ADDI+IVE IMPLANTS

SureMAX™ / SureMAX-X™

CERVICAL SPACER

SURGICAL TECHNIQUE GUIDE

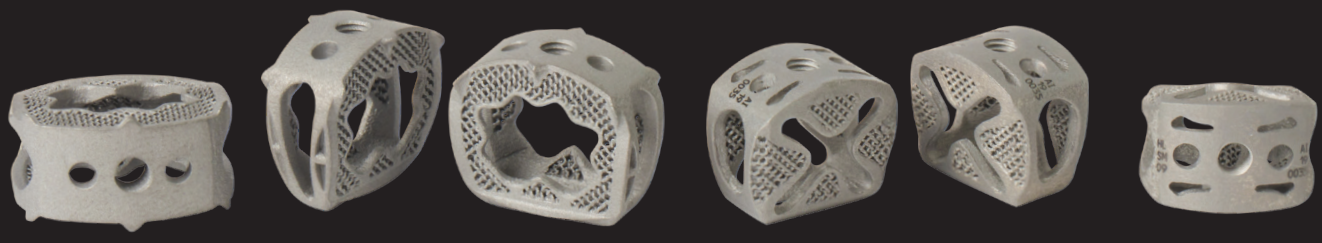
SureMAX™ CERVICAL SPACER

The SureMAX™ Family of Cervical Spacers offers:

+ Roughened and optimized open-pore structures.
+ Convex surfaces to match spinal endplates.
+ Large lateral windows to radiologically visualize bone healing.
+ Lordotic 7°, Mid-Lordotic 10°, and Hyperlordotic 14° options.
+ Multiple footprints: 12 x 14 mm, 14 x 16 mm, 15 x 18 mm, 15 x 20 mm.
+ One set of instruments for both SureMAX™ and SureMAX-X™ Cervical Spacers.
+ Unique Slap Hammer design for rapid insertion/extraction and visualization under a microscope.

These are essential features for the next generation Cervical Interbody Spacer.
They are combined features available in only one family of implants:

SUREMAX™ AND SUREMAX-X™ CERVICAL SPACERS



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INDICATIONS/CONTRAINDICATIONS

Indications

The SureMAX™ and SureMAX-X™ Cervical Spacers are intended for anterior interbody fusion in skeletally mature patients who have had at least six weeks of non-operative treatment. The SureMAX™ and SureMAX-X™ Cervical Spacers are indicated to treat cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at multiple contiguous levels from C2 – T1. The SureMAX™ Family of Cervical Spacers are to be used with supplemental fixation; the Hyperlordotic implants (≥ 10°) are required to be used with an anterior cervical plate. The implants are designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or cortico-cancellous bone to facilitate fusion.

Contraindications

+ Active local infection in or near the operative region.
+ Active systemic infection and/or disease.
+ Severe osteoporosis or insufficient bone density, which in the medical opinion of the physician precludes surgery or contraindicates instrumentation.
+ Current metastatic tumors of the vertebrae adjacent to the implant.
+ Known or suspected metal sensitivity.
+ Endocrine or metabolic disorders known to affect osteogenesis (e.g., Paget's disease, renal osteodystrophy, hypothyroidism).
+ Significant mental disorder or condition that could compromise the patient's ability to remember and comply with preoperative and postoperative instructions.
+ Neuromuscular disorder that would engender unacceptable risk of instability, implant fixation failure, or complications in postoperative care. Neuromuscular disorders include spina bifida, cerebral palsy, and multiple sclerosis.
+ Pregnancy.
+ Patients unwilling or unable to follow postoperative instructions, especially those in athletic and occupational activities.
+ Morbid obesity.
+ Symptomatic cardiac disease.
+ Skeletal immaturity.
+ Grossly distorted anatomy.
+ Any condition not described in the Indications for Use.

