

SUSTAINTM Medium

Anterior Cervical Interbody Fusion



Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

Life moves us 

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.

SURGICAL TECHNIQUE GUIDE

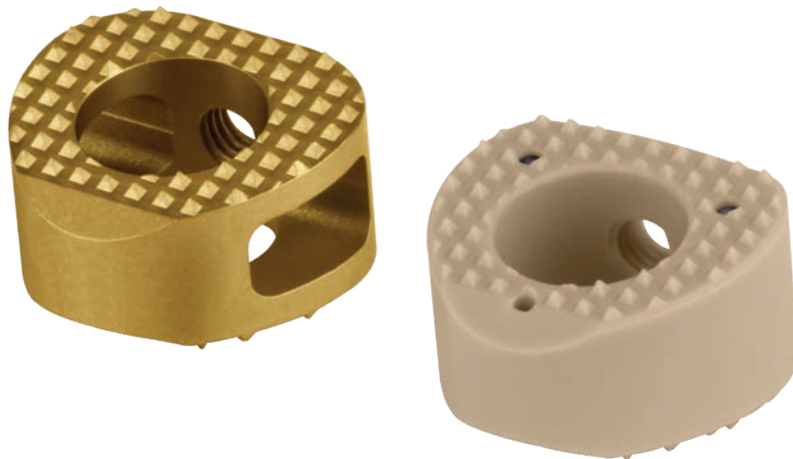
SUSTAIN™ Medium

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SUSTAIN™ Medium

Anterior Cervical Interbody Fusion

SUSTAIN™ Medium is a teardrop shaped cervical interbody fusion device and thoracolumbar vertebral body replacement device, available in three lordotic profiles to match patient anatomy and surgical technique. The implants are available in titanium or PEEK radiolucent polymer (SUSTAIN™-R Medium) to allow radiographic visualization of fusion.

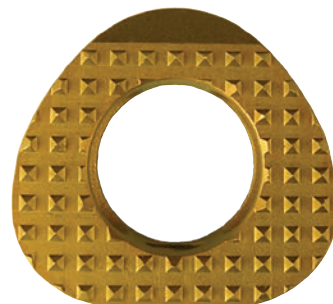


Teardrop Footprint

Designed to closely mimic the vertebral endplates

Multiple Heights and Sagittal Profiles

Accommodate varying patient anatomy



Maximized Visualization

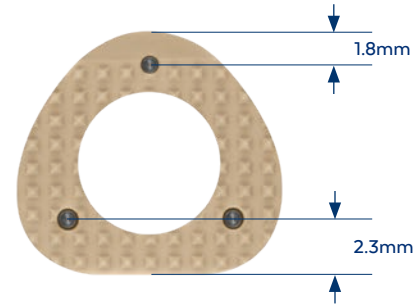
PEEK radiolucent material with tantalum markers to aid in placement and open lateral windows in the titanium design allow radiographic visualization of fusion



IMPLANT OVERVIEW

SUSTAIN™ Medium/SUSTAIN™-R Medium

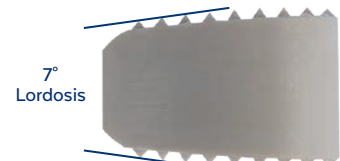
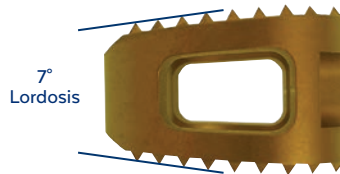
- Titanium (SUSTAIN™)
 - Lateral windows for postoperative fusion evaluation
- PEEK (SUSTAIN™-R)
 - Radiopaque pins aid in positioning
- 13x14mm footprint (11x12mm additionally available)
- Eight heights: 5, 6, 7, 8, 9, 10, 11, 12mm
- Three sagittal profile options: parallel, 7° lordotic, convex
- Teeth on superior and inferior surfaces to help resist migration
- Large axial canal permits packing of graft material



