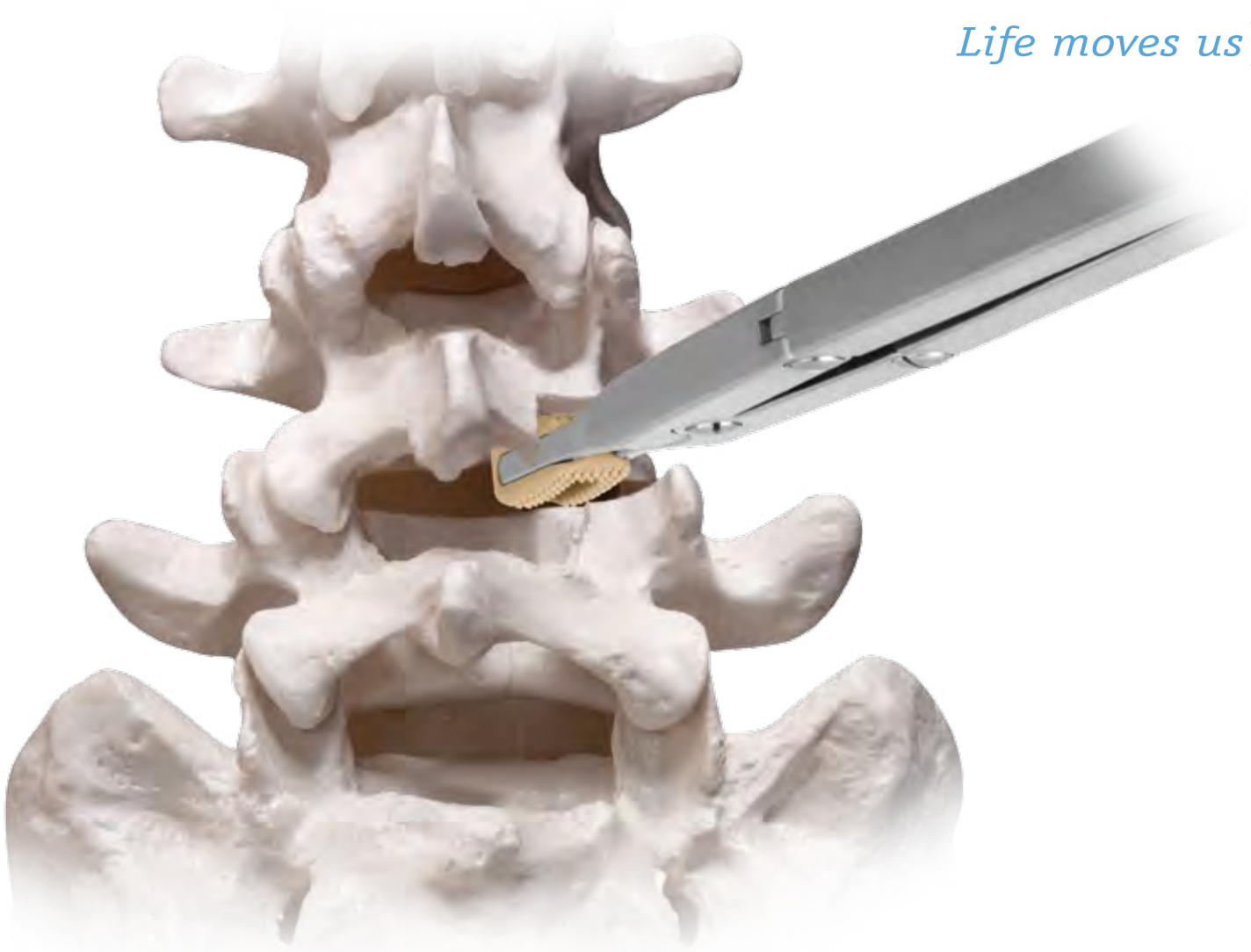
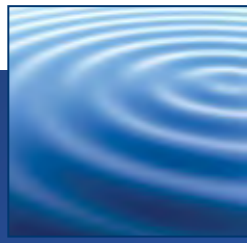
Life moves us



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.

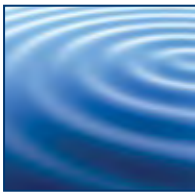
The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

