GLOBUS MEDICAL

SABLE™

3D Printed Expandable Posterior Lumbar Interbody Spacer

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

SABLE™

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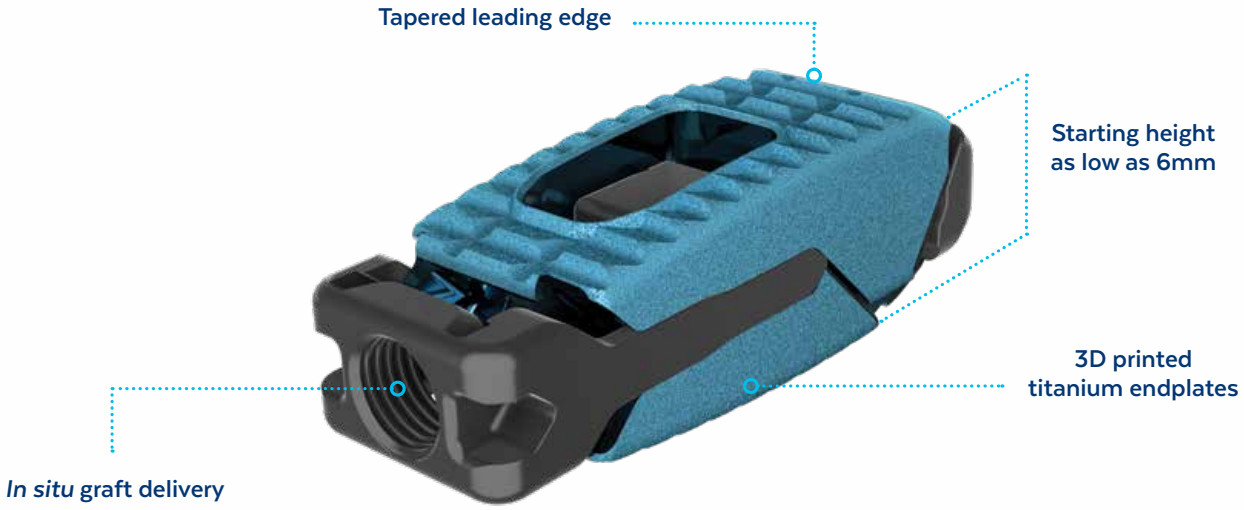
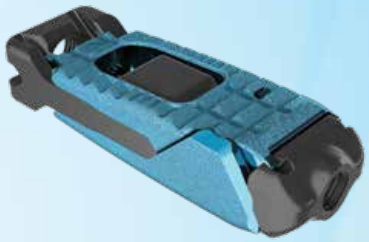
3D Printed Expandable Posterior Lumbar Interbody Spacer

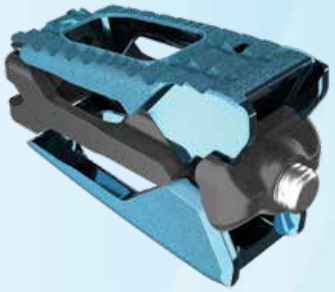
SABLE™ is an expandable posterior lumbar interbody spacer with 3D printed titanium endplates designed for minimal endplate disruption, maximum sagittal balance restoration, and *in situ* graft delivery.

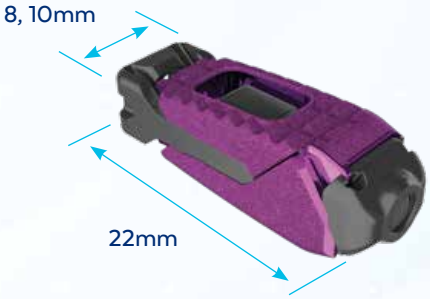


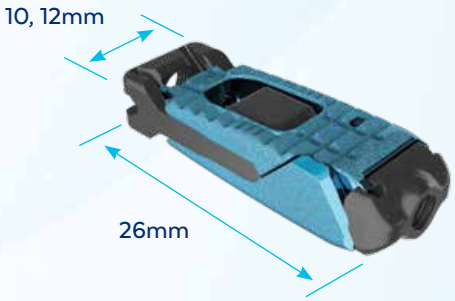
IMPLANT OVERVIEW

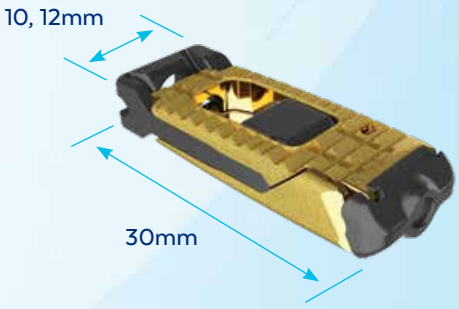
- Contracted insertion height designed to reduce endplate disruption
- Up to 8mm of continuous expansion to restore disc height
- Graft delivery *in situ*
- 3D printed porous titanium endplates
  - Cell culture study on SABLE™ 3D printed surfaces:*
    - Demonstrate increased cellular proliferation compared to PEEK surfaces
    - Facilitate greater cellular expression of bone markers (ALP) than PEEK and TAV surfaces
- Height range 6–18mm
- High lordotic profiles with low starting heights
  - 8° with 6mm starting height
  - 15° with 7mm starting height
  - 22° with 9mm starting height
- Multiple footprint options
  - 8x22mm
  - 10x22, 10x26, and 10x30mm
  - 12x26mm and 12x30mm
- Automatic locking for simple operation
- Insert, expand, and backfill graft through one instrument











**Cell culture study data on file*

INSTRUMENT OVERVIEW

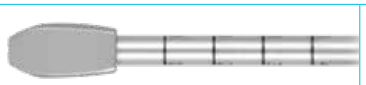
SIZERS/SHAVERS

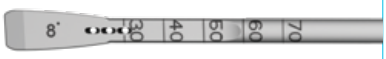
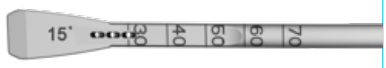
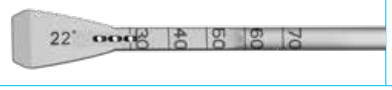
626.505	Sizer/Shaver, 5mm
626.506	Sizer/Shaver, 6mm
626.507	Sizer/Shaver, 7mm
626.508	Sizer/Shaver, 8mm
626.509	Sizer/Shaver, 9mm
626.510	Sizer/Shaver, 10mm
626.511	Sizer/Shaver, 11mm
626.512	Sizer/Shaver, 12mm
626.513	Sizer/Shaver, 13mm
626.514	Sizer/Shaver, 14mm
626.515	Sizer/Shaver, 15mm
626.516	Sizer/Shaver, 16mm
626.517	Sizer/Shaver, 17mm

PADDLE DISTRACTORS

626.405	Paddle Distractors, 5mm
626.406	Paddle Distractors, 6mm
626.407	Paddle Distractors, 7mm

TRIALING INSTRUMENTS

	604.105	5mm Trial
	604.106	6mm Trial
	604.107	7mm Trial

	6172.6008	8° Trial
	6172.6015	15° Trial
	6172.6022	22° Trial

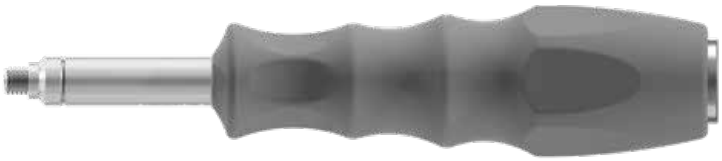
T-Handle with Impaction Cap, 675.005

For use with Shavers, Distractors, Static and Lordotic trials

EXPANDABLE DISTRACTOR

Expandable Distractor, 10x26mm 6-12mm 6172.1210

Expandable Distractor Handle 6172.2000



Counter-Torque Handle 6154.3003

Expandable Distractor, 10x26mm 6-12mm 6172.1210
Expandable Distractor Handle 6172.2000
Counter-Torque Handle 6154.3003
(Assembled)

INSERTER INSTRUMENTS

ML Inserter Sleeve 6172.0001

Inserter Threaded Shaft 6172.0002

Driver 22mm 6172.0022

Driver 26mm 6172.0026

Driver 30mm 6172.0030

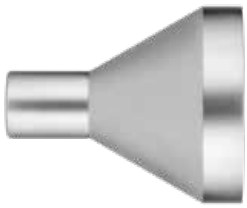
Torque-Limiting Handle, 2.0Nm 6172.0003

INSERTER INSTRUMENTS (CONT'D)

ML Inserter Sleeve 6172.0001
Inserter Threaded Shaft 6172.0002
Driver 22mm 6172.0022
Torque-Limiting Handle, 2.0Nm 6172.0003
(Assembled)

OTHER INSTRUMENTS

Funnel Tube 6172.0006



Funnel 681.013

Graft Plunger 6172.0007

Rigid Driver 6172.0005

Spanner Wrench 6172.0008

SURGICAL TECHNIQUE

SABLE™

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

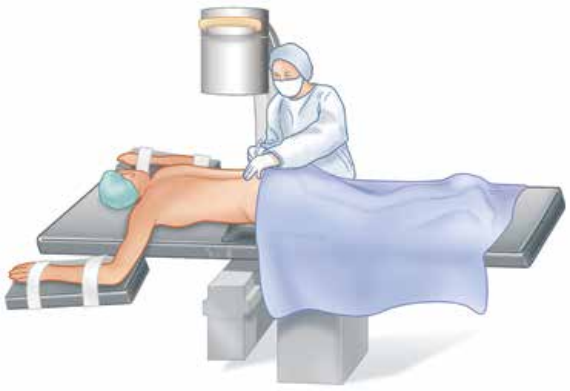
STEP 1 PATIENT POSITIONING AND APPROACH

A posterior or transforaminal approach is used to implant SABLE™. For the purposes of this technique guide, a transforaminal approach is shown. When using a posterior approach, two implants are inserted per level.

Place the patient under anesthesia and position prone. Lateral C-arm fluoroscopy or other radiographic methods may be used throughout the surgery to ensure correct implant placement.

Carefully clean the operative area and create an incision at the appropriate fusion level(s).

The trajectory should be in line with the disc. Finger dissect between the multifidus and longissimus muscles until the facet joint is palpated.



STEP 2 RETRACTION

MARS™3V dilators may be used to retract soft tissue. Insert the initial dilator. Apply downward pressure on the dilator and rotate as needed when approaching the facet. With the initial dilator secure, a series of cannulas are progressively passed over the initial dilator until the retractor diameter is reached.

Ensure that the retractor is fully closed and the blades are securely attached to the frame. Introduce the retractor over the final cannula.

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

Once the retractor has been securely positioned and the **Articulating Arm Assembly** tightened to stabilize the retractor, remove the cannulas. Use AP fluoroscopy to verify positioning.

