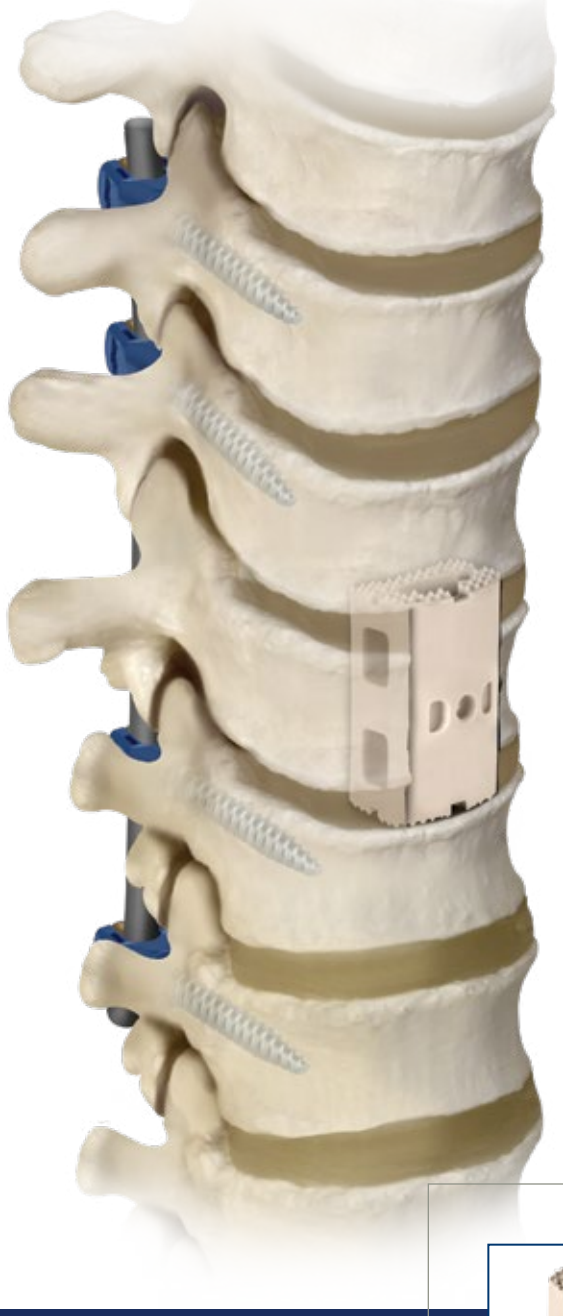
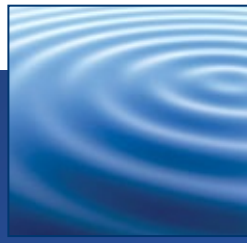


Life moves us

SURGICAL TECHNIQUE



NIKO®

Corpectomy 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

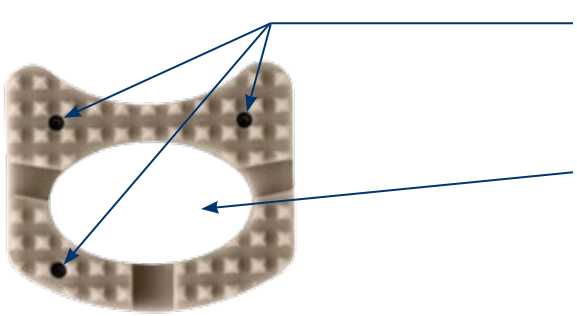
www.globusmedical.com

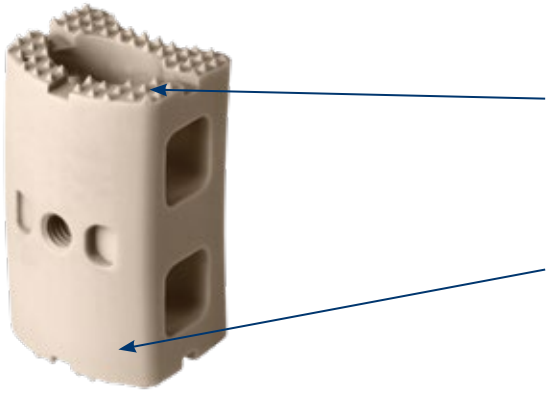
NIKO®

Corpectomy Spacer

NIKO® is a PEEK radiolucent thoracolumbar corpectomy spacer that requires no stacking or cutting. Lordosis is built into the implant to help fit the natural anatomy of the spine. In addition, NIKO® has a large axial graft chamber to help promote fusion.

NIKO®
CORPECTOMY SPACER





Sagittal Alignment Restoration

Three sagittal profiles, two footprints and multiple height options help restore the natural anatomy.

Simple Sizing

The spacer is preassembled and requires no cutting or stacking for proper sizing.

