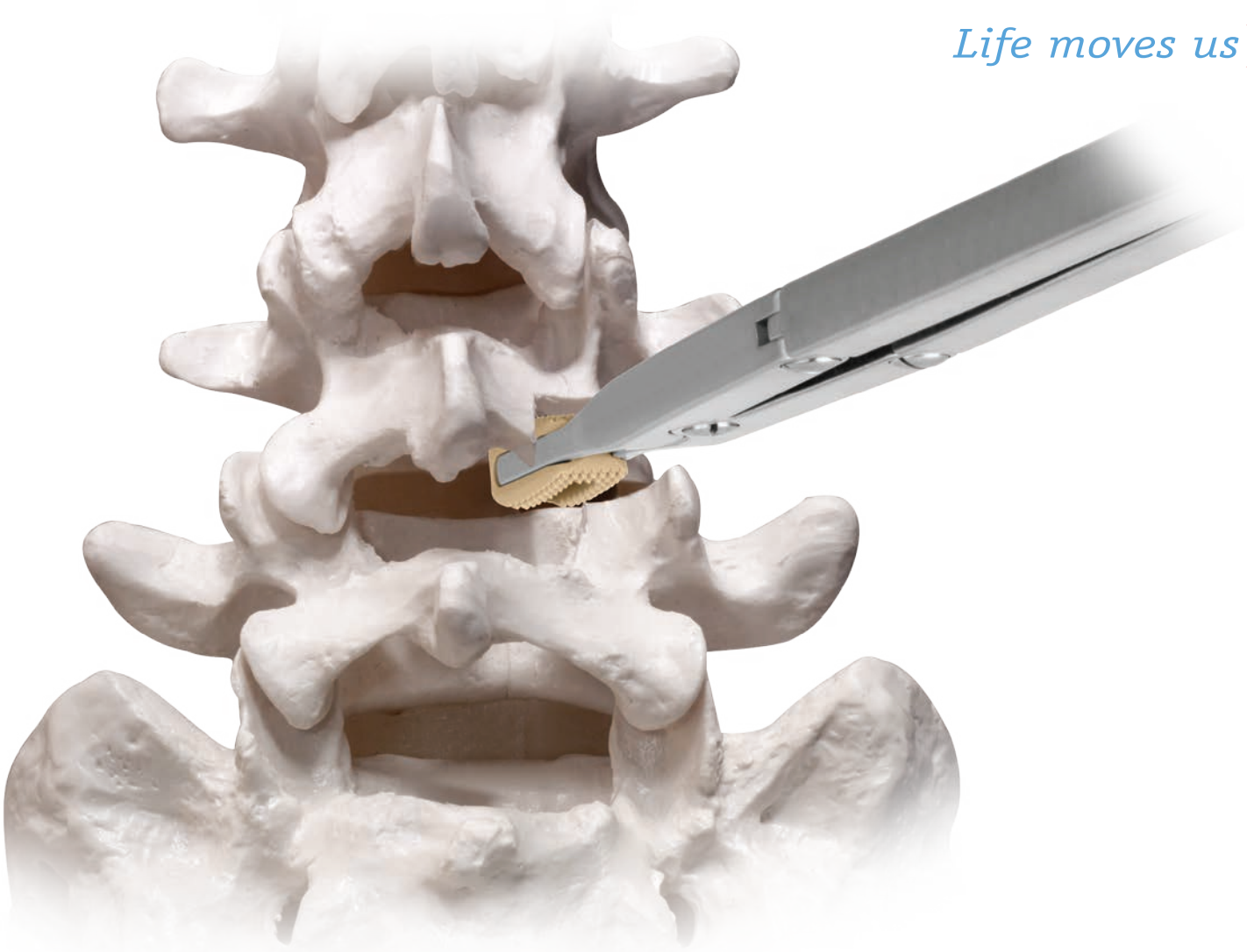
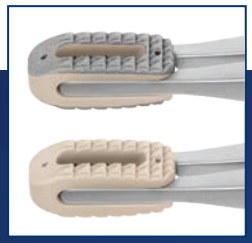
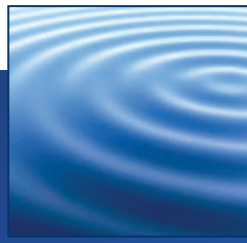
Life moves us



SURGICAL TECHNIQUE



SUSTAIN®-O

Radiolucent Spacer

GLOBUS MEDICAL

Life moves us

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

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

GLOBUS
MEDICAL

www.globusmedical.com

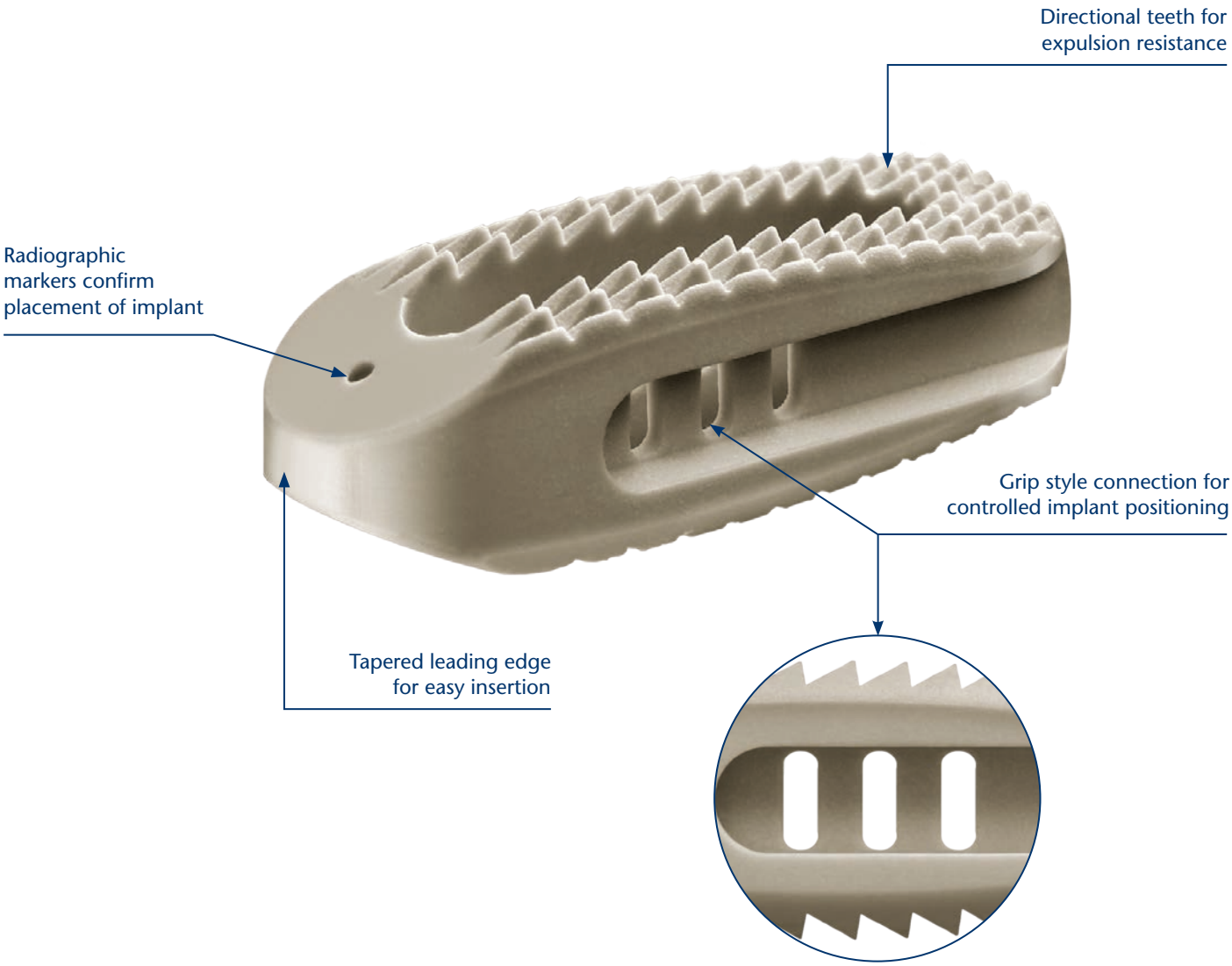
SUSTAIN®-O

Radiolucent Spacer

SUSTAIN®-O is an interbody fusion device made from radiolucent polymer (PEEK), and is available with titanium plasma spray (TPS) coating, designed to combine radiolucency with a titanium interface. The rounded corners, grip-style connection, and robust implant holder allow control during insertion and positioning. The anterior portion of the implant has a tapered leading edge for ease of insertion. The inferior and superior surfaces of the implant feature teeth to resist expulsion.

To accomodate varying patient anatomy, SUSTAIN®-O is offered in several height, width, and length configurations.

SUSTAIN®-O
RADIOLUCENT SPACER



CONTENTS

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

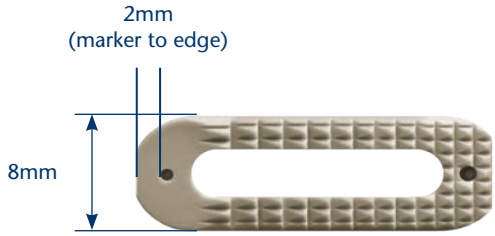
IMPLANT OVERVIEW

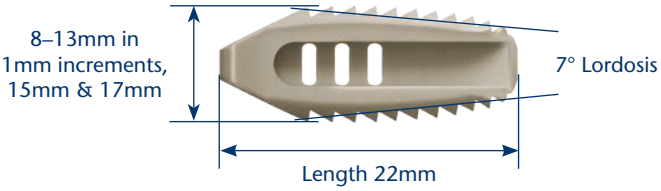
Features

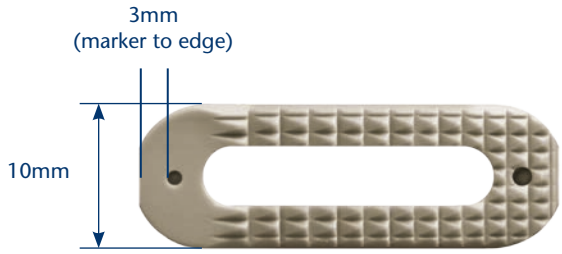
- Made from PEEK radiolucent polymer, available with titanium plasma spray coating
- Tapered leading edge for easier insertion
- Rounded corners allow for rotation during insertion
- Grip-style connection for controlled implant positioning
- Teeth to resist explusion
- 1mm height increments for accurate fit
- 22mm, 26mm and 30mm lengths to accommodate patient anatomy
- 8mm, 10mm, and 12mm width options for an ideal fit

