SureMAX™ Family of Cervical Spacers

Instructions for Use

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

DESCRIPTION: The SureMAX™ Family of Cervical Spacers includes the SureMAX™ and SureMAX™-X implants. These are interbody devices additively manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F3001, Grade 23). Each device is designed to provide surgical stabilization of the cervical spine. The superior and inferior surfaces have a lattice mesh surrounding a central cavity for placement of bone graft which extends vertically through the implant. 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 (width x depth): 14 mm x 12 mm, 16 mm x 14 mm and 18 mm x 15 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.
The SureMAX™ Family of Cervical Spacers are provided sterile only.

INDICATIONS FOR USE: The SureMAX™ Family of Cervical Spacers is intended for anterior intervertebral body fusion in skeletally mature patients who have had at least six weeks of non-operative treatment. The SureMAX™ Family of Cervical Spacers is 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 is 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 corticocancellous bone to facilitate fusion.

CONTRAINDICATIONS:

1. Active local infection in or near the operative region.
2. Active systemic infection and/or disease.
3. Severe osteoporosis or insufficient bone density, which in the medical opinion of the physician precludes surgery or contraindicates instrumentation.
4. Current metastatic tumors of the vertebrae adjacent to the implant.
5. Known or suspected metal sensitivity.
6. Endocrine or metabolic disorders known to affect osteogenesis (e.g., Paget's disease, renal osteodystrophy, hypothyroidism).
7. Significant mental disorder or condition that could compromise the patient's ability to remember and comply with preoperative and postoperative instructions.
8. 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.
9. Pregnancy.
10. Patients unwilling or unable to follow postoperative instructions, especially those in athletic and occupational activities.
11. Morbid obesity.
12. Symptomatic cardiac disease.
13. Skeletal immaturity.
14. Grossly distorted anatomy.
15. Any condition not described in the Indications for Use.

INSTRUCTIONS:

All applicable instruction manuals should be carefully followed. A copy of the surgical technique can be obtained by contacting Additive Implants at: 3101 East Shea Boulevard, Suite 122; Phoenix, AZ 85028; (602) 795-8850.

Preoperative:

1. Only patients that meet the criteria as described in the indications should be selected.
2. When using the SureMAX™ Family of Cervical Spacers, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may adversely impact on the performance of this system.
3. Safety and effectiveness has not been established in patients with the following conditions: morbid obesity; symptomatic cardiac disease; pregnancy; signs of local inflammation; fever or leukocytosis; metal sensitivity/allergy to the implants materials; any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count; grossly distorted anatomy due to congenital abnormalities; osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft); long term systemic corticosteroid use; active drug abuse; any case requiring the mixing of metals from different components; any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition; any patient unwilling to cooperate with the postoperative instructions; or any time implant utilization would interfere with anatomical structures or expected physiological performance. Patient conditions and/or predispositions such as these should be avoided. Other conditions may exist where safety and effectiveness have not been established.
4. Care should be used in handling and storage of the implants and instruments. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments. Instrumentation should be routinely inspected; if they exhibit wear, damage, corrosion, or discoloration they should be returned to Additive Implants for further evaluation.
5. The type of construct to be assembled for the case should be determined prior to beginning the surgery.
6. The surgeon should be familiar with the various components before using the equipment and should personally assemble the implants to verify that all parts and necessary instruments are present before the surgery begins.
7. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences. Postoperative care is important. The surgeon should provide postoperative care and management instructions to the patient. The patient should be instructed that non-compliance with post-operative instructions may lead to compromised results including implant failure. The patient must be informed that, as with any spine surgery, multiple complications may develop.
8. Careful planning should be undertaken when implanting the SureMAX™ Family of Cervical Spacers in patients with a prior attempt at fusion at the level(s) to be treated.

Intraoperative:

1. All applicable instruction manuals should be carefully followed.
2. Prepare the endplates to accept the device by using the appropriately sized rasp and ensuring a close fit between the implant and the anatomy.
3. Care should be taken when positioning the device around the spinal cord and nerve roots. Damage to nerves may occur resulting in loss of neurological functions.
4. Bone graft must be placed in the device and the graft must be in contact with viable bone in order to achieve arthrodesis.
5. Placement of the device should be confirmed radiographically.
6. The implant surfaces should not be scratched or notched since such actions may reduce the functional strength of the construct.