Streamlined Instrumentation

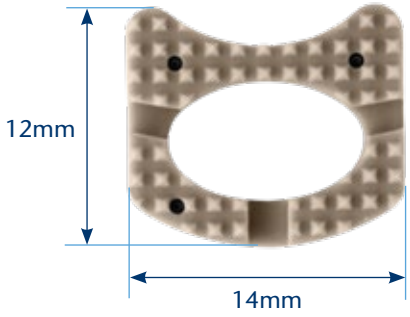
Holder designed for rigid and stable connection to implant. Threaded connection allows minimal insertion window.

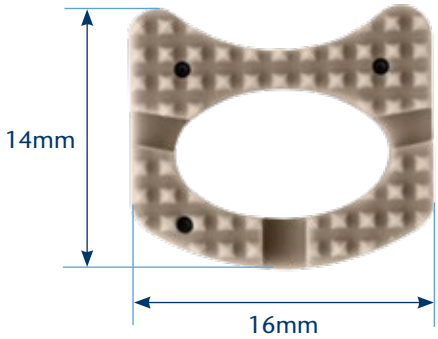
CONTENTS

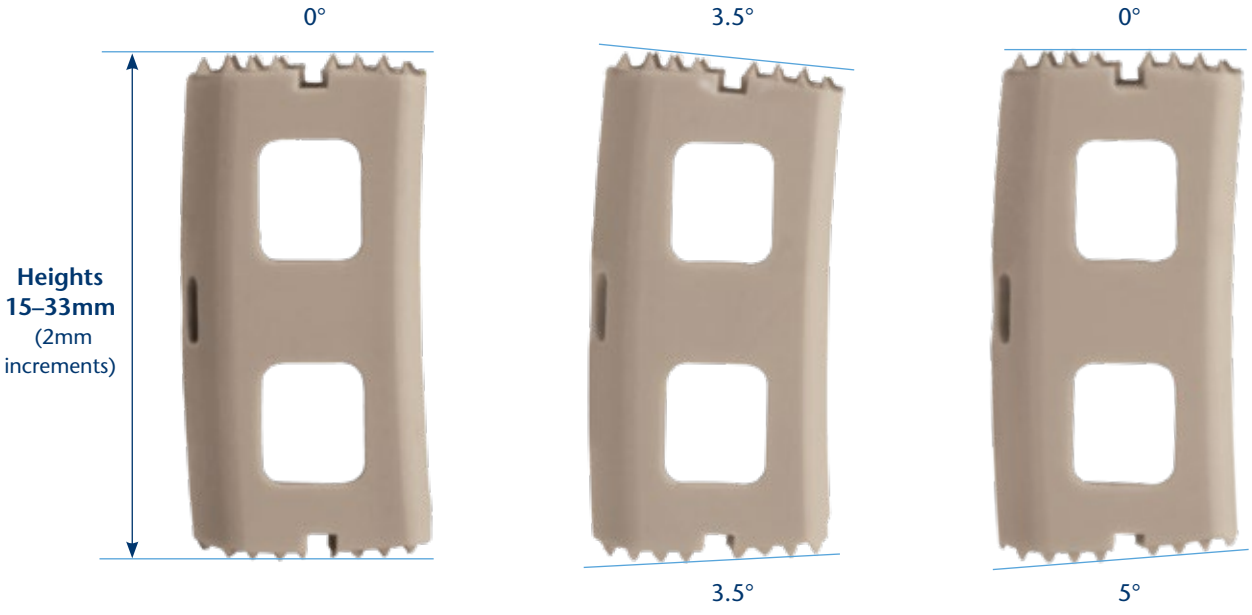
The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be 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

Static Footprint	Heights	Angles
12x14	15–33mm (2mm increments)	0°/0°
		3.5°/3.5°
14x16		0°/5°







INSTRUMENT OVERVIEW

Implant Holder

Medium Holder 601.024*

Implant Sizing Instruments

Caliper 610.801*

12x14

Trial, Small 616.110*

*Medium Holder 601.024**
*Trial, Small 616.110**
(Assembled)

