GLOBUS MEDICAL

SUSTAIN®-G

Radiolucent Spacer

SURGICAL TECHNIQUE GUIDE

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GLOBUS MEDICAL

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

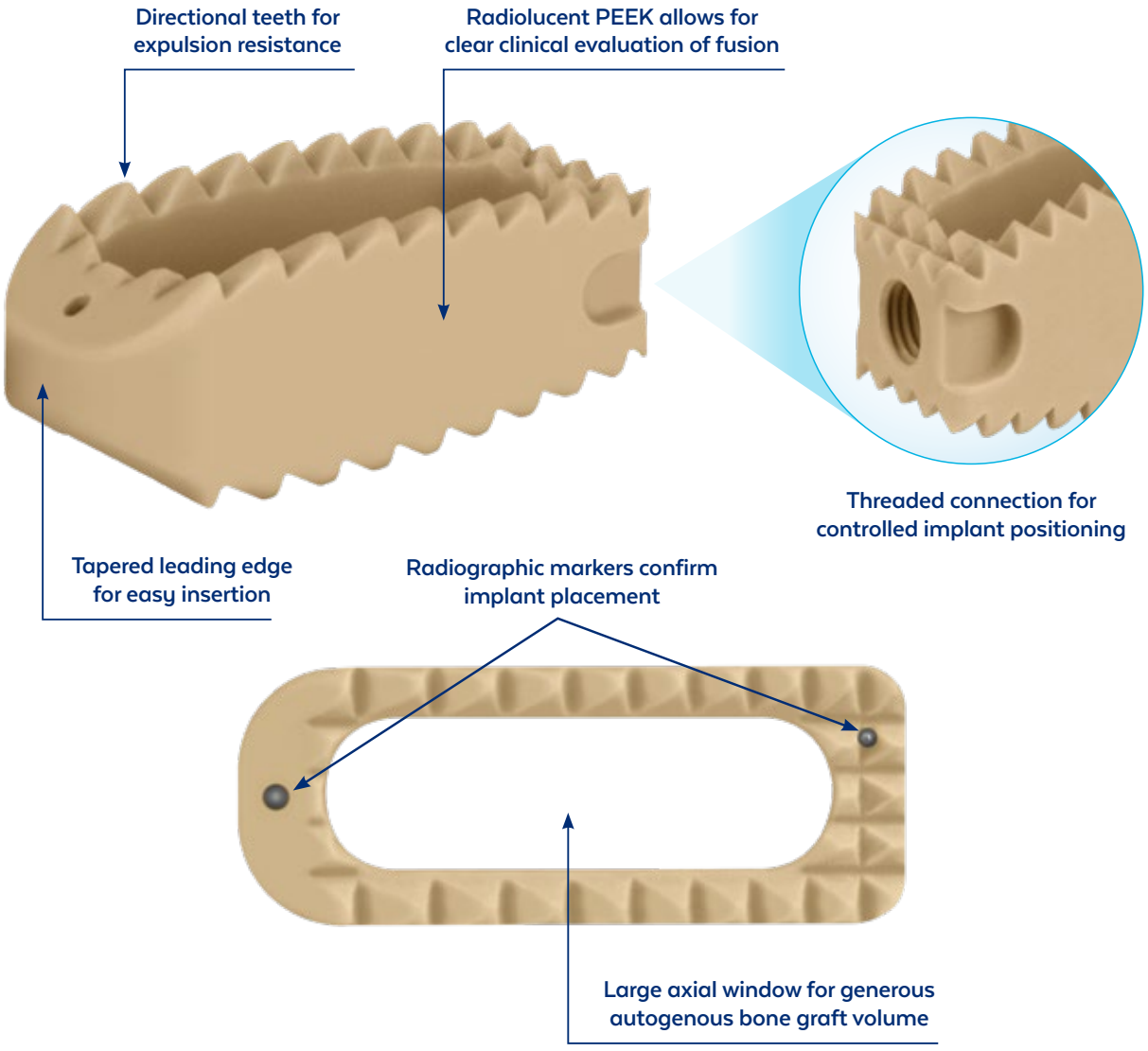
SUSTAIN®-G

SUSTAIN®- G

Radiolucent Spacer

SUSTAIN®-G is a lumbar interbody fusion device made from radiolucent polymer (PEEK). The generous graft window allows for optimal autogenous bone graft volume. The in-line connection provides for optimal visibility during insertion.

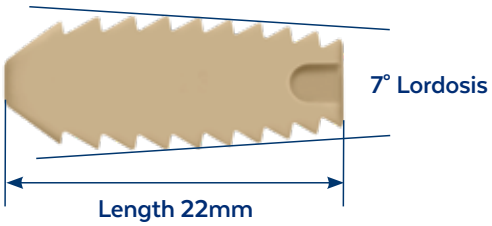
The implant has a threaded connection for controlled implant positioning, while the inferior and superior surfaces of the implant feature directional teeth to resist expulsion. The anterior portion of the implant has a tapered leading edge for ease of insertion.

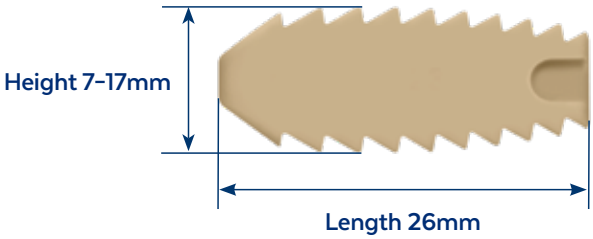


IMPLANT OVERVIEW

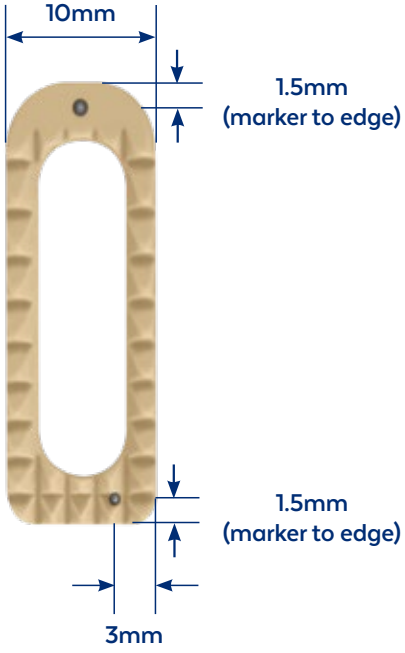
Features of SUSTAIN®-G

- Large graft volume for generous autogenous bone graft volume
- In-line connection for optimal visibility during insertion
- Threaded connection for controlled implant positioning
- Tapered leading edge for easy insertion
- 7° lordosis designed to help restore sagittal balance
- Heights 7–17mm, in 1mm increments
- 10x22mm and 10x26mm footprint options
- Directional teeth for expulsion resistance





SUSTAIN®-G 10x22mm Implant Set 904.995 SUSTAIN®-G 10x26mm Implant Set 904.996		
Height	*10x22mm*	*10x26mm*
7mm	504.207	504.227
8mm	504.208	504.228
9mm	504.209	504.229
10mm	504.210	504.230
11mm	504.211	504.231
12mm	504.212	504.232
13mm	504.213	504.233
14mm	504.214	504.234
15mm	504.215	504.235
16mm	504.216	504.236
17mm	504.217	504.237



INSTRUMENT OVERVIEW

DISTRACTION INSTRUMENTS

Scrapers

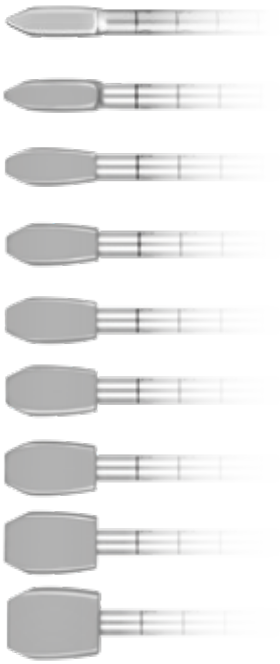
HEIGHT	PART NO.
5mm	604.305
6mm	604.306
7mm	604.307
8mm	604.308
9mm	604.309
10mm	604.310
11mm	604.311
12mm	604.312
13mm	604.313
15mm	604.315
17mm	604.317

Paddle Distractors

HEIGHT	PART NO.
5mm	604.805
6mm	604.806
7mm	604.807
8mm	604.808
9mm	604.809
10mm	604.810
11mm	604.811
12mm	604.812
13mm	604.813
15mm	604.815
17mm	604.817

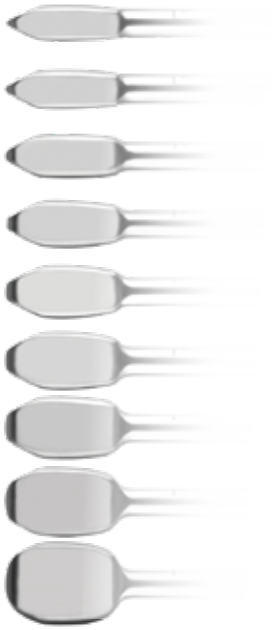
Items highlighted in gray are additoinally available.

Trials, 10mm Wide x 22mm Long



HEIGHT	22mm
7mm	673.207
8mm	673.208
9mm	673.209
10mm	673.210
11mm	673.211
12mm	673.212
13mm	673.213
15mm	673.215
17mm	673.217

Trials, 10mm Wide x 26mm Long



HEIGHT	26mm
7mm	604.107
8mm	604.108
9mm	604.109
10mm	604.110
11mm	604.111
12mm	604.112
13mm	604.113
15mm	604.115
17mm	604.117

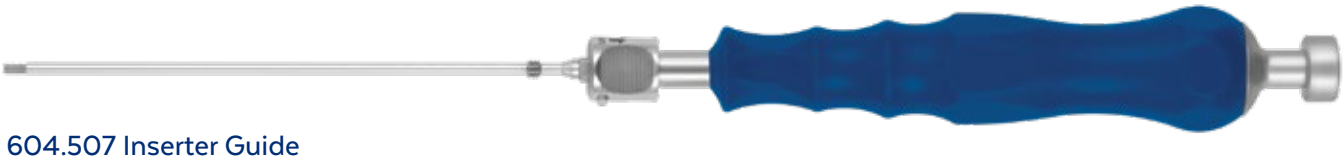
Items highlighted in gray are additoinally available.