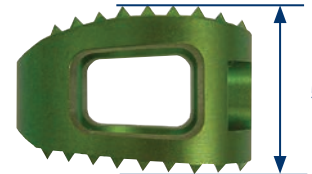
Parallel



Lordotic



Convex



INSTRUMENT OVERVIEW

DISTRACTION INSTRUMENTS



Distraction Pins - 14mm 601.022



Screwdriver for Pins, 610.020

ENDPLATE PREPARATION INSTRUMENTS



Box Curette 601.026

TRIALING INSTRUMENTS



Trial Spacers

		Parallel	Lordotic	Convex
				
	5mm	601.405	601.505	601.605
	6mm	601.406	601.506	601.606
	7mm	601.407	601.507	601.607
	8mm	601.408	601.508	601.608
	9mm	601.409	601.509	601.609
	10mm	601.410	601.510	601.610
	11mm	601.411	601.511	601.611
	12mm	601.412	601.512	601.612

INSERTION INSTRUMENTS



Holder 601.024



Packer 601.028



Packing Block 601.027

SURGICAL TECHNIQUE

ACDF

STEP 1 APPROACH

The patient is placed under anesthesia and positioned supine with support of the posterior cervical spine to maintain cervical lordosis. The operative area is carefully cleaned and an incision is made at the appropriate fusion level(s).

STEP 2 DISTRACTION

Distraction may be accomplished using the **Distractor (Left or Right)**, available in this system, or other standard methods.

To use the distractor, first determine **Distraction Pin** placement within the vertebral bodies. Place the pins into adjacent vertebral bodies using the **Screwdriver for Pins**. Care should be taken in placing pins if subsequent plate fixation is considered.



Inserting Distraction Pins
using screwdriver



Distraction Pins inserted

DISTRACTION (CONT'D)

Place the Distractor over the pins until seated. Rotate the ratchet handle to distract to the desired level, while being careful not to over-distract the segment. This method or other methods may be used throughout the technique to provide visualization and access to the disc and osseous structures.



Distracting disc space
using Distractor

STEP

3

DISCECTOMY/ENDPLATE PREPARATION

Leaving the lateral annulus intact, remove the intervertebral disc and osteophytes as needed, using rongeurs and other instruments. The **Box Curette** can be used to remove the disc as well as superficial layers or the cartilaginous endplates to expose bleeding bone. Further removal of the posterior annulus may be required for access to the posterior longitudinal ligament.

NOTE: The vertebral endplates should not be compromised so as to result in bony weakening and subsidence.



Endplate preparation
using Box Curette

STEP

4

SIZING

Determine which implant profile (parallel, lordotic, or convex) is suitable for the desired segment. Select an appropriate size **Trial Spacer** and insert into the disc space. Determine which trial best fits the prepared disc space. A secure fit is desirable in order to maintain disc height and stabilize the segment. This can be confirmed using fluoroscopy and tactile feel.



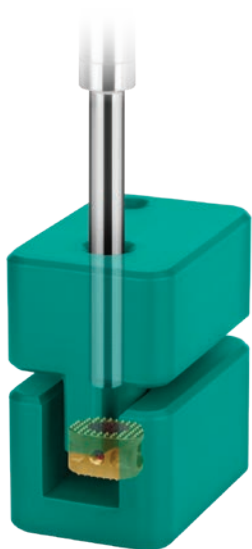
Sizing disc space with Trial Spacer

STEP 5 INSERTION

Select an appropriate size spacer. Pack with autograft and/or allogenic bone graft material using the **Packing Block** and **Packer**.

Insert the implant into the intervertebral space using the **Holder**. If needed, the flat end of the Holder may be used for light impaction. The implant should be slightly recessed into the disc space.

An anterior cervical plate, such as XTEND™, should be used for supplemental fixation.