SUREMAX™ FAMILY OF CERVICAL SPACERS

The SureMAX™ Family of Cervical Spacers are interbody fusion devices manufactured from Ti-6Al- 4V ELI titanium alloy (ASTM F3001, Grade 23). The device is designed to provide surgical stabilization of the cervical spine. The superior and inferior surfaces have a lattice mesh surrounding a large central cavity for placement of bone graft which extends vertically through the implant. Three pyramidal spikes extend outward from the implant at the anterior-inferior and anterior-superior edges to aid in securing the device within the disc space. The lateral aspects of the spacer are open to facilitate radiographic fusion assessment. The anterior face incorporates three holes, the center one threaded, for inserter attachment.

The SureMAX™ Cervical Spacer is available in three footprint sizes (depth x width):
12 mm x 14 mm, 14 mm x 16 mm, and 15 mm x 18 mm. All three footprint sizes are available in heights of 5 mm to 12 mm, in 1 mm increments. The superior-inferior surfaces form either a lordotic (7°) or a hyperlordotic (14°) sagittal angulation.

The SureMAX-X™ Cervical Spacer is available in four footprint sizes (depth x width):
12 mm x 14 mm, 14 mm x 16 mm, 15 mm x 18 mm and 15 mm x 20 mm. All four footprint sizes are available in heights of 5 mm to 9 mm, in 1 mm increments. The superior-inferior surfaces form either a lordotic (7°), a mid-lordotic (10°) or a hyperlordotic (14°) sagittal angulation.

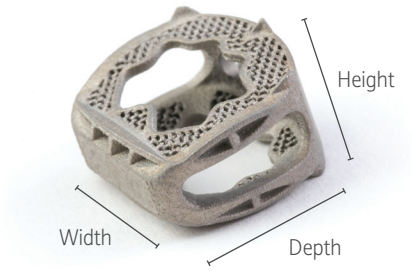
All the SureMAX™ Family of Cervical Spacers are provided sterile only.

SureMAX™ CERVICAL SPACER

SureMAX-X™ CERVICAL SPACER

SureMAX™ CERVICAL SPACER

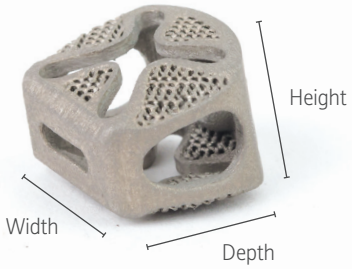
Implants



Depth x Width (mm)	Height (mm)	Part Numbers	
		Lordotic 7°	Hyperlordotic 14°
Small 12 x 14	5	1002-07121405	1002-14121405
	6	1002-07121406	1002-14121406
	7	1002-07121407	1002-14121407
	8	1002-07121408	1002-14121408
	9	1002-07121409	1002-14121409
	10	1002-07121410	1002-14121410
	11	1002-07121411	1002-14121411
	12	1002-07121412	1002-14121412
Medium 14 x 16	5	1002-07141605	1002-14141605
	6	1002-07141606	1002-14141606
	7	1002-07141607	1002-14141607
	8	1002-07141608	1002-14141608
	9	1002-07141609	1002-14141609
	10	1002-07141610	1002-14141610
	11	1002-07141611	1002-14141611
	12	1002-07141612	1002-14141612
Large 15 x 18	5	1002-07151805	1002-14151805
	6	1002-07151806	1002-14151806
	7	1002-07151807	1002-14151807
	8	1002-07151808	1002-14151808
	9	1002-07151809	1002-14151809
	10	1002-07151810	1002-14151810
	11	1002-07151811	1002-14151811
	12	1002-07151812	1002-14151812