Postoperative:

1. The physician's postoperative directions and warnings to the patient and corresponding patient compliance are extremely important.
2. Detailed instructions on the use and limitations of the implant(s) should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the implant(s) are complications which can occur as a result of excessive or early weight bearing or excessive muscular activity. The risk of bending, loosening or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active or if the patient is debilitated, or has mental incapacity. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. To allow maximum chances for a successful surgical result, the patient's implant(s) should not be exposed to mechanical vibrations that may loosen the implant(s). The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
4. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction on body motion.
5. If a nonunion develops or if the implant(s) loosen, bend and /or break, the implant(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant(s). By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the implant(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
6. Any retrieved implants should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Additive Implants Interbody Fusion implants should ever be reused under any circumstances. Reuse may result in, but is not limited to the following; infection, bending, loosening or breakage due to impairment of implant integrity.

MRI SAFETY INFORMATION: The SureMAX™ Family of Cervical Spacers has 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 the SureMAX™ Family of Cervical Spacers in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

ADVERSE EVENTS: Possible adverse effects include, but are not limited to, bending, loosening, or fracture of the implants or instruments; loss of fixation; sensitivity to a metallic foreign body, including possible tumor formation; skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications; nonunion or delayed union; infection; nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis, and cerebral fluid leakage; gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency, and/or loss of consortium; pain or discomfort; bone loss due to resorption or stress shielding, or bone fracture at, above, or below the level of surgery (fracture of the vertebra); hemorrhage of blood vessels and/or hematomas; malalignment of anatomical structures, including loss of proper spine curvature, correction, reduction, and/or height; bursitis; bone graft donor site pain; inability to resume activities of normal daily living; reoperation or death.

IMPLANTS – HOW SUPPLIED: SureMAX™ Family of Cervical Spacers are provided sterile, via gamma radiation. Please inspect the package for damage and note the package labeling for the expiration date. Do not use any implant from an opened or damaged package. Do not use implants after the expiration date. Implants are single use only and are not to be resterilized under any conditions. Implants removed from sterile packaging, but not used in surgery, as well as implants found in damaged packaging must be returned to Additive Implants for proper disposition.

INSTRUMENTS – CLEANING & STERILIZATION

SureMAX™ Family of Cervical Spacers instrumentation is provided non-sterile and must be cleaned and sterilized prior to use. Instruments must first be thoroughly cleaned before sterilization and introduction into a sterile surgical field. To facilitate proper cleaning, instruments which allow for assembly should be disassembled.

Disassembly

There are two instrument types that can be disassembled:

1. Inserters (with Guard Tip or without Guard Tip): To disassemble either of the (2) styles of Inserter: unthread, in a counterclockwise direction, the Inserter Central Rod and pull it out of the Inserter Shaft.
2. Slap Hammers (Egg Shaped or Ergonomic): To disassemble the Slap Hammer: unthread, in a clockwise direction, the Slap Hammer Barrier Nut and pull the Slap Hammer Central Rod out of the Slap Hammer Shaft. Slide the Slap Hammer Handle (Egg Shaped or Ergonomic) off the Slap Hammer Shaft.

Cleaning

Step 1: Prepare a cleaning solution using Steris Prolystica 2X Concentrate Enzymatic Cleaner according to manufacturer's instructions using at least a concentration of 1/8 oz. per gallon of 20°C tap water.

Step 2: Instruments should be fully immersed in the cleaning solution and allowed to soak for at least five (5) minutes.

Step 3: While still immersed in the cleaning solution, each instrument must be brushed with a soft-bristled nylon brush for a minimum of one (1) minute.

Step 4: Rinse instruments under 20°C running tap water for thirty (30) seconds to remove any detergent residue.