Packing bone graft material



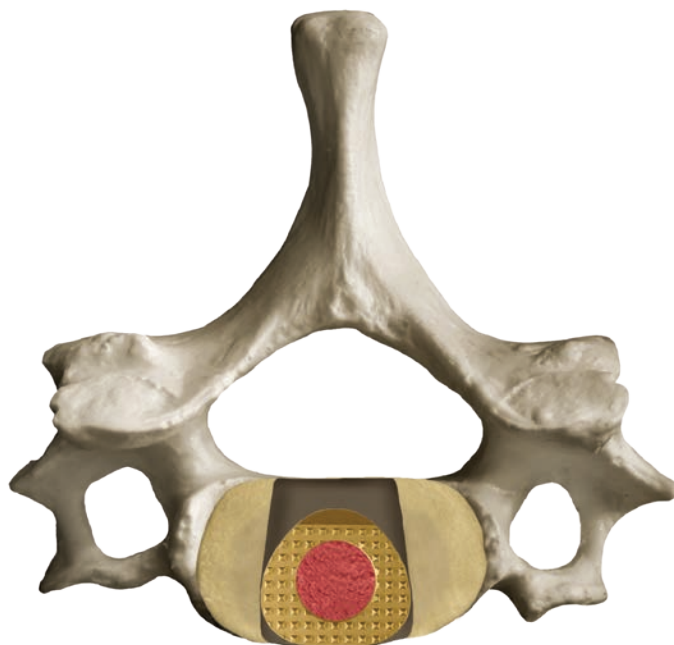
Implant insertion

Multi-Level Implant Insertion

To implant an additional spacer, repeat the steps from distraction to implant insertion. A four level construct is shown at right.