INSERTER INSTRUMENTS

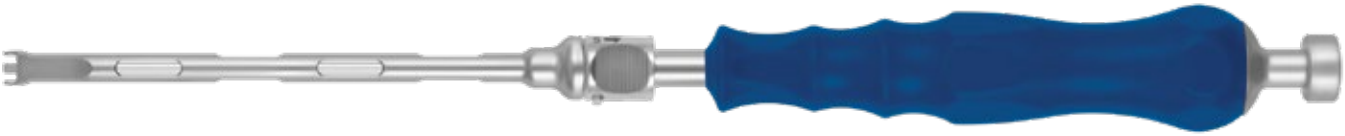
604.510 Inserter Tube

694.018 Slide Hammer

601.800 T-Handle



604.507 Inserter Guide



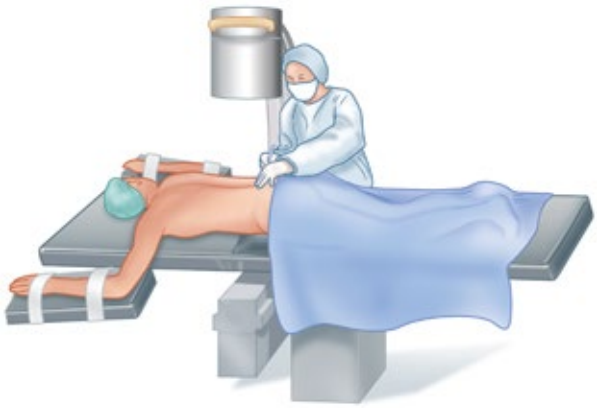
604.507 Inserter Guide
604.510 Inserter Tube
(Assembled)

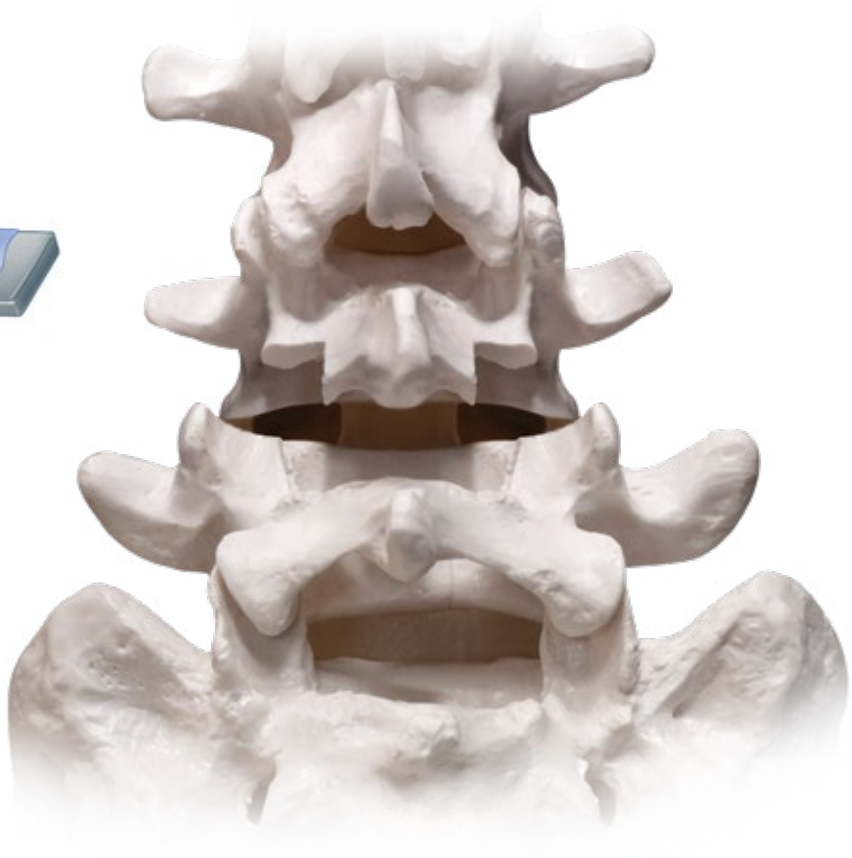
SURGICAL TECHNIQUE
SUSTAIN®-G

STEP 1 APPROACH

The patient is placed under anesthesia and positioned prone, preserving the lordosis of the lumbar spine during positioning. Lateral C-arm fluoroscopy and other radiographic methods may be utilized throughout the surgery to ensure the correct implant placement. The operative area is carefully cleaned and an incision is made at the appropriate fusion level(s).

In addition to the described interbody fusion technique, posterior stabilization, such as CREO®, REVERE® or REVOLVE®, must be used at the appropriate level(s).





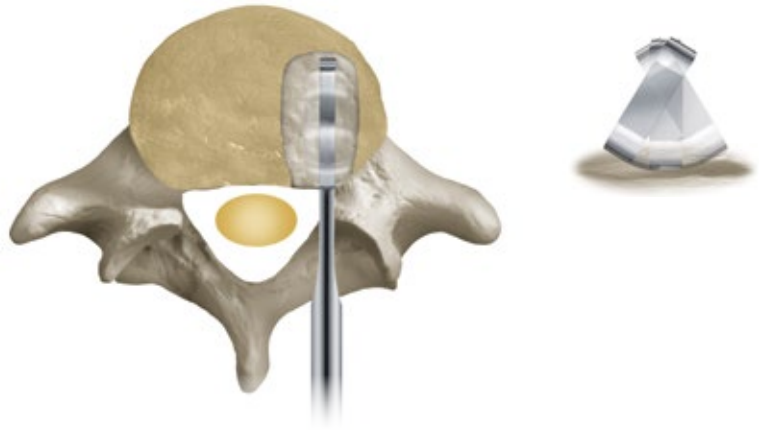
Bilateral windows to disc space

STEP 2 DISCECTOMY/ENDPLATE PREPARATION

Expose the intervertebral disc through a window of approximately 10–12mm on either side of the dura. Bony resection can be achieved using an osteotome, laminectomy, punch or other standard instrument.

Remove gross disc material using the rongeurs and other suitable instruments. Insert the smallest **Scraper** into the disc space for further disc removal and endplate preparation, moving to larger Scrapers as needed. Careful disc removal and endplate preparation maximizes the potential for a successful fusion.

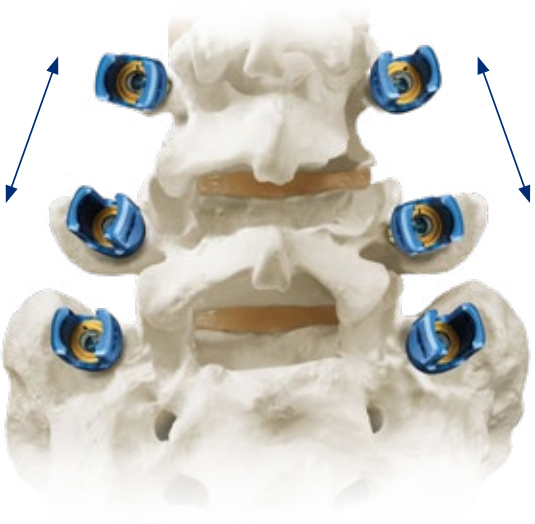
Note: The anterior and lateral walls of the annulus should be preserved to provide peripheral support for the implant.



Endplate preparation using the Scraper

STEP 3 DISTRACTION

Distraction of the disc space aids in visualization as well as decompression and restoration of disc height. Distraction can be achieved using CREO®, REVERE® or REVOLVE® pedicle screws.

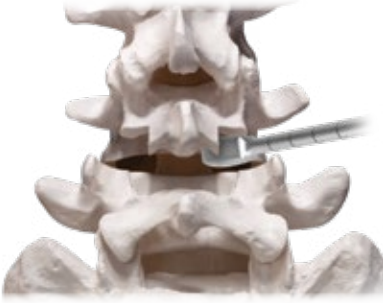


Distraction using CREO® or REVERE® screws

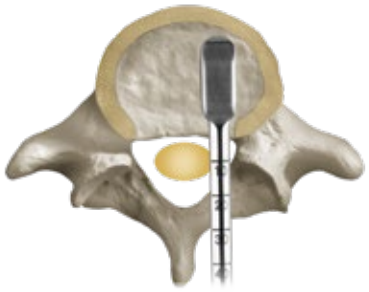
DISTRACTION (Cont'd)

Distraction Using the Trial

To use the **Trial** for distraction, begin with the smallest Trial and insert, using larger sizes until the desired distraction is achieved.



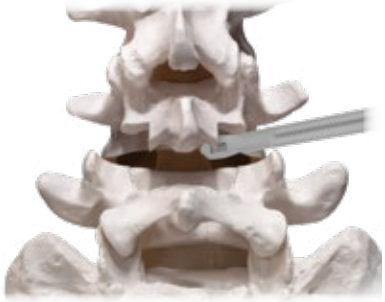
Distraction of disc space using the Trial



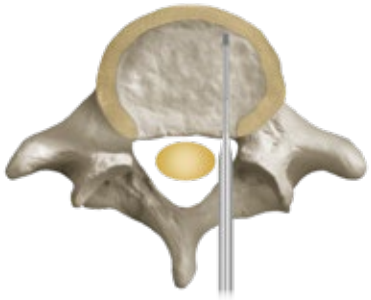
Trial in disc space

Distraction Using the Paddle Distractor or Scraper

To use the **Paddle Distractors** for distraction, begin with the smallest distractor and insert, using larger sizes until the desired distraction is achieved.



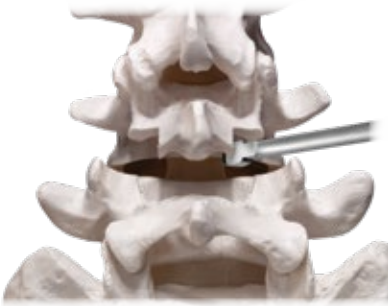
Distraction of disc space using the Paddle Distractor



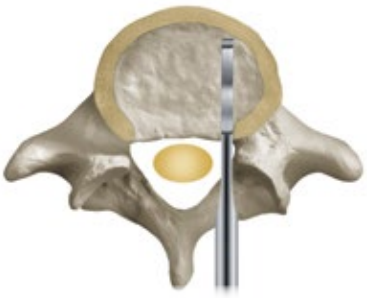
Paddle Distractor in disc space

To use the Scraper for distraction, begin with the smallest Scraper and insert, using larger sizes until the desired distraction is achieved.

Note: Use caution while using Scrapers or Paddle Distractors for distraction to avoid damage to the endplates.