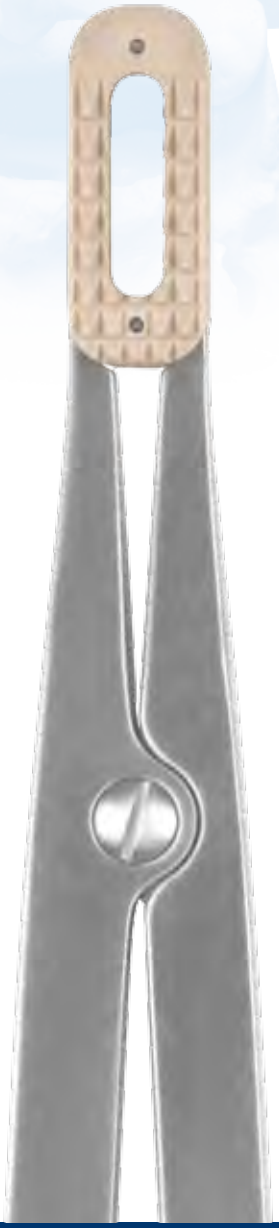
GLOBUS
MEDICAL

www.globusmedical.com

SUSTAIN®-O

Radiolucent Spacer

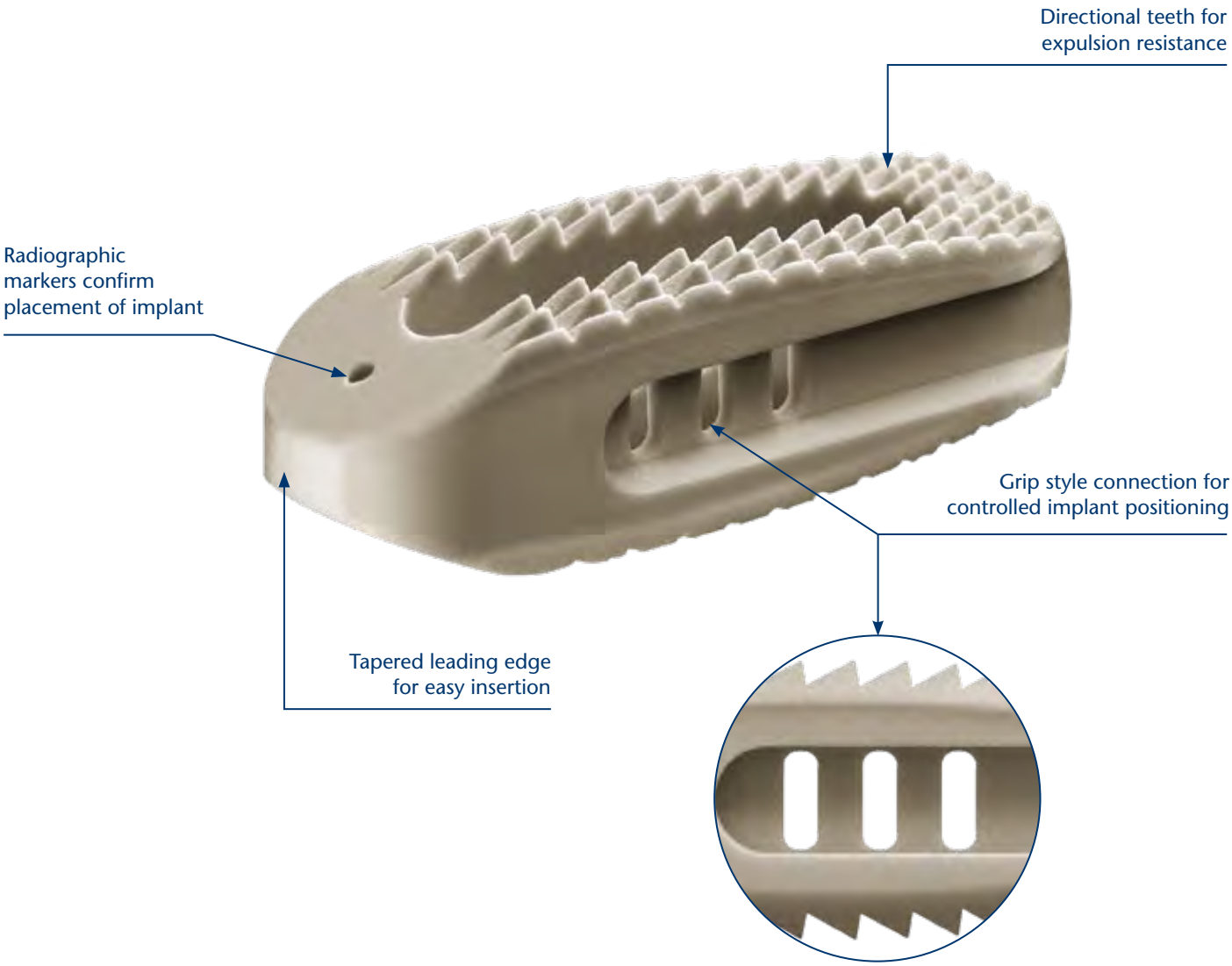




SUSTAIN®-O is an interbody fusion device made from radiolucent polymer (PEEK). The rounded corners, grip-style connection, and robust implant holder allow control during insertion and positioning. The anterior portion of the implant has a tapered leading edge for ease of insertion. The inferior and superior 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



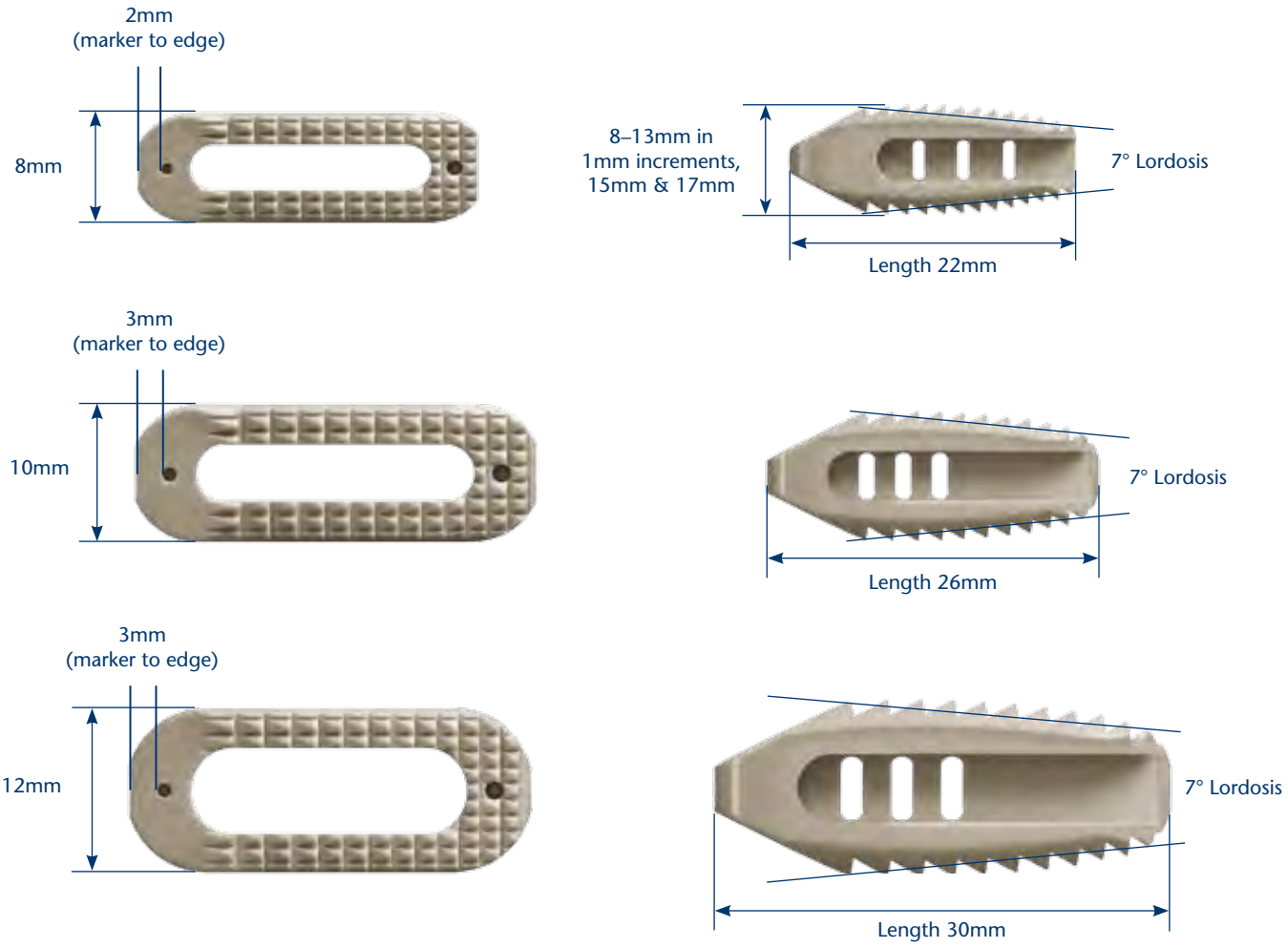
CONTENTS

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

- 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



INSTRUMENT OVERVIEW

Distraction Instruments

Scrapers

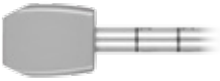
	Height	Part No.
	8mm	604.308
	9mm	604.309
	10mm	604.310
	11mm	604.311
	12mm	604.312
	13mm	604.313
	15mm	604.315
	17mm	604.317