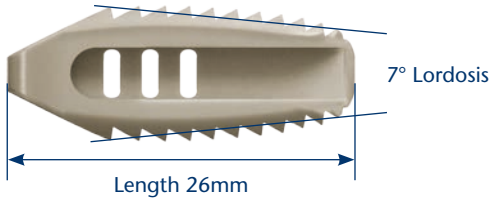
SUSTAIN®-O

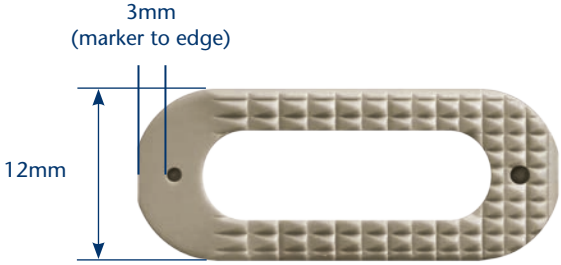
SUSTAIN®-O TPS

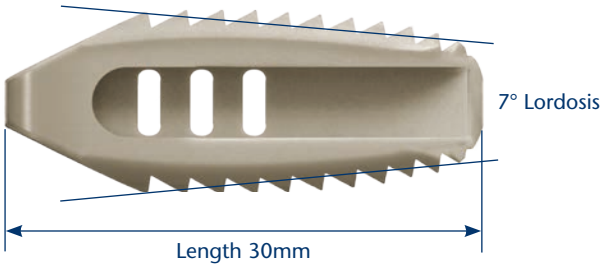












INSTRUMENT OVERVIEW

Distraction Instruments

Scrapers

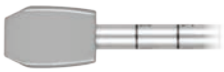
	Height	Part No.
	8mm	604.308
	9mm	604.309
	10mm	604.310
	11mm	604.311
	12mm	604.312
	13mm	604.313
	15mm	604.315
	17mm	604.317

Paddle Distractors

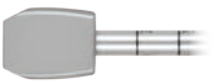
	Height	Part No.
	8mm	604.808
	9mm	604.809
	10mm	604.810
	11mm	604.811
	12mm	604.812
	13mm	604.813
	15mm	604.815
	17mm	604.817

Trials

Trials, 8mm Wide x 22mm Long

	Height	22mm
	8mm	673.108
	9mm	673.109
	10mm	673.110
	11mm	673.111
	12mm	673.112
	13mm	673.113
	15mm	673.115
	17mm	673.117

Trials, 10mm Wide x 22mm Long

	Height	22mm
	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

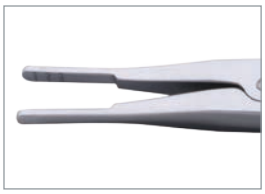
	Height	26mm
	8mm	604.108
	9mm	604.109
	10mm	604.110
	11mm	604.111
	12mm	604.112
	13mm	604.113
	15mm	604.115
	17mm	604.117

Trials, 10mm Wide x 30mm Long

	Height	30mm
	8mm	604.208
	9mm	604.209
	10mm	604.210
	11mm	604.211
	12mm	604.212
	13mm	604.213
	15mm	604.215
	17mm	604.217

Holder Instruments

Implant Holder 601.001



Holder, Straight 604.001

Holder, Angled 604.002

T-Handle 601.800

MIS Instruments

MIS Holder 673.001

MIS Hex Driver, 2.5mm and 1.5mm 673.002

MIS Handle 673.003

Implant Jaw with Teeth, SUSTAIN®-O Small 673.004

Implant Jaw with Teeth, SUSTAIN®-O 10mm Wide 673.006

Implant Jaw with Teeth, SUSTAIN®-O 12mm Wide 673.008

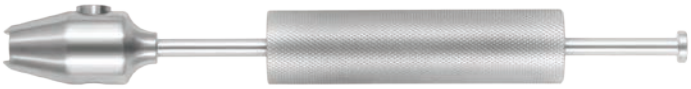
Implant Jaw without Teeth, SUSTAIN®-O Small 673.005

Implant Jaw without Teeth, SUSTAIN®-O 10mm Wide 673.007

Implant Jaw without Teeth, SUSTAIN®-O 12mm Wide 673.009

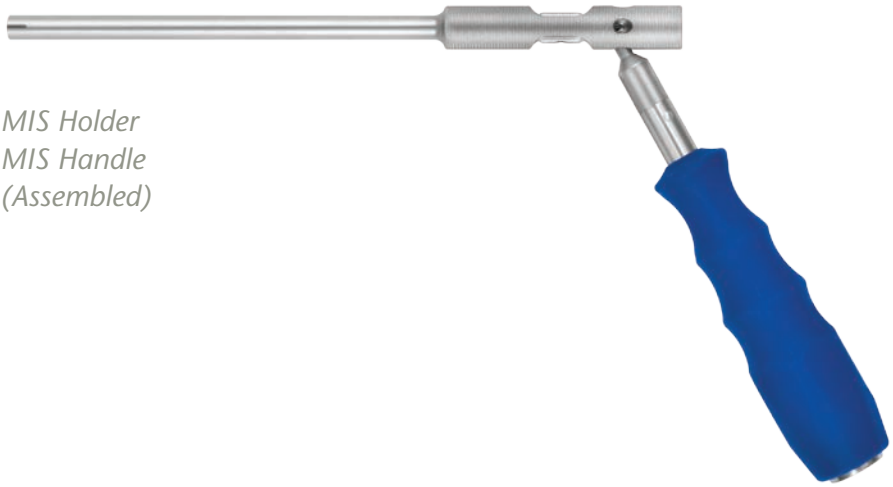
Items highlighted in gray are additionally available.

MIS Instruments (cont'd)



Slide Hammer, Quick Disconnect 673.017

MIS Slap Hammer, Shaft 29mm 673.019



MIS Holder
MIS Handle
(Assembled)

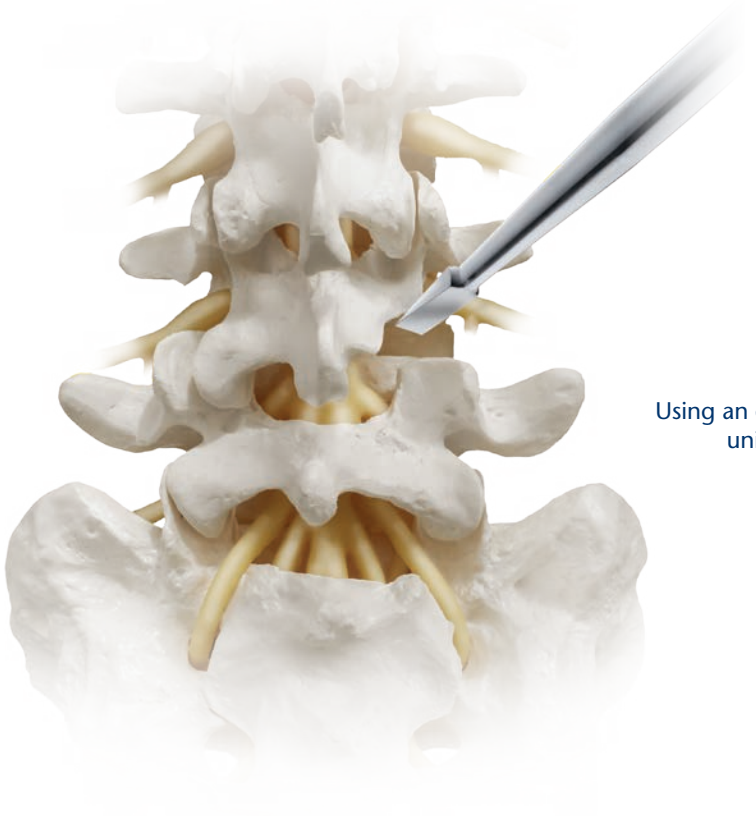
MIS Holder
MIS Handle
MIS Slap Hammer, Shaft, 29mm
Slide Hammer, Quick Disconnect
(Assembled)

Items highlighted in gray are additionally available.

SUSTAIN®-O
SURGICAL TECHNIQUE

Step 1 Approach

The patient is placed under anesthesia and positioned prone. Lateral C-arm fluoroscopy or other radiographic methods can be utilized throughout the surgery to ensure correct graft 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, supplemental posterior stabilization must be used at the appropriate level(s).



Using an osteotome to create unilateral access

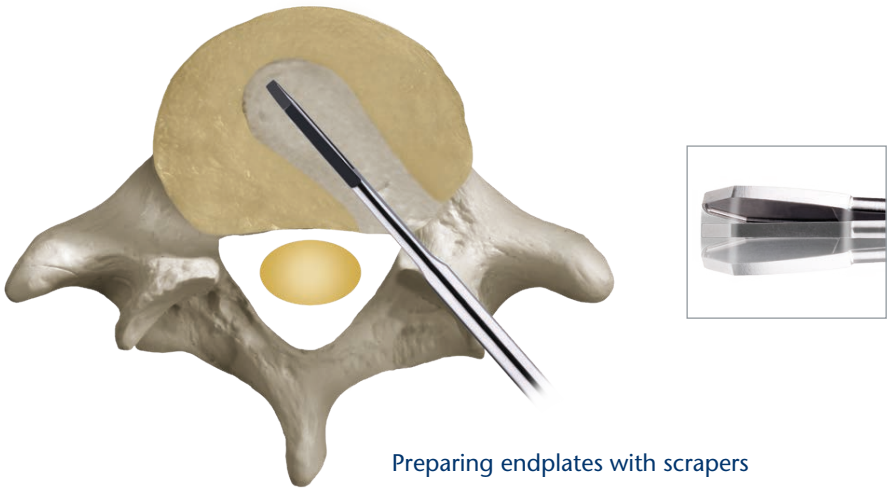
Step 2 Creating Unilateral Access

Use an osteotome and a laminectomy punch to remove the inferior facet of the cranial vertebrae and the superior facet of the caudal vertebrae of the appropriate level(s). This creates a working unilateral access window to the disc.

Step 3 Endplate Preparation

Remove gross disc material with rongeurs or 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.