FINAL POSITION



Final position, axial view



Final position, AP view

SUSTAIN™ MEDIUM IMPLANT SETS

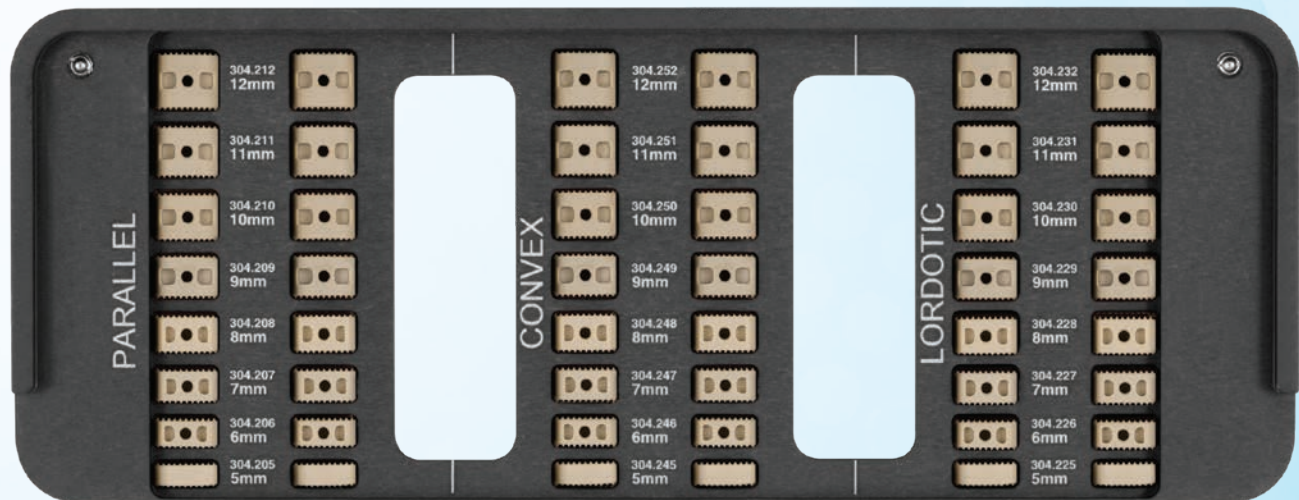
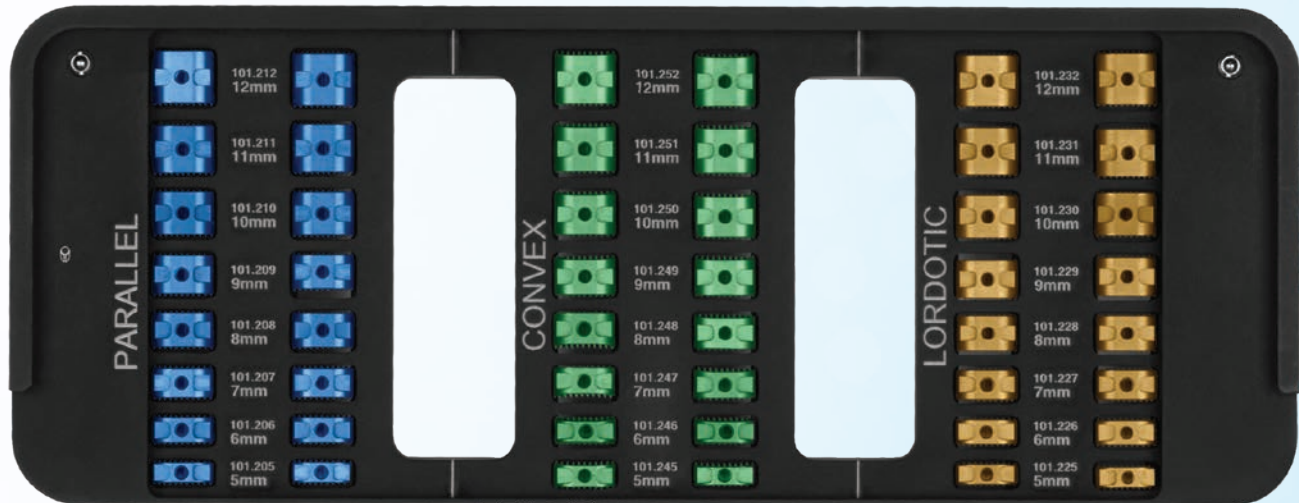
SUSTAIN™ Medium Implant Set 901.902