Distractor

Vertebral Body Spreader, Small 616.112*

** Found in XPand® Instrument Set 916.910*

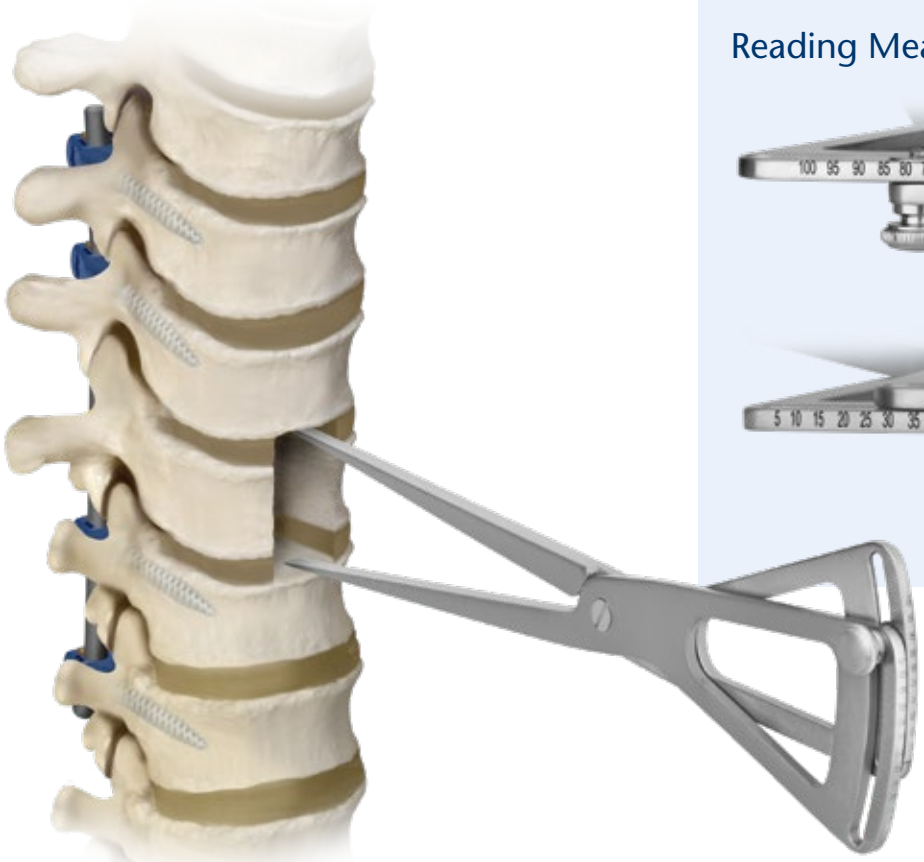
Step 1 Approach/Corpectomy

The NIKO® Corpectomy Spacer may be inserted using one of the following approaches: anterior, anterolateral or lateral. In addition, NIKO® is intended for use with supplemental fixation. For the purpose of this technique guide, an anterior approach is shown where posterior fixation is shown inserted prior to the corpectomy procedure.

Place the patient in the appropriate position for the desired approach. Remove the vertebral body(s) at the desired level(s) to achieve a partial or complete corpectomy. Remove disc material using rongeurs, rasps, curettes, and other suitable preparation instruments.

Step 2 Distraction and Implant Sizing

Determine the approximate height of the corpectomy space using the **Caliper***. The **Vertebral Body Spreader, Small*** may be used in conjunction with the Caliper* to determine the approximate height under distraction.