Paddle Distractors

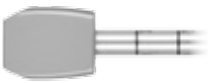
	Height	Part No.
	8mm	604.808
	9mm	604.809
	10mm	604.810
	11mm	604.811
	12mm	604.812
	13mm	604.813
	15mm	604.815
	17mm	604.817

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

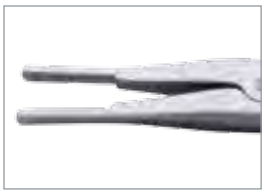
	Height	26mm
	8mm	604.108
	9mm	604.109
	10mm	604.110
	11mm	604.111
	12mm	604.112
	13mm	604.113
	15mm	604.115
	17mm	604.117

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

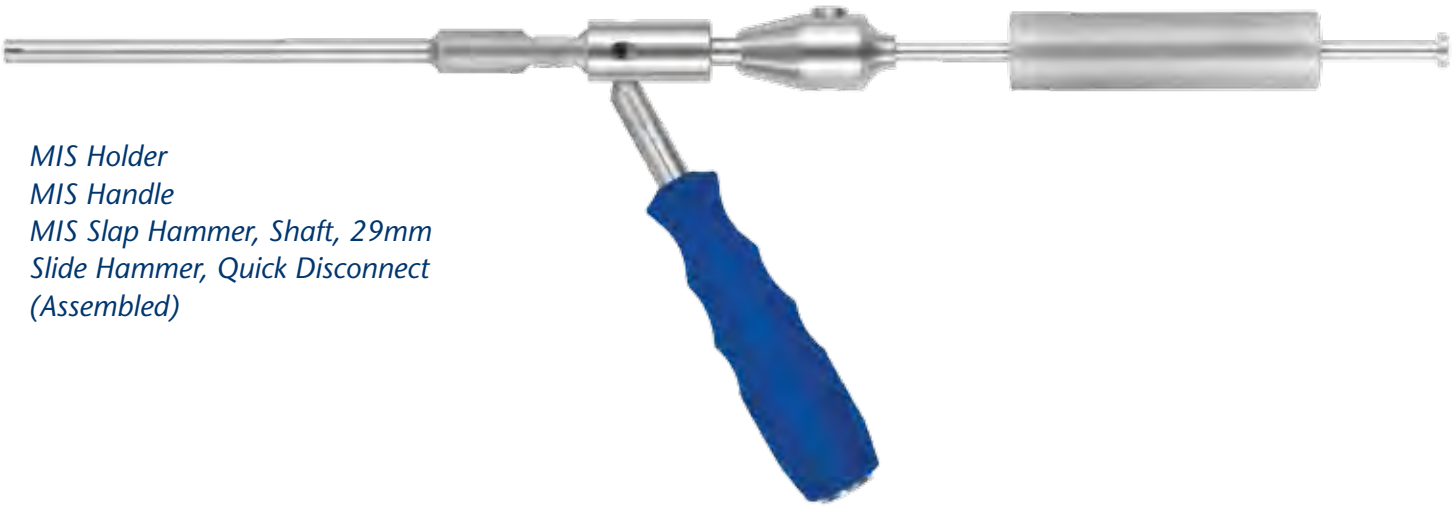
Implant Jaw without Teeth, SUSTAIN®-O 12mm Wide 673.009

MIS Instruments (cont'd)

Slide Hammer, Quick Disconnect 673.017

MIS Slap Hammer, Shaft 29mm 673.019

MIS Holder
MIS Handle
(Assembled)

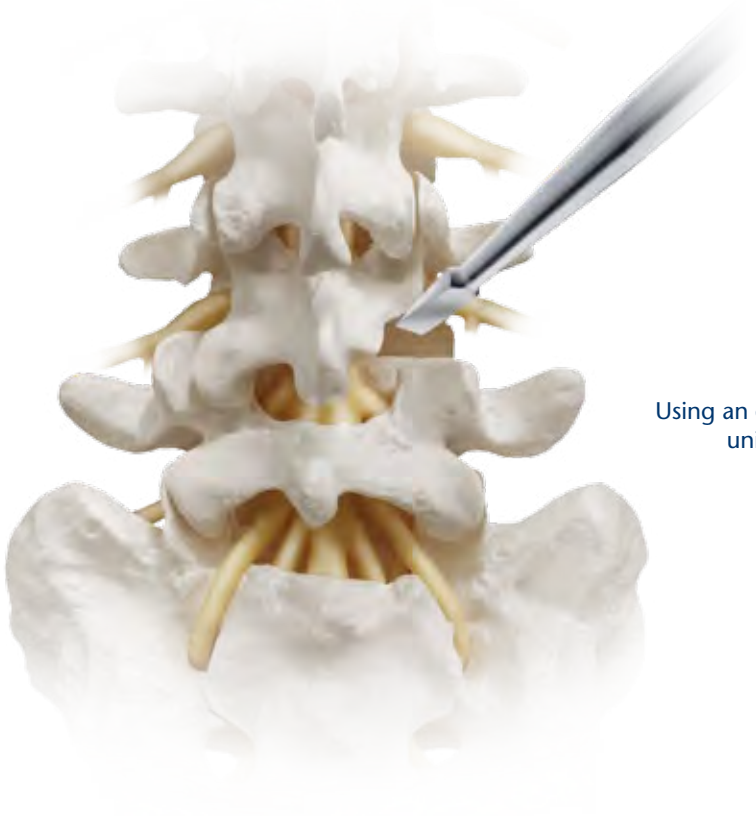


MIS Holder
MIS Handle
MIS Slap Hammer, Shaft, 29mm
Slide Hammer, Quick Disconnect
(Assembled)