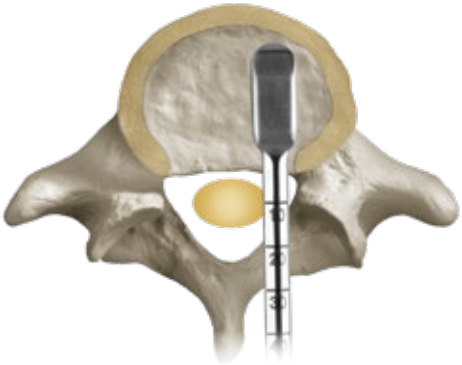
Distraction of disc space using the Scraper

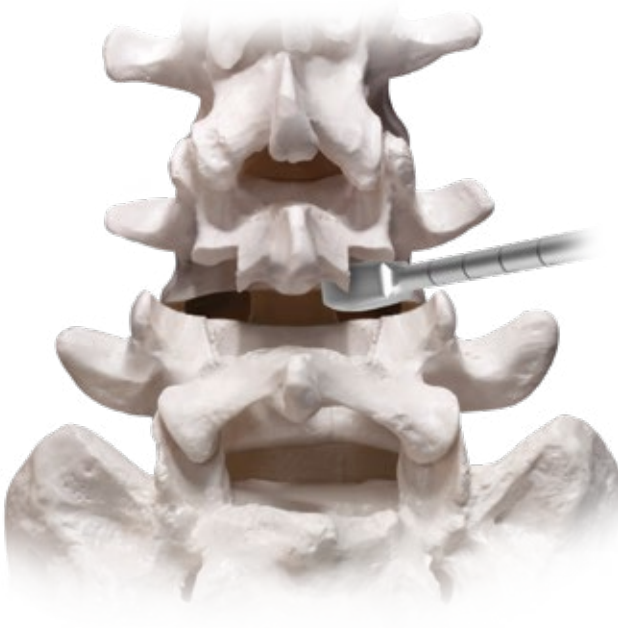


Scraper in disc space

STEP 4 SIZING

Assemble the desired Trial onto the **T-Handle**. Insert the smallest Trial into the disc space, using gentle impaction if needed. Determine which Trial and corresponding implant best fits the prepared disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment, and may be confirmed using fluoroscopy and tactile feel.



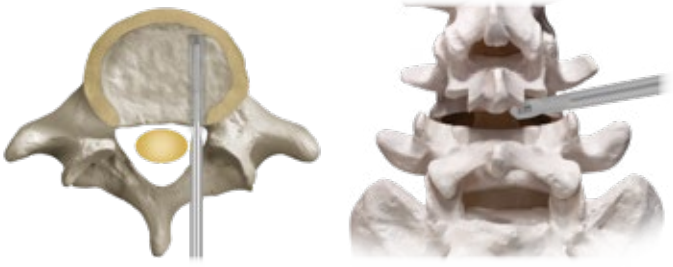


Sizing disc space using the Trial

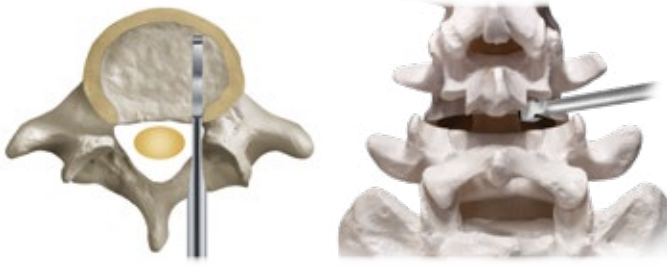
Sizing the Disc Space Using the Paddle Distractors and Scrapers

Alternately, Paddle Distractors and Scrapers may be used to size the disc space, inserting horizontally, and rotating to determine the appropriate height.

Note: Use caution while using Scrapers or Paddle Distractors for sizing to avoid damage to the endplates.



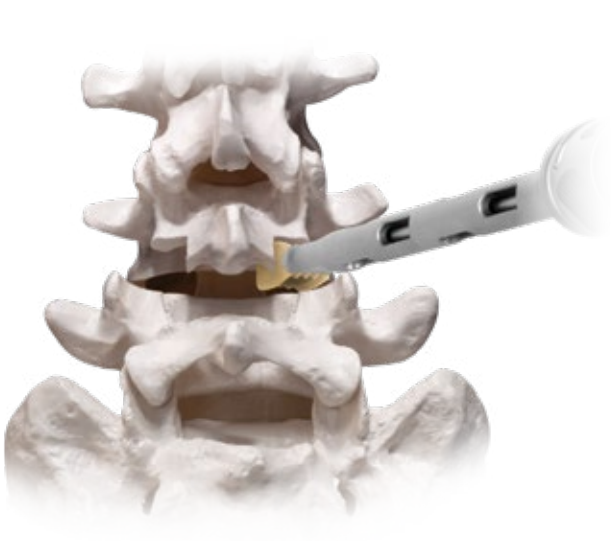
Sizing the disc space using Paddle Distractor

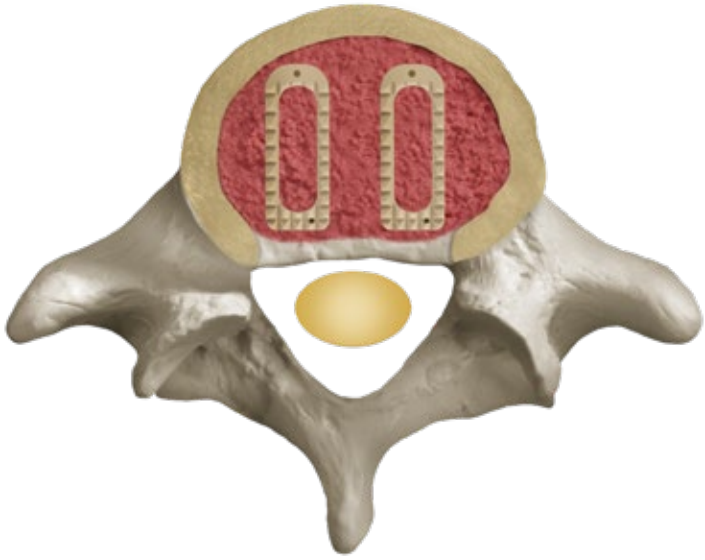


Sizing disc space using Scraper

STEP 5 INSERTION

Select an appropriately sized spacer and fill the chamber with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft material. Insert into the intervertebral space using the Inserter Assembly. To set the spacer, gently impact the inserter until the spacer is in the desired position. The spacer should be recessed into the disc space. Supplemental autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft material should be placed around the spacer. Compression may be necessary to help restore sagittal alignment and resist posterior migration. Supplemental fixation using CREO®, REVERE® or REVOLVE® pedicle screws or other fixation is required.



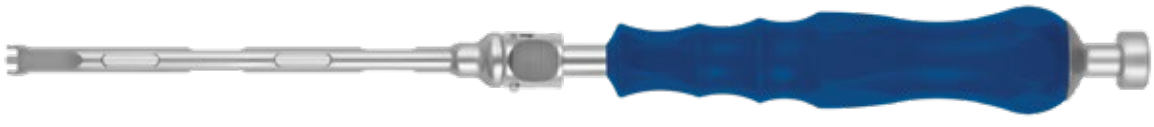


PLIF final position

Using the Implant Inserter Assembly

Ensure the **Inserter Guide** is in the unlocked position. Thread the guide into the **Inserter Tube** by rotating the handle clockwise. Thread the Inserter Assembly onto the implant. Lock the inserter by pressing the release button and pushing the lock forward. To disengage, pull the locking sleeve back and rotate the handle counterclockwise.

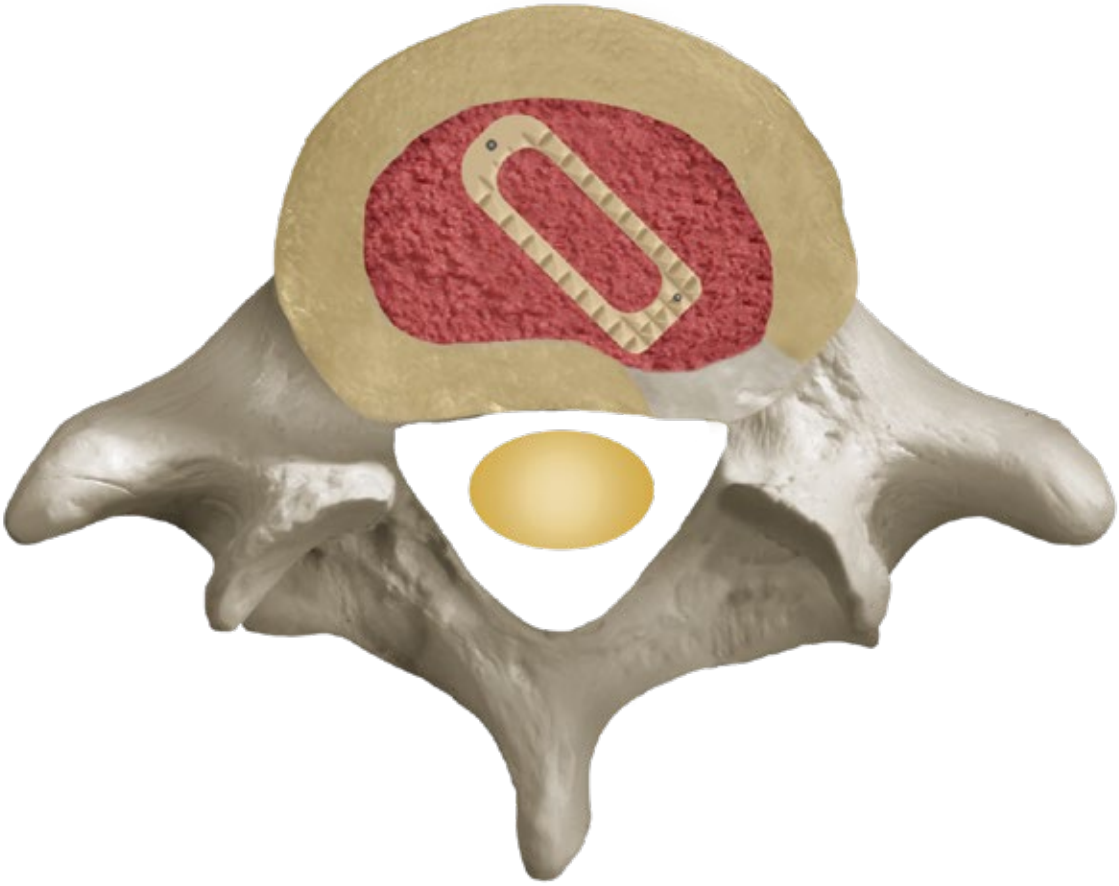
Note: Do not apply excessive torque when tightening the implant onto the inserter assembly as this may cause the implant threads to strip.



Locked Unlocked

OPTIONAL TECHNIQUE: TLIF

SUSTAIN®-G may be implanted through a transforaminal approach. The final position of the spacer in the disc space for a TLIF technique is shown below. Please refer to the SUSTAIN®-O Technique Guide (GMTGD115) for more information.



TLIF final position

OPTIONAL: IMPLANT REMOVAL

For implant removal, the Implant Holder Assembly may be repositioned onto the implant and the **Slide Hammer** may be used to remove the implant. Forceps or other manual surgical instruments may also be used to grasp and extract the implant.