Reading Measurement on Caliper

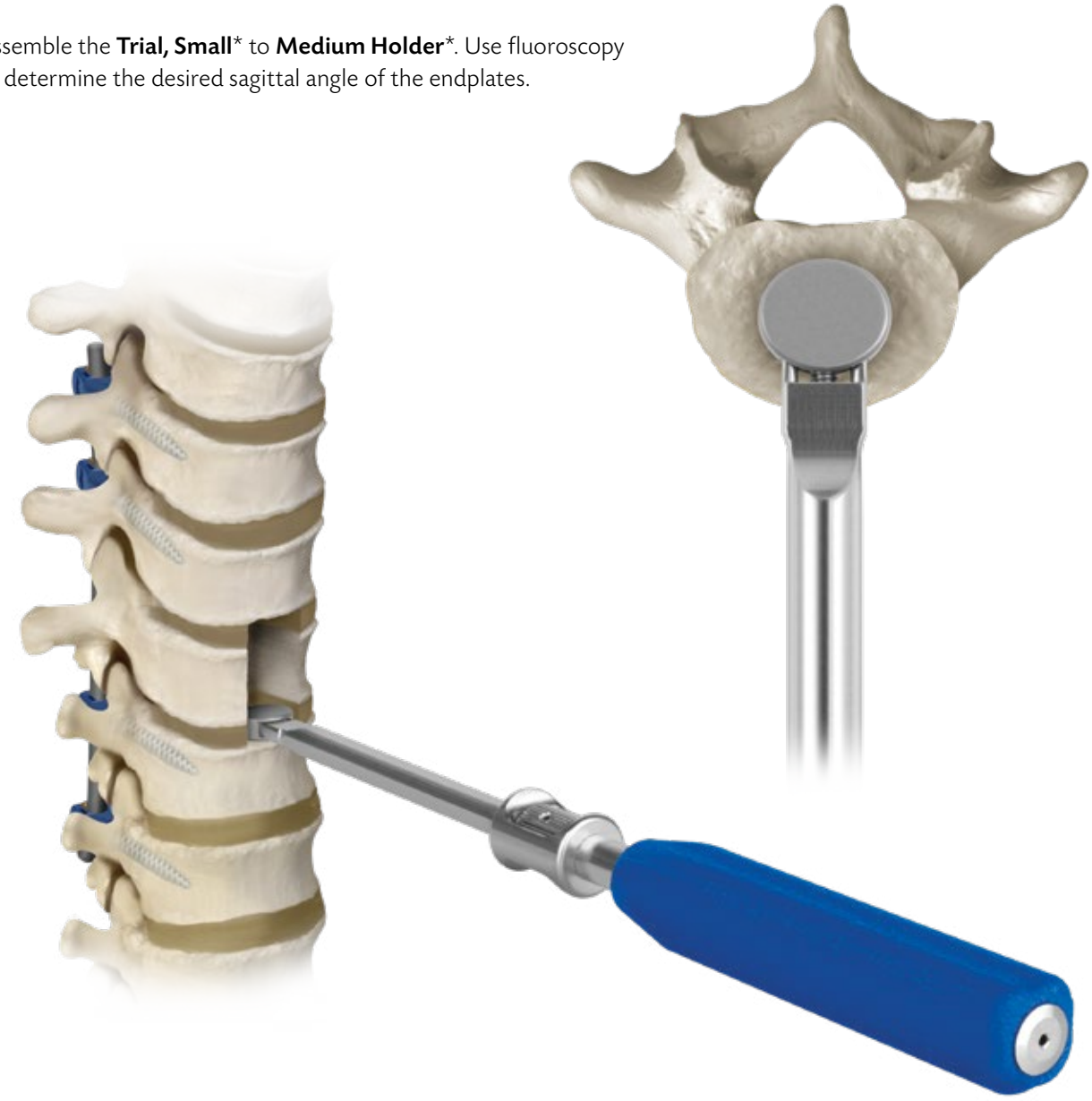
30mm

95mm

** Found in XPand® Instrument Set 916.910*

Step 3 Endplate Measurement

Assemble the **Trial, Small*** to **Medium Holder***. Use fluoroscopy to determine the desired sagittal angle of the endplates.

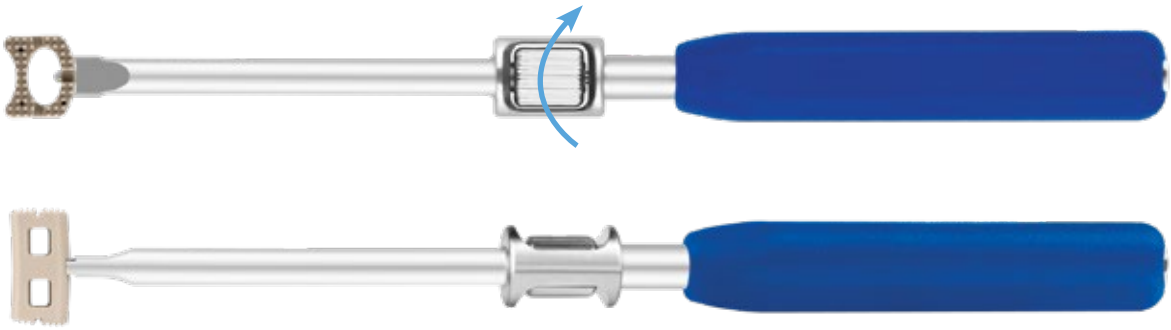


Endplate measurement using the Trial Holder, Short

** Found in XPand® Instrument Set 916.910*

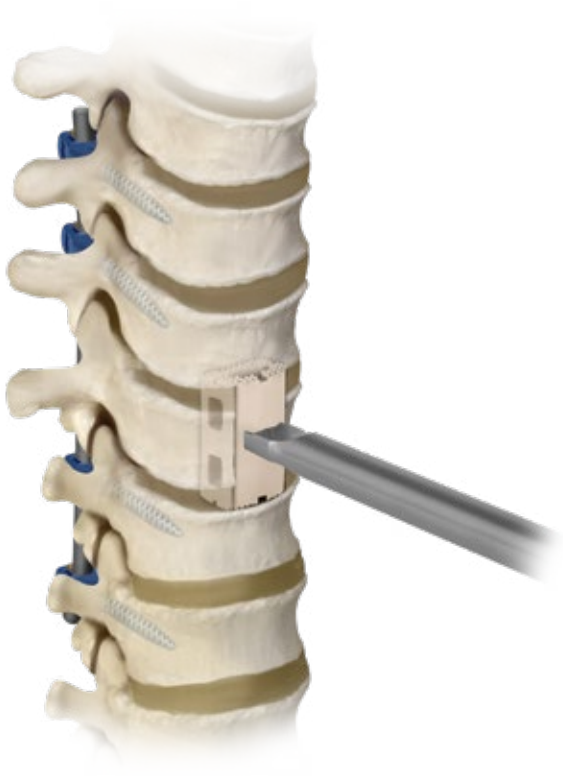
Step 4 Implant Attachment

After determining the appropriate implant height and footprint, thread the desired implant on to the Medium Holder* by rotating the knurled knob clockwise.



