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LUMBAR SPINE IMPLANTS AND INSTRUMENTATION (LUNA® XD EXPANDABLE INTERBODY AND INSERTER, GRAFT INJECTOR AND ASSOCIATED INSTRUMENTS)

This package insert covers Spinal Elements lumbar spine systems: Luna® XD Interbody Fusion System, Graft Injector, and Accessory Instruments that are used for the implantation of Luna® XD devices. Specific system information for Luna® XD Inserter (containing the Luna® XD Implant), Graft Injector, and the associated instruments are highlighted in individual sections below.

LUNA XD EXPANDABLE INTERBODY

GENERAL INFORMATION

The Luna® XD Interbody Fusion System is comprised of an implant, disposable, and reusable instruments. The Luna® XD Implant is made of PEEK (polyetheretherketone; ASTM F2026), Nitinol (nickel titanium alloy; ASTM F2063) and tantalum (ASTM F560).

INDICATIONS

The Luna® XD Interbody Fusion System consists of a Luna XD Implant and associated accessories. This system is indicated for spinal fusion procedures in skeletally mature patients with symptomatic degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to grade I spondylolisthesis or retrolisthesis at the involved level(s). The Luna XD Interbody Fusion System is to be used with autogenous bone graft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion. Patients receiving the device should have had at least six months of non-operative treatment prior to receiving the Luna XD Implant. The Luna XD Interbody Fusion System is to be used with supplemental fixation.

CONTRAINDICATIONS

1. Active systemic or local infection in the proposed area of surgery.
2. Involved level is a revision of a previous intervertebral fusion procedure(s).
3. Known allergy to the device materials, especially nickel.
4. Severe osteoporosis, osteopenia, and/or osteomalacia.
5. A medical condition that interferes with postoperative management program.
6. Active malignancy.
7. Morbid obesity.
8. Grade II or greater spondylolisthesis or retrolisthesis at involved spine level.
9. DDD affecting three or more spine motion segments.
10. Abnormal anticoagulation status.
11. Any condition not described in the Indications for Use.

WARNINGS

The user should inspect the device for damage prior to use. If the device appears damaged, do not use. If a device appears damaged, discard or return to the manufacturer.

This device must be used with direct visualization. Failure to use direct visualization could result in serious patient injury. Failure to observe recommendations may contribute to serious patient injury.

Always carefully prepare the disc space by using appropriate tools to remove all nucleus material and prepare the endplates for fusion.

Always use Luna XD sizing paddles to determine the appropriate disc distraction height and to ensure the appropriate size of Luna XD Implant. Never attempt to advance the implant without the use of the Implant Inserter and Pusher Tool. Always use posterior fixation to supplement the Luna XD Implant.

Do not use a mallet on the Inserter or any of the Luna XD Instruments. Never apply force to the Inserter when the implant outer members are fully deployed. Do not manipulate (twist, rotate or translate) the Inserter while the Implant is out of the cannula. This may break the Implant.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. System components are temporary implants used for the correction and stabilization of the spine. Devices are intended to be used to augment the development of a spinal fusion by providing temporary stabilization. Devices are not intended to be the sole means of spinal support. Use of these products without a bone graft will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will occur.

Implantation of devices should be performed only by experienced surgeons with training in the use of the device. This is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of this device by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. The physician should consider the levels of implantation, patient weight, patient activity level, and all other patient conditions that may have an impact on the performance of this device. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

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

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, and warnings given in this document must be conveyed to the patient.

MAGNETIC RESONANCE ENVIRONMENT

Non-clinical testing has demonstrated that the Luna XD Implant is MR Conditional. A patient with this device can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 or 3 Tesla only
- Maximum spatial gradient magnetic field of 3,000 Gauss/cm (30 T/m)
- Maximum MR system reported, whole body average specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the Luna XD Implant is expected to produce a maximum temperature rise of 1.6°C after 15 minutes of continuous scanning (i.e., per pulse sequence).
In non-clinical testing, the image artifact caused by the Luna XD Implant extends approximately 7mm from the implant when imaged with gradient echo pulse sequence in a 3.0 Tesla system.

POSSIBLE ADVERSE EFFECTS

1. Early or late loosening of any or all components.
2. Disassembly, bending, and/or breakage of any or all components.
3. Loss of fixation (implant migration).
4. Foreign body (allergic) reaction to implants.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, persistent CSF leakage, meningitis.
8. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
9. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
10. Loss of bladder control or other types of urological system compromise.
11. Gastrointestinal, reproductive system compromise, including sterility, impotency and/or loss of consortium
12. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
13. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
14. Soft tissue injury, vertebral endplate injury, vascular or visceral injury.
15. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
16. Non-union (pseudo-arthrosis), delayed union, mal-union.
17. Hemorrhage of blood vessels and/or hematomas
18. Decrease in bone density due to stress shielding
19. Cessation of any potential growth of the operated portion of the spine.
20. Loss of or increase in spinal mobility or function.