SUSTAIN®-G IMPLANT SETS

SUSTAIN®-G 10x22mm Implant Set 904.995

HEIGHT	PART NO.	QTY
7mm	504.207	4
8mm	504.208	4
9mm	504.209	4
10mm	504.210	4
11mm	504.211	4
12mm	504.212	4
13mm	504.213	4
14mm	504.214	4
15mm	504.215	2
16mm	504.216	2
17mm	504.217	2

904.111 SUSTAIN®-G 10x22mm Implant Module

10x22mm Graft Volumes

Height	Part No.	Graft Volume (cc)
7mm	504.207	0.61
8mm	504.208	0.69
9mm	504.209	0.76
10mm	504.210	0.85
11mm	504.211	0.94
12mm	504.212	1.03
13mm	504.213	1.11
14mm	504.214	1.20
15mm	504.215	1.29
16mm	504.216	1.38
17mm	504.217	1.47

SUSTAIN®-G 10x26mm Implant Set 904.996

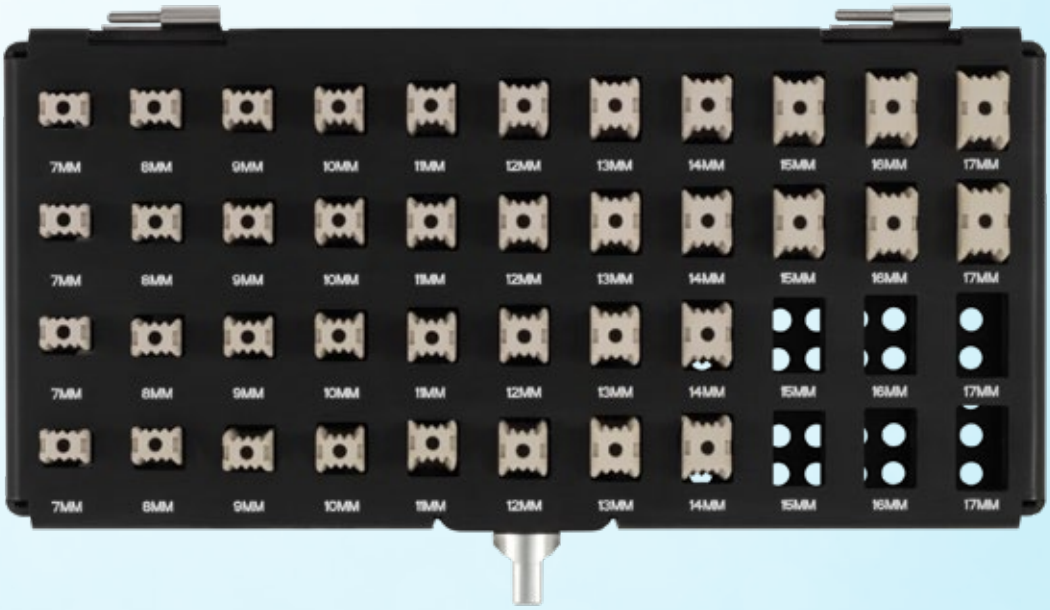
HEIGHT	PART NO.	QTY
7mm	504.227	4
8mm	504.228	4
9mm	504.229	4
10mm	504.230	4
11mm	504.231	4
12mm	504.232	4
13mm	504.233	4
14mm	504.234	4
15mm	504.235	2
16mm	504.236	2
17mm	504.237	2

904.112 SUSTAIN®-G 10x26mm Implant Module

10x26mm Graft Volumes

Height	Part No.	Graft Volume (cc)
7mm	504.227	0.76
8mm	504.228	0.87
9mm	504.229	0.97
10mm	504.230	1.07
11mm	504.231	1.17
12mm	504.232	1.29
13mm	504.233	1.40
14mm	504.234	1.51
15mm	504.235	1.62
16mm	504.236	1.74
17mm	504.237	1.85

10x22mm

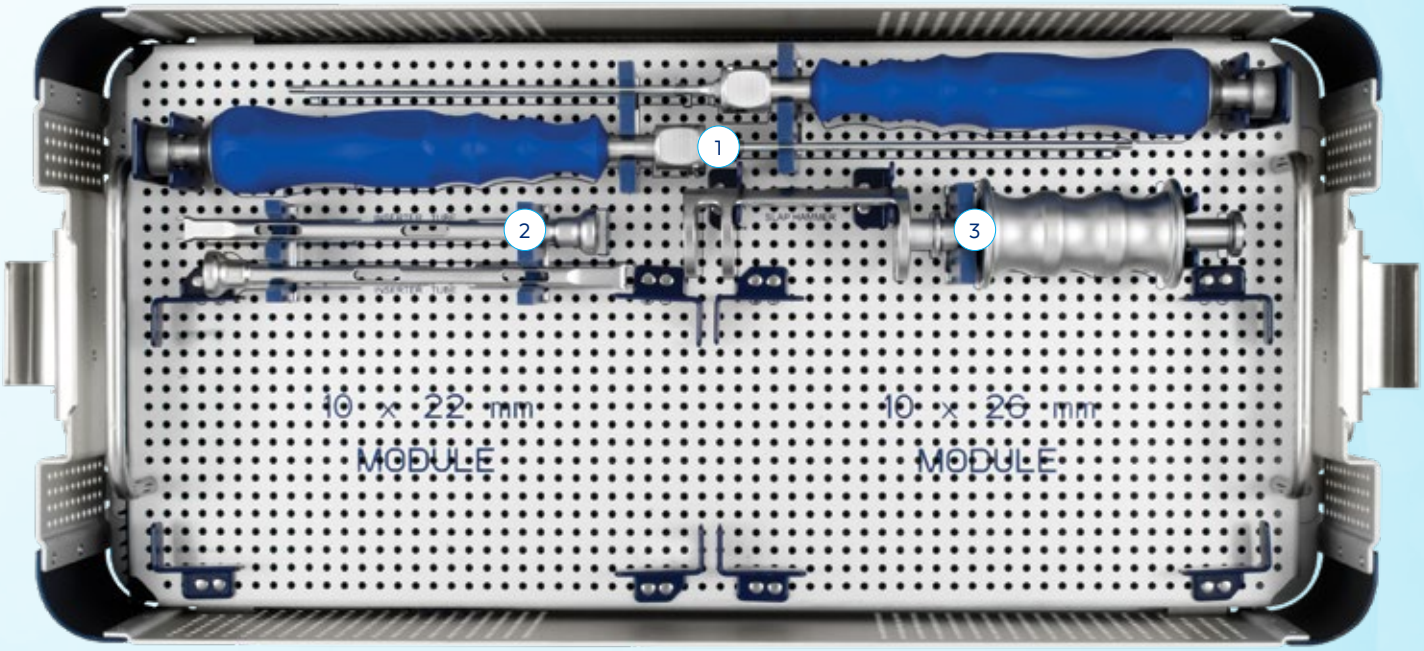


10x26mm

SUSTAIN®-G RADIOLUCENT SPACER INSTRUMENT SET 904.991

	PART NO.	DESCRIPTION	QTY
1	604.507	Inserter Guide	2
2	604.510	Inserter Tube	2
3	694.018	Slide Hammer	1

904.990 SUSTAIN®-G Instruments Graphic Case

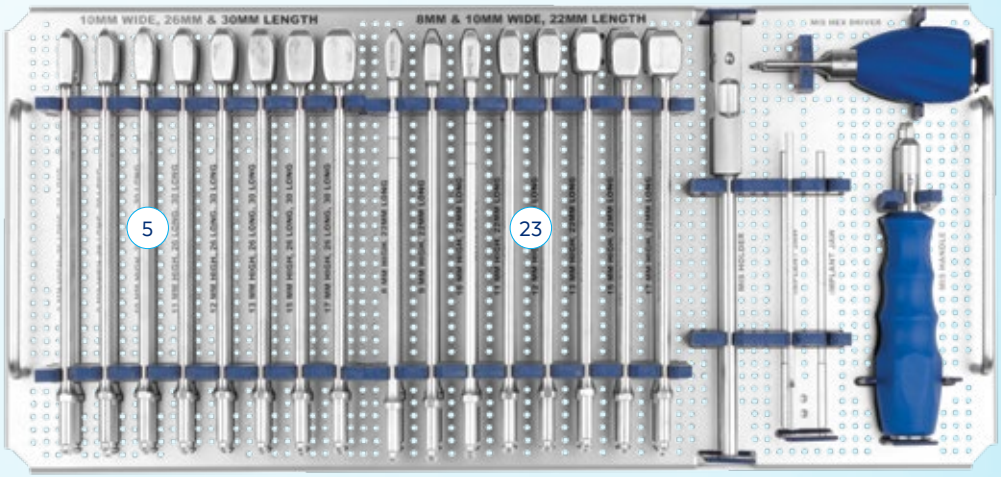

1
2
3
10 x 22 mm
MODULE
10 x 26 mm
MODULE

PRESERVE® POSTERIOR UNILATERAL INSTRUMENT SET 904.907

		INSTRUMENTS	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, 8x22mm wide, 8mm, SUSTAIN® Oblique, Small	1
	673.109	Trial Shaft, 8x22mm, 9mm, SUSTAIN® Oblique, Small	1
	673.110	Trial Shaft, 8x22mm, 10mm, SUSTAIN® Oblique, Small	1
	673.111	Trial Shaft, 8x22mm wide, 11mm, SUSTAIN® Oblique, Small	1
	673.112	Trial Shaft, 8x22mm wide, 12mm, SUSTAIN® Oblique, Small	1
	673.113	Trial Shaft, 8x22mm wide, 13mm, SUSTAIN® Oblique, Small	1
	673.115	Trial Shaft, 8x22mm wide, 15mm, SUSTAIN® Oblique, Small	1
	673.117	Trial Shaft, 8x22mm wide, 17mm, SUSTAIN® Oblique, Small	1
	673.208	Trial Shaft, 10x22mm wide, 8mm, SUSTAIN® Oblique, Small	1
	673.209	Trial Shaft, 10x22mm wide, 9mm, SUSTAIN® Oblique, Small	1
	673.210	Trial Shaft, 10x22mm wide, 10mm, SUSTAIN® Oblique, Small	1
	673.211	Trial Shaft, 10x22mm wide, 11mm, SUSTAIN® Oblique, Small	1
	673.212	Trial Shaft, 10x22mm wide, 12mm, SUSTAIN® Oblique, Small	1
	673.213	Trial Shaft, 10x22mm wide, 13mm, SUSTAIN® Oblique, Small	1
	673.215	Trial Shaft, 10x22mm wide, 15mm, SUSTAIN® Oblique, Small	1
	673.217	Trial Shaft, 10x22mm wide, 17mm, SUSTAIN® Oblique, Small	1