Step 5 Implant Insertion

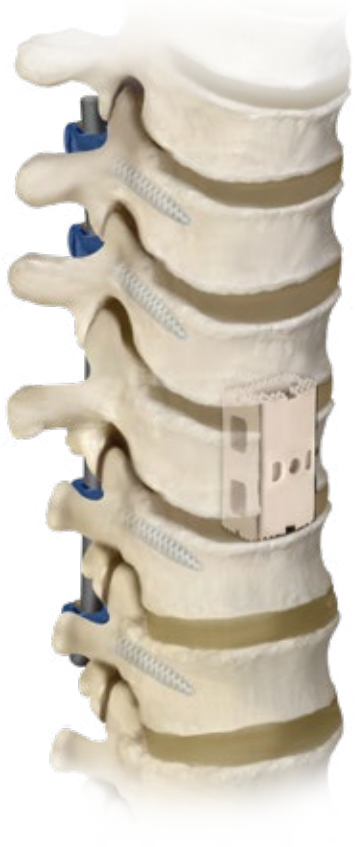
Insert the selected implant into the corpectomy space. If needed, tamp the Medium Holder* for light impaction. To disengage the implant from the Medium Holder*, rotate the knurled knob counterclockwise.



** Found in XPand® Instrument Set 916.910*

Final Construct

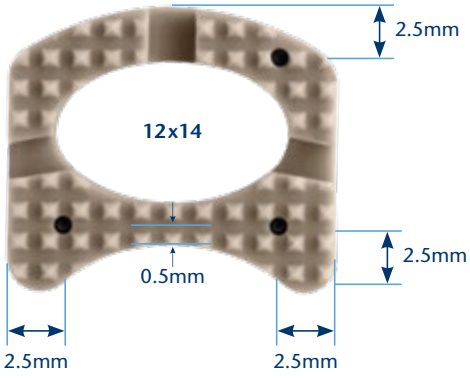
The NIKO® Corpectomy Spacer is intended to be used with supplemental fixation.

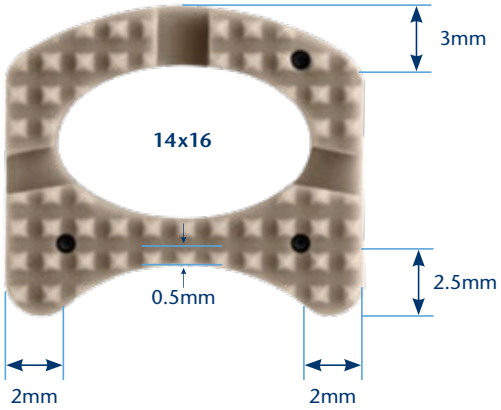


Optional: Implant Removal

For removal, reinsert the Medium Holder*; attach the implant by rotating the knurled knob counterclockwise.