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CONTRAINDICATIONS:

1. Active local infection in or near the operative region.
2. Active systemic infection and/or disease.
3. Severe osteoporosis or insufficient bone density, which in the medical opinion of the physician precludes surgery or contraindicates instrumentation.
4. Current metastatic tumors of the vertebrae adjacent to the implant.
5. Known or suspected metal sensitivity.
6. Endocrine or metabolic disorders known to affect osteogenesis (e.g., Paget's disease, renal osteodystrophy, hypothyroidism).
7. Significant mental disorder or condition that could compromise the patient's ability to remember and comply with preoperative and postoperative instructions.
8. 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.
9. Pregnancy.
10. Patients unwilling or unable to follow postoperative instructions, especially those in athletic and occupational activities.
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Preoperative:

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2. When using the SureMAX™ Family of Cervical Spacers, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may adversely impact on the performance of this system.
3. Safety and effectiveness has not been established in patients with the following conditions: morbid obesity; symptomatic cardiac disease; pregnancy; signs of local inflammation; fever or leukocytosis; metal sensitivity/allergy to the implants materials; any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count; grossly distorted anatomy due to congenital abnormalities; osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft); long term systemic corticosteroid use; active drug abuse; any case requiring the mixing of metals from different components; any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition; any patient unwilling to cooperate with the postoperative instructions; or any time implant utilization would interfere with anatomical structures or expected physiological performance. Patient conditions and/or predispositions such as these should be avoided. Other conditions may exist where safety and effectiveness have not been established.
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8. Careful planning should be undertaken when implanting the SureMAX™ Family of Cervical Spacers in patients with a prior attempt at fusion at the level(s) to be treated.

Intraoperative:

1. All applicable instruction manuals should be carefully followed.
2. Prepare the endplates to accept the device by using the appropriately sized rasp and ensuring a close fit between the implant and the anatomy.
3. Care should be taken when positioning the device around the spinal cord and nerve roots. Damage to nerves may occur resulting in loss of neurological functions.
4. Bone graft must be placed in the device and the graft must be in contact with viable bone in order to achieve arthrodesis.
5. Placement of the device should be confirmed radiographically.
6. The implant surfaces should not be scratched or notched since such actions may reduce the functional strength of the construct.

Postoperative:

1. The physician's postoperative directions and warnings to the patient and corresponding patient compliance are extremely important.
2. Detailed instructions on the use and limitations of the implant(s) should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the implant(s) are complications which can occur as a result of excessive or early weight bearing or excessive muscular activity. The risk of bending, loosening or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active or if the patient is debilitated, or has mental incapacity. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. To allow maximum chances for a successful surgical result, the patient's implant(s) should not be exposed to mechanical vibrations that may loosen the implant(s). The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
4. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction on body motion.

5. If a nonunion develops or if the implant(s) loosen, bend and /or break, the implant(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant(s). By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the implant(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
6. Any retrieved implants should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Additive Implants Interbody Fusion implants should ever be reused under any circumstances. Reuse may result in, but is not limited to the following; infection, bending, loosening or breakage due to impairment of implant integrity.

MRI SAFETY INFORMATION: The SureMAX™ Family of Cervical Spacers has 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 the SureMAX™ Family of Cervical Spacers in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

ADVERSE EVENTS: Possible adverse effects include, but are not limited to, bending, loosening, or fracture of the implants or instruments; loss of fixation; sensitivity to a metallic foreign body, including possible tumor formation; skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications; nonunion or delayed union; infection; nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis, and cerebral fluid leakage; gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency, and/or loss of consortium; pain or discomfort; bone loss due to resorption or stress shielding, or bone fracture at, above, or below the level of surgery (fracture of the vertebra); hemorrhage of blood vessels and/or hematomas; malalignment of anatomical structures, including loss of proper spine curvature, correction, reduction, and/or height; bursitis; bone graft donor site pain; inability to resume activities of normal daily living; reoperation or death.

IMPLANTS – HOW SUPPLIED: SureMAX™ Family of Cervical Spacers are provided sterile, via gamma radiation. Please inspect the package for damage and note the package labeling for the expiration date. Do not use any implant from an opened or damaged package. Do not use implants after the expiration date. Implants are single use only and are not to be resterilized under any conditions. Implants removed from sterile packaging, but not used in surgery, as well as implants found in damaged packaging must be returned to Additive Implants for proper disposition.

INSTRUMENTS – CLEANING & STERILIZATION

SureMAX™ Family of Cervical Spacers instrumentation is provided non-sterile and must be cleaned and sterilized prior to use. Instruments must first be thoroughly cleaned before sterilization and introduction into a sterile surgical field. To facilitate proper cleaning, instruments which allow for assembly should be disassembled.