904.009 PRESERVE® Posterior Unilateral Instruments

Additionally Available Instruments (Page 32)


10MM WIDE, 26MM & 30MM LENGTH
8MM & 10MM WIDE, 22MM LENGTH
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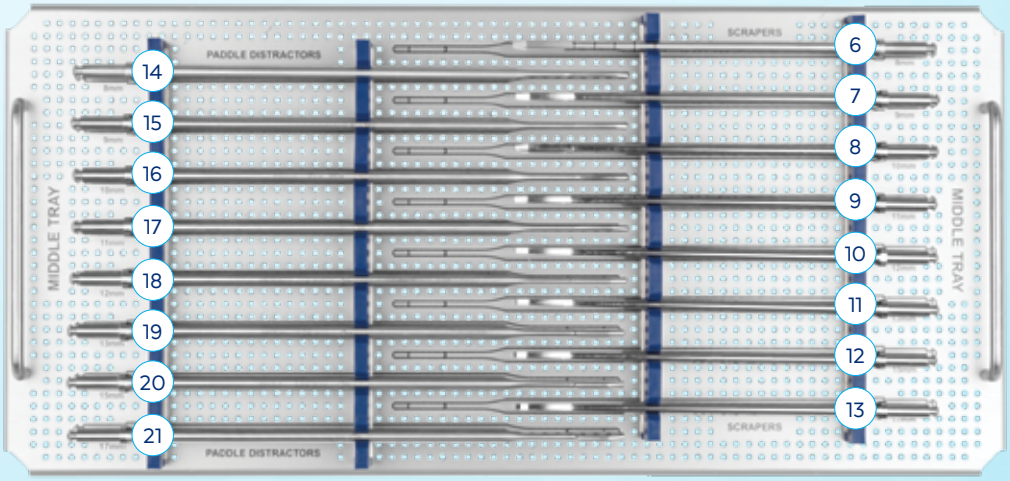
23


PADDLE DISTRACTORS
SCRAPERS
MIDDLE TRAY
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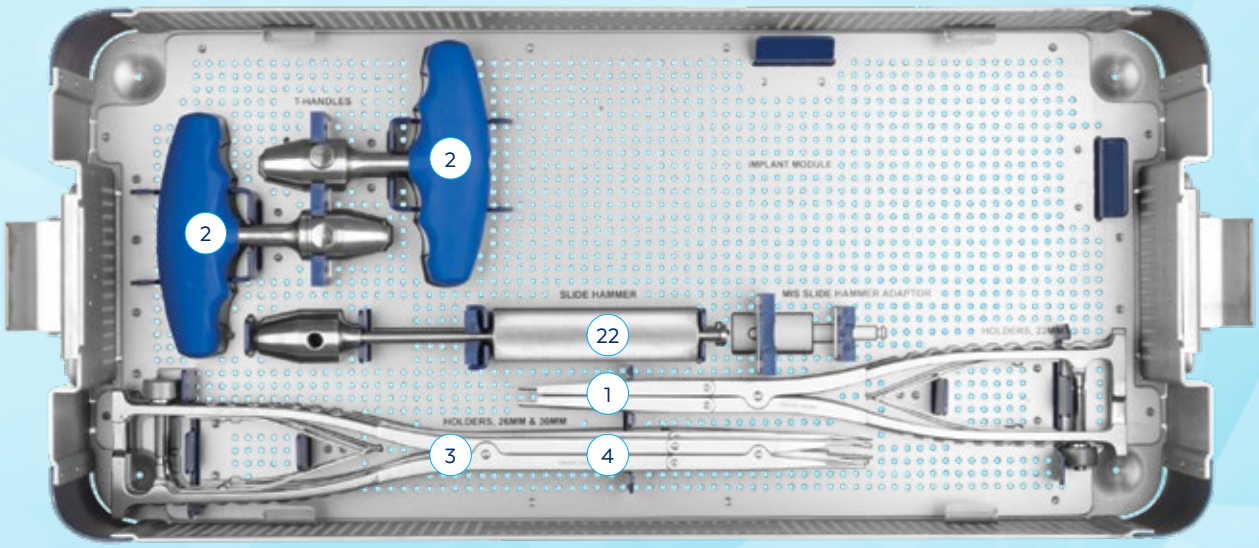
T-HANDLES
IMPLANT MODULE
SLIDE HAMMER
MIS SLIDE HAMMER ADAPTOR
HOLDERS, 26MM & 30MM
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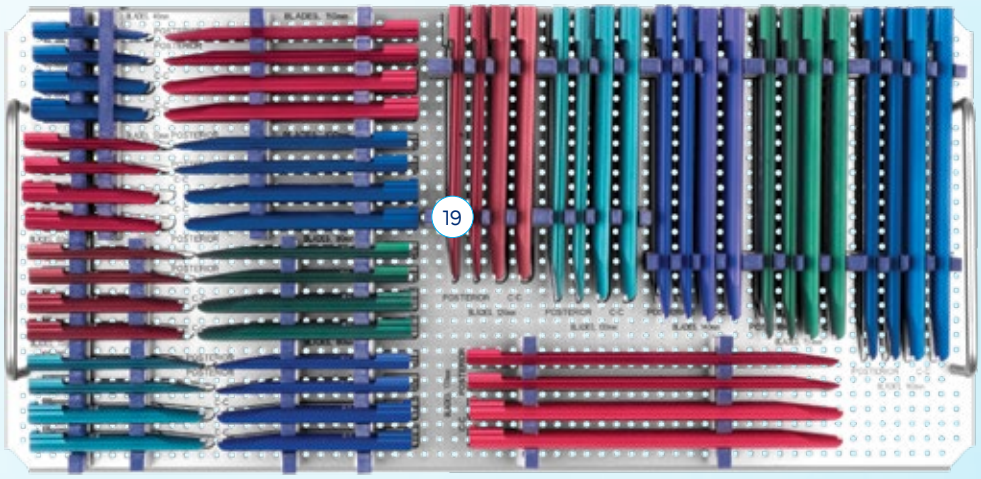
MARS™ 3V RETRACTOR SET 998.901

	INSTRUMENTS		QTY
1	623.003	K-Wire Gripper	1
2	698.100	Retractor 3 Blade Frame	1
3	632.102	Retractor 2 Blade Frame	1
4	632.150	10mm Socket Driver	1
5	698.250	Hook and Latch Driver	1
6	675.403	Flouro Modulator	1
7	675.404	Incision Locator	1
8	675.513	8” Suction	1
9	675.800	Radiolucent Initial Dilator Holder	1
10	698.205	Cannula A	1
11	698.210	Cannula B	1
12	698.215	Cannula C	1
13	698.220	Cannula D	1
14	698.230	Frame Handle	1
15	698.240	Shim Tool, CC	1
16	698.260	Docking Pin Tool	1
17	698.330	Disc Shim Tool	1
18	698.350	Docking Pin Sleeve	4
19	RETRACTOR BLADES		
	698.450	Blade, Posterior, 40mm	2
	698.452	Blade, Posterior, 50mm	2
	698.454	Blade, Posterior, 60mm	2
	698.456	Blade, Posterior, 70mm	2
	698.458	Blade, Posterior, 80mm	2
	698.460	Blade, Posterior, 90mm	2
	698.462	Blade, Posterior, 100mm	2
	698.464	Blade, Posterior, 110mm	2
	698.466	Blade, Posterior, 120mm	2
	698.468	Blade, Posterior, 130mm	2
	698.470	Blade, Posterior, 140mm	2
	698.472	Blade, Posterior, 150mm	2
	698.474	Blade, Posterior, 160mm	2

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

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

Items highlighted in gray are additoinally available.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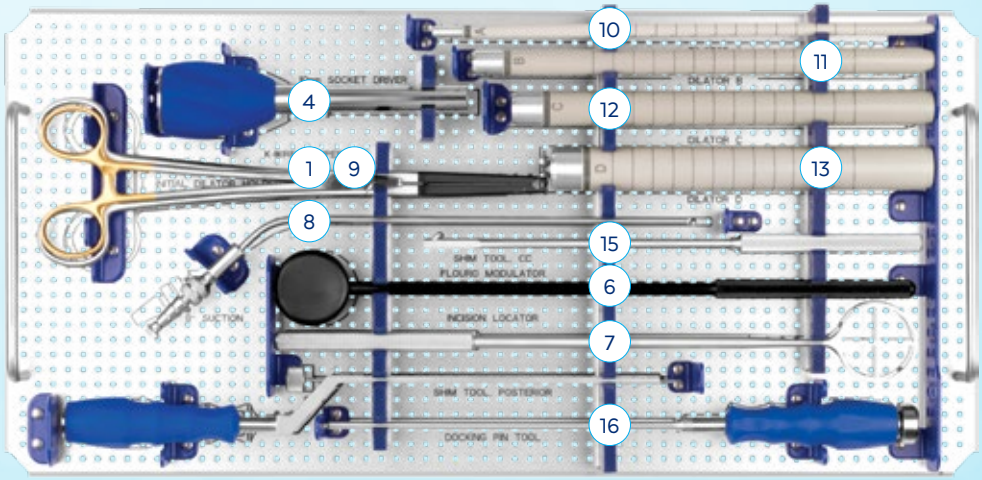
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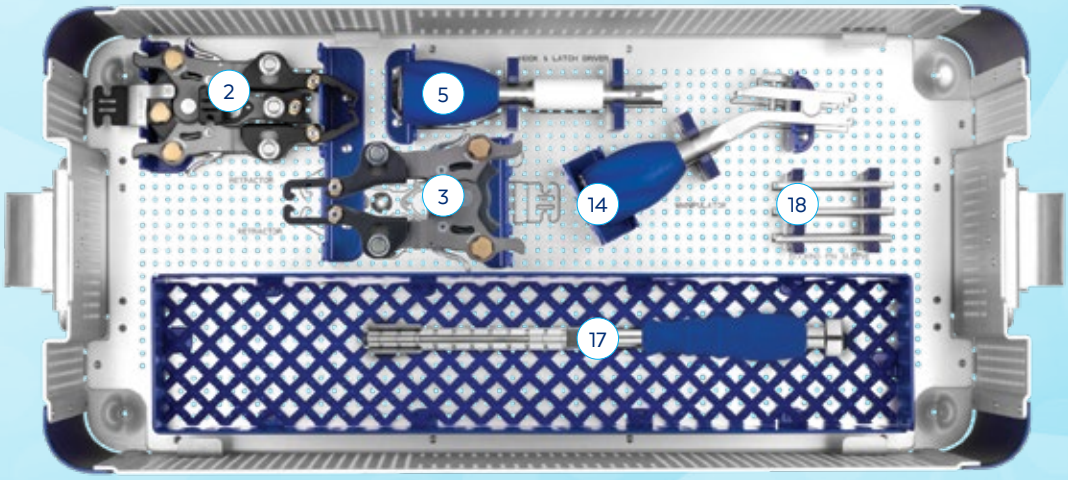
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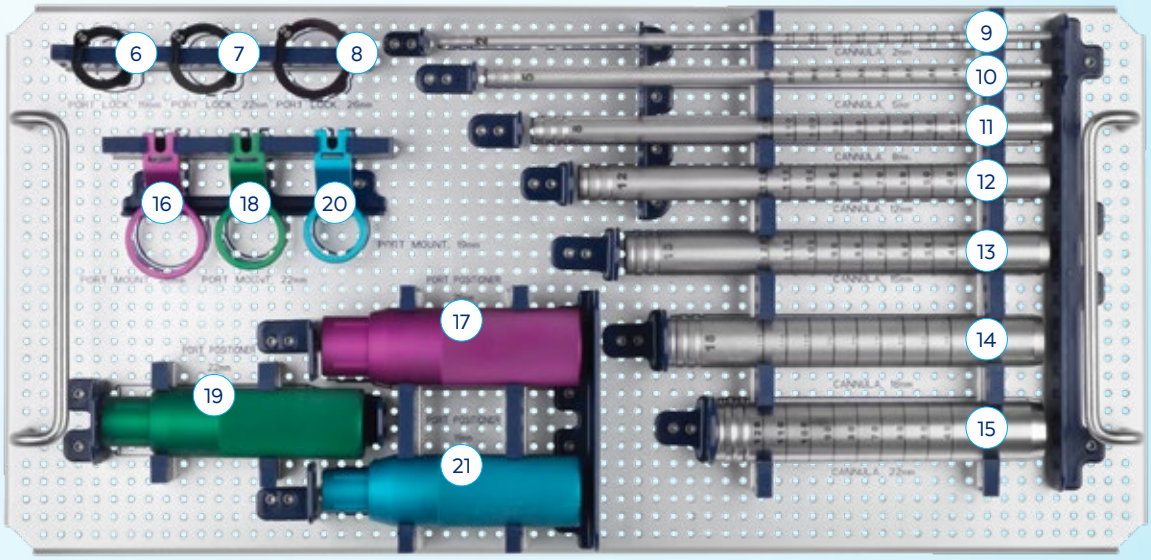
MARS™ INSTRUMENTS II SET 932.902