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

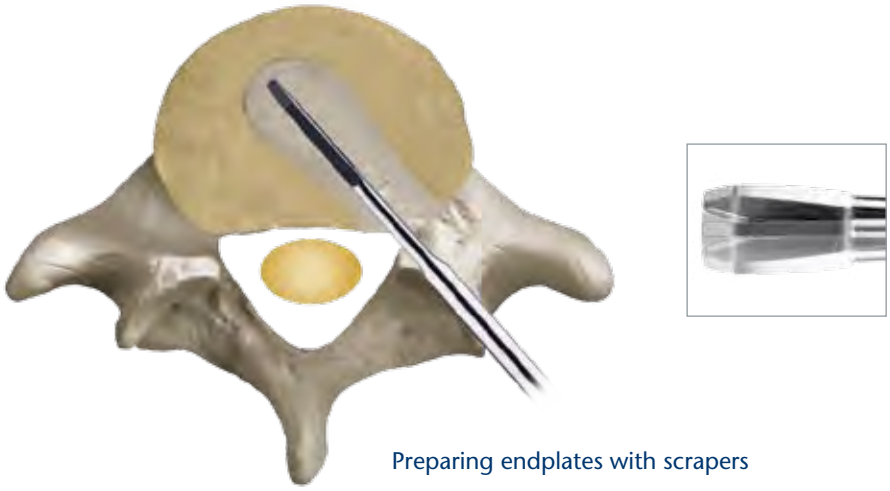
Step 2 Creating Unilateral Access

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.

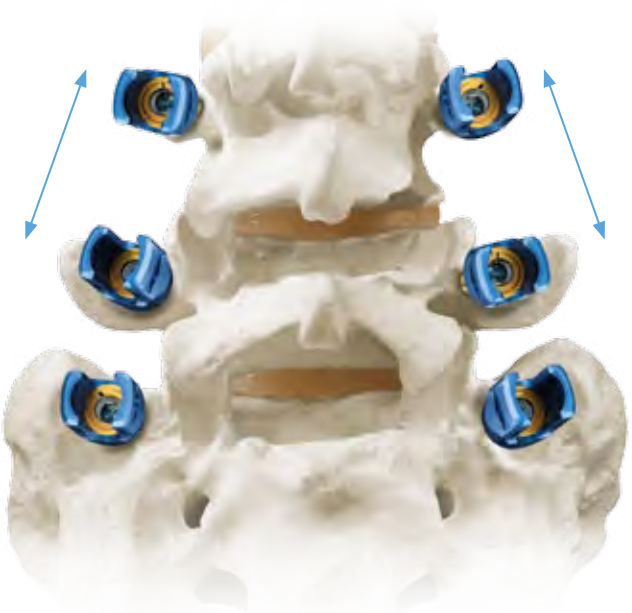
Note: The anterior and lateral walls of the annulus should be preserved to provide peripheral support for the implant.



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.

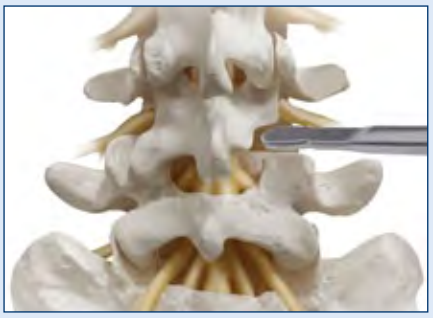


Distraction using REVERE® screws

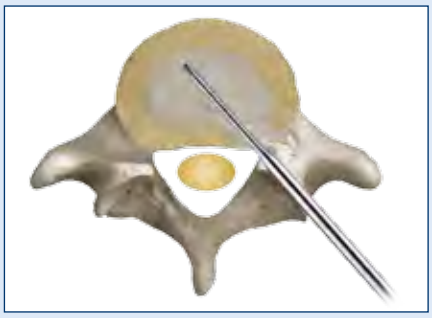
Distraction (cont'd)

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.