SureMAX-X™ CERVICAL SPACER

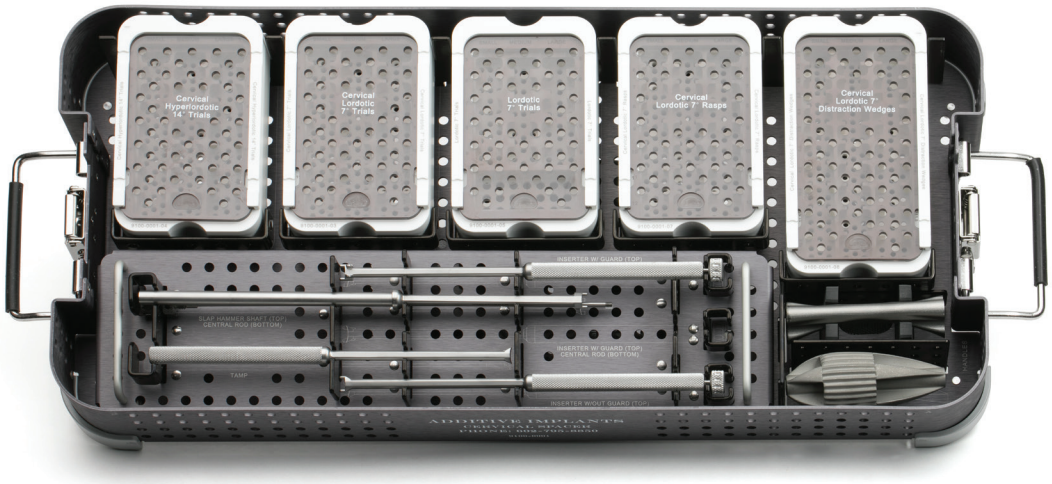
Implants



Depth x Width (mm)	Height (mm)	Part Numbers		
		Lordotic 7˚	Mid-Lordotic 10˚	Hyperlordotic 14˚
Small 12 x 14	5	1802-07121405	1802-10121405	1802-14121405
	6	1802-07121406	1802-10121406	1802-14121406
	7	1802-07121407	1802-10121407	1802-14121407
	8	1802-07121408	1802-10121408	1802-14121408
	9	1802-07121409	1802-10121409	1802-14121409
Medium 14 x 16	5	1802-07141605	1802-10141605	1802-14121405
	6	1802-07141606	1802-10141606	1802-14121406
	7	1802-07141607	1802-10141607	1802-14121407
	8	1802-07141608	1802-07141608	1802-14121408
	9	1802-07141609	1802-10141609	1802-14121409
Large 15 x 18	5	1802-07151805	1802-10151805	1802-14151805
	6	1802-07151806	1802-10151806	1802-14151806
	7	1802-07151807	1802-10151807	1802-14151807
	8	1802-07151808	1802-10151808	1802-14151808
	9	1802-07151809	1802-10151809	1802-14151809
Extra Large 15 x 20	5	1802-07152005	1802-10152005	1802-14152005
	6	1802-07152006	1802-10152006	1802-14151806
	7	1802-07152007	1802-10152007	1802-14152007
	8	1802-07152008	1802-10152008	1802-14152008
	9	1802-07152009	1802-10152009	1802-14152009

SUREMAX™ SPACER INSTRUMENTATION PLATFORM

The SureMAX™ Cervical Spacer Instrumentation is designed to aid in the implantation of Additive Implants' SureMAX™ and SureMAX-X™ Cervical Spacers. The Smith-Robinson surgical technique is utilized with standard instruments, except those specifically related to the sizing and insertion of the SureMAX-X™ Cervical Spacer device.

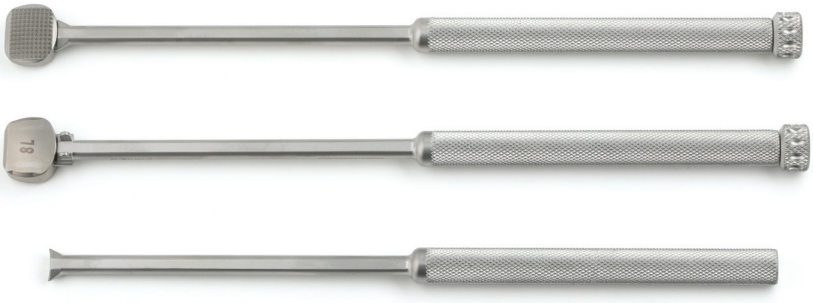


Single Modular Tray

Distraction Wedges to help open collapsed disc spaces.

