthesis unable to be reduced to Grade 1
19. Any case where the implant components selected for use would be too large or too small to achieve a successful result
20. Any case that requires the mixing of metals from two different components or systems
21. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality
22. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS

Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential need for additional surgery to correct these effects:
- Loosening, bending or breakage of components
- Displacement/migration of device components
- Tissue sensitivity to implant material
- Potential for skin breakdown and/or wound complications
- Non-union or delayed union or mal-union
- Infection
- 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. Instruments should be checked to ensure that they are in working order prior to surgery. All instruments should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

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

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures.

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

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

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

CONTACT INFORMATION

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

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, double pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below. Sterile implants meet pyrogen limit specifications.

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

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

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

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

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes
Steam	Pre-vacuum	134°C (273°F)	3 Minutes	30 Minutes

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

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

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

DI185A Rev D

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Phone 1-866-GLOBUS1 (or 1-866-456-2871)
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