		INSTRUMENTS	QTY
1	632.300	Fiber-Optic Cord	1
2	632.305	Adapter, ACMI	1
3	632.306	Adapter, Wolf	1
4	632.307	Adapter, Olympus	1
5	632.308	Adapter, Storz	1
	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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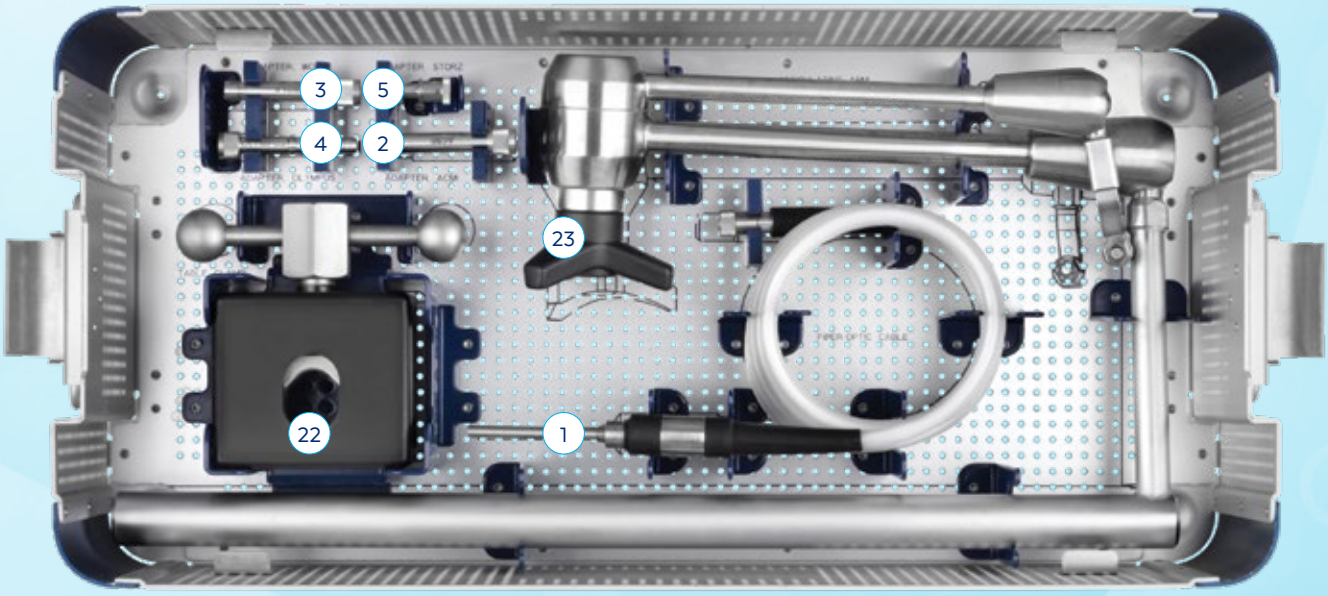
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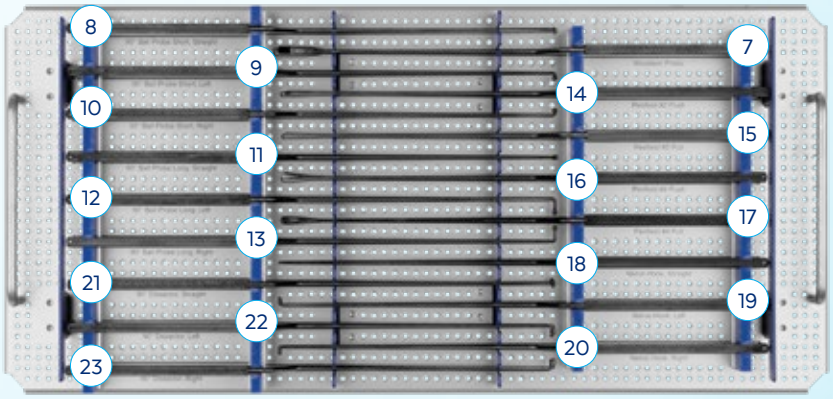
MARS™ INSTRUMENTS III SET 932.903

	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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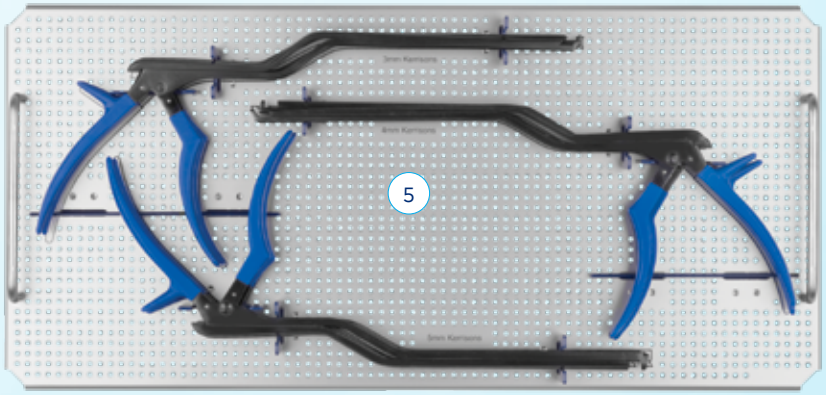
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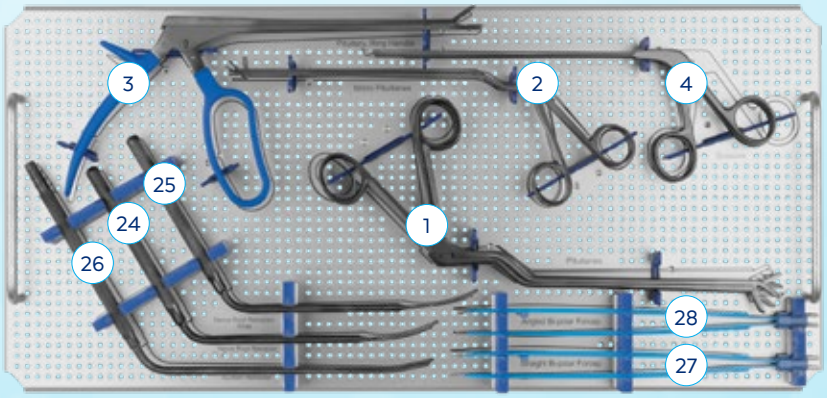
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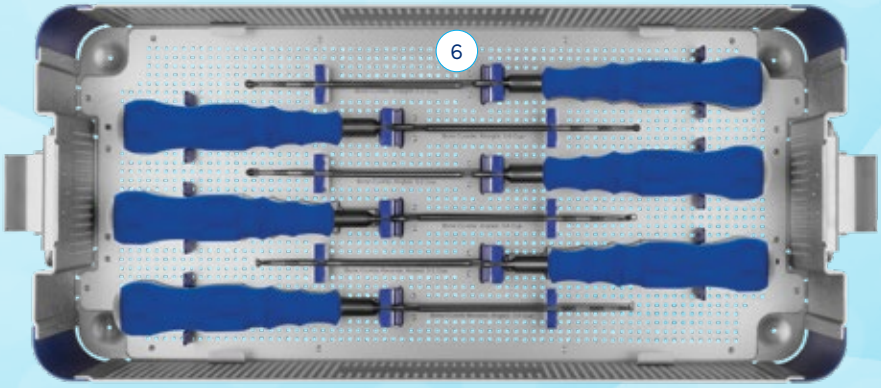
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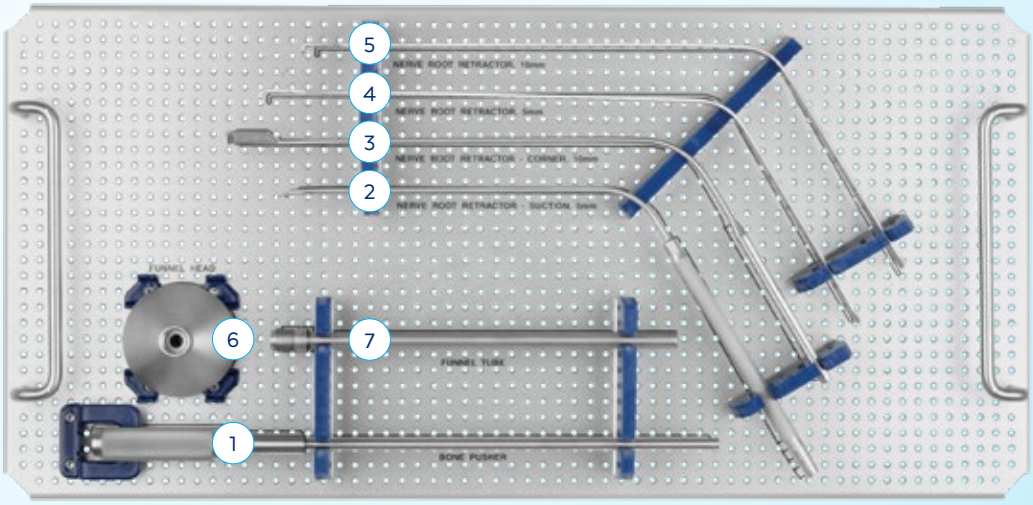
POSTERIOR DISC PREP INSTRUMENTS I SET 926.901