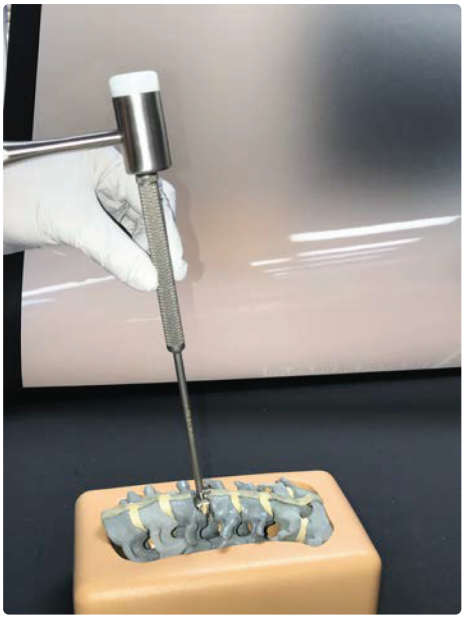
Aggressive Rasps with convex surfaces to strip and shape the concavity of the vertebral endplates.

Trials match the geometry of the implants for an accurate assessment of size.



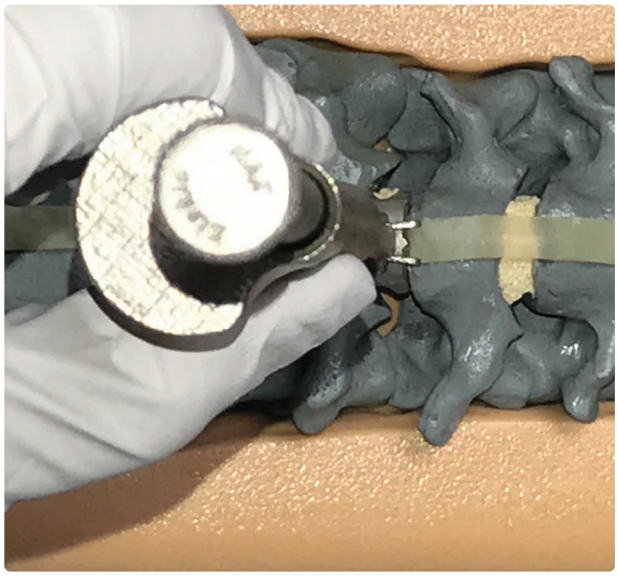
Variety of Inserter Tools, with and without guards, allow for single handed tool/implant application.

Unique Slap Hammer designs allow for enhanced visualization of the operative site when using a microscope.



TAMP WITH MALLET

Assists in final implant placement by tamping directly down on the implant



ERGONOMIC HAMMER

Top View

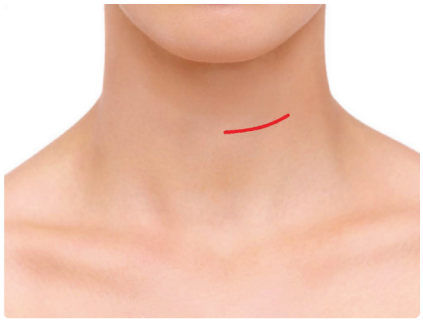
EGG SHAPE HAMMER

Top View

SURGICAL TECHNIQUE

STEP 1:

Pre-Operative Planning and Patient Positioning

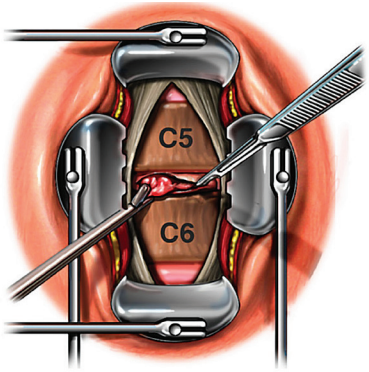


Pre-operatively, the surgeon must identify the proper intervertebral level to fuse using diagnostic techniques such as radiographs, MRI, myelography, patient history and physical examination.