Radiographic Marker Locations





** Found in XPand® Instrument Set 916.910*

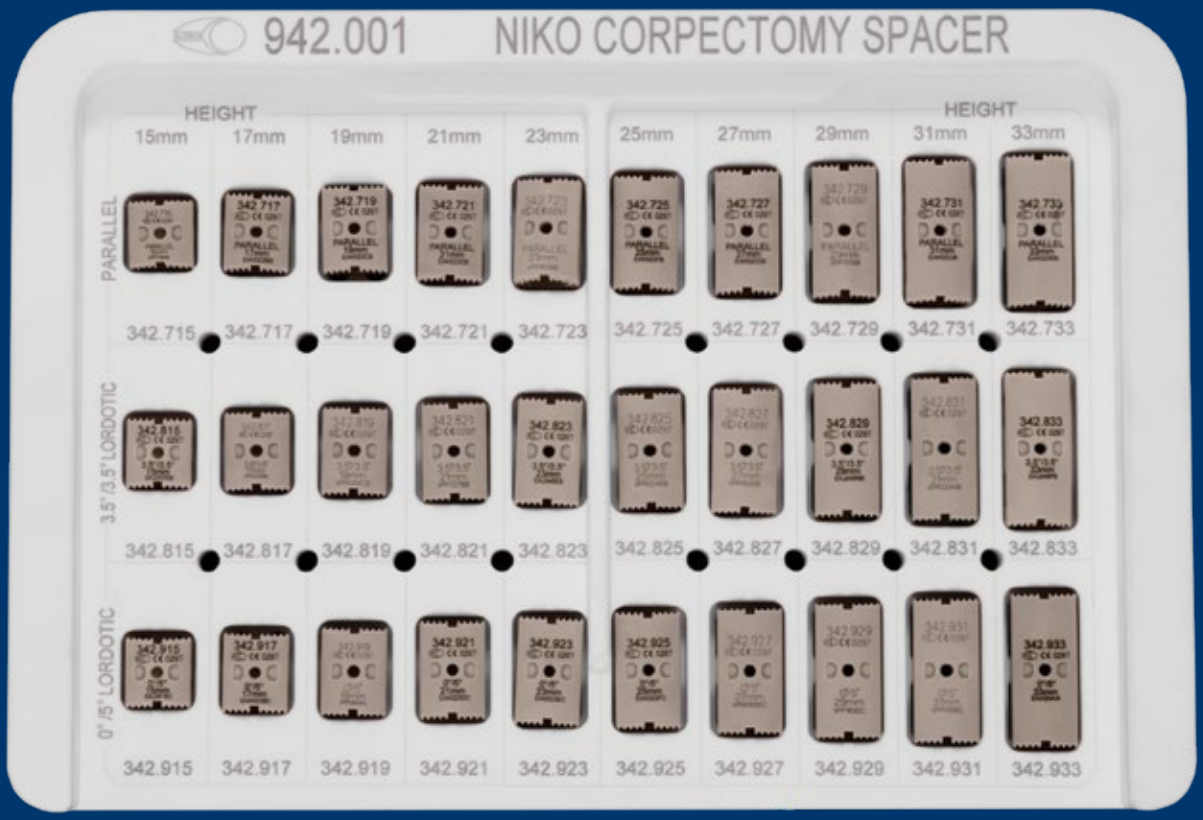
ADDITIONAL SPECIFICATIONS

NIKO® Bone Graft Volume 12x14mm (cc)				
Footprint	**Product**	**Part Number**	**Description**	**Bone Graft Volume (cc)**
12x14mm	0° Parallel	342.715	NIKO® Corpectomy Spacer, Small 12x14 0° 15mm	0.7
		342.717	NIKO® Corpectomy Spacer, Small 12x14 0° 17mm	0.8
		342.719	NIKO® Corpectomy Spacer, Small 12x14 0° 19mm	0.9
		342.721	NIKO® Corpectomy Spacer, Small 12x14 0° 21mm	1.0
		342.723	NIKO® Corpectomy Spacer, Small 12x14 0° 23mm	1.1
		342.725	NIKO® Corpectomy Spacer, Small 12x14 0° 25mm	1.2
		342.727	NIKO® Corpectomy Spacer, Small 12x14 0° 27mm	1.3
		342.729	NIKO® Corpectomy Spacer, Small 12x14 0° 29mm	1.4
		342.731	NIKO® Corpectomy Spacer, Small 12x14 0° 31mm	1.5
		342.733	NIKO® Corpectomy Spacer, Small 12x14 0° 33mm	1.6
	7° Lordotic (3.5°/3.5°)	342.815	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 15mm	0.7
		342.817	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 17mm	0.8
		342.819	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 19mm	0.9
		342.821	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 21mm	1.0
		342.823	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 23mm	1.1
		342.825	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 25mm	1.2
		342.827	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 27mm	1.3
		342.829	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 29mm	1.4
		342.831	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 31mm	1.5
		342.833	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 33mm	1.5
	0°/5° Lordotic	342.915	NIKO® Corpectomy Spacer, Small 12x14 0/5° 15mm	0.7
		342.917	NIKO® Corpectomy Spacer, Small 12x14 0/5° 17mm	0.8
		342.919	NIKO® Corpectomy Spacer, Small 12x14 0/5° 19mm	0.9
		342.921	NIKO® Corpectomy Spacer, Small 12x14 0/5° 21mm	1.0
		342.923	NIKO® Corpectomy Spacer, Small 12x14 0/5° 23mm	1.1
		342.925	NIKO® Corpectomy Spacer, Small 12x14 0/5° 25mm	1.2
		342.927	NIKO® Corpectomy Spacer, Small 12x14 0/5° 27mm	1.3
		342.929	NIKO® Corpectomy Spacer, Small 12x14 0/5° 29mm	1.4
		342.931	NIKO® Corpectomy Spacer, Small 12x14 0/5° 31mm	1.5
		342.933	NIKO® Corpectomy Spacer, Small 12x14 0/5° 33mm	1.5

ADDITIONAL SPECIFICATIONS

NIKO® Bone Graft Volume 14x16mm (cc)				
Footprint	**Product**	**Part Number**	**Description**	**Bone Graft Volume (cc)**
14x16mm	0° Parallel	342.415	NIKO® Corpectomy Spacer, Small 14x16 0° 15mm	1.0
		342.417	NIKO® Corpectomy Spacer, Small 14x16 0° 17mm	1.2
		342.419	NIKO® Corpectomy Spacer, Small 14x16 0° 19mm	1.3
		342.421	NIKO® Corpectomy Spacer, Small 14x16 0° 21mm	1.5
		342.423	NIKO® Corpectomy Spacer, Small 14x16 0° 23mm	1.6
		342.425	NIKO® Corpectomy Spacer, Small 14x16 0° 25mm	1.8
		342.427	NIKO® Corpectomy Spacer, Small 14x16 0° 27mm	1.9
		342.429	NIKO® Corpectomy Spacer, Small 14x16 0° 29mm	2.1
		342.431	NIKO® Corpectomy Spacer, Small 14x16 0° 31mm	2.2
		342.433	NIKO® Corpectomy Spacer, Small 14x16 0° 33mm	2.4
	7° Lordotic (3.5°/3.5°)	342.515	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 15mm	1.0
		342.517	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 17mm	1.2
		342.519	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 19mm	1.3
		342.521	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 21mm	1.5
		342.523	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 23mm	1.6
		342.525	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 25mm	1.8
		342.527	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 27mm	1.9
		342.529	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 29mm	2.1
		342.531	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 31mm	2.2
		342.533	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 33mm	2.4
	0°/5° Lordotic	342.615	NIKO® Corpectomy Spacer, Small 14x16 0/5° 15mm	1.0
		342.617	NIKO® Corpectomy Spacer, Small 14x16 0/5° 17mm	1.2
		342.619	NIKO® Corpectomy Spacer, Small 14x16 0/5° 19mm	1.3
		342.621	NIKO® Corpectomy Spacer, Small 14x16 0/5° 21mm	1.5
		342.623	NIKO® Corpectomy Spacer, Small 14x16 0/5° 23mm	1.6
		342.625	NIKO® Corpectomy Spacer, Small 14x16 0/5° 25mm	1.8
		342.627	NIKO® Corpectomy Spacer, Small 14x16 0/5° 27mm	1.9
		342.629	NIKO® Corpectomy Spacer, Small 14x16 0/5° 29mm	2.1
		342.631	NIKO® Corpectomy Spacer, Small 14x16 0/5° 31mm	2.2
		342.633	NIKO® Corpectomy Spacer, Small 14x16 0/5° 33mm	2.4