		INSTRUMENTS	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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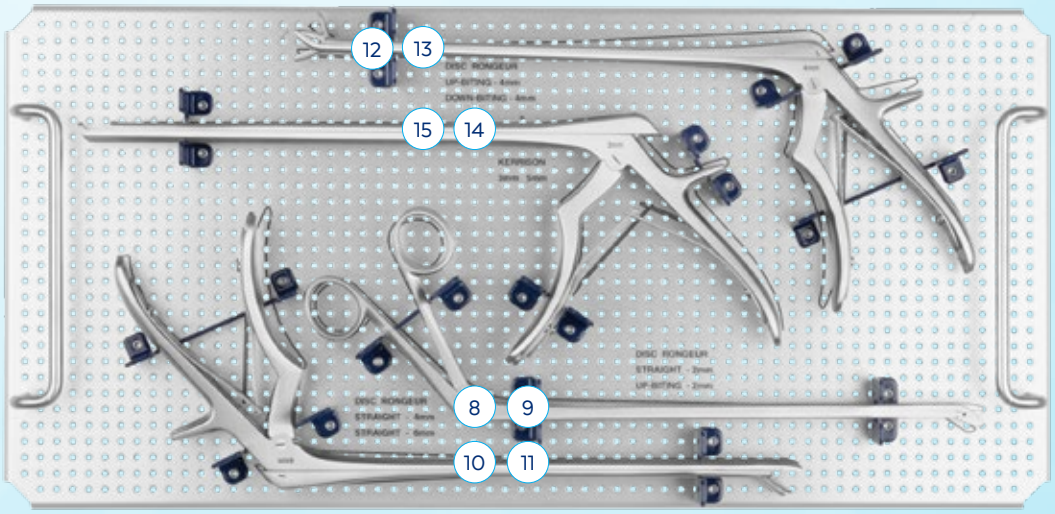
FUNNEL HEAD
FUNNEL TUBE
BONE PUSHER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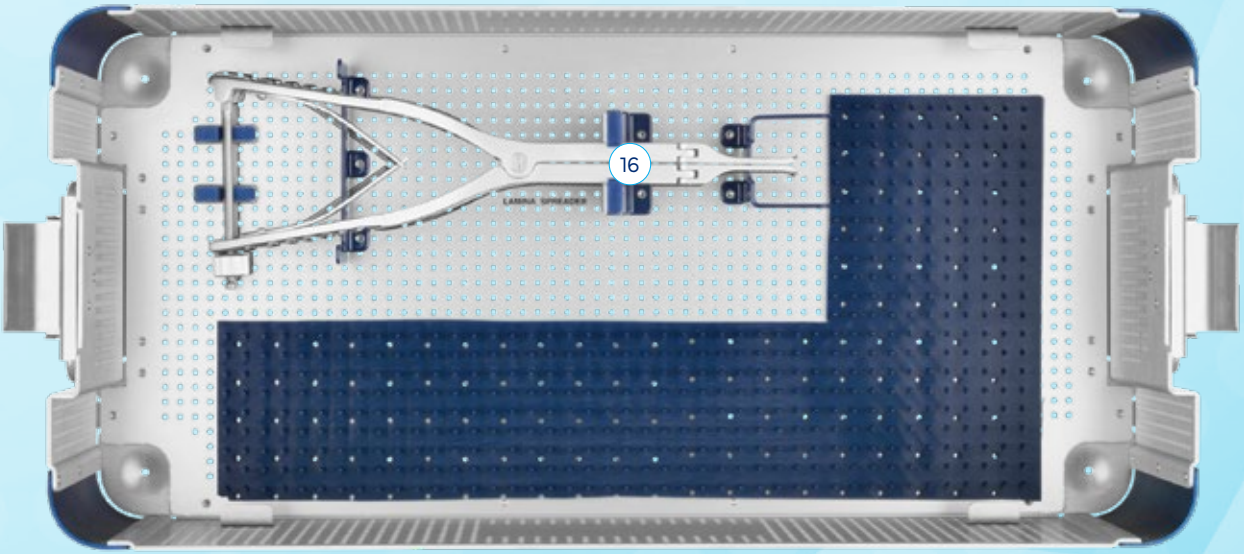
DISC RONGEUR
STRAIGHT - 2mm
UP-BITING - 2mm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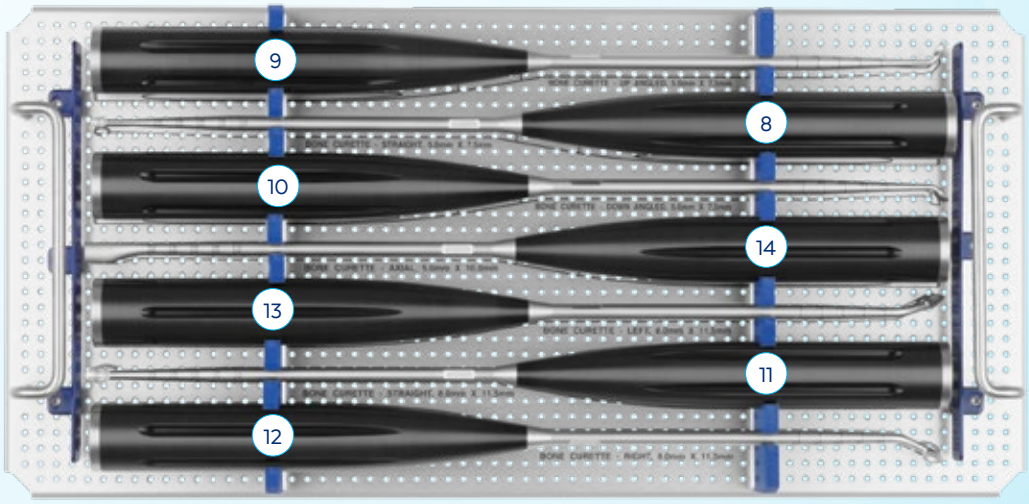
POSTERIOR DISC PREP INSTRUMENTS II SET 926.902

		INSTRUMENTS	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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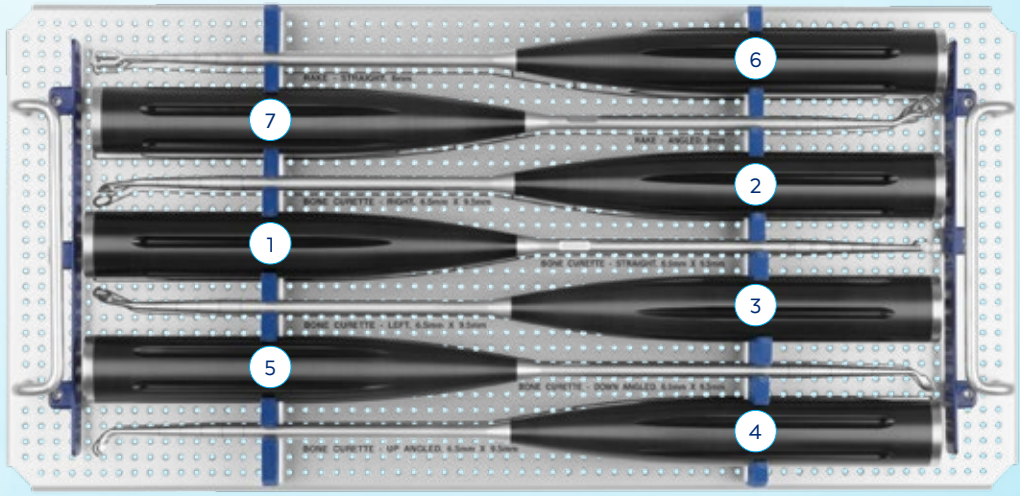
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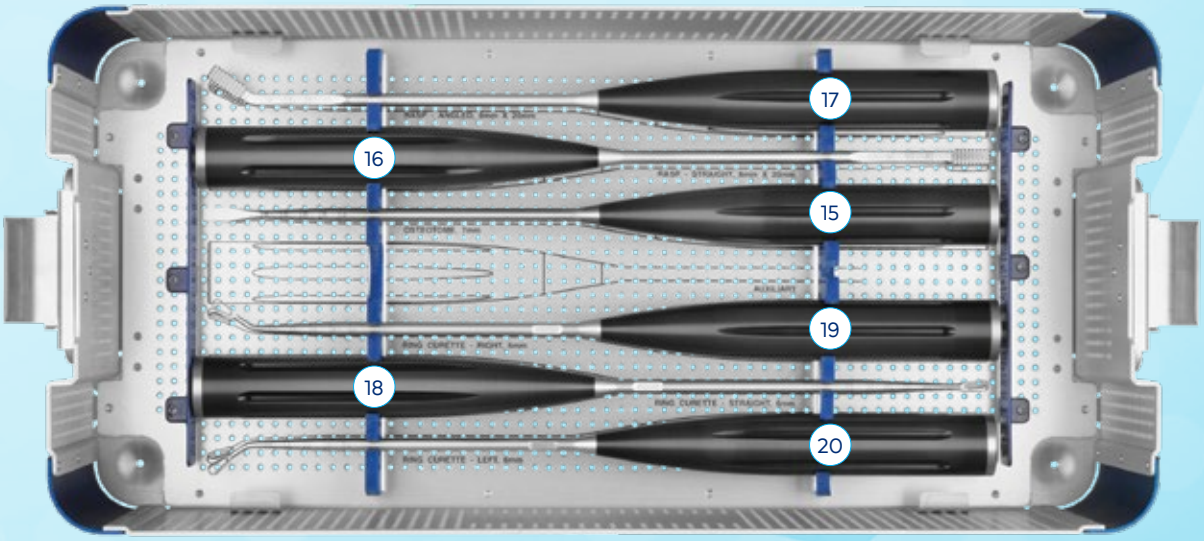
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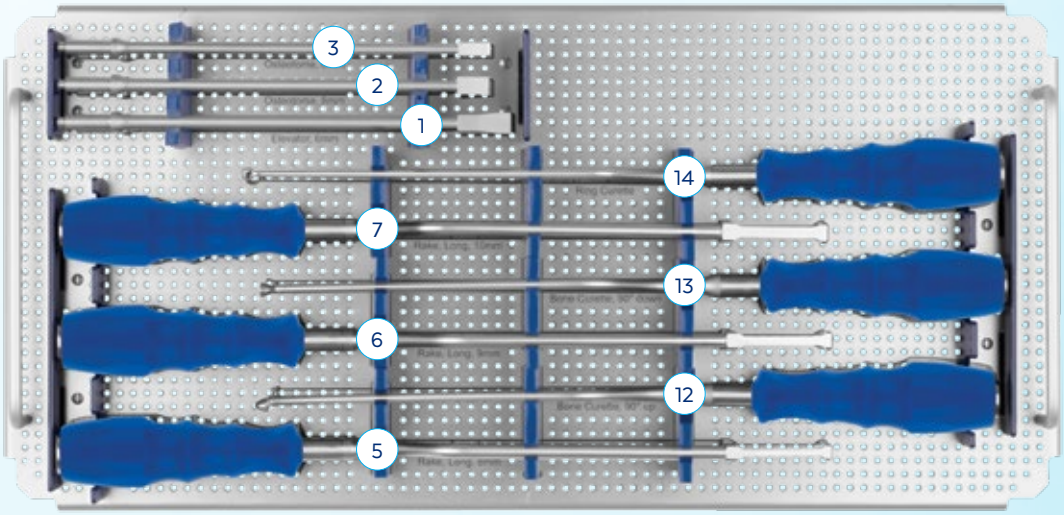
MIS LUMBAR DISCECTOMY INSTRUMENT SET 979.901