TABLE ARM ATTACHMENT

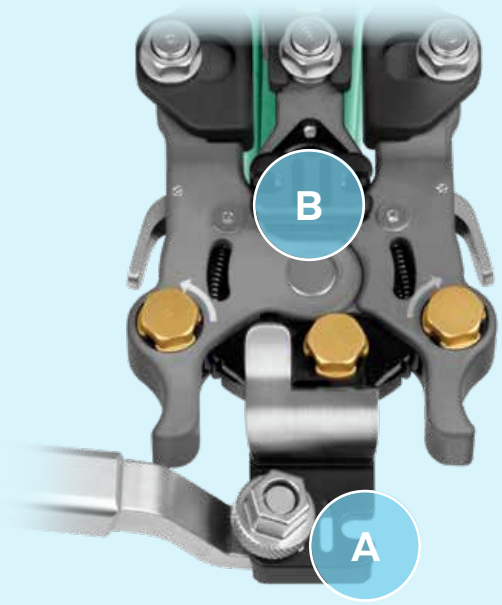
Attach the **Table Clamp** onto the bed rail attachment. Insert the Articulating Arm Assembly into the Table Clamp and secure. Attach the opposite end of the Articulating Arm Assembly to the **Retractor 3 Blade Frame**.

Attachment Options

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

Attaching the arm to point B maintains the retractor position relative to the cephalad and caudal blade position and translates the posterior blade medially.

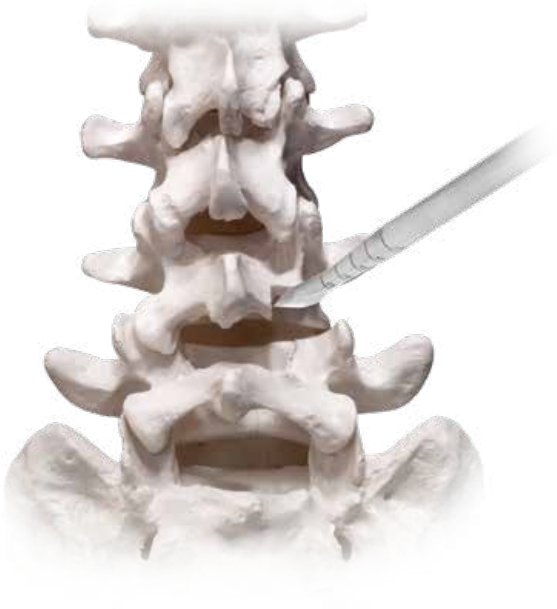
Refer to the MARS™ 3V Technique Guide (GMTGD149) when using the MARS™ 3V Retractor.



STEP 3 CREATING TRANSFORAMINAL ACCESS

To create a working transforaminal access corridor to the disc, 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). Osteotomes are available in the Posterior Disc Prep Instruments Set III.

Transforaminal approach with MARS™ 3V Retractor System



Transforaminal access

STEP 4 ENDPLATE PREPARATION

After creating an adequate annular window, remove disc material using rongeurs, rasps, curettes or other suitable preparation instruments. The anterior and lateral walls of the annulus should be preserved to provide peripheral support for the implant. **Shavers** may be used to remove superficial layers of the cartilaginous endplates.

Insert the smallest Shaver into the disc space for further disc removal and endplate preparation, moving to larger Shavers as needed. Use caution while using the Shavers to avoid damage to the endplate.

Careful disc removal and endplate preparation maximizes the potential for a successful fusion.

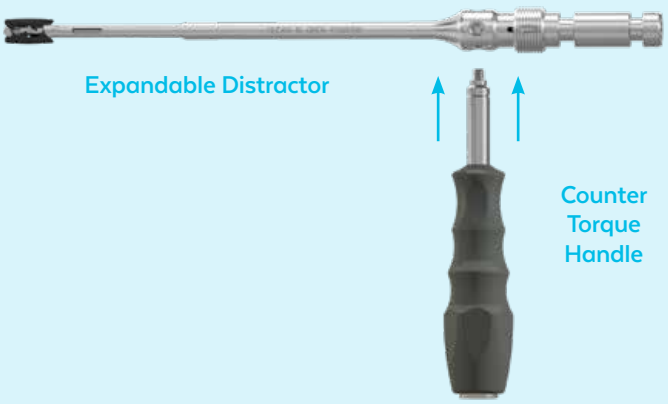
STEP 5 DISTRACTION

Distract the disc space to the desired amount using Paddle Distractors, an Expandable Distractor, or by distracting pedicle screws.

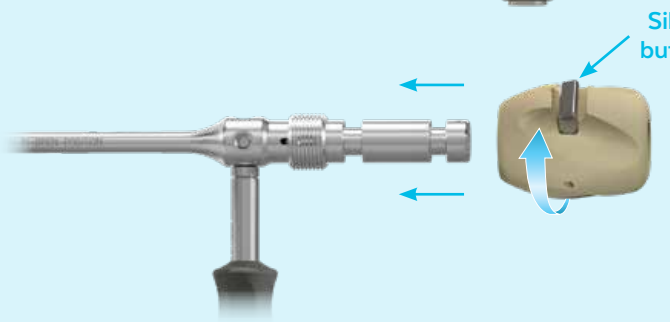
ASSEMBLING THE EXPANDABLE DISTRACTOR

Thread the **Counter-Torque Handle** into the **Expandable Distractor** until finger tight. Do not over-tighten.

Four attachment options are available for preferred orientation.



Press the silver button to attach the **Distractor Handle**. Once seated, rotate the handle clockwise until it snaps in place.



Contract the Expandable Distractor to the starting height by rotating the handle counterclockwise until it stops.

Insert the Expandable Distractor into the disc space at its contracted height. Expand the assembly gradually by rotating the handle clockwise. The Expandable Distractor height is shown on the back of the Distractor Handle. Use caution during expansion to avoid excessive distraction and endplate damage. Rotate the handle counterclockwise to contract the distractor before removing from the disc space.

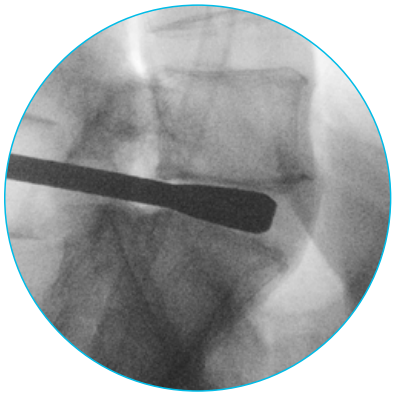
Line indicates height in mm (6mm shown)

DISASSEMBLING THE EXPANDABLE DISTRACTOR ASSEMBLY

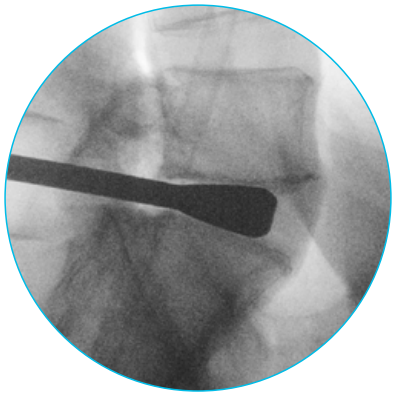
To remove the Distractor Handle, rotate counterclockwise until it stops. Slightly loosen the handle by rotating it clockwise one quarter turn. Press the silver button on the handle and hold while rotating counterclockwise one full turn. Release the silver button and continue to unthread the handle to fully disengage. Once fully unthreaded, press the silver button to fully remove the handle. Completely unthread the Counter-Torque Handle from the Expandable Distractor.

STEP 6 SIZING

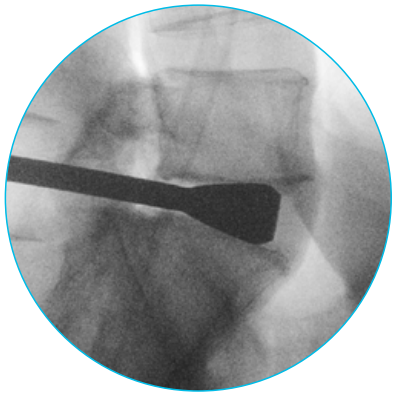
Determine the size of the intervertebral space using appropriately sized **Trials**. A secure fit is desirable in order to maintain disc height and stabilize the segment and can be confirmed using fluoroscopy and tactile feel. Insert the least lordotic Trial into the disc space and rotate to determine height and lordosis. Increase size as needed. Use fluoroscopy to determine the appropriate lordosis before selecting an implant.



8° trial



15° trial



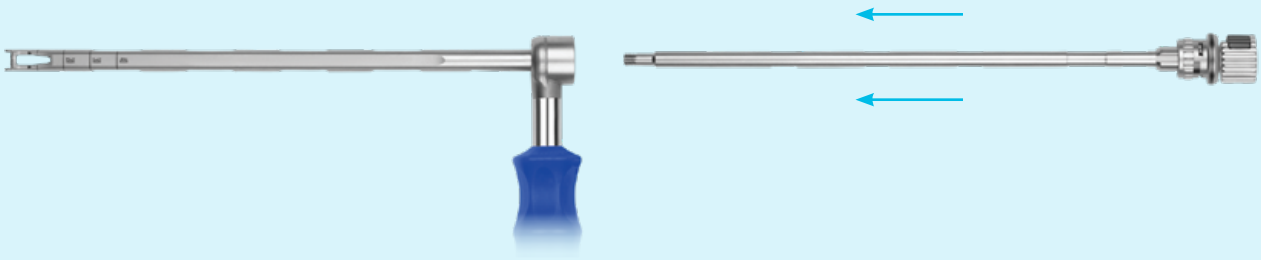
22° trial

STEP 7 INSERTION

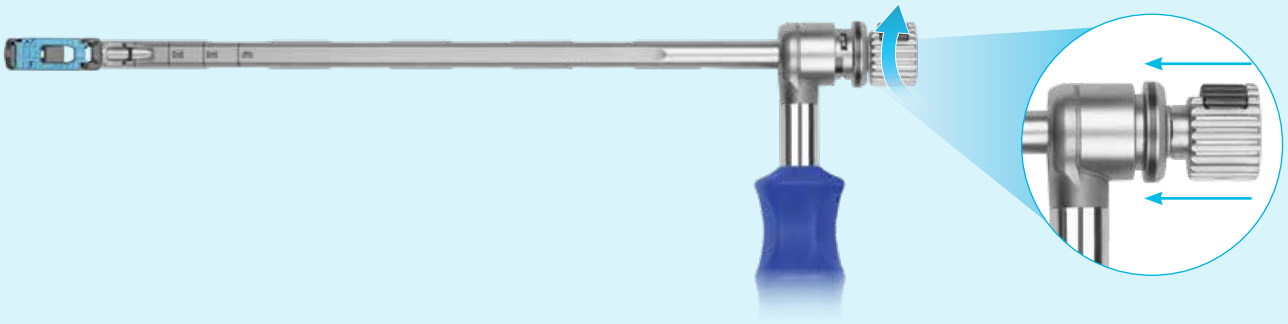
Assemble the Inserter and load the selected implant as shown below. Ensure the implant is fully collapsed. Insert the implant into the disc space in collapsed state using the Inserter assembly. Lightly impact on the back of the assembly as necessary. The implant should be slightly recessed into the disc space.