NIKO® IMPLANT SET I



NIKO® Implant Set I 942.901

Instruments		Qty
342.715	NIKO® Corpectomy Spacer, Small 12x14 0° 15mm	1
342.717	NIKO® Corpectomy Spacer, Small 12x14 0° 17mm	1
342.719	NIKO® Corpectomy Spacer, Small 12x14 0° 19mm	1
342.721	NIKO® Corpectomy Spacer, Small 12x14 0° 21mm	1
342.723	NIKO® Corpectomy Spacer, Small 12x14 0° 23mm	1
342.725	NIKO® Corpectomy Spacer, Small 12x14 0° 25mm	1
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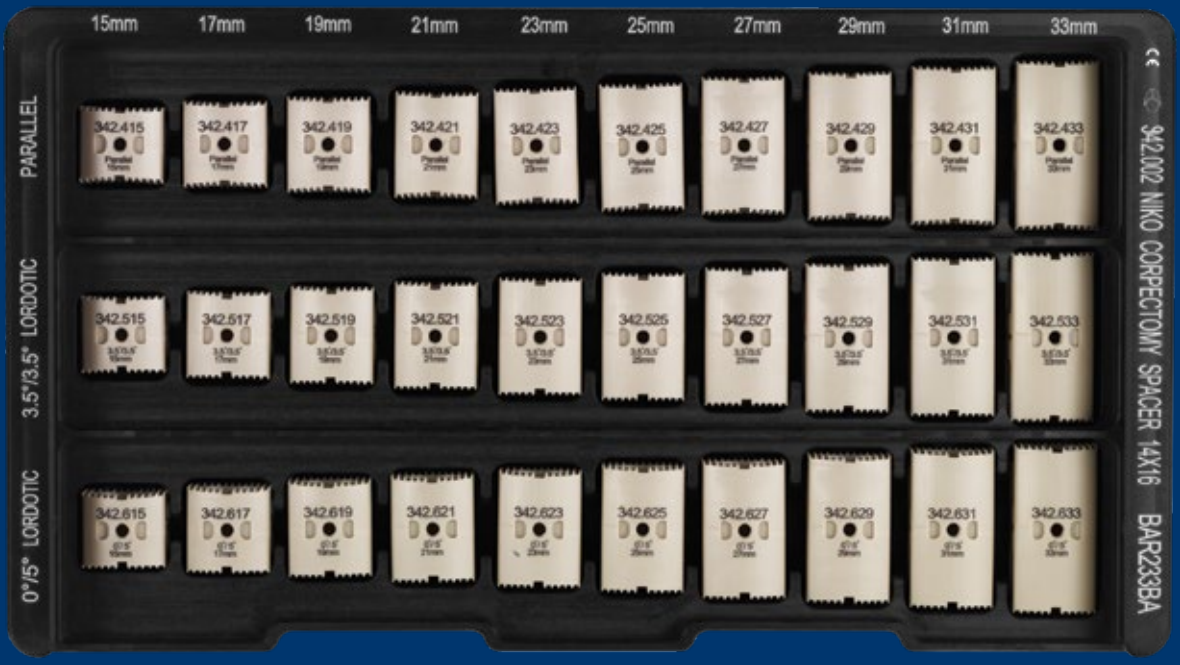
342.731	NIKO® Corpectomy Spacer, Small 12x14 0° 31mm	1
342.733	NIKO® Corpectomy Spacer, Small 12x14 0° 33mm	1
342.815	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 15mm	1
342.817	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 17mm	1
342.819	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 19mm	1
342.821	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 21mm	1
342.823	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 23mm	1
342.825	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 25mm	1
342.827	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 27mm	1
342.829	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 29mm	1
342.831	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 31mm	1
342.833	NIKO® Corpectomy Spacer, Small 12x14 3.5/3.5° 33mm	1
342.915	NIKO® Corpectomy Spacer, Small 12x14 0/5° 15mm	1
342.917	NIKO® Corpectomy Spacer, Small 12x14 0/5° 17mm	1
342.919	NIKO® Corpectomy Spacer, Small 12x14 0/5° 19mm	1
342.921	NIKO® Corpectomy Spacer, Small 12x14 0/5° 21mm	1
342.923	NIKO® Corpectomy Spacer, Small 12x14 0/5° 23mm	1
342.925	NIKO® Corpectomy Spacer, Small 12x14 0/5° 25mm	1
342.927	NIKO® Corpectomy Spacer, Small 12x14 0/5° 27mm	1
342.929	NIKO® Corpectomy Spacer, Small 12x14 0/5° 29mm	1
342.931	NIKO® Corpectomy Spacer, Small 12x14 0/5° 31mm	1
342.933	NIKO® Corpectomy Spacer, Small 12x14 0/5° 33mm	1
942.001	NIKO® Corpectomy Spacer System Module 12x14	