		INSTRUMENTS	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 highlighted in gray are additoinally available.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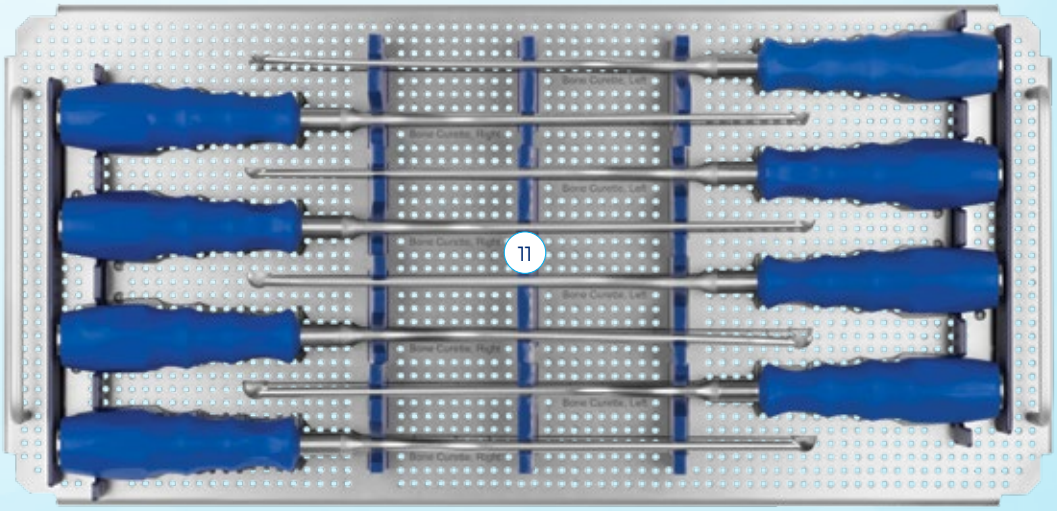
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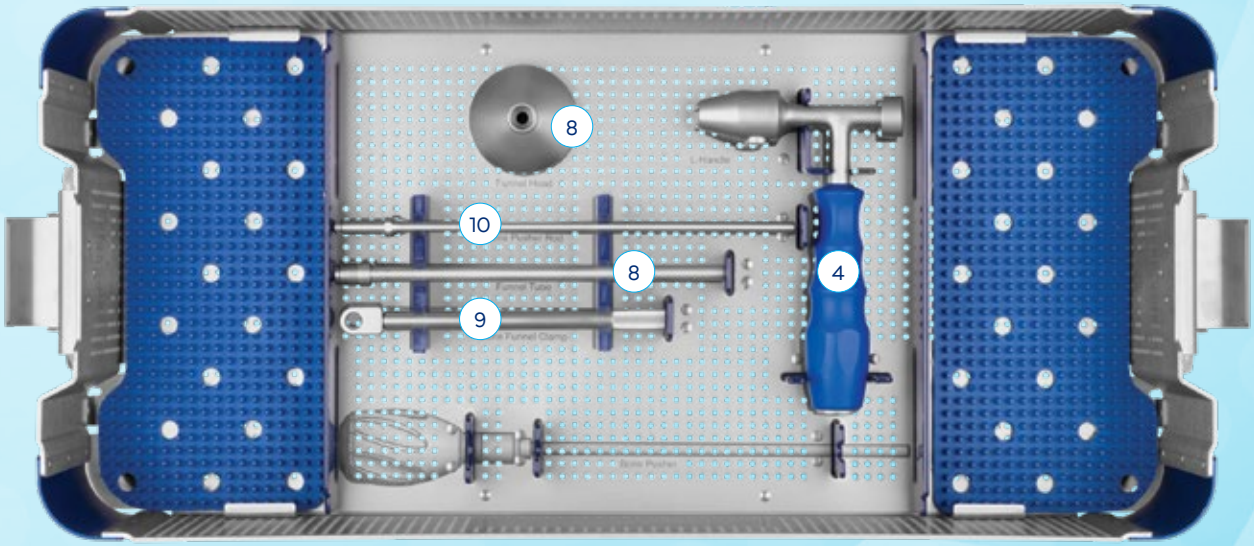
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ADDITIONALLY AVAILABLE

PART NO.	DESCRIPTIONS
604.107	Trial, 26mm Length, 7mm
604.114	Trial, 26mm Length, 14mm
604.116	Trial, 26mm Length, 16mm
673.207	Trial, 22mm Length, 7mm
673.214	Trial, 22mm Length, 14mm
673.216	Trial, 22mm Length, 16mm
604.307	Scraper, Oblique, 7mm
604.314	Scraper, Oblique, 14mm
604.316	Scraper, Oblique, 16mm
604.807	Paddle Distractor, 7mm
604.814	Paddle Distractor, 14mm
604.816	Paddle Distractor, 16mm

Items highlighted in gray are additoinally available.

IMPORTANT INFORMATION ON SUSTAIN® SPACERS

DESCRIPTION

SUSTAIN® Spacers (including SUSTAIN® R, SUSTAIN®-IR, and SUSTAIN®-RT) are devices that can be used as intervertebral fusion devices or as vertebral body replacement devices. When used as interbody fusion devices, each of the spacers provides a different shape to accommodate various surgical approaches to the spine. SUSTAIN® Small, SUSTAIN®-IR, and SUSTAIN®-RT Spacers are inserted using a posterior or transforaminal approach. SUSTAIN® Arch Spacers are inserted using a transforaminal or lateral approach. SUSTAIN® Large Spacers are inserted using an anterior, anterolateral, or lateral approach. SUSTAIN® Oblique and SUSTAIN® G Spacers are inserted using a posterior, transforaminal, or lateral approach. These spacers are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion. Each spacer has an axial hole to allow grafting material to be packed inside the spacer.

These spacers are used to provide structural stability in skeletally mature individuals following discectomy, corpectomy, or vertebrectomy (including partial). All approaches may be used in the lumbar spine; only the anterior, anterolateral, or lateral approach may be used in the thoracic spine. An anterior approach is used in the cervical spine.

The SUSTAIN® Spacers are made from commercially pure titanium or titanium alloy as specified in ASTM F67, F136, and F1295. SUSTAIN® Radiolucent (SUSTAIN® R) and SUSTAIN® R TPS Spacers are made from radiolucent PEEK polymer with titanium alloy or tantalum markers as specified in ASTM F136, F560, F1295, and F2026. SUSTAIN® R TPS Spacers, SUSTAIN®-IR TPS Spacers and SUSTAIN®-RT TPS Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

INDICATIONS

When used as thoracolumbar intervertebral body fusion devices, SUSTAIN® Spacers (including SUSTAIN® R, SUSTAIN®-IR and SUSTAIN®-RT) are indicated 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. SUSTAIN® Spacers are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. 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). All SUSTAIN® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

When used as cervical intervertebral body fusion devices, SUSTAIN® Spacers including SUSTAIN® R are intended for one or more levels of the cervical spine C2-T1 in patients with cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. These patients should be skeletally mature and have had at least six 6 weeks of non-operative treatment. All SUSTAIN® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

SUSTAIN® Spacers are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or corticocancellous bone. These devices are intended to be used with supplemental fixation, such as the ASSURE®, PROVIDENCE®, or XTEND® Anterior Cervical Plate Systems.

When used as vertebral body replacement devices, SUSTAIN® Spacers (including SUSTAIN® and SUSTAIN® R TPS) are intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The spacers are intended to be used with supplemental spinal fixation systems that have been labeled for use in the thoracic and/or lumbar spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The interior of the spacers can be packed with bone grafting material. SUSTAIN® Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. All SUSTAIN® TPS coated spacers are indicated for the same use as non-coated PEEK versions.

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.

These warnings do not include all adverse effects that could occur with surgery in general, but are important consideration 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 these 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 SUSTAIN® 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 SUSTAIN® 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 SUSTAIN® 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 a suspected or documented allergy, foreign body sensitivity, or known intolerance to any of the implant materials.
2. Signs of local inflammation.
3. Prior fusion at the level(s) to be treated.
4. Severe osteoporosis, which may prevent adequate fixation.
5. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risk versus the benefits to the patient.
6. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
7. Any patient not willing to cooperate with postoperative instructions.

IMPORTANT INFORMATION ON SUSTAIN® SPACERS

8. Any condition not described in the indications for use.

9. Fever or leukocytosis.

10. Pregnancy.

11. 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.

12. Any case not needing a fusion.

13. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.

14. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.

15. Spondylolisthesis unable to be reduced to Grade 1.

16. Any case where the implant components selected for use would be too large or too small to achieve a successful result.

17. Any case that requires the mixing of metals from two different components or systems.

18. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.

19. 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
- 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 implants from the packaging using aseptic technique.

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

HANDLING AND USE

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

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

CLEANING

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

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

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

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

CONTACT INFORMATION

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

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are

packaged in a heat sealed, double pouch or container/pouch. The expiration date is provided 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

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	Rx ONLY	PRESCRIPTION USE ONLY

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CE 0297

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