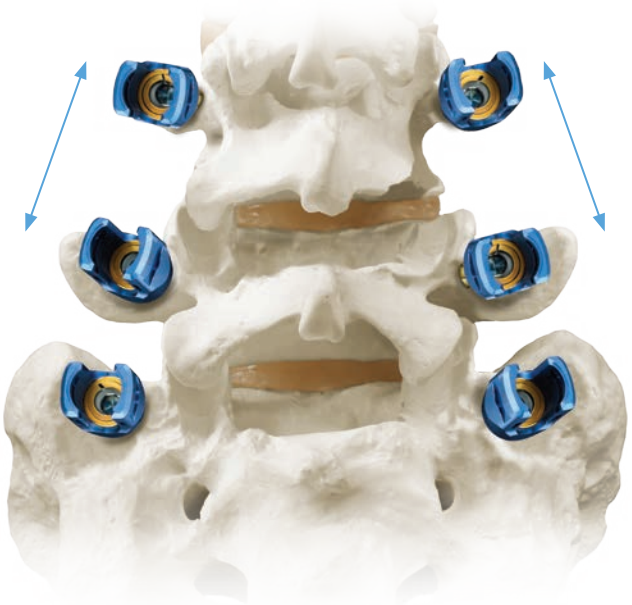
Note: The anterior and lateral walls of the annulus should be preserved to provide peripheral support for the implant.



Preparing endplates with scrapers

Step 4 Distraction

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



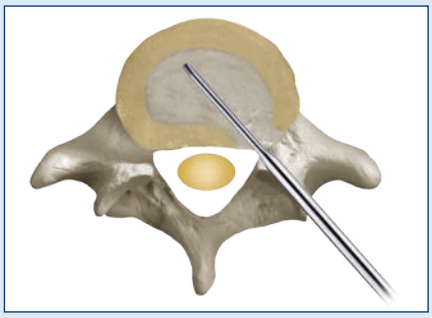
Distraction using REVERE® screws

Distraction (cont'd)

Distraction Using Paddle Distractors, Trials or Scrapers

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

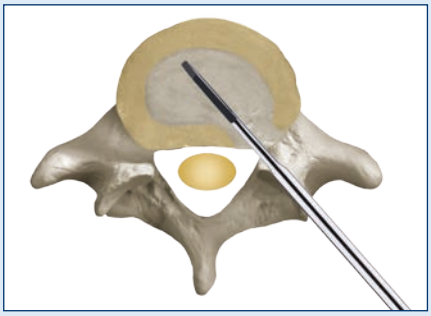
Distraction of disc space using the Paddle Distractor



Paddle Distractor in disc space

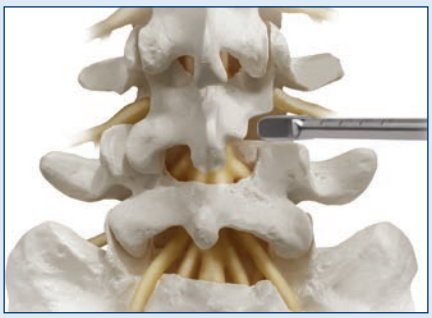
To use the Scraper for distraction, begin with the smallest Scraper and insert, using larger sizes until the desired distraction is achieved.

Distraction of disc space using the Scraper

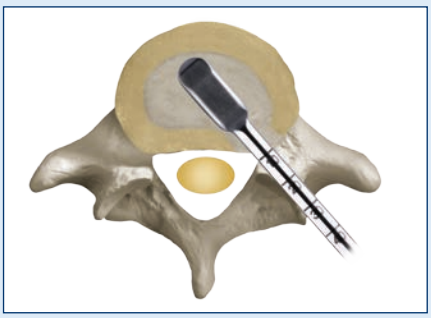


Scraper in disc space

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

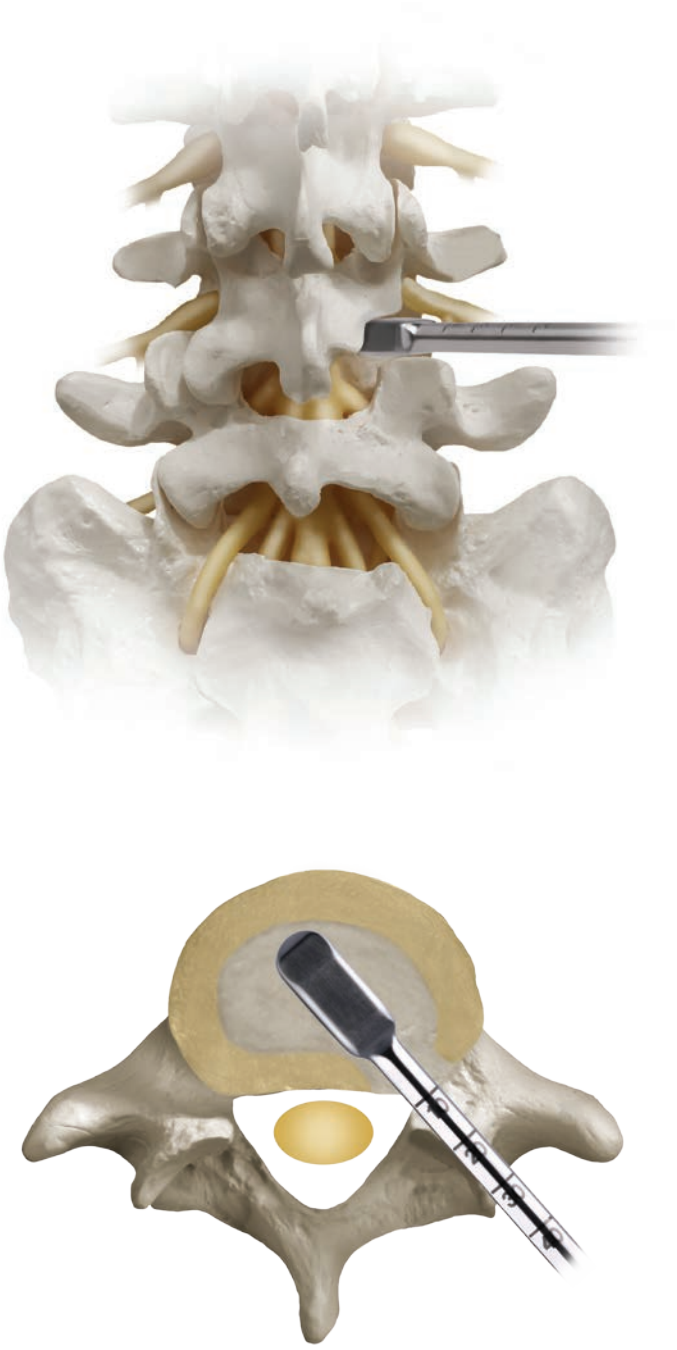


Trial in disc space

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

Step 5 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 graft best fits the prepared disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment, and can be confirmed using fluoroscopy and tactile feel.



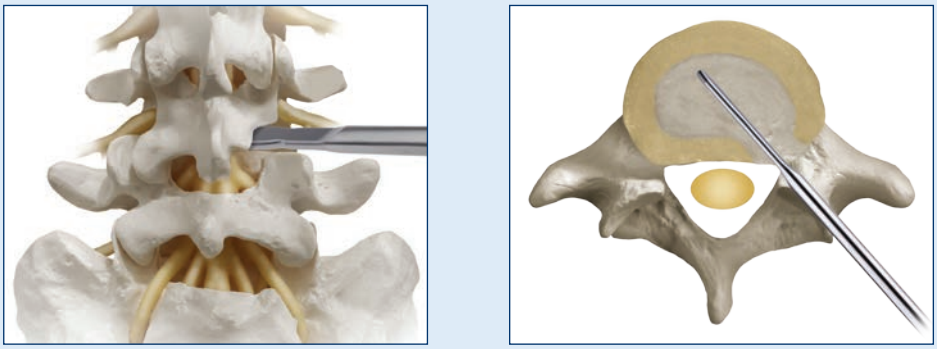
Sizing the disc space
using the Trial

Sizing (cont'd)

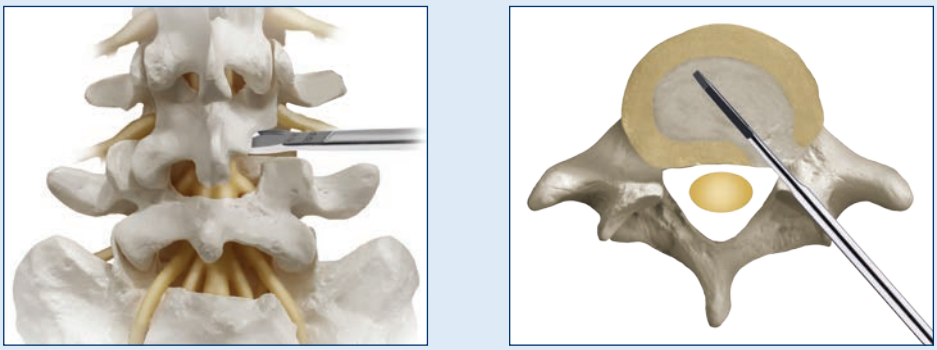
Sizing the Disc Space Using the Paddle Distractors and Scrapers

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.



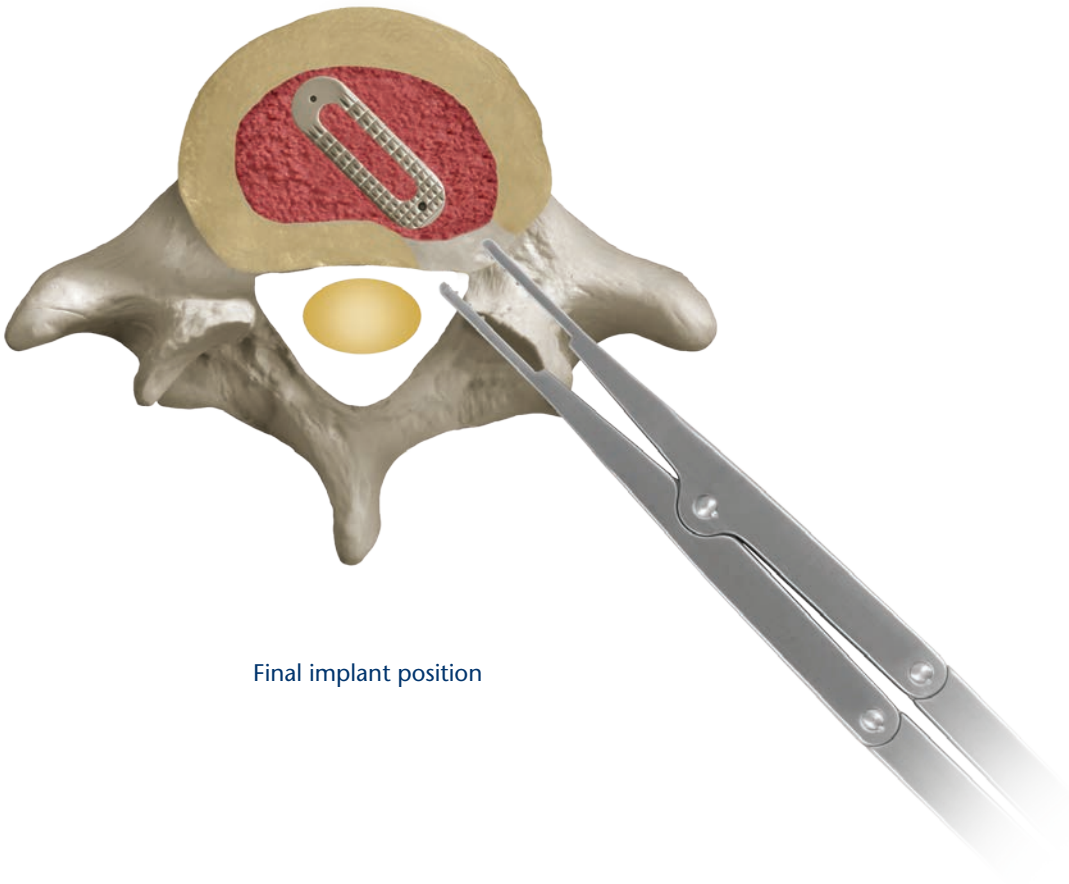
Sizing the disc space using Paddle Distractor