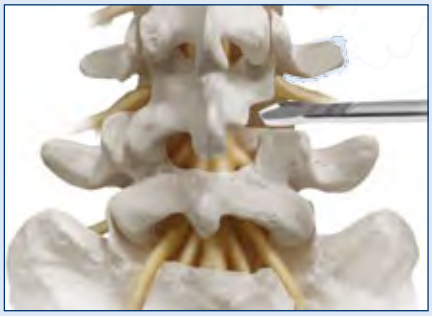


Distraction of disc space using the Paddle Distractor

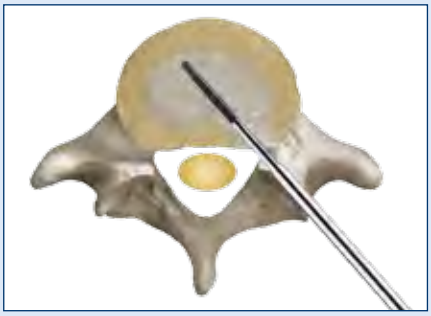


Paddle Distractor in disc space

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

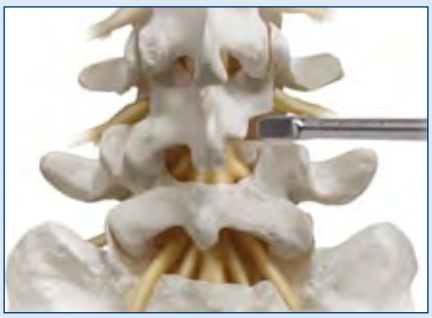


Distraction of disc space using the Scraper

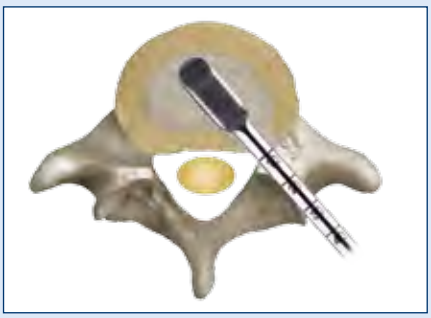


Scraper in disc space

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

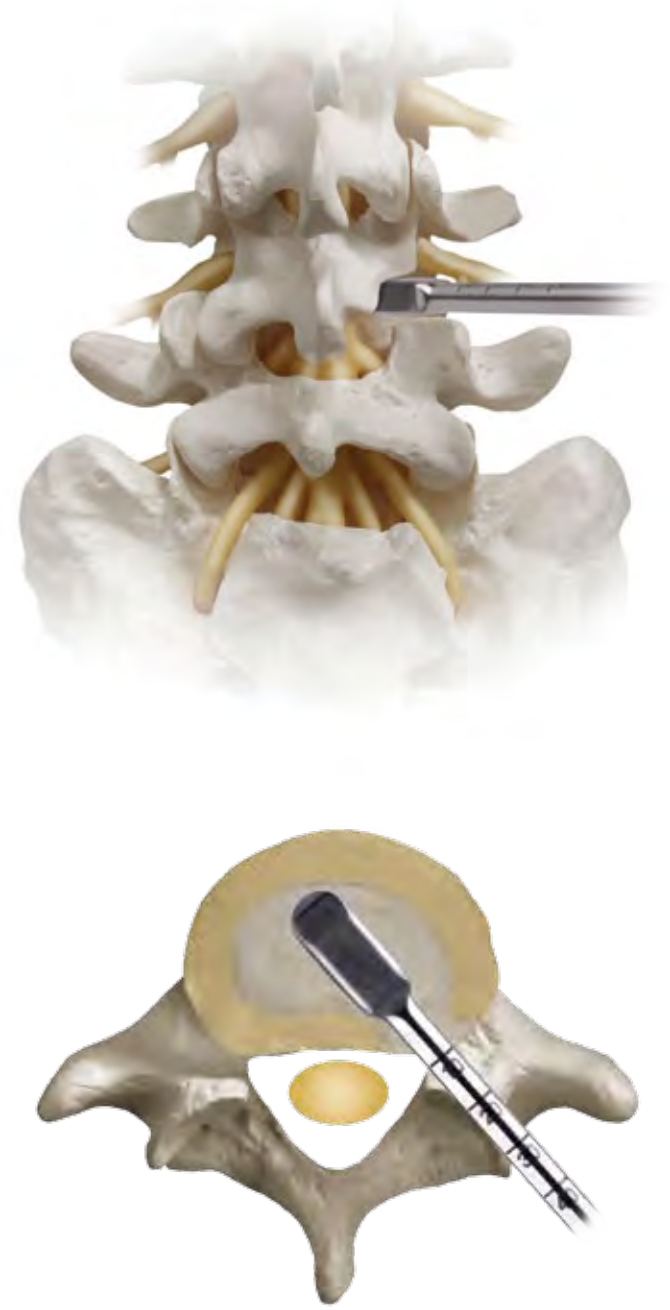


Trial in disc space

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.

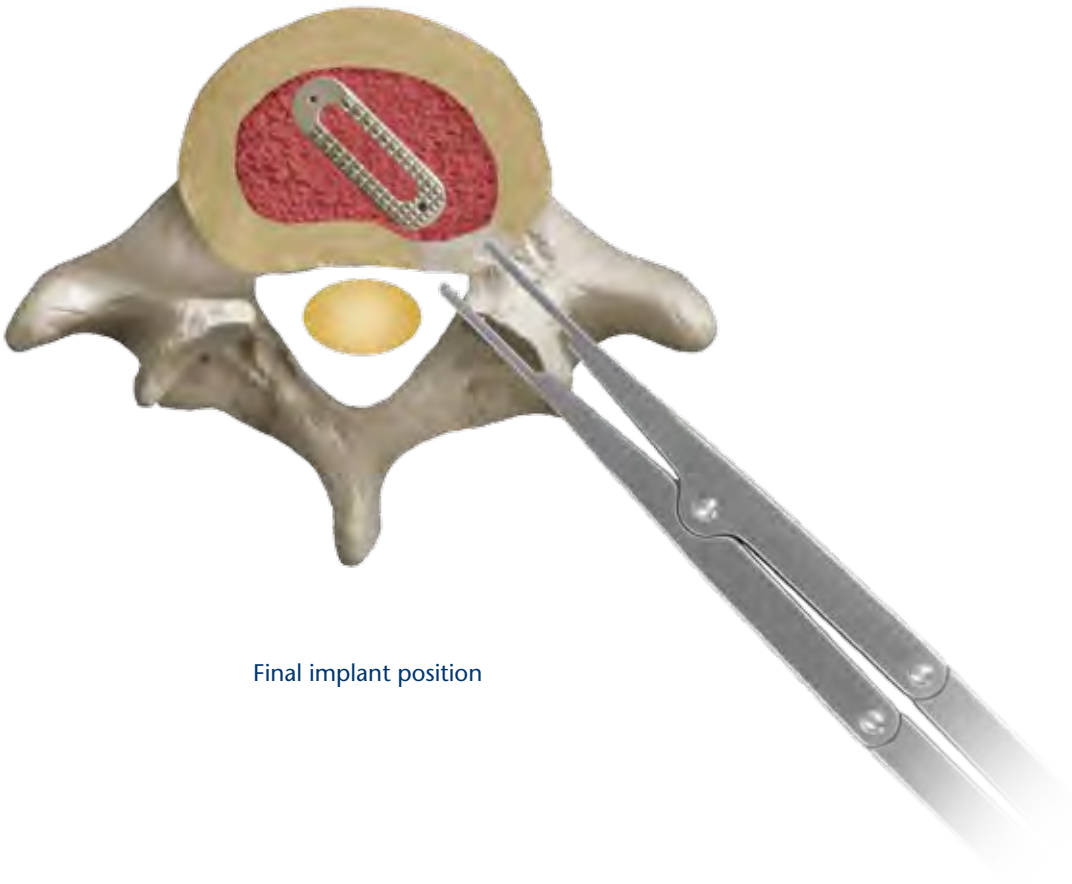
Note: Use caution while using Scrapers or Paddle Distractors for sizing to avoid damage to the endplates.