Height	Parallel	Lordotic	Convex
5mm	101.205	101.225	101.245
6mm	101.206	101.226	101.246
7mm	101.207	101.227	101.247
8mm	101.208	101.228	101.248
9mm	101.209	101.229	101.249
10mm	101.210	101.230	101.250
11mm	101.211	101.231	101.251
12mm	101.212	101.232	101.252

SUSTAIN™-R Medium Implant Set 904.902

Height	Parallel	Lordotic	Convex
5mm	304.205	304.225	304.245
6mm	304.206	304.226	304.246
7mm	304.207	304.227	304.247
8mm	304.208	304.228	304.248
9mm	304.209	304.229	304.249
10mm	304.210	304.230	304.250
11mm	304.211	304.231	304.251
12mm	304.212	304.232	304.252

SUSTAIN™ MEDIUM IMPLANT SETS



SUSTAIN™ MEDIUM NARROW IMPLANT SETS

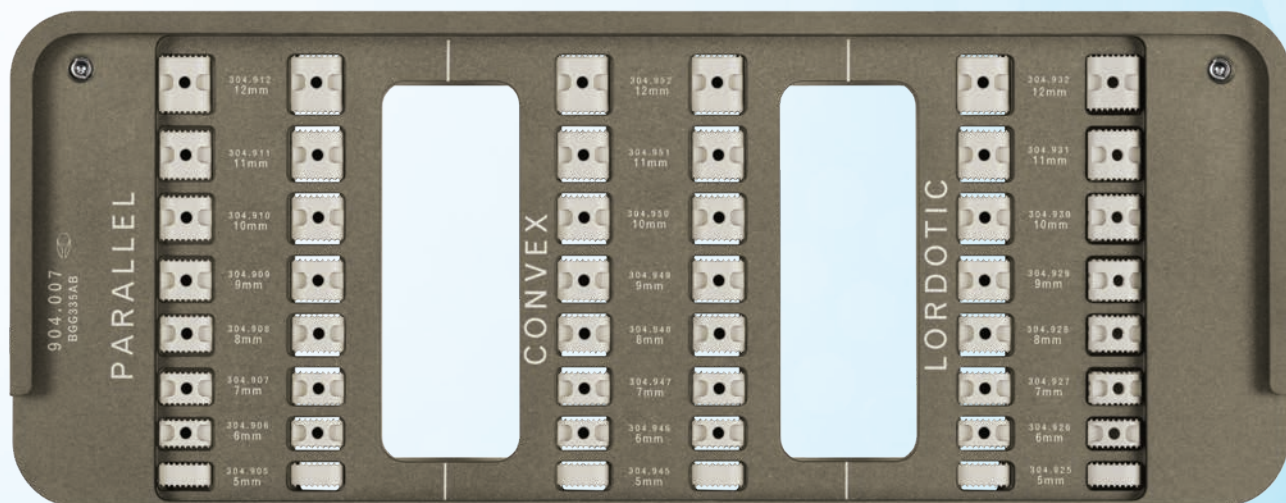
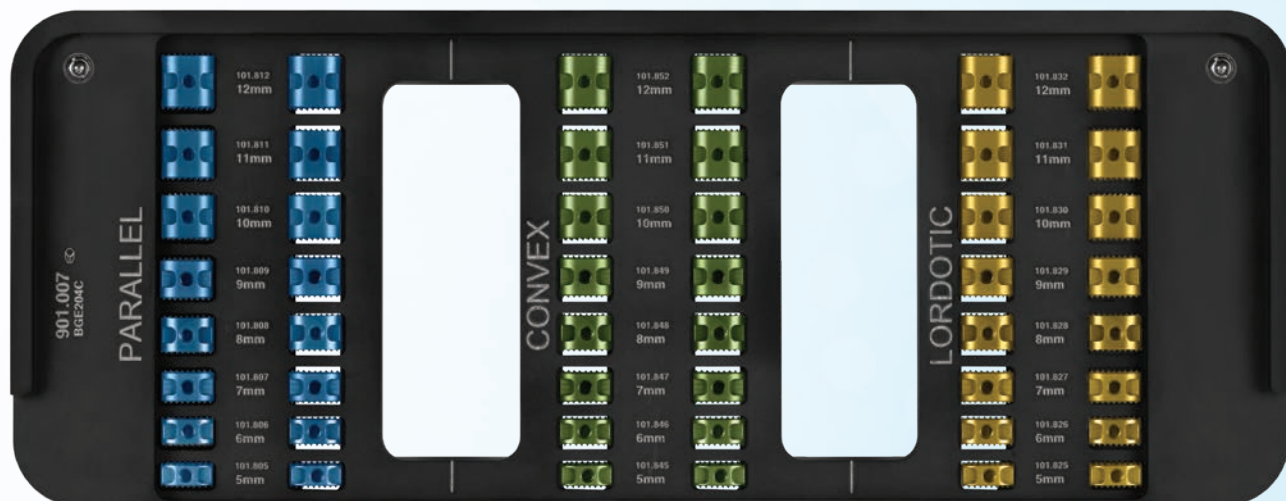
SUSTAIN™ Medium Narrow 11x12mm Implant Set 901.907