Sizing disc space using Scraper

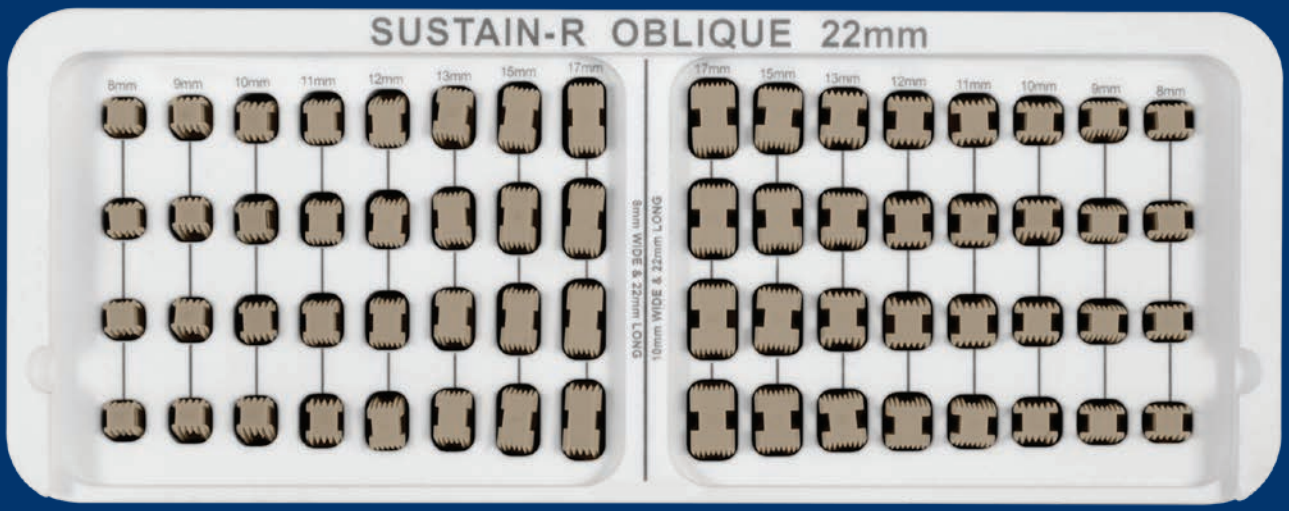
Step 6 Insertion

Select an appropriately sized spacer and fill the chamber with autogenous bone graft material. Insert into the intervertebral space using the **Implant Holder**. To seat the spacer, gently impact the holder until the spacer is in the desired position. The spacer should be recessed into the disc space. Supplemental autogenous 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 is required.



Final implant position

SUSTAIN®-O SMALL IMPLANT SET



SUSTAIN®-O Small Implant Set 904.903

SUSTAIN® Radiolucent Spacer Oblique, Small, 8x22

Height	Part No.	Qty
8mm	304.078	4
9mm	304.079	4
10mm	304.080	4
11mm	304.081	4
12mm	304.082	4
13mm	304.083	4
14mm	304.084	0
15mm	304.085	4
16mm	304.086	0
17mm	304.087	4

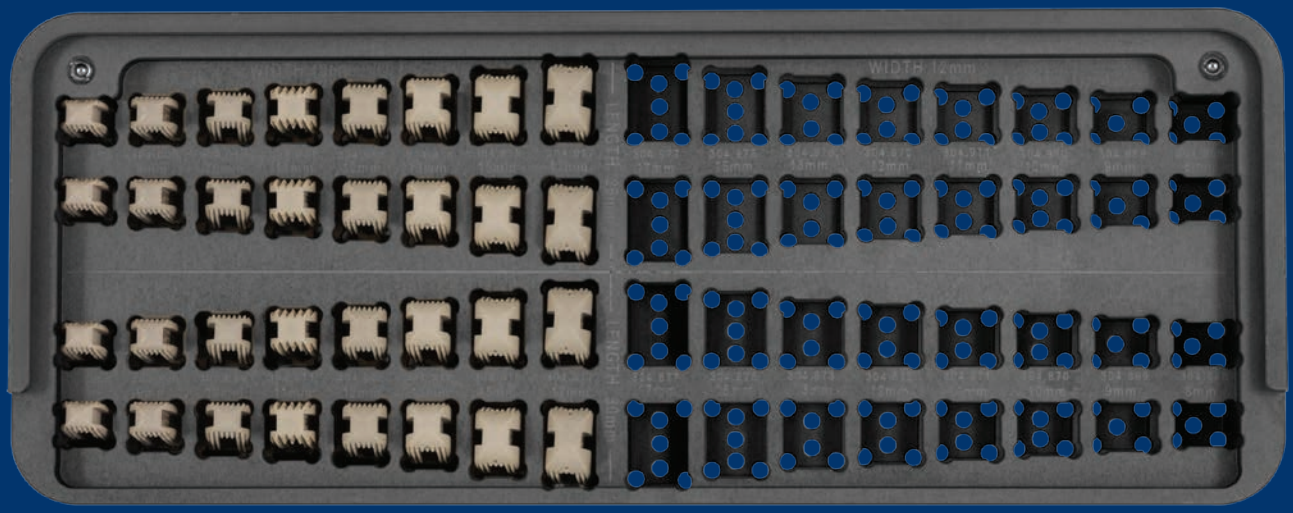
SUSTAIN® Radiolucent Spacer Oblique, Small, 10x22

Height	Part No.	Qty
8mm	304.088	4
9mm	304.089	4
10mm	304.090	4
11mm	304.091	4
12mm	304.092	4
13mm	304.093	4
14mm	304.094	0
15mm	304.095	4
16mm	304.096	0
17mm	304.097	4

904.003 SUSTAIN® Radiolucent Oblique, Small, Module Assembly

Items highlighted in gray are additionally available.

SUSTAIN®-O IMPLANT SET



SUSTAIN®-O Implant Set 904.908

SUSTAIN® Radiolucent Spacer Oblique, 10x26

Height	Part No.	Qty
8mm	304.008	2
9mm	304.009	2
10mm	304.010	2
11mm	304.011	2
12mm	304.012	2
13mm	304.013	2
14mm	304.014	0
15mm	304.015	2
16mm	304.016	0
17mm	304.017	2

SUSTAIN® Radiolucent Spacer Oblique, 12x26

Height	Part No.	Qty
8mm	304.968	0
9mm	304.969	0
10mm	304.970	0
11mm	304.971	0
12mm	304.972	0
13mm	304.973	0
14mm	304.974	0
15mm	304.975	0
16mm	304.976	0
17mm	304.977	0

SUSTAIN® Radiolucent Spacer Oblique, 10x30

Height	Part No.	Qty
8mm	304.808	2
9mm	304.809	2
10mm	304.810	2
11mm	304.811	2
12mm	304.812	2
13mm	304.813	2
14mm	304.814	0
15mm	304.815	2
16mm	304.816	0
17mm	304.817	2

SUSTAIN® Radiolucent Spacer Oblique, 12x30

Height	Part No.	Qty
8mm	304.868	0
9mm	304.869	0
10mm	304.870	0
11mm	304.871	0
12mm	304.872	0
13mm	304.873	0
14mm	304.874	0
15mm	304.875	0
16mm	304.876	0
17mm	304.877	0

904.008 SUSTAIN® Radiolucent Oblique, Implant Module

Items highlighted in gray are additionally available.

SUSTAIN®-O TPS SPACER SMALL IMPLANT SET

SUSTAIN®-O TPS Spacer Small Implant Set 904.953

Part #	Description	Qty
304.078CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 8x22, 8mm	4
304.079CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 8x22, 9mm	4
304.080CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 8x22, 10mm	4
304.081CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 8x22, 11mm	4
304.082CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 8x22, 12mm	4
304.083CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 8x22, 13mm	4
304.084CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 8x22, 14mm	
304.085CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 8x22, 15mm	4
304.086CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 8x22, 16mm	
304.087CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 8x22, 17mm	4
304.088CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 10x22, 8mm	4
304.089CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 10x22, 9mm	4
304.090CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 10x22, 10mm	4
304.091CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 10x22, 11mm	4
304.092CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 10x22, 12mm	4
304.093CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 10x22, 13mm	4
304.094CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 10x22, 14mm	
304.095CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 10x22, 15mm	4
304.096CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 10x22, 16mm,	
304.097CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, Small, 10x22, 17mm	4
904.010	Soft Case	1

Sterile packaged.

Items highlighted in gray are additionally available.