Place the patient in a supine position. Support the posterior cervical spine to maintain or restore normal lordosis and chose a right or left-sided approach. Identify the symptomatic level and make a skin incision to the corresponding pathology.

STEP 2:

Exposure and Location

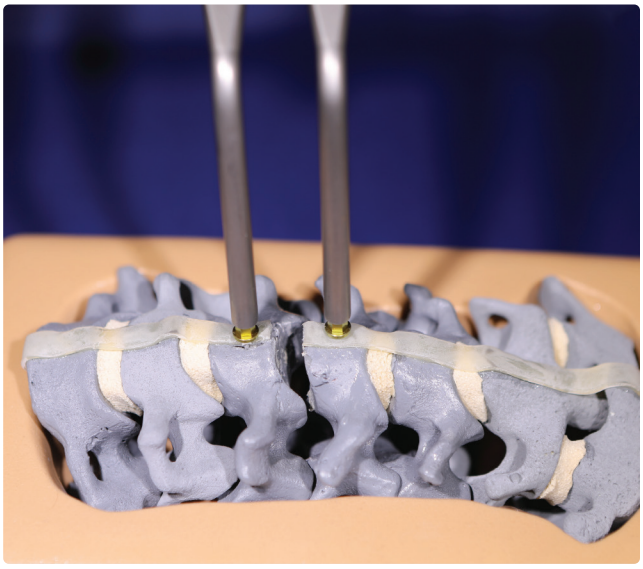


The anterior cervical anatomy is exposed in the standard fashion by identifying a dissection plane. Exposure is then held in place utilizing self-retaining or other retractors.

The proper level is confirmed using a marker and fluoroscopy imaging. A vertebral Caspar Pin Distractor must then be placed through the open incision in the adjacent vertebrae to the discectomy.

STEP 3:

Discectomy

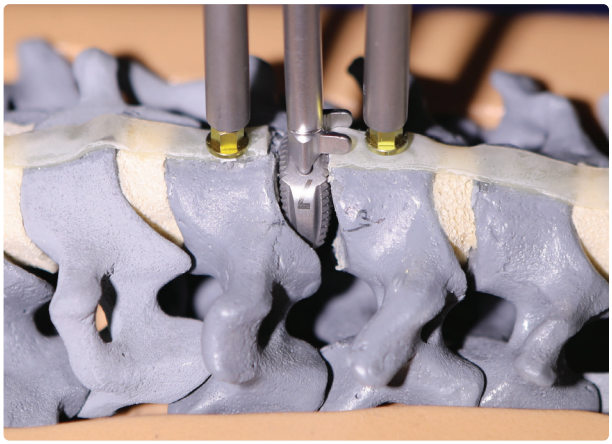


A Caspar Pin Distractor is required for the distraction of the adjacent endplates. Perform a standard cervical discectomy and decompression by resecting the anterior longitudinal ligament over the corresponding vertebrae. Remove the intervertebral disc out to the uncovertebral joints using general instrumentation such as Curettes, Rongeurs or burr.

Caution: *Great care should be taken to ensure that all exposed blood vessels, nerve and other structures are properly retracted prior to the discectomy to avoid injury.*

STEP 4:

Endplate Distraction



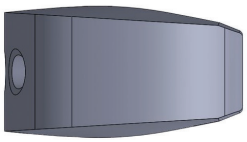
End plates should be distracted by using the Wedge Distractors provided in the set. Distraction should be performed starting with the smallest distractor that fits into the disc space. Distract sequentially in 1 mm increments using tension on the Caspar pins to maintain the achieved space between the vertebral end plates. Caspar pins should only be used to maintain the distraction obtained by the distracting wedges to decrease the likelihood of the Caspar Pins cutting through the vertebral body. Distracting Wedges come in 1 mm increments, and from 2.5 mm to 12.5 mm.