Height	Parallel	Lordotic	Convex
5mm	101.805	101.825	101.845
6mm	101.806	101.826	101.846
7mm	101.807	101.827	101.847
8mm	101.808	101.828	101.848
9mm	101.809	101.829	101.849
10mm	101.810	101.830	101.850
11mm	101.811	101.831	101.851
12mm	101.812	101.832	101.852

SUSTAIN™-R Medium Narrow 11x12mm Implant Set 904.909

Height	Parallel	Lordotic	Convex
5mm	304.905	304.925	304.945
6mm	304.906	304.926	304.946
7mm	304.907	304.927	304.947
8mm	304.908	304.928	304.948
9mm	304.909	304.929	304.949
10mm	304.910	304.930	304.950
11mm	304.911	304.931	304.951
12mm	304.912	304.932	304.952

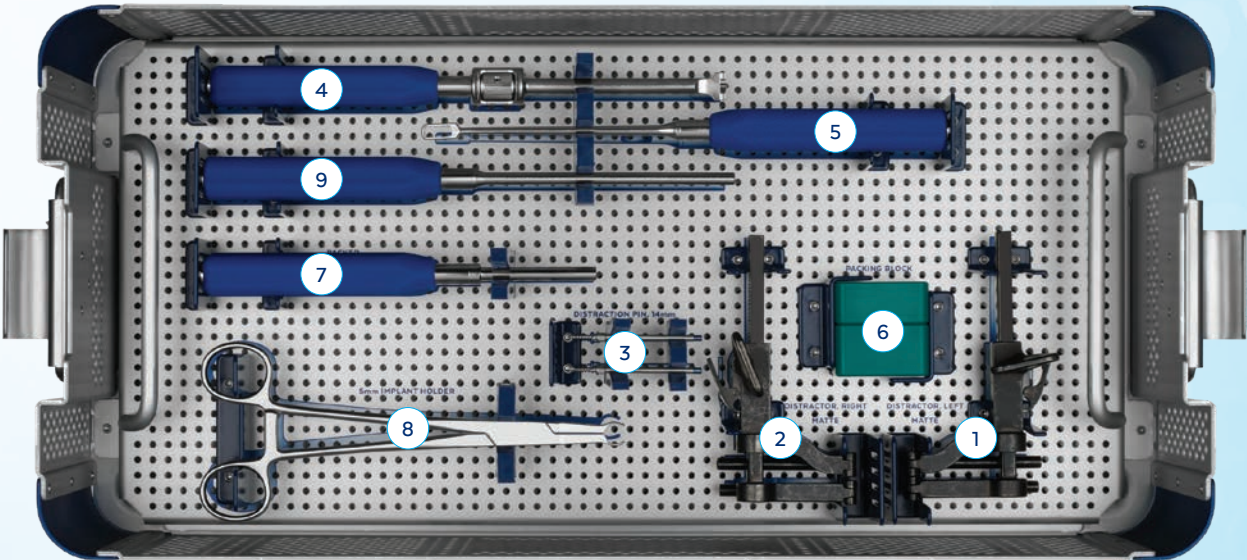
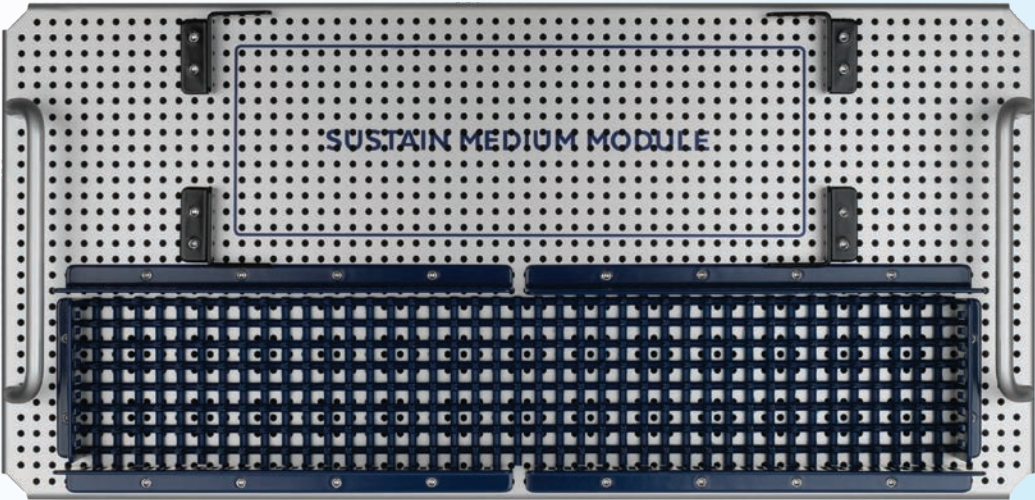
SUSTAIN™ MEDIUM NARROW IMPLANT SETS



PRESERVE™ ANTERIOR CERVICAL INSTRUMENT SET 901.904

	Part No.	Description	Qty
	601.015	Paddle Distractor	0
1	601.02	Distractor, Left - Matte	1
2	601.021	Distractor, Right - Matte	1
3	601.022	Distraction Pin, 14mm	2
	601.023	Screwdriver for Pins	0
4	601.024	Medium Holder	1
5	601.026	Box Curette	1
6	601.027	Packing Block	1
7	601.028	Packer	1
8	601.035	Implant Holder for 5mm Implants	1
	601.135	Maintain Holder	0
9	610.02	Pin Driver, 4.0mm Hex	1
	901.008	PRESERVE™ Cervical Instrument Graphic Case	