SUSTAIN®-O TPS SPACER IMPLANT SET

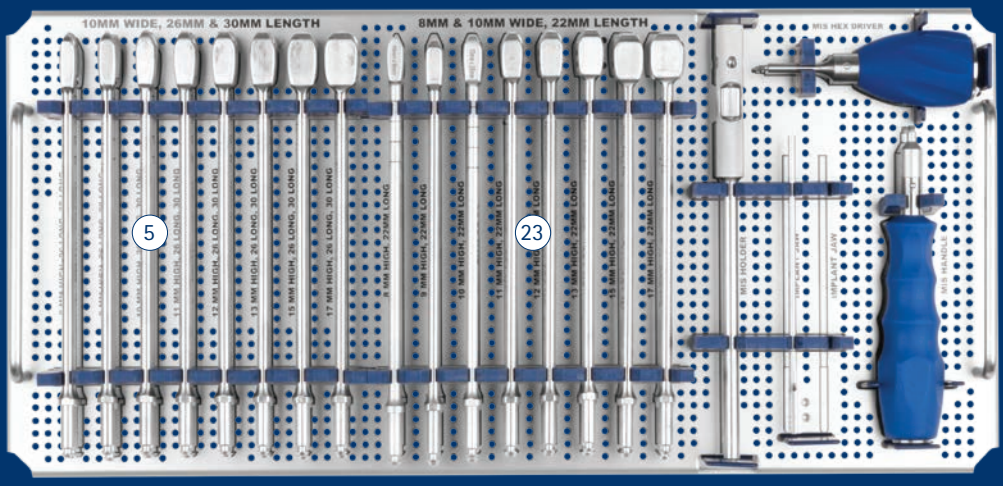
SUSTAIN®-O TPS Spacer Implant Set 904.951

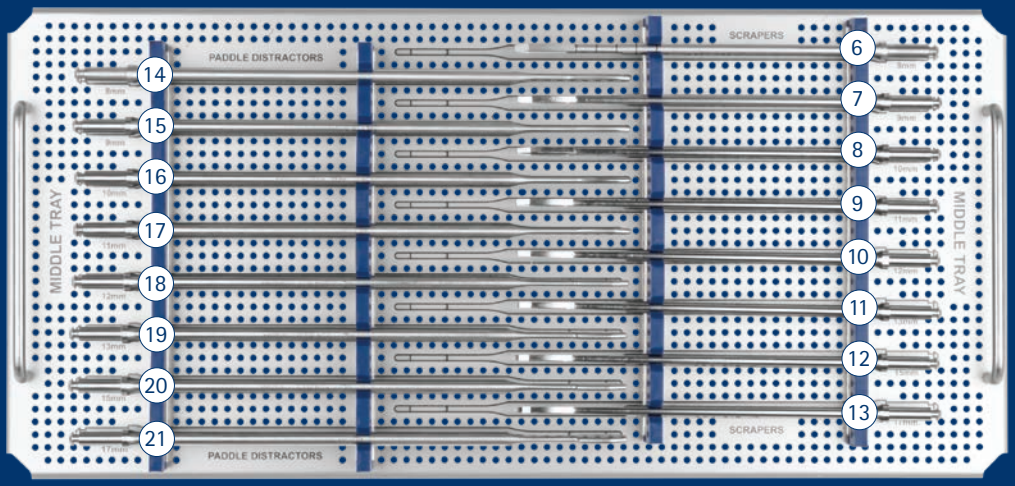
Part #	Description	Qty
304.008CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x26, 8mm	2
304.009CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x26, 9mm	2
304.010CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x26, 10mm	2
304.011CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x26, 11mm	2
304.012CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x26, 12mm	2
304.013CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x26, 13mm	2
304.014CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x26, 14mm	
304.015CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x26, 15mm	2
304.016CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x26, 16mm	
304.017CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x26, 17mm	2
304.808CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x30, 8mm	2
304.809CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x30, 9mm	2
304.810CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x30, 10mm	2
304.811CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x30, 11mm	2
304.812CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x30, 12mm	2
304.813CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x30, 13mm	2
304.814CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x30, 14mm	
304.815CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x30, 15mm	2
304.816CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x30, 16mm	
304.817CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 10x30, 17mm	2
304.868CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x30, 8mm	2
304.869CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x30, 9mm	2
304.870CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x30, 10mm	2
304.871CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x30, 11mm	2
304.872CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x30, 12mm	2
304.873CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x30, 13mm	2
304.874CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x30, 14mm	
304.875CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x30, 15mm	2
304.876CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x30, 16mm	
304.877CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x30, 17mm	2
304.968CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x26, 8mm	2
304.969CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x26, 9mm	2
304.970CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x26, 10mm	2
304.971CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x26, 11mm	2
304.972CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x26, 12mm	2
304.973CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x26, 13mm	2
304.974CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x26, 14mm	
304.975CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x26, 15mm	2
304.976CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x26, 16mm	
304.977CS	SUSTAIN® Radiolucent TPS Spacer, Oblique, 12x26, 17mm	2
904.010	Soft Case	1

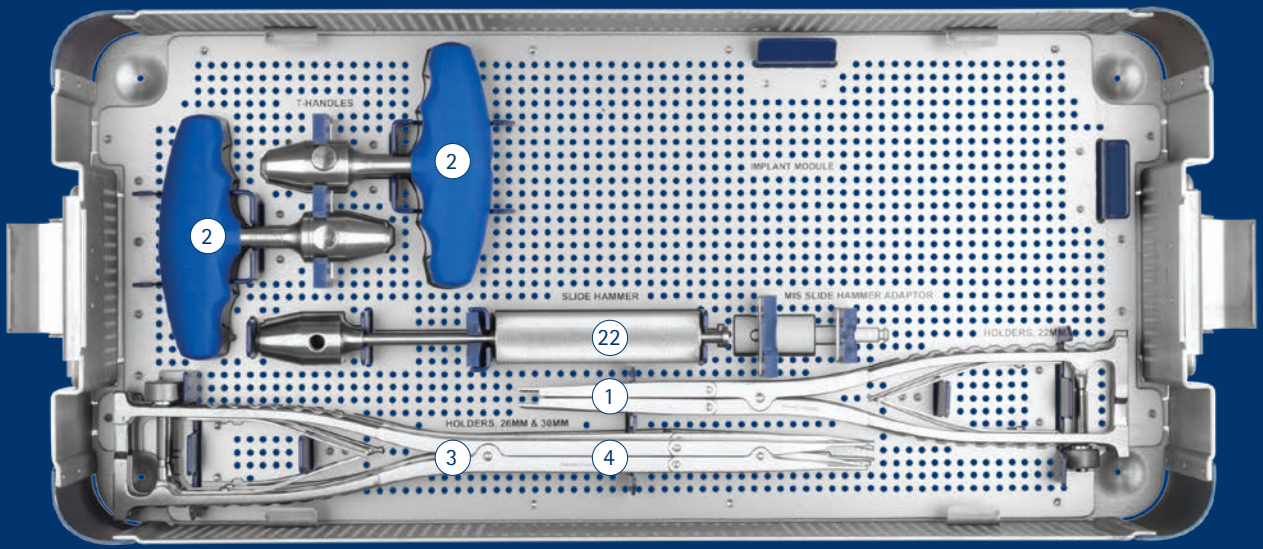
Sterile packaged.

Items highlighted in gray are additionally available.