ASSEMBLING THE IMPLANT INSERTER

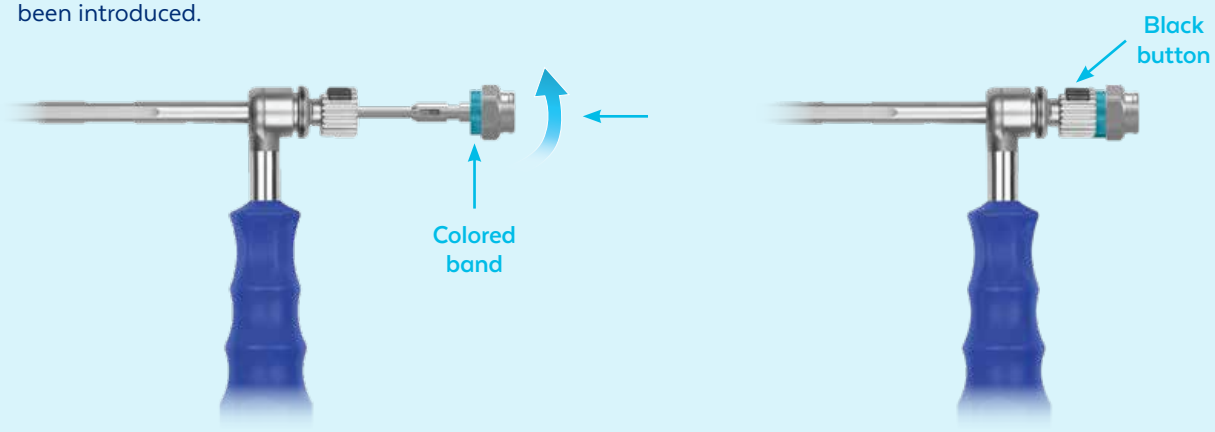
Slide the **Inserter Threaded Shaft** into the **Inserter Sleeve**. Ensure slider with black ring is positioned toward the black button. Then slide the Inserter Threaded Shaft into the Inserter Sleeve.



With the implant in the forks of the Inserter Sleeve, press the shaft into the sleeve and rotate clockwise until finger tight to attach the implant. Ensure the implant is secure. Do not use the **Spanner Wrench** to over-tighten. Push the slider forward to lock.



Introduce the appropriate Driver into the Inserter assembly. Press down with a slight rotation to fully seat the Driver. The black button on the Inserter Threaded Shaft will return to its resting state once the Driver is fully seated. Bands on the Drivers are color-coded to match the selected implant. **DO NOT** pre-pack the implant until the driver has been introduced.



The Inserter Sleeve is available in two orientations to accommodate the desired approach and anatomy.

STEP 8 EXPANSION

Once implant placement is confirmed using fluoroscopy, attach the **Torque-Limiting Handle 2.0Nm** to the Inserter assembly. An audible click confirms the handle is fully seated.

Rotate the driver clockwise to expand the implant to the appropriate height.

Expansion is determined by the tactile feel of the implant in the disc space. The desired fit is confirmed visually or under fluoroscopy by comparing to adjacent disc level heights. Minor adjustments in height may be made before the implant is detached from the Inserter assembly by rotating the handle clockwise (expand) or counterclockwise (collapse).

The overall implant height is determined by counting the number of revolutions of the Torque-Limiting Handle. Approximately 1.75 revolutions equal 1mm of expansion. The arrow on the end of the Torque-Limiting Handle may be used to count revolutions.

If inserting two implants, count the number of revolutions to ensure that both implants are expanded to the same height.

The Torque-Limiting Handle helps to identify when the following conditions occur:

- The implant has reached its maximum height expansion

OR

- The implant exerts the maximum allowable output of distraction force

Use caution while expanding the implant to avoid excessive distraction and endplate damage. The torque limit is designed to protect the integrity of the implant and not the vertebral endplates. Do not impact on the Torque-Limiting Handle.

Rotations Required to Reach Height

Expansion Ranges	Final Heights (mm)												
	6	7	8	9	10	11	12	13	14	15	16	17	18
6-12mm	0	1.75	3.5	5.25	7.0	8.75	10						
7-13mm		0	1.75	3.5	5.25	7.0	8.75	10					
7-14mm		0	1.75	3.5	5.25	7.0	8.75	10	11.75				
9-15mm				0	1.75	3.5	5.25	7.0	8.75	10			
9-16mm				0	1.75	3.5	5.25	7.0	8.75	10	11.75		
10-17mm					0	1.75	3.5	5.25	7.0	8.75	10	11.75	
10-18mm					0	1.75	3.5	5.25	7.0	8.75	10	11.75	13.5
11-17mm						0	1.75	3.5	5.25	7.0	8.75	10	11.75

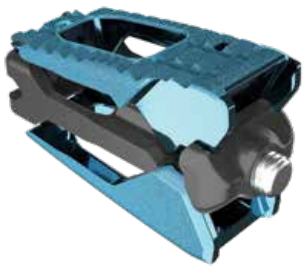
1 rotation = 0.6mm

The tables below provide the number of revolutions required for the endplates to achieve lordotic profile based on length, lordosis, and starting height.

22mm Length Implants		
Starting Height	**Lordosis**	**No. of rotations to tilt**
6mm	8°	2.0
9mm	8°	2.0
7mm	15°	4.0
10mm	15°	4.0
9mm	22°	5.0
11mm	22°	5.0

26mm Length Implants		
Starting Height	**Lordosis**	**No. of rotations to tilt**
6mm	8°	3.0
9mm	8°	4.5
9mm	8°	4.5
7mm	15°	4.5
10mm	15°	4.5
9mm	22°	6.0

30mm Length Implants		
Starting Height	**Lordosis**	**No. of rotations to tilt**
6mm	8°	3.5
9mm	8°	4.5
7mm	15°	5.5
10mm	15°	5.5
10mm	22°	6.5



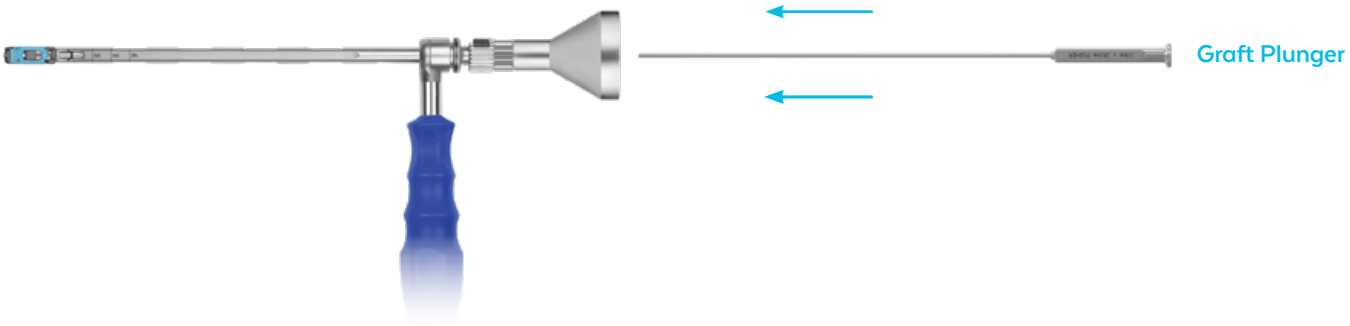
STEP 9 GRAFT PACKING

With the Inserter assembly in place, autograft or allograft (cortical or corticocancellous) bone graft material may be packed into the graft chamber of the implant after expansion. **Post-expansion graft packing should only occur once placement and expansion are fully confirmed and finalized**. Remove the Torque-Limiting Handle and release the Driver from the Inserter assembly by pressing the black button and remove.

Fill the **Funnel** and **Funnel Tube** halfway with morselized graft material. Advance the graft through the tube to confirm that the graft particulate size can be easily advanced.

Insert the conical tip of the Funnel Tube into the proximal end of the Inserter assembly. Insert the **Graft Plunger** through the Funnel Tube to advance the graft material into the implant until tightly packed. Additional autograft or allograft bone should be packed around the implant if possible. Alternatively, the conical tip of the Funnel Tube may be seated into the back of the implant (once the inserter is disconnected) for graft packing.

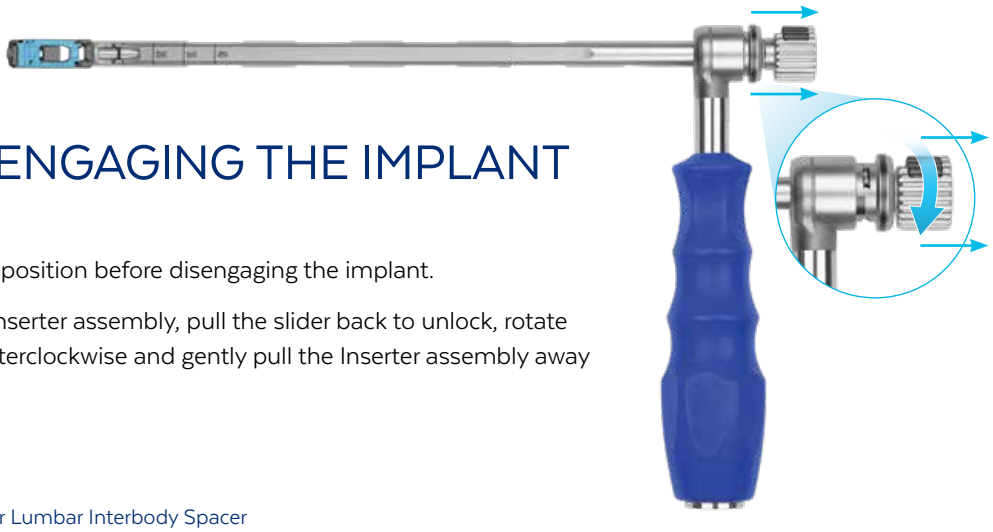
Note: Take care when backfilling the outside of the inserter as the Graft Plunger sticks out beyond the Funnel Tube.



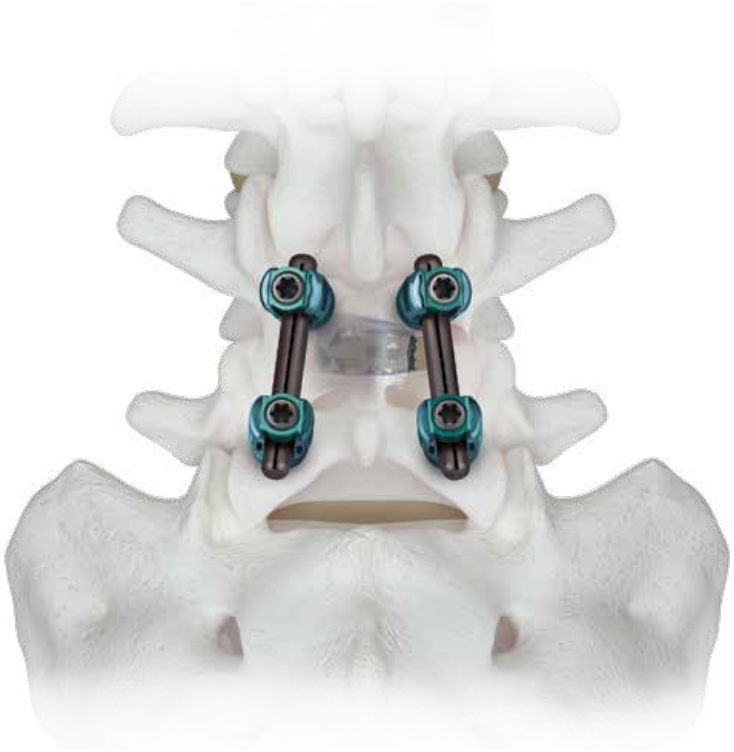
STEP 10 DISENGAGING THE IMPLANT

Using fluoroscopy, verify implant position before disengaging the implant.