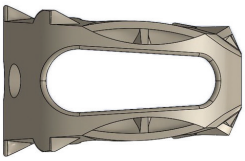
After removing the cartilage, on the endplate using a standard Curette prepare the bone surface using the appropriately sized Rasp. This step is important as it ensures a conforming fit between the implant and the anatomy. As appropriate, a burr may be used to create holes in the endplate in order to enhance blood flow from the subcondral bone to the interface.

Caution: *Using excessive force with the instrumentation can inadvertently damage the vertebral bodies.*

STEP 5:

Sizing





Determine the implant footprint and degree of lordosis by measuring disc space using the Trial Spacers and select the size that best fits the disc space. The Trials are dimensionally identical to the implant.

The Trials do not possess the three anterior spikes which are present on the SureMAX™ Cervical Spacer.

STEP 6:

Bone Grafting

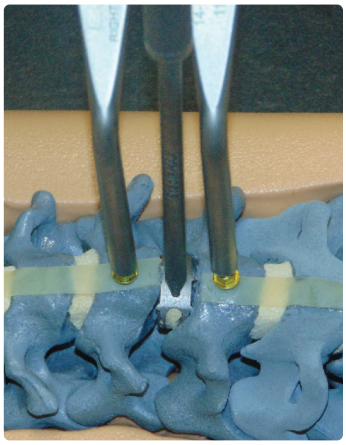
The graft window of the implant must be filled with autogenous and/or allogeneic bone graft comprised of cancellous and/or cortico-cancellous bone.

Implant Insertion Options

Select an implant inserter to hold the device for final placement into the disc space.

INSERTER

Select an inserter with or without guard, insure that the Inserter is engaging the anterior convex edge of the implant. Turn the knob of the Central Threaded Rod clockwise until the implant is securely attached to the Inserter for placement into the disc space.



To remove the Inserter from the device, securely hold the handle of the Inserter and turn the knob of the Central Threaded Rod counterclockwise until the thread has disengaged from the implant.

Caution: *Excessive force on the inserter can damage the instrument or the device.*

ERGONOMIC OR EGG SHAPED SLAP HAMMER

Alternatively, the Ergonomic or Egg Shaped Slap Hammer may be used. Insert the tip of the Slap Hammer Shaft into the implant and rotate the Central Rod counterclockwise in order to engage the threaded hole located on the anterior convex face of the implant. Note, the Slap Hammer Knob is reverse threaded to prevent inadvertent loosening.

SLAP HAMMER DISASSEMBLY

Hold the shaft of the Slap Hammer and turn the knob under the Central Threaded Rod clockwise.

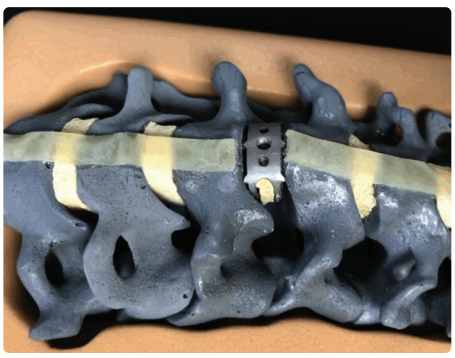
FINAL IMPLANT POSITIONING

It may be necessary to use a Tamp for final implant seating. The concave surfaces of the Tamp match the convex anterior wall of the device. Moderately tap on the Tamp to fully seat the implant to desired location. Tapping on the device should move the implant posteriorly. If no motion occurs, remove the device and check for an obstruction of bone or a narrow posterior opening.

POSITION CONFIRMATION

Final placement of the implant should be slightly posterior to the anterior aspect of the vertebral bodies. Lateral and A/P radiography may be taken to assure proper implant placement.

Caution: *If difficulty inserting the cervical spacer device is encountered, do not vigorously tap on the implant. Excessive force on the implant may deform or damage the device. Rather, remove the implant and check for an impediment. Additional endplate preparation may be required.*



SUPPLEMENTAL FIXATION

After implantation, anterior or posterior supplemental fixation must be used. Only titanium alloy systems should be used. Care must be taken to avoid using dissimilar metals or corrosion may occur.