PRESERVE® INSTRUMENT SET



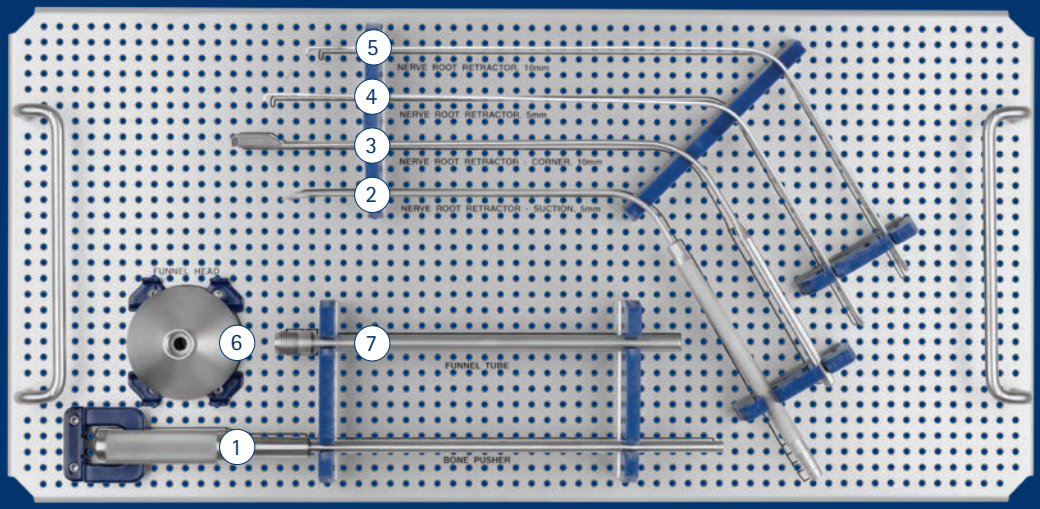


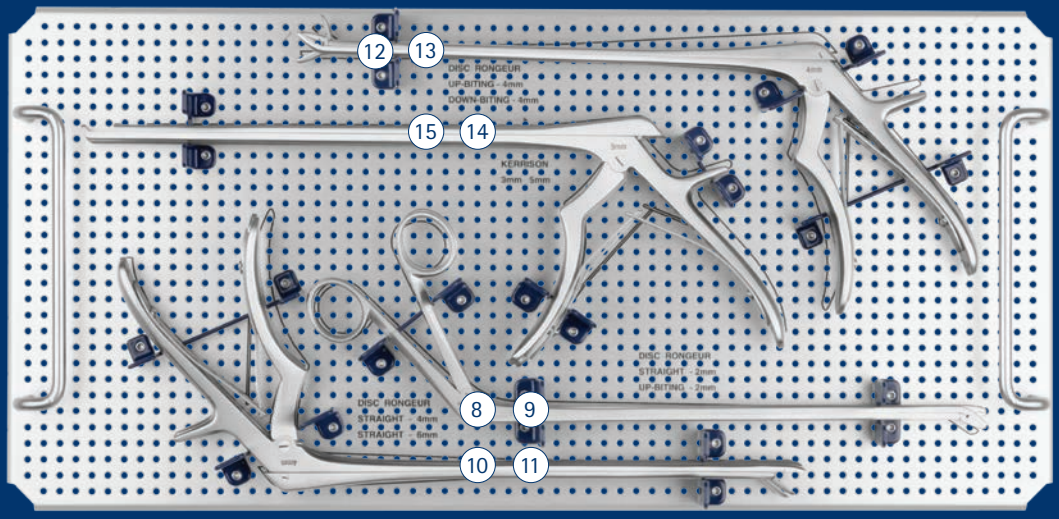


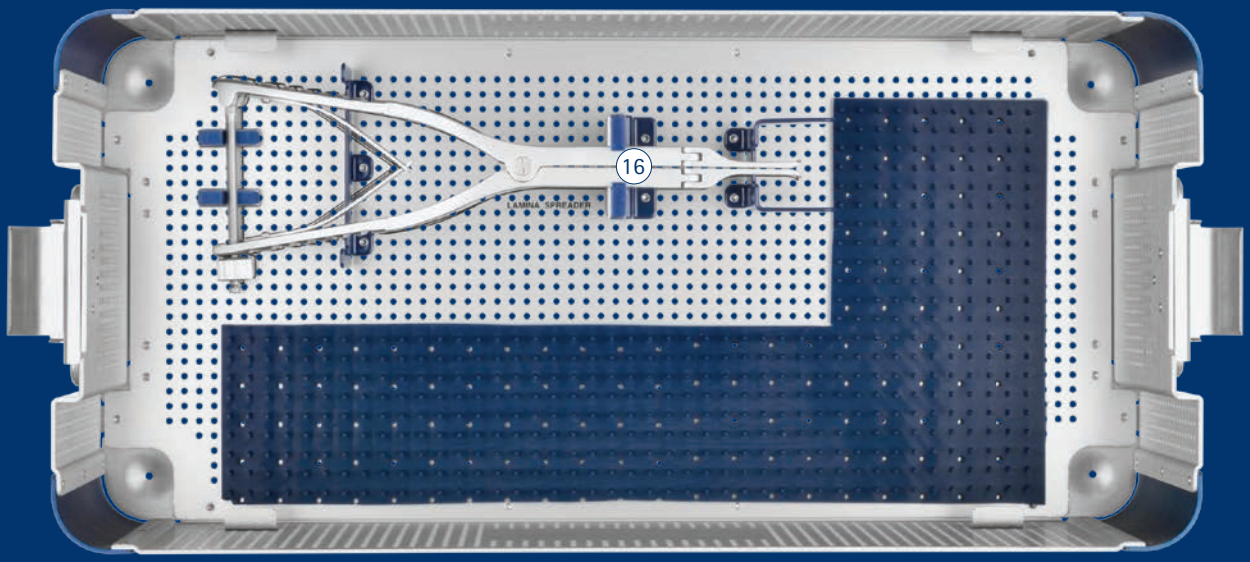
PRESERVE® Posterior Unilateral Instrument Set 904.907

	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	

POSTERIOR DISC PREP INSTRUMENTS I SET



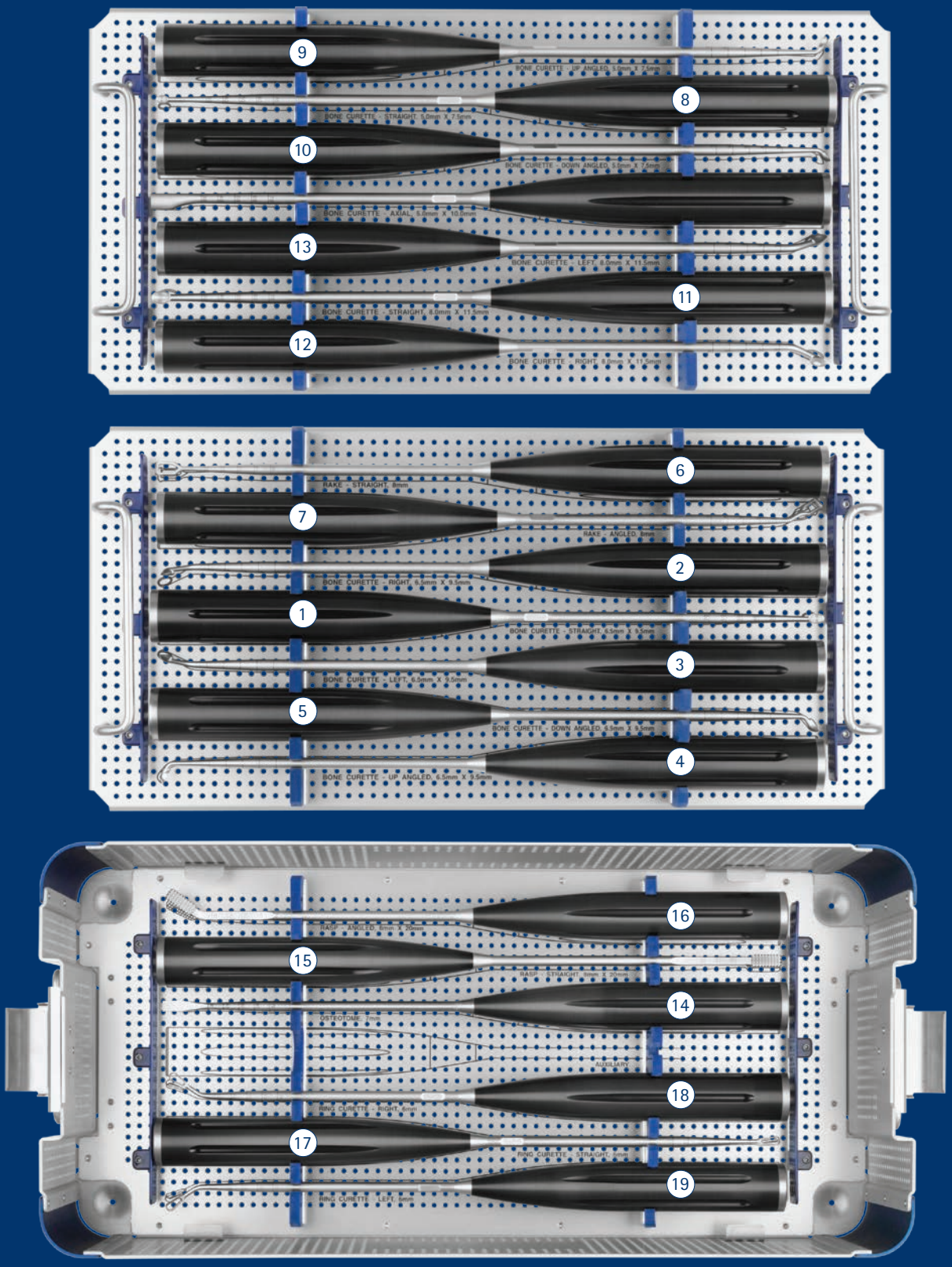




Posterior Disc Prep Instruments I Set 926.901

	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	

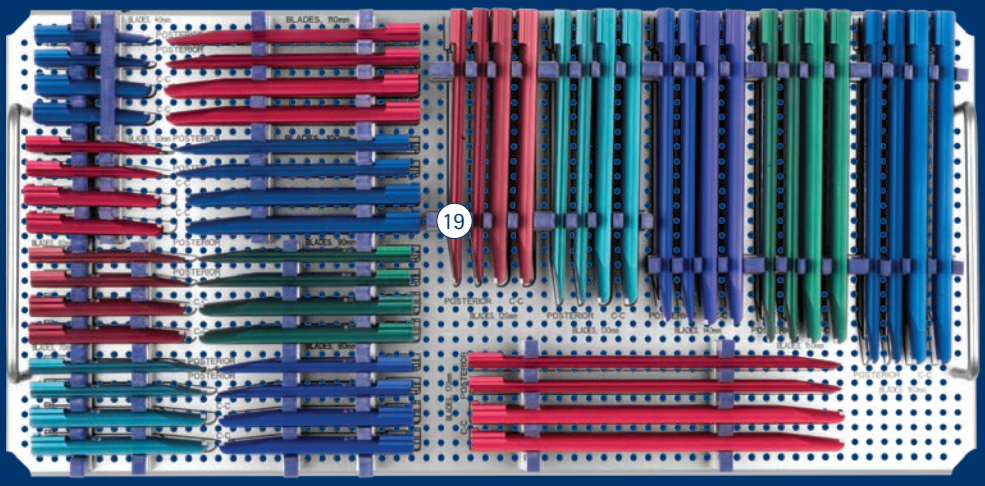
POSTERIOR DISC PREP INSTRUMENTS II SET

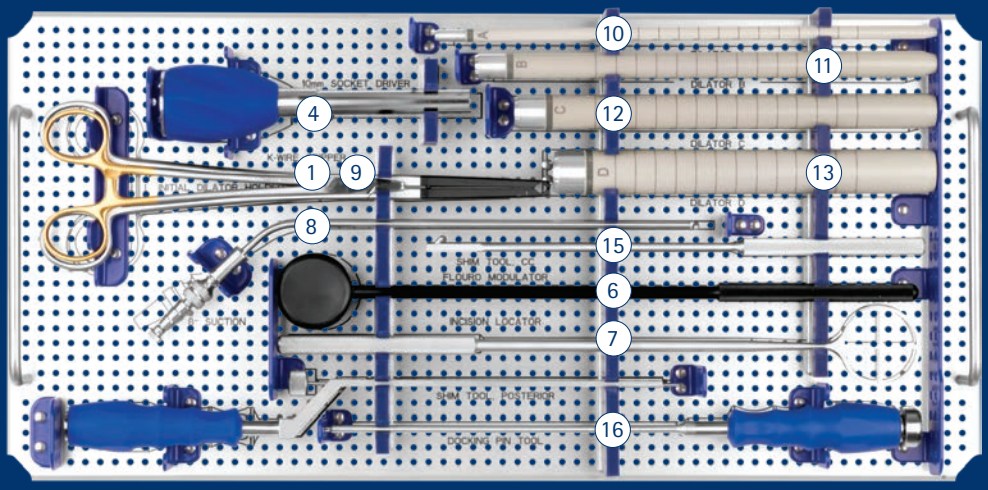


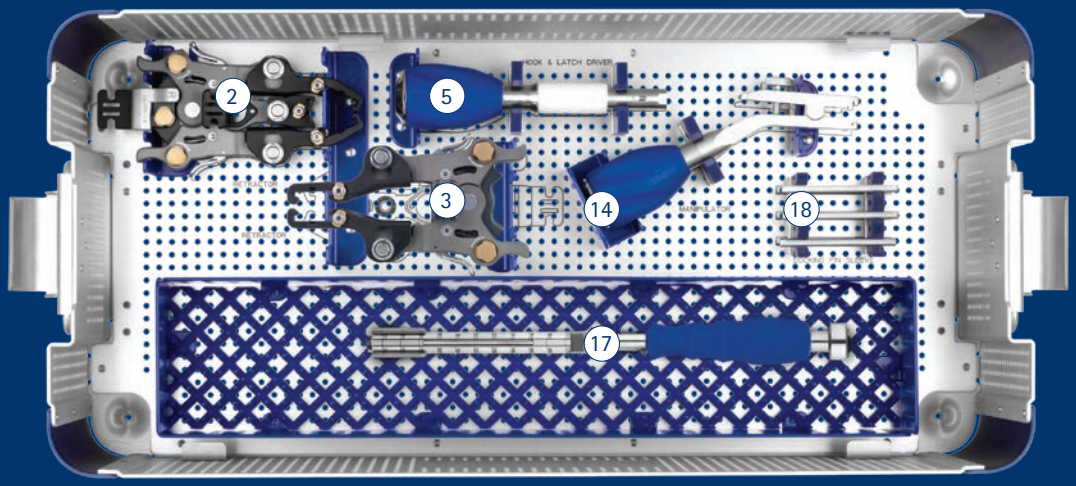
Posterior Disc Prep Instruments II Set 926.902