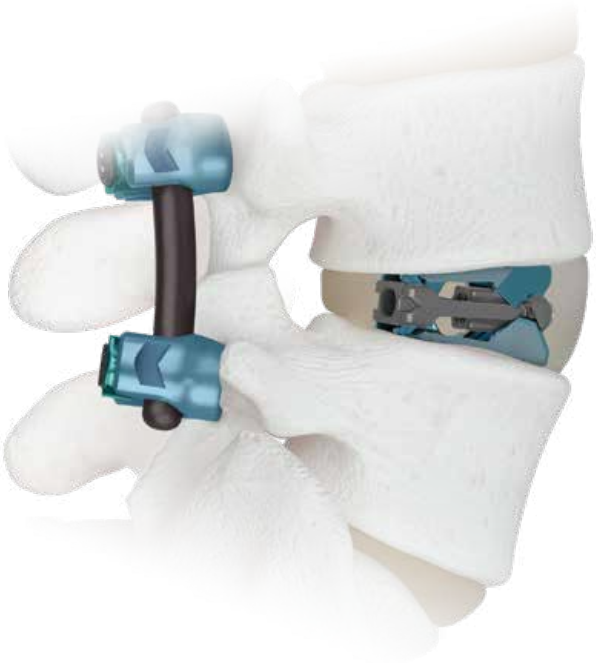
To detach the implant from the Inserter assembly, pull the slider back to unlock, rotate the Inserter Threaded Shaft counterclockwise and gently pull the Inserter assembly away from the implant.



FINAL CONSTRUCT



Posterior view



Lateral view

FINAL POSITION

Posterior Placement

Transforaminal Placement

SUPPLEMENTAL FIXATION

Supplemental fixation such as CREO®, REVERE® or REVOLVE® is required at all interbody level(s). Please refer to the corresponding surgical technique guides for additional instructions.

OPTIONAL: REMOVAL

If bone graft has already been inserted into the implant, an **Irrigation Needle** and **Suction Tip** are available to loosen the graft and re-engage the Driver in the implant. The clearing wire included in the Suction Tip may be used to clear debris from the Irrigation Needle.

To remove, place the **Rigid Driver** into the Inserter assembly to help locate the implant. Place the Inserter Sleeve forks onto the implant and thread the Inserter Threaded Shaft. Attach the Torque-Limiting Handle and reduce the implant's height by applying downward pressure and rotating counterclockwise until it fully collapses. **Do not over-collapse the implant**. Use fluoroscopy to confirm that the implant is fully collapsed.

Alternatively, the implant may be rotated 90° without being collapsed and subsequently extracted using forceps or other manual surgical instruments.

Rigid Driver and Insterter assembly

SABLE™
8mm STERILE IMPLANT SET 9172.9002

Part No.	Description	Qty
1172.0010S	SABLE™ Spacer, 8x22mm, 6-12mm, 8°	2
1172.0013S	SABLE™ Spacer, 8x22mm, 9-15mm, 8°	2
1172.0021S	SABLE™ Spacer, 8x22mm, 7-13mm, 15°	2
1172.0024S	SABLE™ Spacer, 8x22mm, 10-16mm, 15°	2
1172.0033S	SABLE™ Spacer, 8x22mm, 9-15mm, 22°	2
1172.0035S	SABLE™ Spacer, 8x22mm, 11-17mm, 22°	2
6172.0012S	Irrigation Needle	1
9172.0002	SABLE™ 8mm Sterile Implant Soft Case	

SABLE™
10mm STERILE IMPLANT SET 9172.9003

Part No.	Description	Qty
1172.2010S	SABLE™ Spacer, 10x22mm, 6-12mm, 8°	2
1172.2013S	SABLE™ Spacer, 10x22mm, 9-15mm, 8°	2
1172.2021S	SABLE™ Spacer, 10x22mm, 7-13mm, 15°	2
1172.2024S	SABLE™ Spacer, 10x22mm, 10-16mm, 15°	2
1172.2033S	SABLE™ Spacer, 10x22mm, 9-15mm, 22°	2
1172.2035S	SABLE™ Spacer, 10x22mm, 11-17mm, 22°	2
1172.2110S	SABLE™ Spacer, 10x26mm, 6-12mm, 8°	2
1172.2113S	SABLE™ Spacer, 10x26mm, 9-16mm, 8°	2
1172.2121S	SABLE™ Spacer, 10x26mm, 7-14mm, 15°	2
1172.2124S	SABLE™ Spacer, 10x26mm, 10-17mm, 15°	2
1172.2133S	SABLE™ Spacer, 10x26mm, 9-17mm, 22°	2
1172.2210S	SABLE™ Spacer, 10x30mm, 6-12mm, 8°	2
1172.2213S	SABLE™ Spacer, 10x30mm, 9-16mm, 8°	2
1172.2221S	SABLE™ Spacer, 10x30mm, 7-14mm, 15°	2
1172.2224S	SABLE™ Spacer, 10x30mm, 10-17mm, 15°	2
1172.2234S	SABLE™ Spacer, 10x30mm, 10-18mm, 22°	2
6172.0012S	Irrigation Needle	1
9172.0003	SABLE™ 10mm Sterile Implant Soft Case	

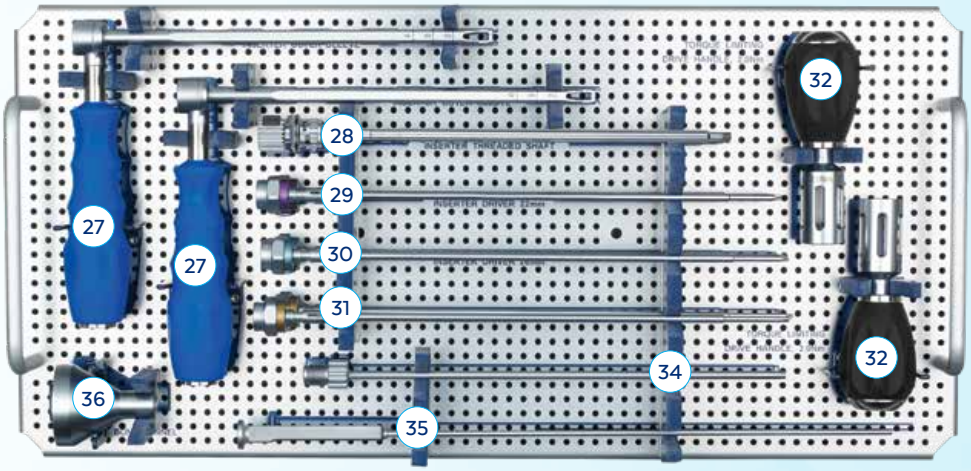
SABLE™
12mm STERILE IMPLANT SET 9172.9004

Part No.	Description	Qty
1172.4110S	SABLE™ Spacer, 12x26mm, 6-12mm, 8°	2
1172.4113S	SABLE™ Spacer, 12x26mm, 9-16mm, 8°	2
1172.4121S	SABLE™ Spacer, 12x26mm, 7-14mm, 15°	2
1172.4124S	SABLE™ Spacer, 12x26mm, 10-17mm, 15°	2
1172.4133S	SABLE™ Spacer, 12x26mm, 9-16mm, 22°	2
1172.4210S	SABLE™ Spacer, 12x30mm, 6-12mm, 8°	2
1172.4213S	SABLE™ Spacer, 12x30mm, 9-16mm, 8°	2
1172.4221S	SABLE™ Spacer, 12x30mm, 7-14mm, 15°	2
1172.4224S	SABLE™ Spacer, 12x30mm, 10-17mm, 15°	2
1172.4234S	SABLE™ Spacer, 12x30mm, 10-17mm, 22°	2
6172.0012S	Irrigation Needle	1
9172.0004	SABLE™ 12mm Sterile Implant Soft Case	

SABLE™
INSTRUMENT SET 9172.9001

	Instrument		Qty
1	675.005	T-Handle, w/ Impaction Cap	2
2	626.405	Paddle Distractors, 5mm	1
3	626.406	Paddle Distractors, 6mm	1
4	626.407	Paddle Distractors, 7mm	1
5	604.105	5mm Static Trial	1
6	604.106	6mm Static Trial	1
7	604.107	7mm Static Trial	1
8	626.505	Sizer/Shaver, 5mm	1
9	626.506	Sizer/Shaver, 6mm	1
10	626.507	Sizer/Shaver, 7mm	1
11	626.508	Sizer/Shaver, 8mm	1
12	626.509	Sizer/Shaver, 9mm	1
13	626.510	Sizer/Shaver, 10mm	1
14	626.511	Sizer/Shaver, 11mm	1
15	626.512	Sizer/Shaver, 12mm	1
16	626.513	Sizer/Shaver, 13mm	1
17	626.514	Sizer/Shaver, 14mm	1
18	626.515	Sizer/Shaver, 15mm	1
19	626.516	Sizer/Shaver, 16mm	1
20	626.517	Sizer/Shaver, 17mm	1
21	6172.1210	Expandable Distractor 10x26mm, 6-12mm	1