NIKO® IMPLANT SET II



NIKO® Implant Set II 942.902

Instruments		Qty
342.415	NIKO® Corpectomy Spacer, Small 14x16 0° 15mm	1
342.417	NIKO® Corpectomy Spacer, Small 14x16 0° 17mm	1
342.419	NIKO® Corpectomy Spacer, Small 14x16 0° 19mm	1
342.421	NIKO® Corpectomy Spacer, Small 14x16 0° 21mm	1
342.423	NIKO® Corpectomy Spacer, Small 14x16 0° 23mm	1
342.425	NIKO® Corpectomy Spacer, Small 14x16 0° 25mm	1
342.427	NIKO® Corpectomy Spacer, Small 14x16 0° 27mm	1
342.429	NIKO® Corpectomy Spacer, Small 14x16 0° 29mm	1
342.431	NIKO® Corpectomy Spacer, Small 14x16 0° 31mm	1
342.433	NIKO® Corpectomy Spacer, Small 14x16 0° 33mm	1
342.515	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 15mm	1
342.517	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 17mm	1
342.519	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 19mm	1
342.521	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 21mm	1
342.523	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 23mm	1
342.525	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 25mm	1
342.527	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 27mm	1
342.529	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 29mm	1
342.531	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 31mm	1
342.533	NIKO® Corpectomy Spacer, Small 14x16 3.5/3.5° 33mm	1
342.615	NIKO® Corpectomy Spacer, Small 14x16 0/5° 15mm	1
342.617	NIKO® Corpectomy Spacer, Small 14x16 0/5° 17mm	1
342.619	NIKO® Corpectomy Spacer, Small 14x16 0/5° 19mm	1
342.621	NIKO® Corpectomy Spacer, Small 14x16 0/5° 21mm	1
342.623	NIKO® Corpectomy Spacer, Small 14x16 0/5° 23mm	1
342.625	NIKO® Corpectomy Spacer, Small 14x16 0/5° 25mm	1
342.627	NIKO® Corpectomy Spacer, Small 14x16 0/5° 27mm	1
342.629	NIKO® Corpectomy Spacer, Small 14x16 0/5° 29mm	1
342.631	NIKO® Corpectomy Spacer, Small 14x16 0/5° 31mm	1
342.633	NIKO® Corpectomy Spacer, Small 14x16 0/5° 33mm	1
942.002	NIKO® Corpectomy Spacer System Module 14x16	

IMPORTANT INFORMATION ON THE NIKO® CORPECTOMY SPACER

DESCRIPTION

NIKO® Corpectomy Spacers are vertebral body replacement devices used to provide structural stability in skeletally mature individuals following corpectomy or vertebrectomy. The system is comprised of spacers of various fixed heights to fit the anatomical needs of a variety of patients. Each spacer has an axial hole to allow grafting material to be packed inside the spacer. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion.

NIKO® Corpectomy Spacers are made from radiolucent polymer and titanium alloy or tantalum as specified in ASTM F2026, F136, F1295, and F560. NIKO® TPS Corpectomy Spacers also have a commercially pure titanium plasma spray coating, as specified in ASTM F67 and F1580.

INDICATIONS

NIKO® Corpectomy Spacers are vertebral body replacement devices 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). NIKO® Corpectomy 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. NIKO® Corpectomy Spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. All NIKO® 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 level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Components of this system should not be used with components of any other system or manufacturer.

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 vertebral body replacement 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.

MRI SAFETY INFORMATION

NIKO® Corpectomy 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 NIKO® Corpectomy 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 is not expected to extend beyond 35mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

CONTRAINDICATIONS

Use of these devices is contraindicated in patients with the following conditions:

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 risks 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.
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.

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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 used 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 must be cleaned, as described in the CLEANING section below.

HANDLING AND USE

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

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

CLEANING

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

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

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

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

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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 foil 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. Sterile implants meet pyrogen limit specifications.

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

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

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

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

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

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

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

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

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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)

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