	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	

MARS™ 3V RETRACTOR SET







MARS™ 3V Retractor Set 998.901

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

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

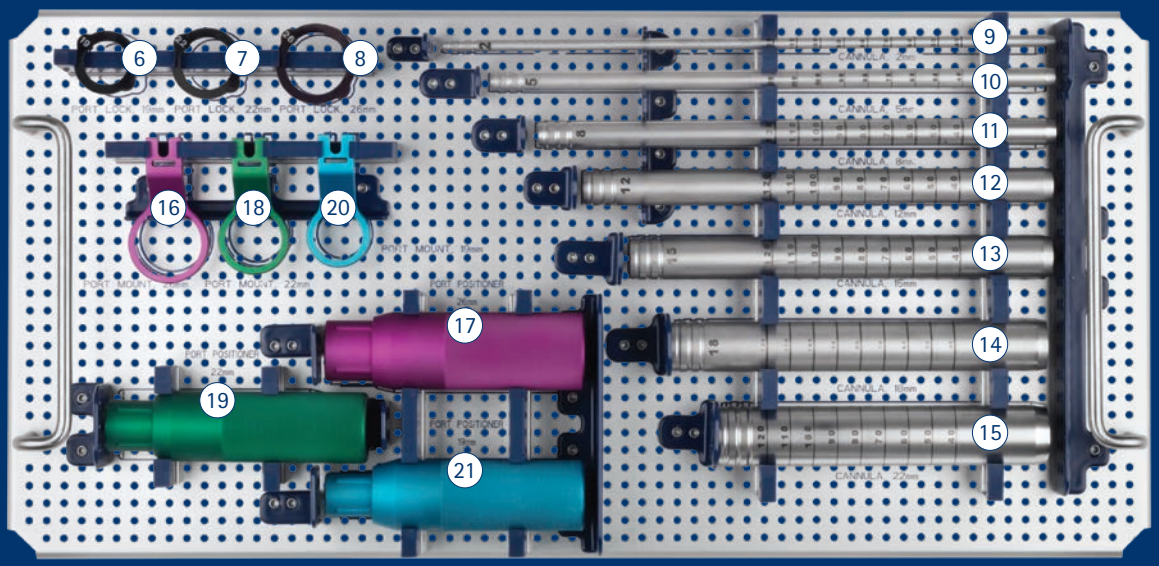
Retractor Blades		Qty
698.476	Blade, Posterior, 170mm	2
698.510	Blade, CC, 40mm	2
698.512	Blade, CC, 50mm	2
698.514	Blade, CC, 60mm	2
698.516	Blade, CC, 70mm	2
698.518	Blade, CC, 80mm	2
698.520	Blade, CC, 90mm	2
698.522	Blade, CC, 100mm	2
698.524	Blade, CC, 110mm	2
698.526	Blade, CC, 120mm	2
698.528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

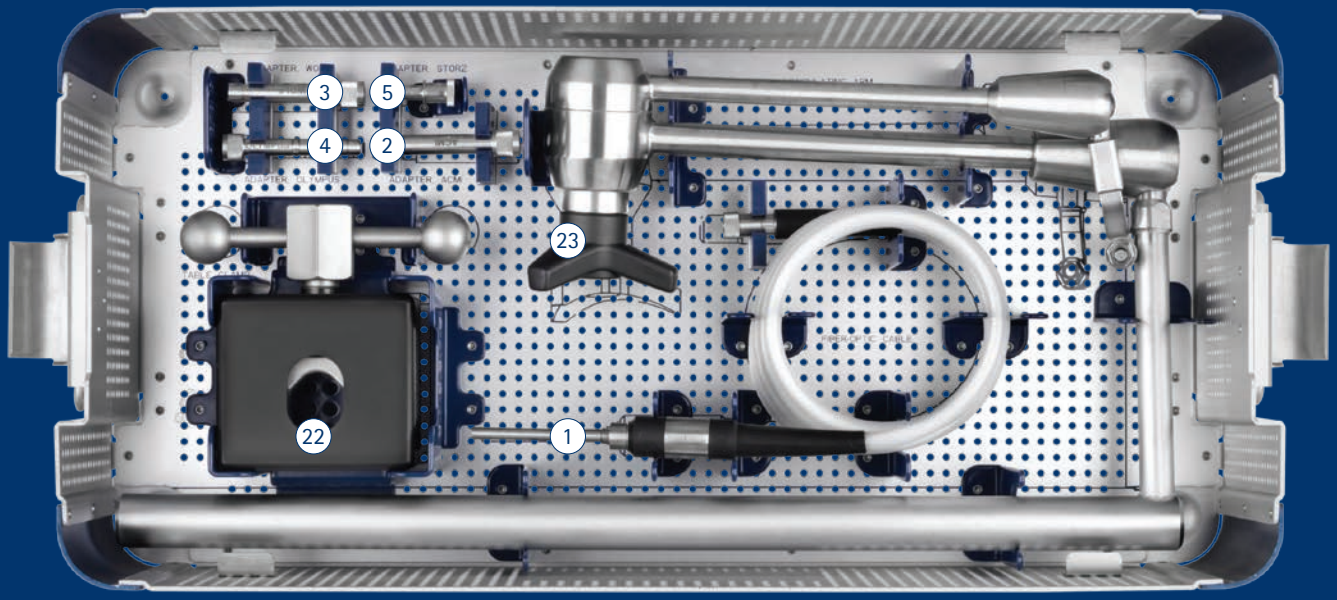
Disposables

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

Items highlighted in gray are additionally available.

MARS™ INSTRUMENTS II SET

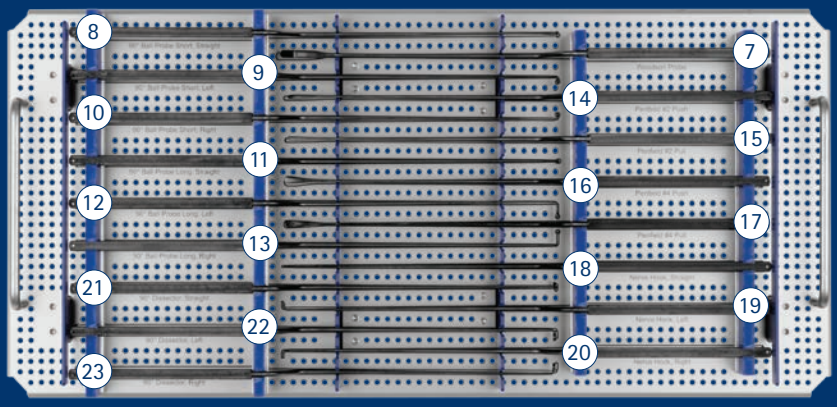


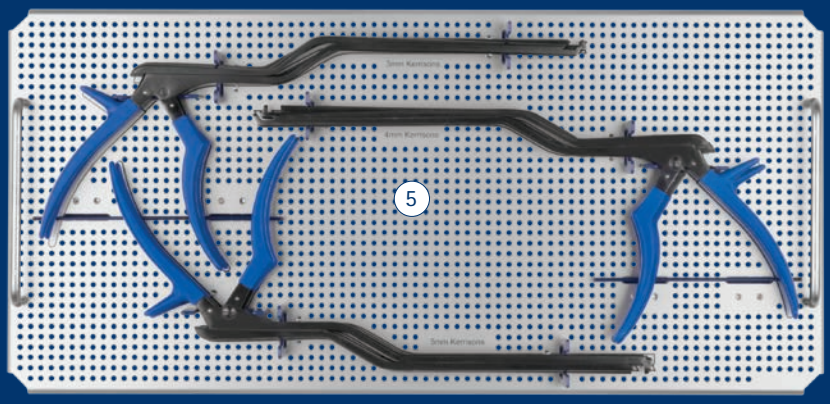


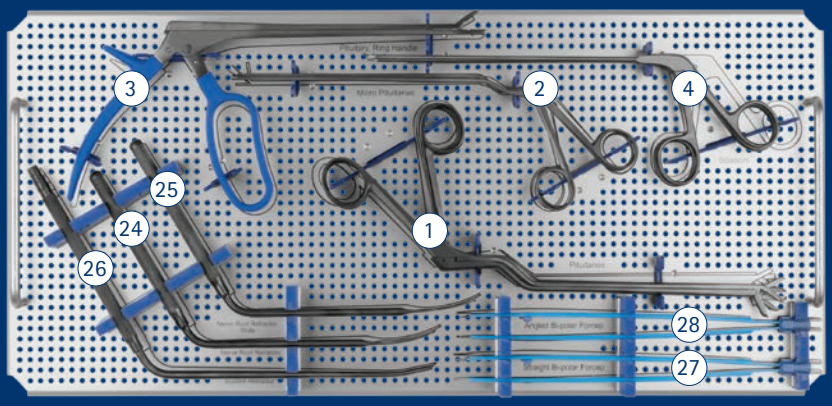
MARS™ Instruments II Set 932.902

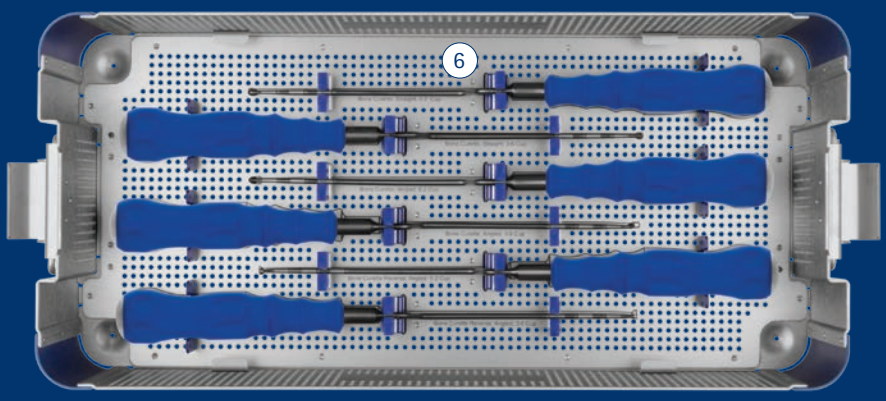
	Instruments		Qty
1	632.300	Fiber-Optic Cord	1
2	632.305	Adapter, ACMI	1
3	632.306	Adapter, Wolf	1
4	632.307	Adapter, Olympus	1
5	632.308	Adapter, Storz	1
	632.310S	Light Cable	1
6	632.390	Port Lock, 19mm	1
7	632.391	Port Lock, 22mm	1
8	632.392	Port Lock, 26mm	1
9	632.401	2mm Cannula	1
10	632.402	5mm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