	Instrument		Qty
22	6172.6008	8° Lordotic Trial	1
23	6172.6015	15° Lordotic Trial	1
24	6172.6022	22° Lordotic Trial	1
25	6172.2000	Expandable Distractor Handle	1
26	6154.3003	Counter-Torque Handle	1
27	6172.0001	Inserter Sleeve, ML	2
28	6172.0002	Inserter Threaded Shaft	2
29	6172.0022	Inserter Driver 22mm	2
30	6172.0026	Inserter Driver 26mm	2
31	6172.0030	Inserter Driver 30mm	2
32	6172.0003	Torque-Limiting Handle, 2.0Nm	2
33	6172.0005	Rigid Driver	1
34	6172.0006	Funnel Tube	1
35	6172.0007	Graft Pusher	1
36	681.013	Bone Funnel	1
37	6172.0008	Spanner Wrench	1
38	6172.0010	Suction Tip	1
39	6172.0011	Needle Guide	1
40	694.018	Slide Hammer	1
	9172.0001	SABLE™ Instrument Graphic Case	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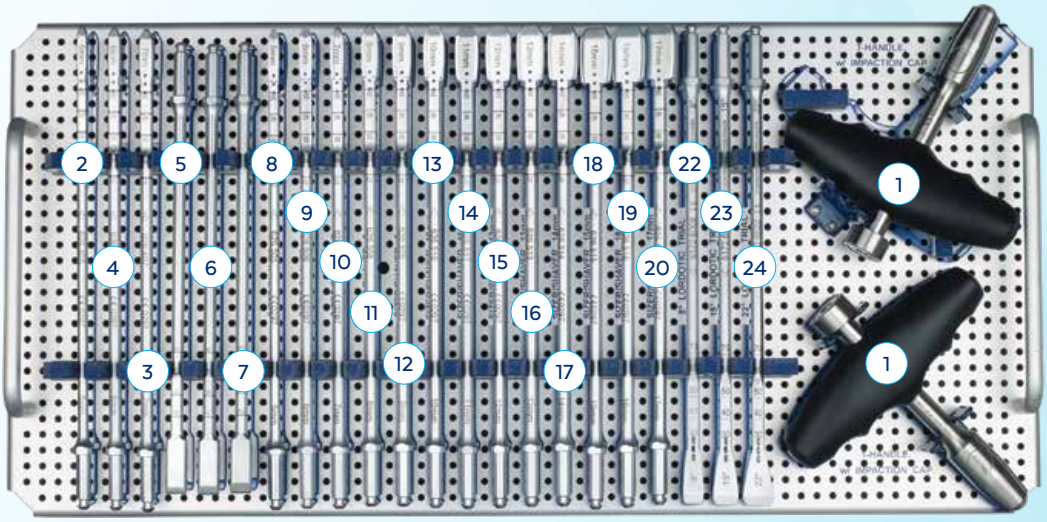
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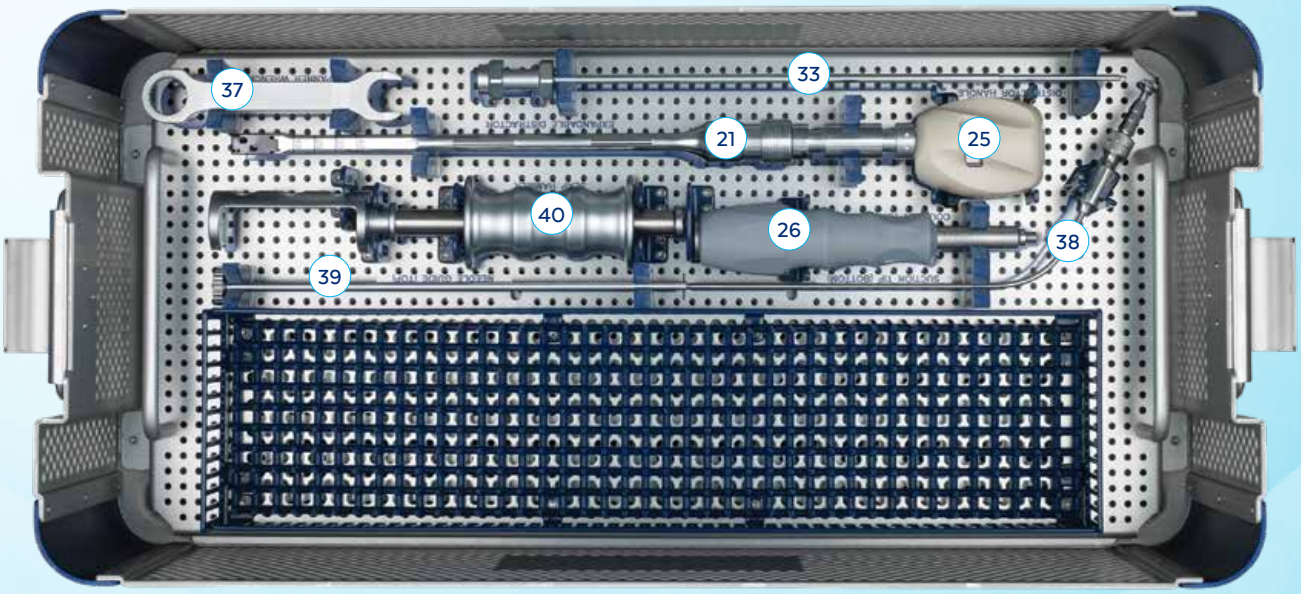
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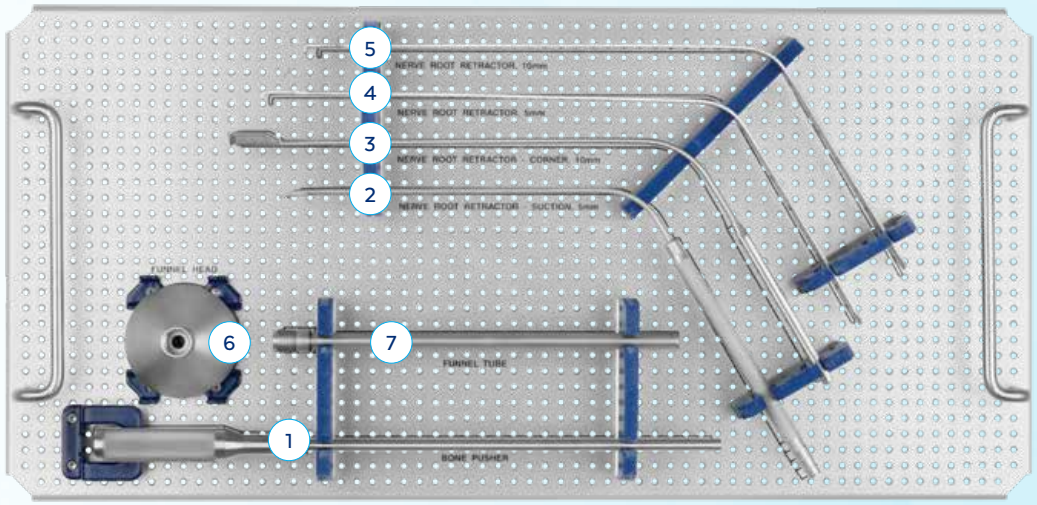
POSTERIOR DISC PREP
INSTRUMENT I SET 926.901

	Instrument		Qty
1	626.210	Push Rod Assembly, Bone Funnel	1
2	626.215	Nerve Retractor, 5mm, Suction	1
3	626.220	Nerve Retractor, Corner	1
4	603.061	Nerve Root Retractor, Fine, 5mm	1
5	603.062	Nerve Root Retractor, Medium, 10mm	1
6	679.015	Bone Funnel	1
7	679.015	Bone Funnel - Tube	1
8	626.235	Disc Rongeur, 250x2mm, Straight	1
9	626.236	Disc Rongeur, 250x2mm, Up Biting	1
10	626.240	Disc Rongeur, 250x4mm, Straight	1
11	626.241	Disc Rongeur, 250x6mm, Straight	1
12	626.242	Disc Rongeur, 250x4mm, Up Biting	1
13	626.243	Disc Rongeur, 250x4mm, Down Biting	1
14	626.250	Kerrison, 250x3mm, Straight	1
15	626.252	Kerrison, 250x5mm, Straight	1
16	626.260	Lamina Spreader, Hinged	1
	926.102	Graphic Case	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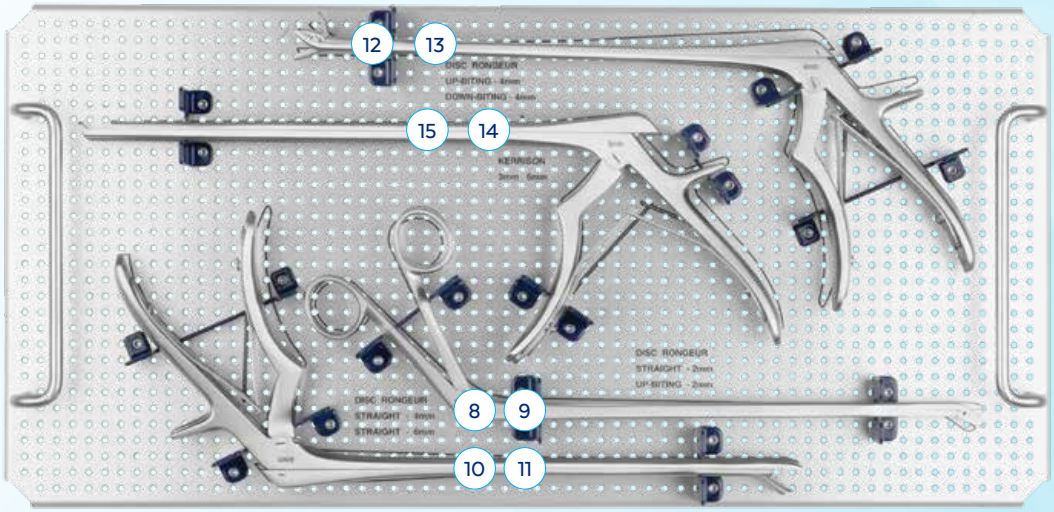
FUNNEL HEAD
FUNNEL TUBE
BONE PUSHER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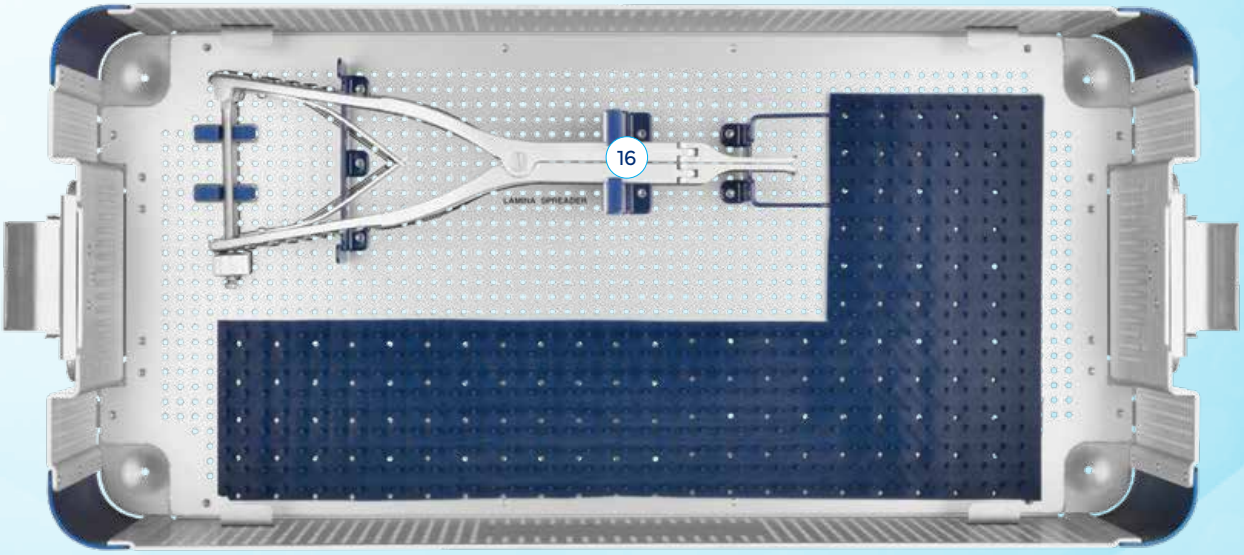
KERRISON
DISC RONGEUR
STRAIGHT - 2mm
UP-BITING - 2mm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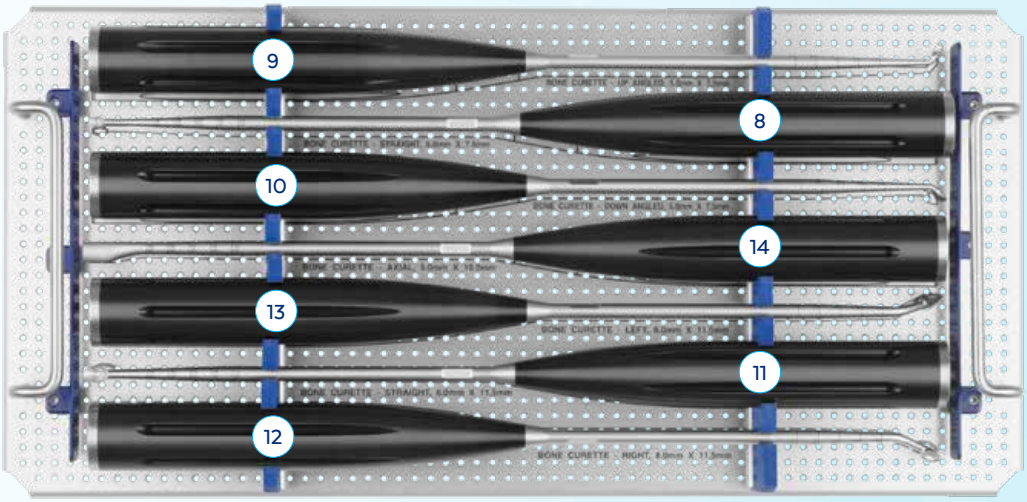
LAMINA SPREADER