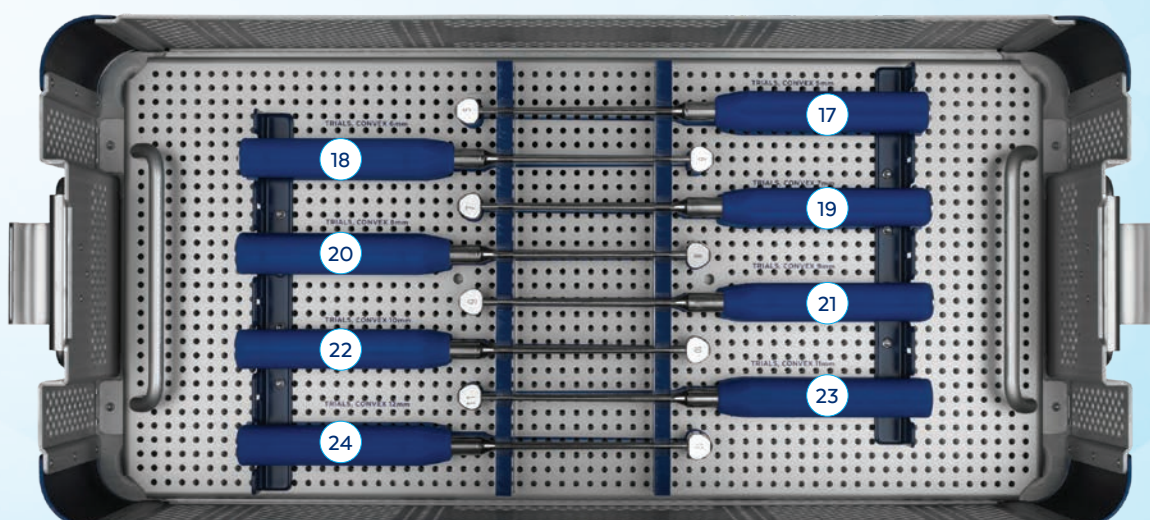
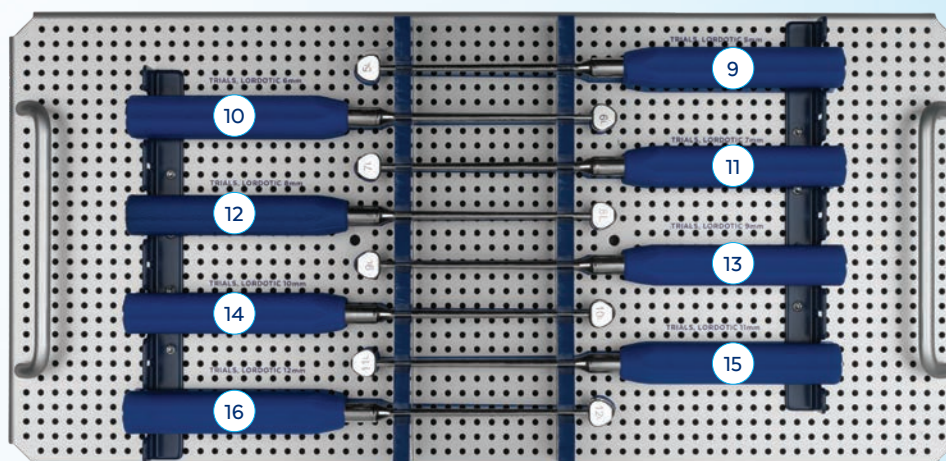
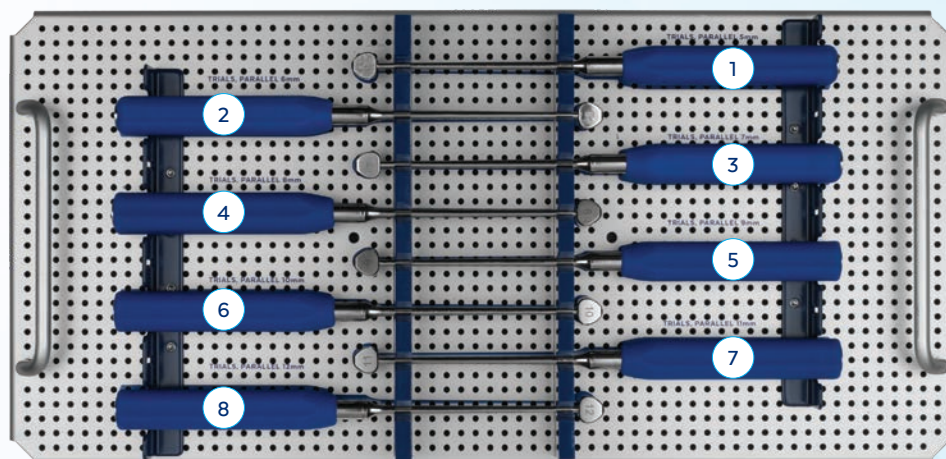
PRESERVE™ ANTERIOR CERVICAL INSTRUMENT SET 901.904