POST-OPERATIVE MANAGEMENT

See package insert for post-operative management regimen.

IMPLANT REMOVAL OR REVISION

Should removal or revision of the device be determined necessary, an Osteotome can be used at the interface between the bone and both the superior and inferior faces of the implant. This effectively cuts the fused column of bone at the level of the boundaries of the implant. Once the fused column is completely cut, Inserter or forceps can be used to remove the implant from the space. This may be done under distraction of the endplates. For a reimplantation, follow the standard surgical technique.

WARNINGS AND PRECAUTIONS

Warnings

+ Surgery is not always successful. Preoperative symptoms may not be relieved or may worsen. Surgical knowledge of the procedure and the device are important, as is patient selection. Patient compliance is also important. Tobacco and or alcohol abuse may lead to unsuccessful results.
+ Implants are single use only and should not be reused. Once a device has been implanted, it must never be reused. Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.
+ Appropriate endplate preparation and device selection is needed to obtain proper fit.
+ Delayed healing can lead to fracture of the implants due to increased stress and material fatigue. Patients must be fully informed of all the risks associated with the implant and the importance of following postoperative instructions regarding weight bearing and activity levels to facilitate proper bone healing.
+ The implant must be handled carefully, following the manufacturer's instructions, to prevent damage to the implant.
+ Implants must not be modified or otherwise processed in any way.
+ Care must be taken to avoid using dissimilar metals, in contact with one another, as corrosion may occur. Additional fixation instrumentation that is used to stabilize the affected level must be made of compatible materials, such as Titanium or Titanium alloy. Corrosion may accelerate metal fatigue and lead to failure of the implant.
+ This surgical procedure requires the use of supplemental fixation systems to stabilize the fusion site.

Precautions

- The implantation of an intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
- The surgeon must have a thorough knowledge of the mechanical and material limitations of surgical implants made of Titanium Alloy and be thoroughly familiar with the surgical technique for implanting the SureMAX™ and SureMAX-X™ Cervical Spacers for the given Indications for Use.
- The surgeon should be familiar with the various devices and instruments and verify that all are available before beginning the surgery. Additionally, the packaging and implant should be inspected for damage prior to implantation.
- In the event that removal of the implant is considered (e.g. due to loosening, fracture, migration of the implant; infection; increased pain, etc.), the risks versus benefits must be carefully weighed. Such events can occur even after healing, especially in more active patients. Appropriate postoperative care must be given following implant removal to avoid further complication.
- The surgeon must be thoroughly familiar with the options for supplemental internal fixation systems and the associated surgical techniques.
- Implants must be fully seated within the inserter prior to use. Care must be taken not to over-tighten the implant-inserter assembly. Additionally, care must be taken not to manipulate the inserter implant interface in a way not recommended by the surgical technique.
- The surgeon must ensure that the implant is properly seated prior to closing of the soft tissue.
- Extreme caution must be used around the spinal cord, nerve roots and blood vessels.

MRI Safety Information

The SureMAX™ Family of Cervical Spacers have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of these Cervical Spacers in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Caution: *Federal (USA) law restricts these devices to sale by or on the order of a licensed physician.*

SOLUTIONS BY THE PEOPLE OF ADDITIVE IMPLANTS

We are devoted to helping your patients obtain excellent surgical outcomes. We are dedicated to supporting you with novel tools, instruments and implants. We are driven by the opportunity to share our developments with the world. We are committed partners who will do everything in our power to assist you in your quest to provide the absolute best in spinal care. You can count on us to always to act as ethical partners with integrity who are worthy of your trust.

ADDI+IVE IMPLANTS

3101 E SHEA BLVD, SUITE 122
PHOENIX, AZ 85028

602-795-8850 phone
602-595-7896 fax

ADDITIVEIMPLANTS.COM

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