Sizing the disc space using Paddle Distractor

Sizing disc space using Scraper

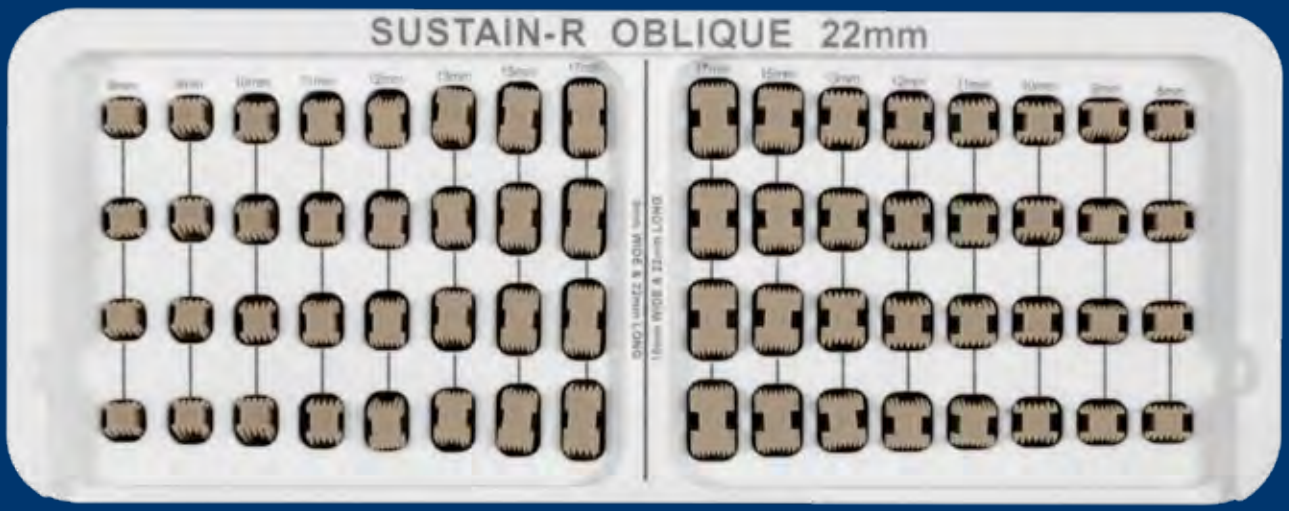
Step 6 Insertion

Select an appropriately sized spacer and fill the chamber with autogenous bone graft material. Insert into the intervertebral space using the **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

Length	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

Length	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

Length	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

Length	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

Length	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

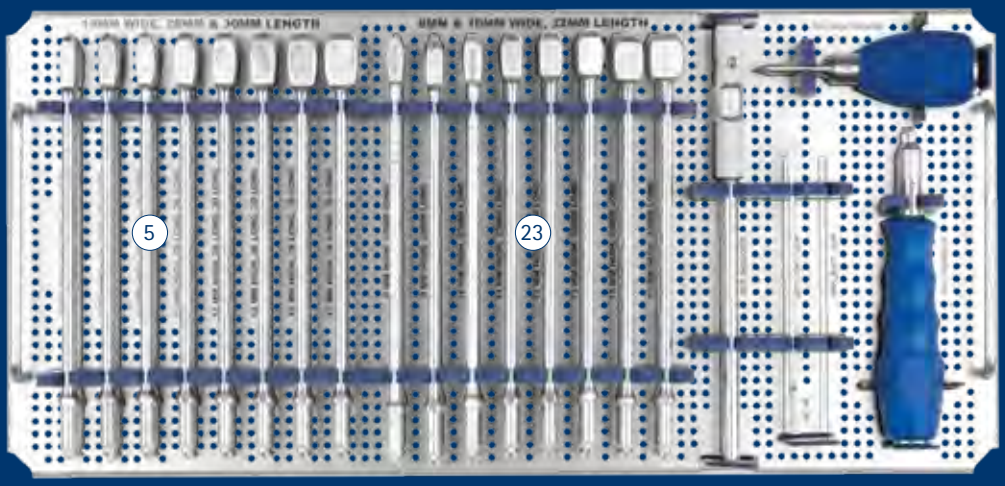
SUSTAIN® Radiolucent Spacer Oblique, 12x30

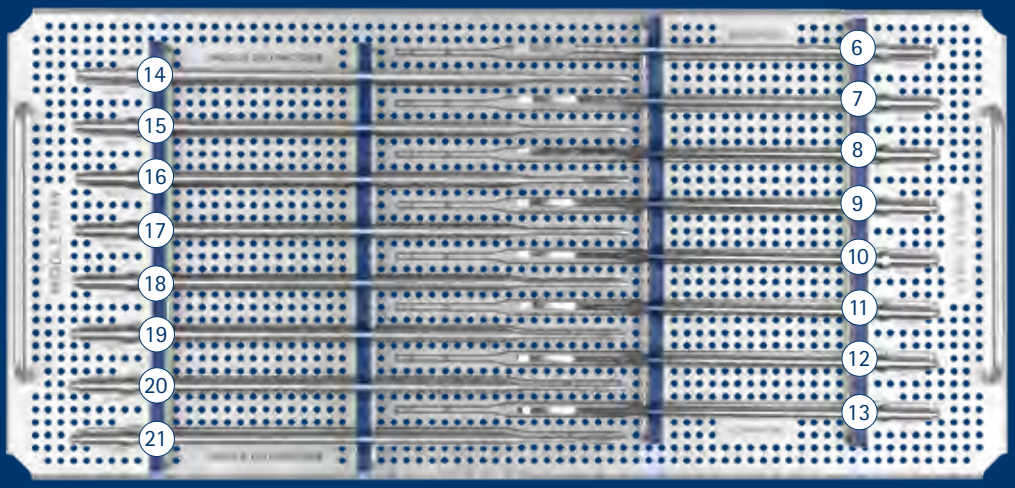
Length	Part No.	Qty
8mm	304.868	0
9mm	304.869	0
10mm	304.870	0
11mm	304.871	0
12mm	304.872	0
13mm	304.873	0
14mm	304.874	0
15mm	304.875	0
16mm	304.876	0
17mm	304.877	0

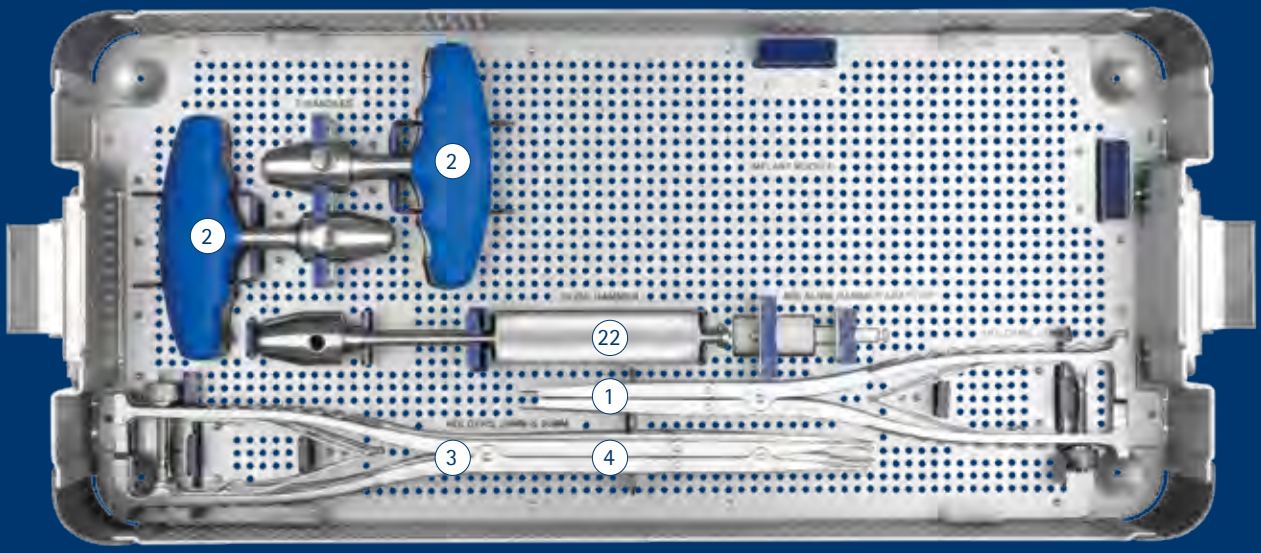
904.008 SUSTAIN® Radiolucent Oblique, Implant Module

Items highlighted in gray are additionally available.