PRESERVE™ ANTERIOR CERVICAL TRIAL SET 901.909

	Part No.	Description	Qty
1	601.405	Trial, Parallel, 5mm	1
2	601.406	Trial, Parallel, 6mm	1
3	601.407	Trial, Parallel, 7mm	1
4	601.408	Trial, Parallel, 8mm	1
5	601.409	Trial, Parallel, 9mm	1
6	601.41	Trial, Parallel, 10mm	1
7	601.411	Trial, Parallel, 11mm	1
8	601.412	Trial, Parallel, 12mm	1
9	601.505	Trial, Lordotic, 5mm	1
10	601.506	Trial, Lordotic, 6mm	1
11	601.507	Trial, Lordotic, 7mm	1
12	601.508	Trial, Lordotic, 8mm	1
13	601.509	Trial, Lordotic, 9mm	1
14	601.51	Trial, Lordotic, 10mm	1
15	601.511	Trial, Lordotic, 11mm	1
16	601.512	Trial, Lordotic, 12mm	1
17	601.605	Trial, Convex, 5mm	1
18	601.606	Trial, Convex, 6mm	1
19	601.607	Trial, Convex, 7mm	1
20	601.608	Trial, Convex, 8mm	1
21	601.609	Trial, Convex, 9mm	1
22	601.61	Trial, Convex, 10mm	1
23	601.611	Trial, Convex, 11mm	1
24	601.612	Trial, Convex, 12mm	1
	901.004	PRESERVE™ Cervical Graphic Case	

PRESERVE™ ANTERIOR CERVICAL TRIAL SET 901.909



IMPORTANT INFORMATION ON SUSTAIN™ SPACERS

DESCRIPTION

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

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

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

INDICATIONS

When used as thoracolumbar intervertebral body fusion devices, SUSTAIN™ Spacers (including SUSTAIN™ R, SUSTAIN™-IR and SUSTAIN™-RT) are indicated at one or more levels of the thoracic spine (T1-T12), thoracolumbar junction (T12-L1), or lumbosacral spine (L1-S1) as an adjunct to fusion in patients with the following indications: degenerative disc disease (DDD), disc herniation (with myelopathy and/or radiculopathy), spondylolisthesis, deformity (degenerative scoliosis or kyphosis), spinal stenosis, and failed previous fusion (pseudarthrosis). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. SUSTAIN™ Spacers are to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the thoracolumbosacral spine (e.g. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). All SUSTAIN™ TPS coated spacers are indicated for the same use as non-coated PEEK versions.

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

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

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

WARNINGS

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

- device component fracture,

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

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

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

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

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

PRECAUTIONS

The implantation of these devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

Surgical implants must never be reused. An explanted implant must never be reimplanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns which could lead to breakage.

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

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

MRI SAFETY INFORMATION



The SUSTAIN™ Spacers are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scan conditions defined above, the SUSTAIN™ Spacers are expected to produce a maximum temperature rise of less than or equal to 3.9°C after 15 minutes of continuous scanning.

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

CONTRAINDICATIONS

Use of SUSTAIN™ Spacer(s) is contraindicated in patients with the following conditions:

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

IMPORTANT INFORMATION ON SUSTAIN™ SPACERS

8. Any condition not described in the indications for use.
9. Fever or leukocytosis.
10. Pregnancy.
11. Any other condition that would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevations of the white blood count (WBC), or a marked left shift in the WBC differential count.
12. Any case not needing a fusion.
13. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
14. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
15. Spondylolisthesis unable to be reduced to Grade 1.
16. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
17. Any case that requires the mixing of metals from two different components or systems.
18. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
19. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

COMPLICATIONS AND POSSIBLE ADVERSE EFFECTS

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

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

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully

checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the implants from the packaging using aseptic technique.

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

HANDLING AND USE

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

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

CLEANING

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

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

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

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

CONTACT INFORMATION

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

STERILIZATION

These implants and instruments may be available sterile or nonsterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10⁻⁶. Sterile products are packaged in a heat sealed, double pouch or container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging

IMPORTANT INFORMATION ON SUSTAIN™ SPACERS

has been opened or damaged. Sterile implants and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below. Sterile implants meet pyrogen limit specifications.

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

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











- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

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

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

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

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

SYMBOL TRANSLATION			
	CATALOGUE NUMBER		STERILIZED BY IRRADIATION
	LOT NUMBER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
	QUANTITY		PRESCRIPTION USE ONLY

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

Customer Service:

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

Fax 1-866-GLOBUS3 (or 1-866-456-2873)

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instructions for use (IFU) for description, indications, contraindications, warnings, precautions and
other important information at globusmedical.com/eIFU.

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