POSTERIOR DISC PREP
INSTRUMENT II SET 926.902

	Instrument		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	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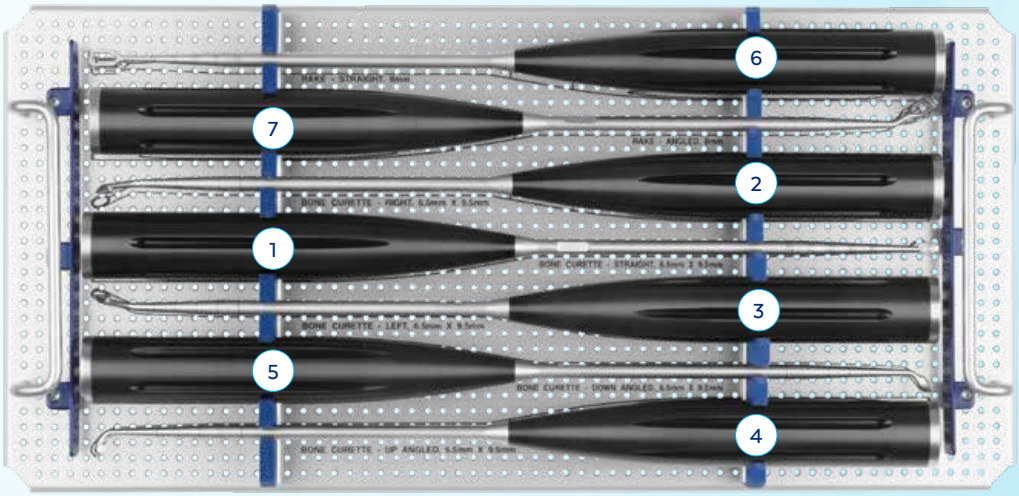
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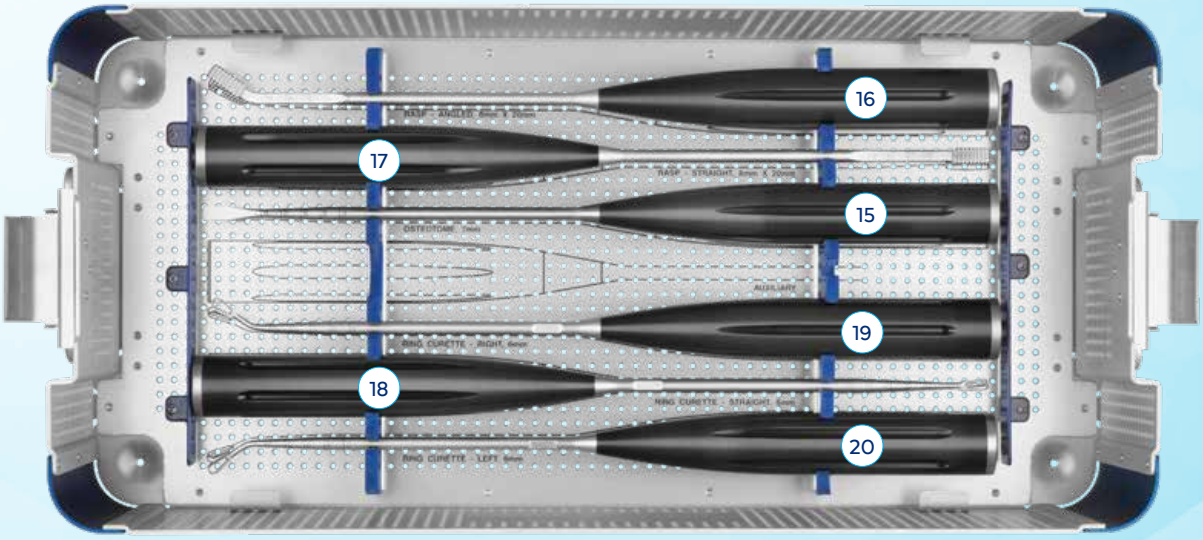
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MARS™ 3V RETRACTOR
INSTRUMENT SET 998.901

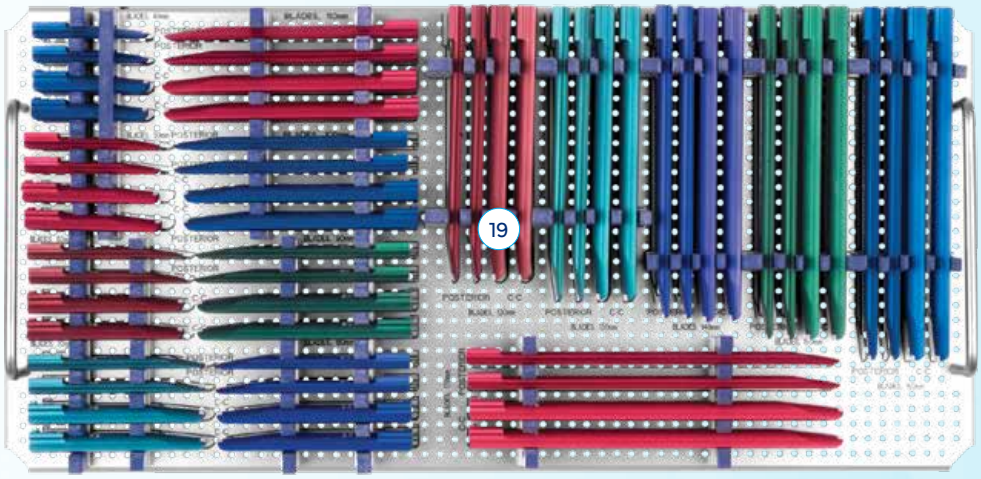
	Instruments		Qty
1	623.003	K-Wire Gripper	1
2	698.100	Retractor 3 Blade Frame	1
3	632.102	Retractor 2 Blade Frame	1
4	632.150	10mm Socket Driver	1
5	698.250	Hook and Latch Driver	1
6	675.403	Flouro Modulator	1
7	675.404	Incision Locator	1
8	675.513	8” Suction	1
9	675.800	Radiolucent Initial Dilator Holder	1
10	698.205	Cannula A	1
11	698.210	Cannula B	1
12	698.215	Cannula C	1
13	698.220	Cannula D	1
14	698.230	Frame Handle	1
15	698.240	Shim Tool, CC	1
16	698.260	Docking Pin Tool	1
17	698.330	Disc Shim Tool	1
18	698.350	Docking Pin Sleeve	4

19	Retractor Blades		Qty
	698.450	Blade, Posterior, 40mm	2
	698.452	Blade, Posterior, 50mm	2
	698.454	Blade, Posterior, 60mm	2
	698.456	Blade, Posterior, 70mm	2
	698.458	Blade, Posterior, 80mm	2
	698.460	Blade, Posterior, 90mm	2
	698.462	Blade, Posterior, 100mm	2
	698.464	Blade, Posterior, 110mm	2
	698.466	Blade, Posterior, 120mm	2
	698.468	Blade, Posterior, 130mm	2
	698.470	Blade, Posterior, 140mm	2
	698.472	Blade, Posterior, 150mm	2
	698.474	Blade, Posterior, 160mm	2

Retractor Blades		Qty
698.476	Blade, Posterior, 170mm	2
698.510	Blade, CC, 40mm	2
698.512	Blade, CC, 50mm	2
698.514	Blade, CC, 60mm	2
698.516	Blade, CC, 70mm	2
698.518	Blade, CC, 80mm	2
698.520	Blade, CC, 90mm	2
698.522	Blade, CC, 100mm	2
698.524	Blade, CC, 110mm	2
698.526	Blade, CC, 120mm	2
698.528	Blade, CC, 130mm	2
698.530	Blade, CC, 140mm	2
698.532	Blade, CC, 150mm	2
698.534	Blade, CC, 160mm	2
698.536	Blade, CC, 170mm	2