PRESERVE® INSTRUMENT SET



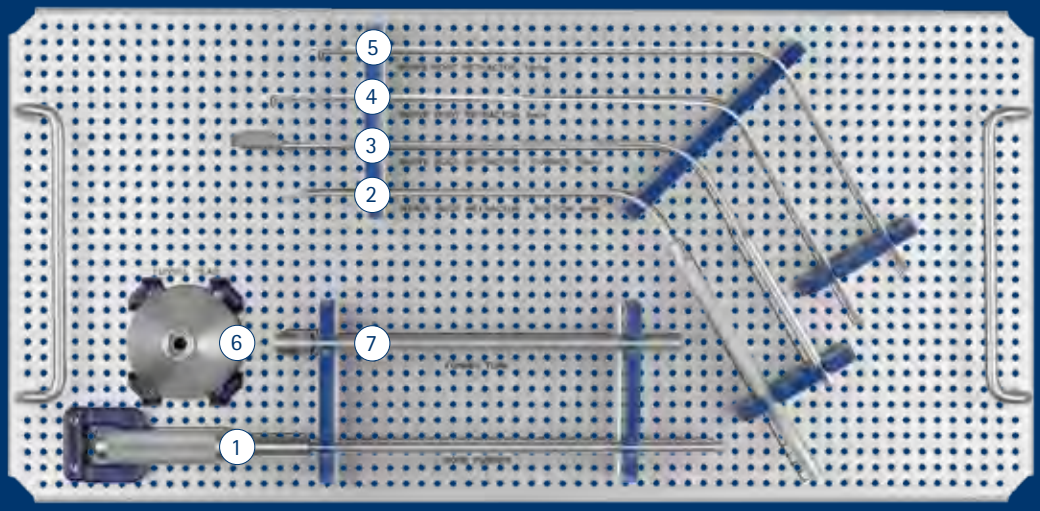


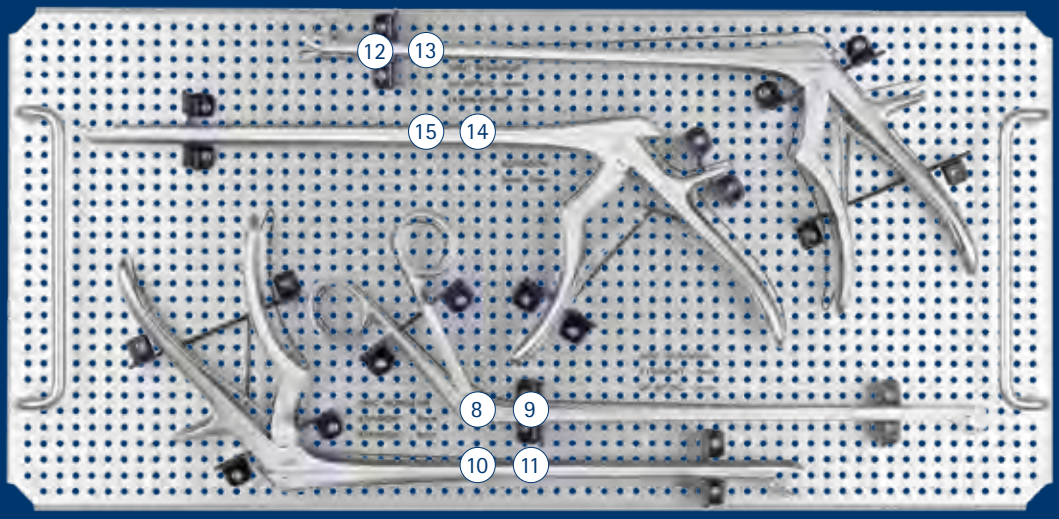


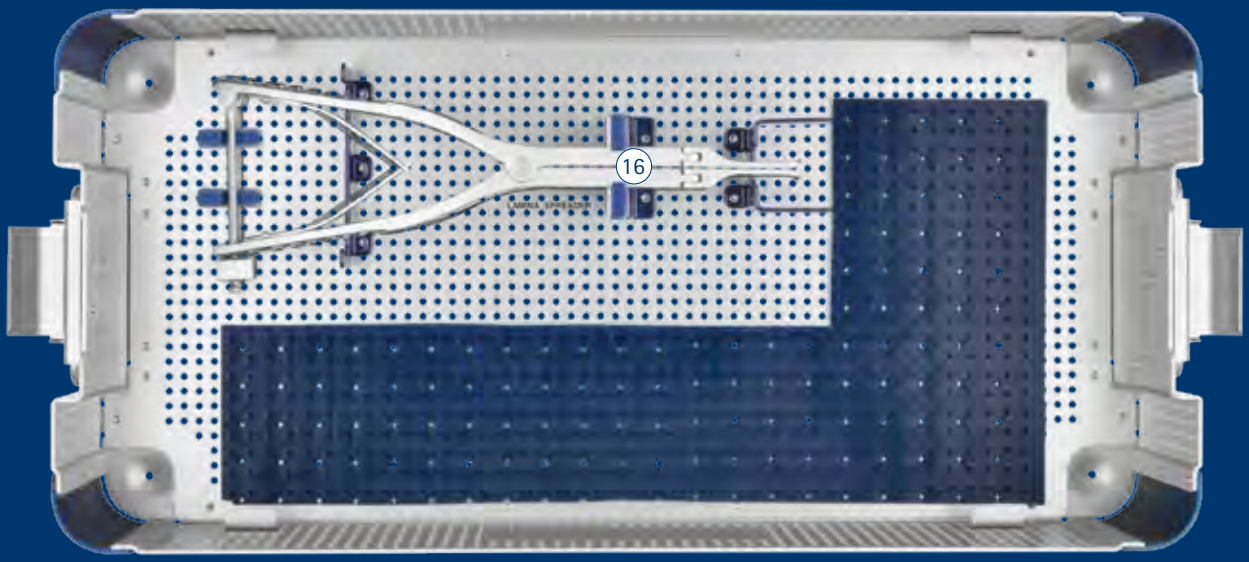
PRESERVE® Posterior Unilateral Instrument Set 904.907