Disassembly

There are two instrument types that can be disassembled:

1. Inserters (with Guard Tip or without Guard Tip): To disassemble either of the (2) styles of Inserter: unthread, in a counterclockwise direction, the Inserter Central Rod and pull it out of the Inserter Shaft.
2. Slap Hammers (Egg Shaped or Ergonomic): To disassemble the Slap Hammer: unthread, in a clockwise direction, the Slap Hammer Barrier Nut and pull the Slap Hammer Central Rod out of the Slap Hammer Shaft. Slide the Slap Hammer Handle (Egg Shaped or Ergonomic) off the Slap Hammer Shaft.

Cleaning

Step 1: Prepare a cleaning solution using Steris Prolystica 2X Concentrate Enzymatic Cleaner according to manufacturer's instructions using at least a concentration of 1/8 oz. per gallon of 20°C tap water.

Step 2: Instruments should be fully immersed in the cleaning solution and allowed to soak for at least five (5) minutes.

Step 3: While still immersed in the cleaning solution, each instrument must be brushed with a soft-bristled nylon brush for a minimum of one (1) minute.

Step 4: Rinse instruments under 20°C running tap water for thirty (30) seconds to remove any detergent residue.

Step 5: Load instruments into mesh wire basket and place into a mechanical washer for cleaning.

Step 6: Upon removal from the mechanical washer, inspect all instruments for functionality and that all markings are legible. Nonfunctional instruments and instruments with illegible markings should not be used in surgery. Please return them to Additive Implants for replacement.

Step 7: Load instrumentation into the supplied instrument tray/cadies. Place the loaded instrument tray into a steam sterilizer using the cycle times listed below.

Sterilization

The following recommended sterilization cycle has been validated to an SAL of 10^{-6}. The use of an FDA cleared sterilization wrap is recommended.

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

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™ Family of 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.

SYMBOL DESCRIPTION:

Reference number and symbol	Reference title	Description of symbol per Standard[1]
5.1.1	Manufactured for	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
5.1.5 LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
5.1.6 REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
5.2.4 STERILE R	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
5.4.3	Consult Instructions for use	Indicates the need for the user to consult the instructions for use.
5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
Rx Only	Prescription Only	CAUTION: Federal law restricts this device to sale by or on the order of a physician. (21 CFR Part 801.109(b)(1))

[1] Unless otherwise indicated, reference numbers and descriptions from ISO 15223-1:2016, *Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied*.

Some parts in the SureMAX™ product family are protected by US Patent No. 10,299,938 and other pending patents.

Manufactured for Additive Implants
at:
3101 East Shea Boulevard, Suite 122
Phoenix, AZ 85028
(602) 795-8850
www.additiveimplants.com

LIT-01-101030 Rev3

Step 5: Load instruments into mesh wire basket and place into a mechanical washer for cleaning.

Step 6: Upon removal from the mechanical washer, inspect all instruments for functionality and that all markings are legible. Nonfunctional instruments and instruments with illegible markings should not be used in surgery. Please return them to Additive Implants for replacement.

Step 7: Load instrumentation into the supplied instrument tray/cadies. Place the loaded instrument tray into a steam sterilizer using the cycle times listed below.

Sterilization

The following recommended sterilization cycle has been validated to an SAL of 10^{-6}. The use of an FDA cleared sterilization wrap is recommended.

Cycle	Temperature	Exposure Time	Dry Time
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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™ Family of 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.

SYMBOL DESCRIPTION:

Reference number and symbol	Reference title	Description of symbol per Standard[1]
5.1.1	Manufactured for	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
5.1.5 LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
5.1.6 REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
5.2.4 STERILE R	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
5.4.3	Consult Instructions for use	Indicates the need for the user to consult the instructions for use.

5.4.4 	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Prescription Only	CAUTION: Federal law restricts this device to sale by or on the order of a physician. (21 CFR Part 801.109(b)(1))

1 Unless otherwise indicated, reference numbers and descriptions from ISO 15223-1:2016, *Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied*.

Some parts in the SureMAX™ product family are protected by US Patent No. 10,299,938 and other pending patents.

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