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

Items in gray are additionally available.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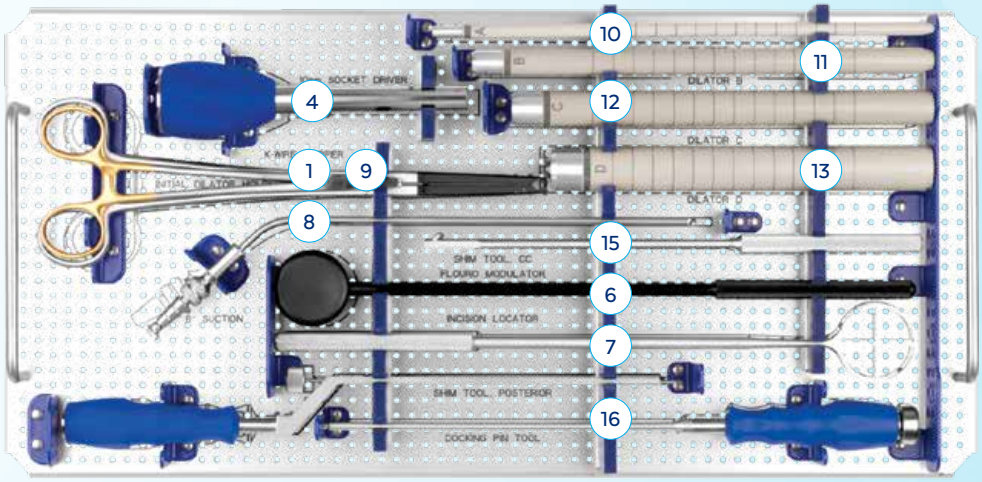
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SOCKET DRIVER
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DILATOR B
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DILATOR D
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SHIM TOOL, CC
FLOURO MODULATOR
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SUCTION
INCISION LOCATOR
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SHIM TOOL, POSTERIOR
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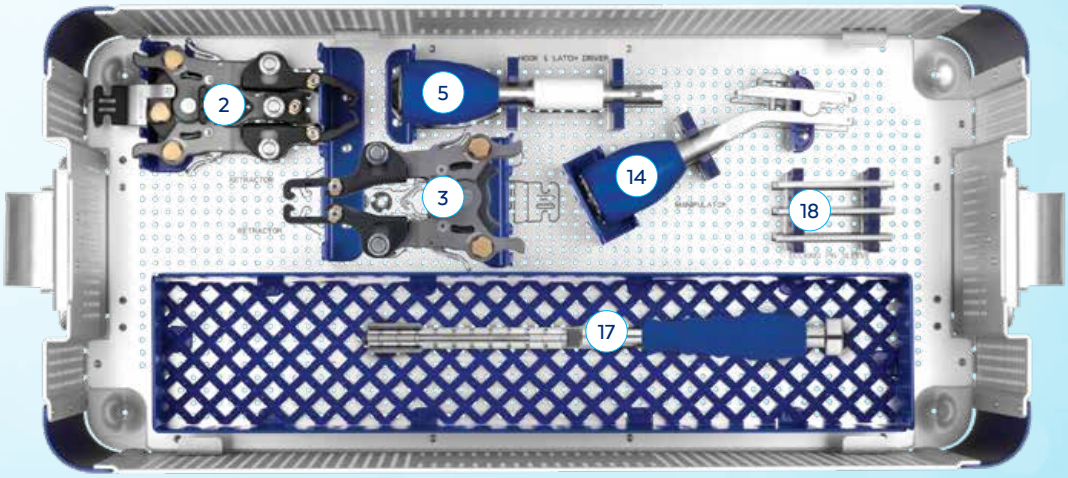
COCKING PIN TOOL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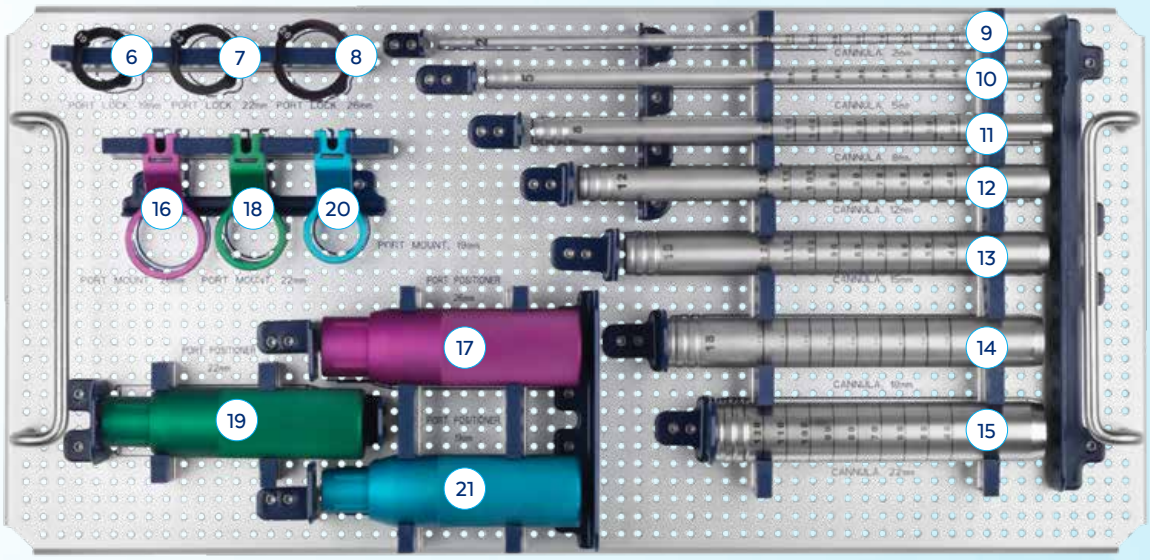
MARS™
INSTRUMENT II SET 932.902

	Instrument		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
	632.310S	Light Cable	1
6	632.390	Port Lock, 19mm	1
7	632.391	Port Lock, 22mm	1
8	632.392	Port Lock, 26mm	1
9	632.401	2mm Cannula	1
10	632.402	5mm Cannula	1
11	632.403	8mm Cannula	1
12	632.404	12mm Cannula	1
13	632.405	15mm Cannula	1
14	632.406	18mm Cannula	1
15	632.407	22mm Cannula	1
16	632.408	26mm Port Mount	1
17	632.409	26mm Port Positioner	1
18	632.410	22mm Port Mount	1
19	632.411	22mm Port Positioner	1
20	632.412	19mm Port Mount	1
21	632.413	19mm Port Positioner	1
22	632.500	Table Clamp	1
23	632.750	Articulating Arm Assembly	1
	932.002	MARS™ Instrument II Graphic Case	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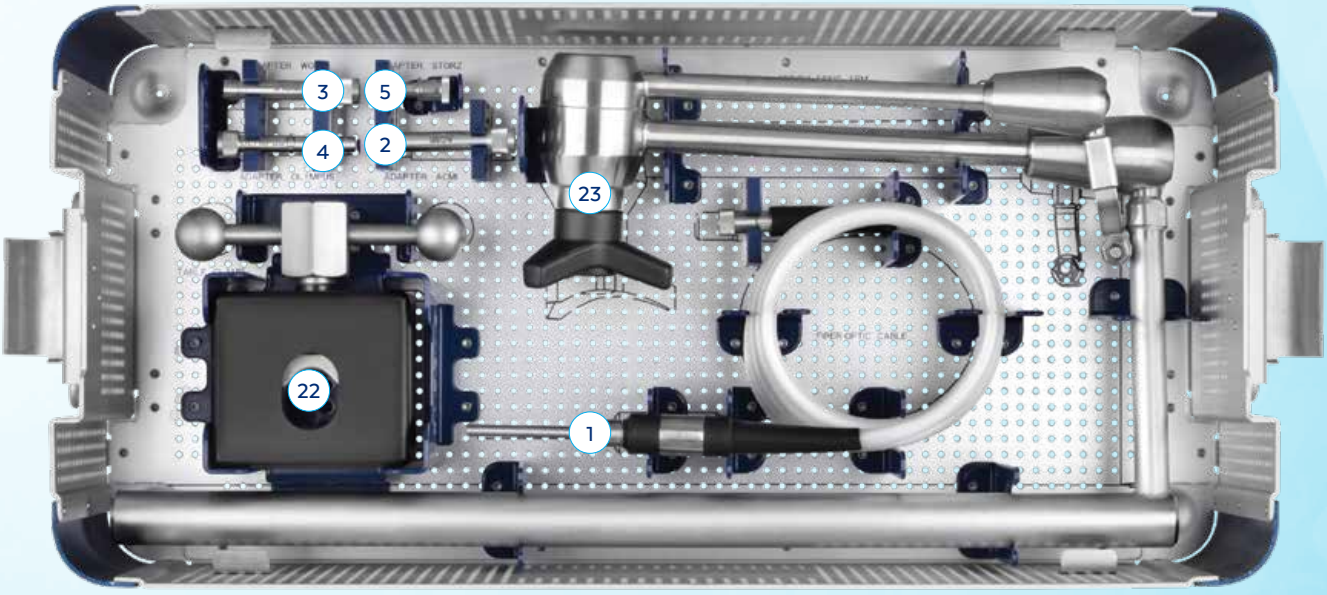
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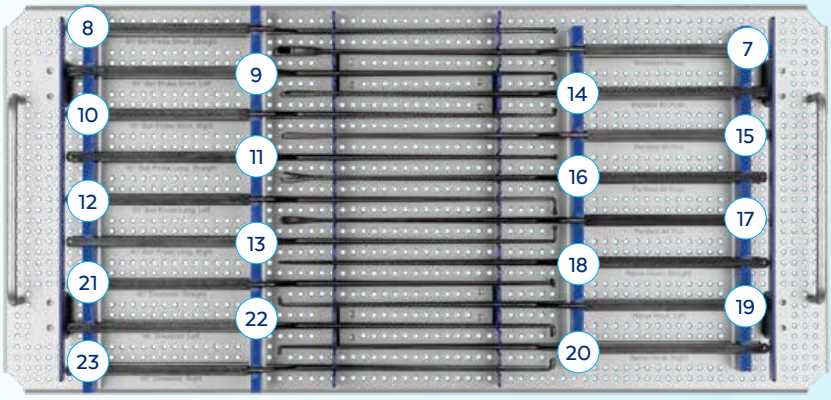
MARS™
INSTRUMENT III SET 932.903

	Instruments		Qty
1	632.600	Pituitary, 2mm Bayoneted	1
	632.601	Pituitary, 2mm, Down-Biting, Bayoneted	1
	632.602	Pituitary, 2mm, Up-Biting, Bayoneted	1
	632.605	Pituitary, 4mm, Up-Biting, Bayoneted	1
2	632.610	Micro Pituitary, 2mm, Up-Biting, Bayoneted	1
	632.611	Micro Pituitary, 2mm, Bayoneted	1
3	632.615	Pituitary, Ring Handle, 2mm	1
4	632.616	Scissors, Straight	1
	632.618	Scissors, Curved Left	1
	632.619	Scissors, Curved Right	1
5	632.620	Kerrison 40°, 3mm, Bayoneted	1
	632.621	Kerrison 90°, 3mm, Bayoneted	1
	632.622	Kerrison 40°, 4mm, Bayoneted	1
	632.623	Kerrison 90°, 4mm, Bayoneted	1
	632.624	Kerrison 40°, 5mm, Bayoneted	1
	632.625	Kerrison 90°, 5mm, Bayoneted	1
6	632.630	Bone Curette Straight, 5.2 Cup, Bayoneted	1
	632.631	Bone Curette Straight, 3.6 Cup, Bayoneted	1
	632.632	Bone Curette Angled, 5.2 Cup, Bayoneted	1
	632.633	Bone Curette Angled, 3.6 Cup, Bayoneted	1
	632.634	Bone Curette Reverse Angled, 5.2 Cup, Bayoneted	1
	632.635	Bone Curette Reverse Angled, 3.6 Cup, Bayoneted	1
7	632.640	Woodson Probe	1
8	632.641	90° Ball Probe Short, Straight, Bayoneted	1
9	632.642	90° Ball Probe Short, Left, Bayoneted	1
10	632.643	90° Ball Probe Short, Right, Bayoneted	1
11	632.644	90° Ball Probe Long, Straight, Bayoneted	1
12	632.645	90° Ball Probe Long, Left, Bayoneted	1
13	632.646	90° Ball Probe Long, Right, Bayoneted	1
14	632.650	Penfield #2 Push, Bayoneted	1
15	632.651	Penfield #2 Pull, Bayoneted	1