MARS™ INSTRUMENTS III SET





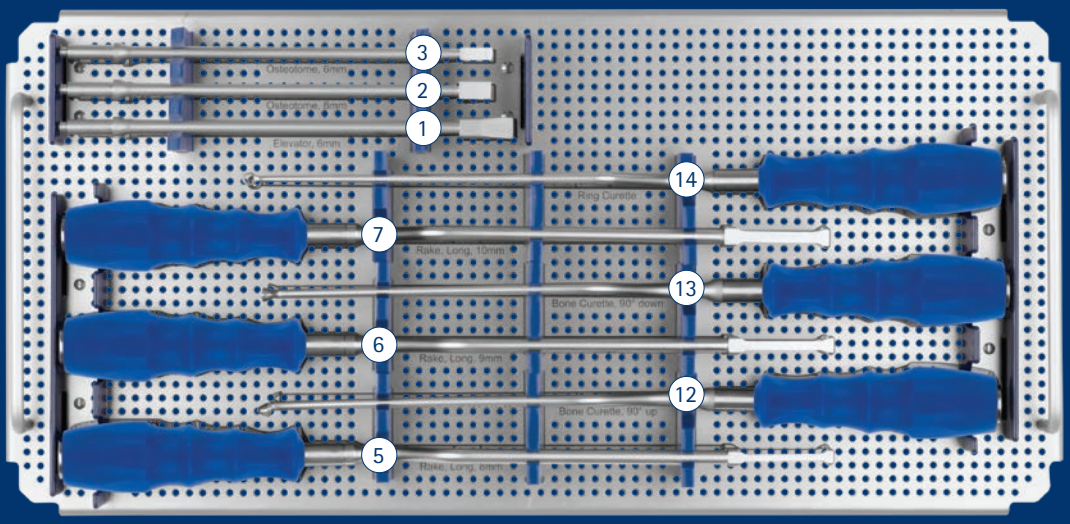


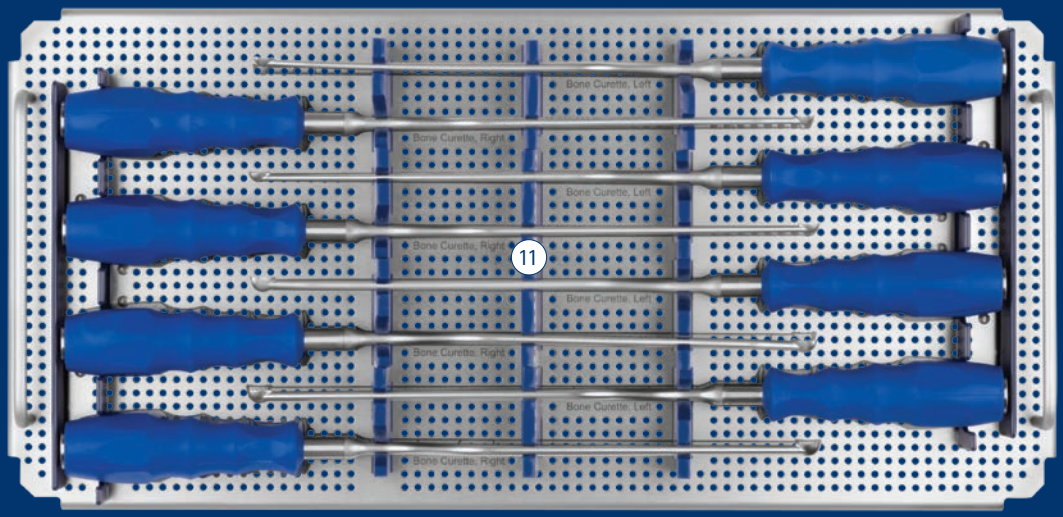


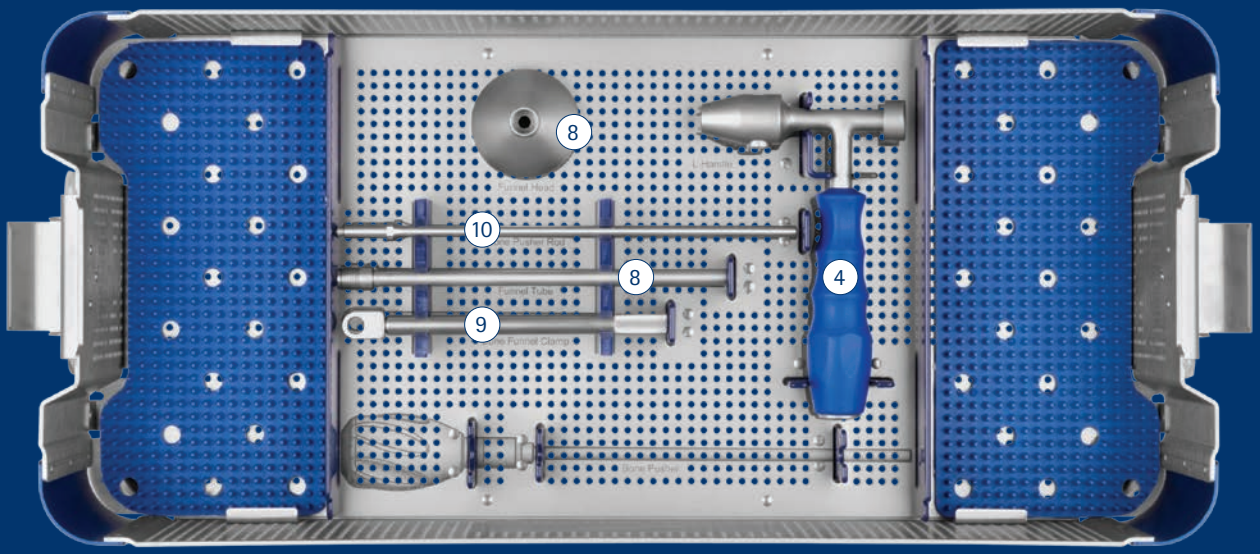
MARS™ Instruments III Set 932.903

	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
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	

MIS LUMBAR DISCECTOMY INSTRUMENT SET







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 additionally available.

Additionally Available

Part No.	Descriptions
604.114	Trial, SUSTAIN®-R Oblique 26mm length, 14mm
604.116	Trial, SUSTAIN®-R Oblique, 26mm length, 16mm
604.214	Trial, SUSTAIN®-R Oblique 30mm length, 14mm
604.216	Trial, SUSTAIN®-R Oblique, 30mm 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
673.001	MIS Holder
673.002	MIS Hex Driver, 2.5mm and 1.5mm
673.003	MIS Handle
673.004	Implant Jaw, with Teeth, SUSTAIN®-O, Small
673.005	Implant Jaw, without Teeth, SUSTAIN®-O, Small
673.006	Implant Jaw, with Teeth, SUSTAIN®-O, 10mm Wide
673.007	Implant Jaw, without Teeth, SUSTAIN®-O, 10mm Wide
673.008	Implant Jaw, with Teeth, SUSTAIN®-O, 12mm Wide
673.009	Implant Jaw, without Teeth, SUSTAIN®-O, 12mm Wide
673.019	MIS Slap Hammer, Shaft, 29mm
673.017	Slide Hammer, Quick Disconnect
673.114	Trial Shaft, 8mm wide,14mm, SUSTAIN® Oblique, Small
673.116	Trial Shaft, 8mm wide, 16mm, SUSTAIN® Oblique, Small
673.214	Trial Shaft, 10mm wide,14mm, SUSTAIN® Oblique, Small
673.216	Trial Shaft, 10mm wide, 16mm, SUSTAIN® Oblique, Small

IMPORTANT INFORMATION ON THE SUSTAIN® AND SUSTAIN®-R SPACERS

DESCRIPTION

SUSTAIN® Spacers (including SUSTAIN® R, SUSTAIN®-IR and SUSTAIN® R TPS) are devices that can be used as intervertebral fusion devices or as vertebral body replacement devices. These spacers are available in different shapes and heights to accommodate various surgical approaches and anatomical needs. 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). Lumbar spacers may be inserted using a posterior, transforaminal, anterior, anterolateral, or lateral lumbar approach. Cervical spacers are inserted using an anterior cervical approach.

The SUSTAIN® Spacers are made from commercially pure titanium or titanium alloy as specified in ASTM F67, F136, and F1295. SUSTAIN® Radiolucent (SUSTAIN® R, SUSTAIN®-IR) 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 also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

INDICATIONS

When used as lumbar intervertebral body fusion devices, SUSTAIN® Spacers (including SUSTAIN® R, SUSTAIN®-IR and SUSTAIN® R TPS) are 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). SUSTAIN®, SUSTAIN® R and SUSTAIN®-IR Spacers are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. SUSTAIN® TPS Spacers are to be used with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the CREO®, REVERE®, REVOLVE®, or BEACON® Stabilization Systems.

When used as cervical intervertebral body fusion devices, SUSTAIN® Spacers (including SUSTAIN® R and SUSTAIN® R TPS) are intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C2-T1) at one level. DDD is defined as discogenic 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) weeks of non-operative treatment. SUSTAIN® Spacers are to be filled with autogenous bone graft material. 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® R 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.

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.

SUSTAIN® Spacers have not been evaluated for safety and compatibility in the MR environment. These devices have not been tested for heating, migration, or image artifact in the MR environment. The safety of SUSTAIN® Spacers in the MR environment is unknown. Scanning a patient who has these devices may result in patient injury.

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.
8. Any condition not described in the indications for use.
9. Fever or leukocytosis.
10. Pregnancy.

IMPORTANT INFORMATION ON THE SUSTAIN® AND SUSTAIN®-R SPACERS (CONT'D)

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 EVENTS

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

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

PACKAGING

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

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

HANDLING AND USE

All implants, instruments, and instrument trays and cases 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 products 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

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products 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 and instrument trays and cases 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.

IMPORTANT INFORMATION ON THE SUSTAIN® AND SUSTAIN®-R SPACERS (CONT'D)

CONTACT INFORMATION

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

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

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

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

Do not stack trays during sterilization. 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		

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REV L

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CE 0297

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