	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



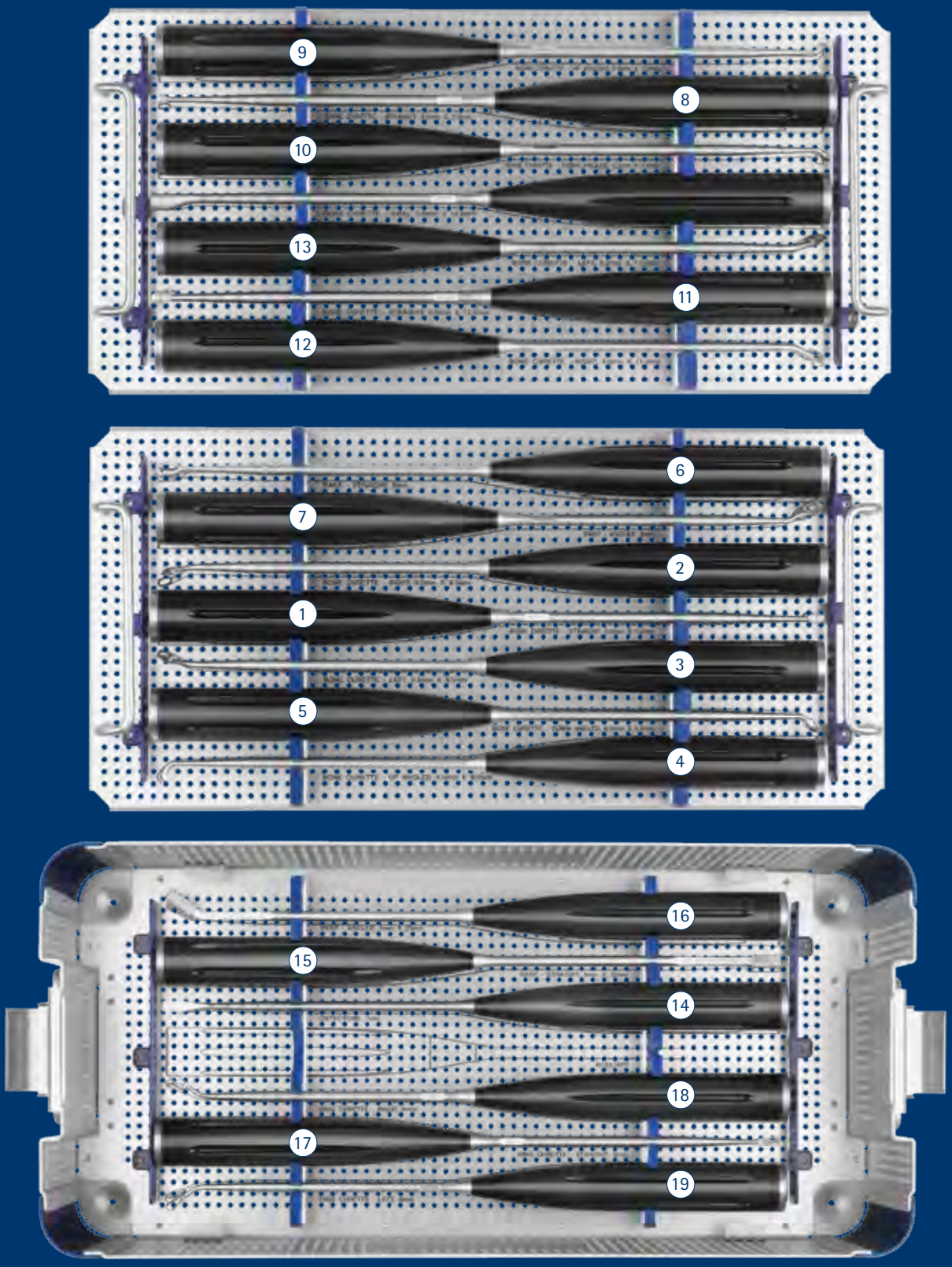




Posterior Disc Prep Instruments I Set 926.901

	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	

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® and SUSTAIN® Radiolucent (SUSTAIN®-R) Spacers 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.

The SUSTAIN® R Spacers are made from radiolucent PEEK polymer with titanium alloy or tantalum markers as specified in ASTM F136, F560, F1295, and F2026.

INDICATIONS

When used as lumbar intervertebral body fusion devices, SUSTAIN® and SUSTAIN® Radiolucent (SUSTAIN® R) Spacers 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).

The SUSTAIN® and SUSTAIN®-R Spacers are to be filled with autogenous bone graft material. These devices are intended to be used with supplemental fixation, such as the REVERE®, REVOLVE® or BEACON® Stabilization Systems.

When used as cervical intervertebral body fusion devices, the SUSTAIN® and SUSTAIN®-R Spacers 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. The SUSTAIN® and SUSTAIN®-R 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® and SUSTAIN®-R Spacers 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 spacer can be packed with bone grafting material. SUSTAIN® and SUSTAIN®-R 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.

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

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

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

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

PRECAUTIONS

The implantation of 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 appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

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

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

SUSTAIN® and SUSTAIN®-R Spacers have not been evaluated for safety and compatibility in the MR environment. SUSTAIN® and SUSTAIN®-R Spacers have not been tested for heating or migration in the MR environment.

CONTRAINDICATIONS

Use of SUSTAIN® and SUSTAIN®-R Spacer(s) is contraindicated in patients with the following conditions:
1. Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Prior fusion at the level(s) to be treated.
3. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopedic implant.
4. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
5. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
6. Any condition not described in the indications for use.

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

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

- 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

SUSTAIN® implants 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

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery. All instruments should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

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. repare 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.

CONTACTIN FORMATION

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

STERILIZATION

SUSTAIN® implants are available sterile or nonsterile. The instruments used with these devices are only available nonsterile.

Sterile SUSTAIN® implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile implants are packaged in a heat sealed, double foil pouch. The expiration date is provided in the package label. Implants are considered sterile unless the packaging has been opened or damaged.

Nonsterile SUSTAIN® implants and instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDAcleared 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 (USA) Law Restricts this Device to Sale by or on the order of a Physician.

REV J

Notes

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

EC REP: RMS – UK Limited
28 Trinity Road, Nailsea, Somerset, BS48 4NU England

CE 0297

GMTGD115
03.14