	Instruments		Qty
16	632.652	Penfield #4 Push, Bayoneted	1
17	632.653	Penfield #4 Pull, Bayoneted	1
18	632.655	Nerve Hook, Straight, Bayoneted	1
19	632.656	Nerve Hook, Left, Bayoneted	1
20	632.657	Nerve Hook, Right, Bayoneted	1
21	632.660	90° Dissector, Straight, Bayoneted	1
22	632.661	90° Dissector, Left, Bayoneted	1
23	632.662	90° Dissector, Right, Bayoneted	1
24	632.673	Nerve Root Retractor	1
25	632.674	Nerve Root Retractor, Wide	1
26	632.675	Suction Retractor	1
27	632.676	Bi-Polar Forcep, Straight, Bayoneted, US Connection	1
28	632.677	Bi-Polar Forcep, Angled, Bayoneted, US Connection	1
	932.003	MARS™ Instrument Graphic Case III	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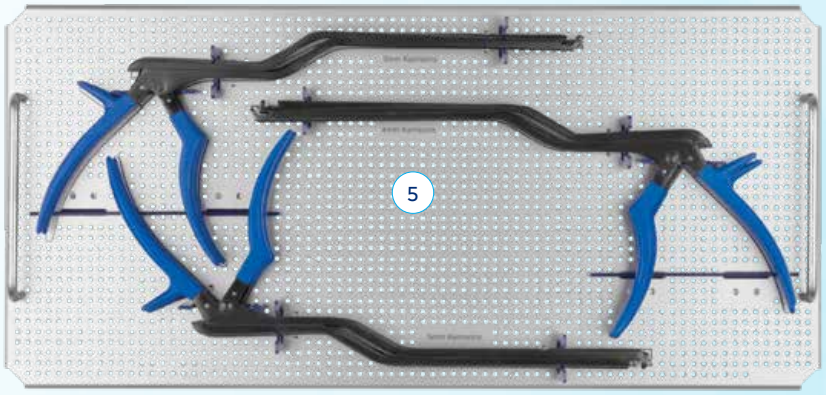
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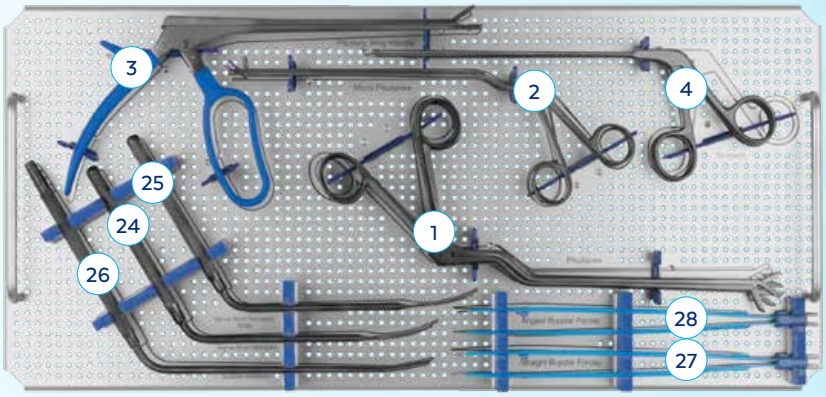
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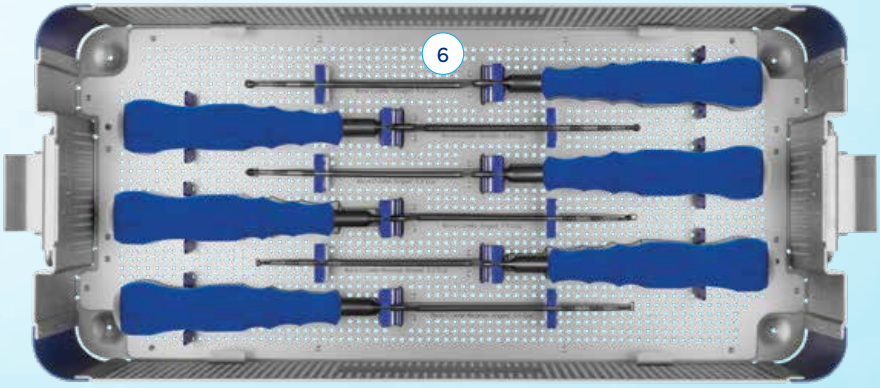
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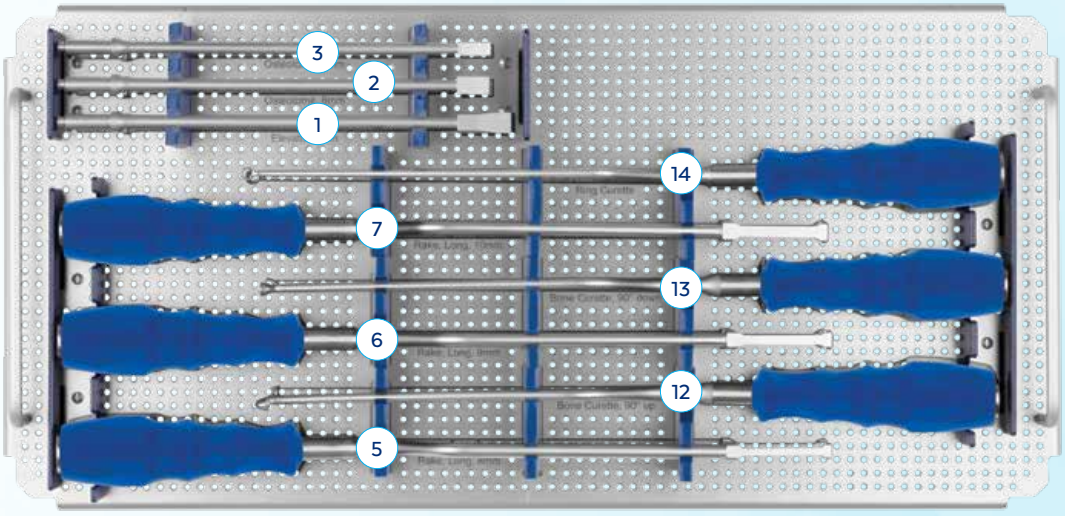
MIS LUMBAR DISCECTOMY
INSTRUMENT SET 979.901

	Instrument		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

Items in gray are additionally available.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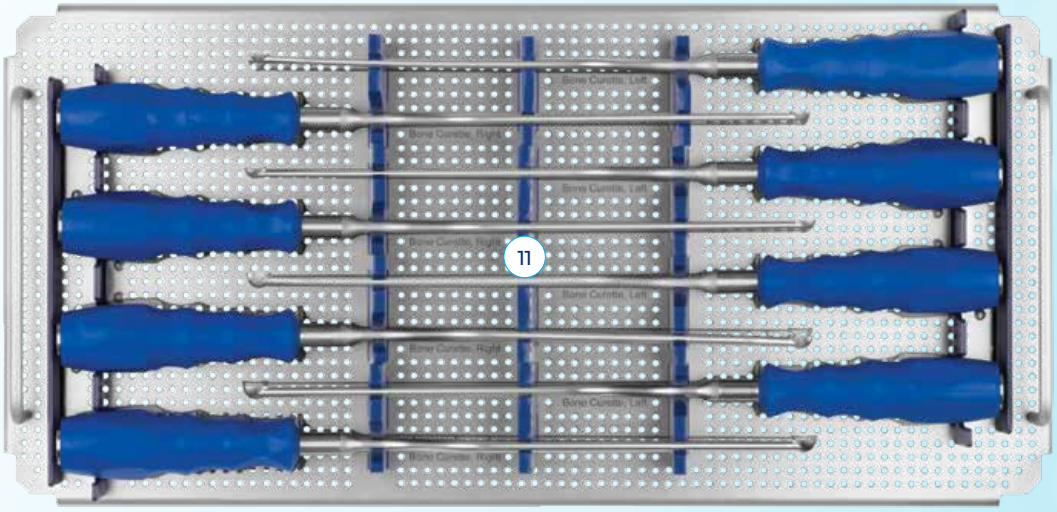
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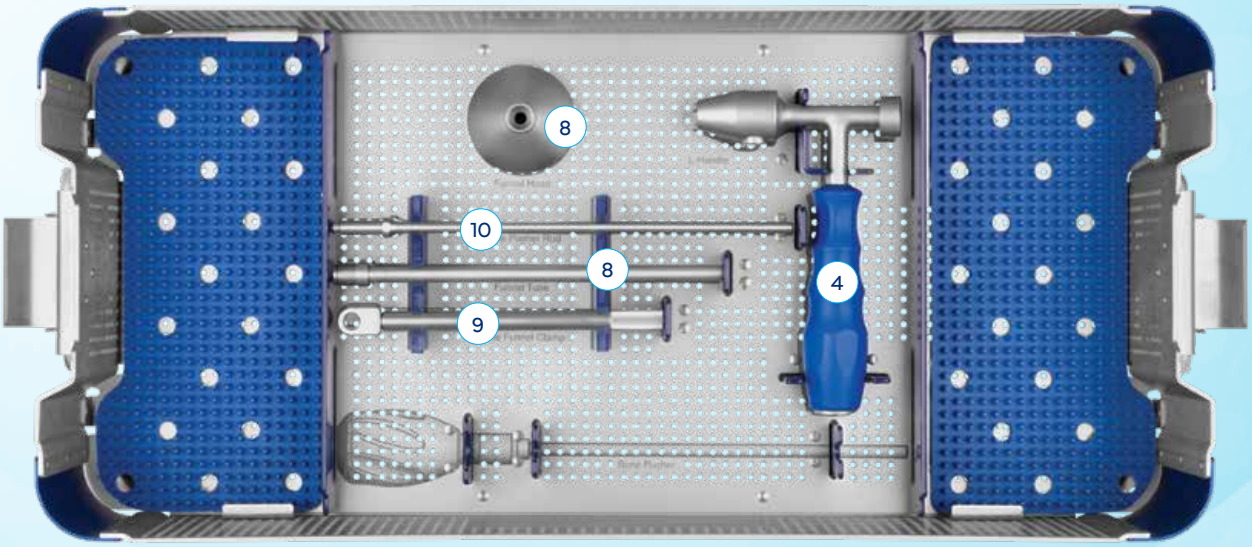
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IMPORTANT INFORMATION ON SABLE™ SPACERS

DESCRIPTION

SABLE™ Spacers are expandable lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. The devices are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients.

SABLE™ Spacers are manufactured from titanium alloy, as specified in ASTM F136 and F1295. The endplates are additively manufactured from titanium alloy powder as specified in ASTM F3001 and an internal component is manufactured from radiolucent PEEK polymer, as specified in ASTM F2026. The drive screw is manufactured from cobalt chromium alloy, as specified in ASTM F1537.

INDICATIONS

SABLE™ Expandable Spacer is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The spacer is to be filled with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone and is to be used with supplemental fixation.

WARNINGS

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

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

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 radiolucent PEEK polymer, commercially pure titanium, titanium alloy, 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 may appear 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.

MRI SAFETY INFORMATION

The SABLE™ 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 SABLE™ 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 these devices is contraindicated in patients with the following conditions:

- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has a suspected or documented allergy, foreign body sensitivity, or known intolerance to any of the implant materials.
- Signs of local inflammation.
- Prior fusion at the level(s) to be treated.
- Severe osteoporosis, which may prevent adequate fixation.
- Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risk versus the benefits to the patient.
- Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
- Any patient not willing to cooperate with postoperative instructions.
- Any condition not described in the indications for use.
- Fever or leukocytosis.
- Pregnancy.
- 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.
- Any case not needing a fusion.
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for used would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

COMPLICATIONS AND POSSIBLE ADVERSE EFFECTS

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

IMPORTANT INFORMATION ON SABLE™ SPACERS

- 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 are 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

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 are available sterile and instruments are nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a thermoplastic polyurethane pouch inside a PETG tray with a heat-sealed Tyvek lid. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants meet pyrogen limit specifications.

Nonsterile 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 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

IMPORTANT INFORMATION ON SABLE™ SPACERS

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 (USA) 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		

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Audubon, PA 19403
www.globusmedical.com

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