21. Inability to perform the activities of daily living.
22. Death.

Additional surgery may be necessary to correct the occurrence of some of these possible adverse events.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Instruments must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. All implants and instrument should be inspected for wear and tear prior to use. Devices presenting damage such as cracks, corrosion, bends etc. should not be used. Compromised devices should be segregated and be returned to Spinal Elements.
7. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the product.
8. The type of implant to be used for the case should be determined prior to beginning the surgery.

INTRAOPERATIVE MANAGEMENT

1. Caution should be taken in handling the implants. Damage to the implants may affect their performance.
2. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. Use great care to ensure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct.
5. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower endplates being fused.
6. Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal fusion applications, and this material will make removal of the components, if necessary, difficult or impossible.
7. The following intra-operative requirements are important to prevent post-operative disassembly and retropulsion of Luna:
   - Correct choice of implant size such that implant is well compressed by endplates after expansion;
   - Proper positioning of Luna, biased anteriorly, with proximal end well within disc space;
   - Proper assembly of Luna with the middle member engaged with the outer members;
   - Complete deployment of the middle member to interlock with the outer members; and
   - Adequate posterior fixation.
8. If any of the aforementioned intra-operative requirements are not achieved, then removal and replacement of Luna should be strongly considered.
9. Never attempt to remove the Implant from a posterior approach without the use of the Luna Accessory Instrument Set. If posterior removal is not viable, the Implant can be removed as a whole cage from anterior or lateral approaches.
10. Use caution when removing the middle component of the Luna XD Implant, as the nitinol spine firmly maintains a circular shape. The middle component must be removed by pulling into a protective tube or cannula using the extraction instruments provided. In some cases, under extreme load conditions, the middle component may break during attempted removal. In those instances, the nitinol spine and the proximal middle portion securing the nitinol spine will be safely removed, but the remaining implant components must be removed in a fashion similar to static PEEK cages, such as breaking into pieces.
11. An imaging system must be utilized to facilitate surgery.
12. Implants should not be reused under any circumstances.

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity as determined by their surgeon. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be

increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.

3. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone healing process.
4. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction of body motion.
5. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible
7. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.

SINGLE USE

The single-use device is intended for single-use only. Single-use devices should not be reused. The reuse of the device could result in infection, cross-contamination from contact with blood, bone, tissue or other body fluids may lead to patient or user injury and/or failure of the device to perform in a safe manner as intended. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, serious injury, transmission of infectious agents and death.

SHELF LIFE

The product expiration date is indicated by the hourglass symbol on the product label. Use the device prior to the Use By Date noted on the package. **Caution**: Do not use sterile devices if the packaging providing the sterile barrier has been compromised.

STERILIZATION

The Luna® XD Implant and Pusher Tool are supplied sterile through gamma irradiation in peel open packages and are for single use only. The devices should not be re-sterilized. Do not use device if the package is damaged, opened, accidentally contaminated, or past the Use By Date listed on the package.

PYROGEN INFORMATION: Meets pyrogen limit specification of < 20 endotoxin units/device.

LUNA® GRAFT INJECTOR

GENERAL INFORMATION

The Luna® Graft Injector is a disposable instrument designed to deliver bone graft to the interior of the Luna XD Implant. The Loading Hopper is provided as an accessory to aid in loading bone graft into the Injector.

INDICATIONS

The Luna® Graft Injector is indicated for delivering bone graft to the interior of the XD Implant. The Luna Graft Injector is to be used with autogenous bone graft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

CONTRAINDICATIONS

1. Known allergy to the device materials—stainless steel, low-density polyethylene, and polycarbonate.
2. Any patient anatomy that does not allow for use of the device under direct visualization.
3. Any condition not described in the Indications for Use.

WARNINGS

The user should inspect the device for damage prior to use. If the device appears damaged, do not use. If a device appears damaged, discard or return to the manufacturer.
The physician shall be trained in the use of the device prior to surgery.
This device must be used with direct visualization. Failure to use direct visualization could result in serious patient injury.
Failure to observe recommendations may contribute to serious patient injury.
Do not use a mallet or hammer on the device.

POSSIBLE ADVERSE EFFECTS

1. Disassembly, bending, and/or breakage of any or all of the components.
2. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
3. Infection.
4. Dural tears, persistent CSF leakage, meningitis.
5. Soft tissue injury, vertebral endplate injury, vascular or visceral injury.
6. Non-union (pseudo-arthrosis), delayed union, mal-union.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of the device.
5. Devices should be received and accepted only in packages that have not been damaged or tampered with. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. All devices should be inspected for wear and tear prior to use. Devices presenting damage such as cracks, corrosion, bends etc. should not be used. Compromised devices should be segregated and be returned to Spinal Elements.

INTRAOPERATIVE MANAGEMENT

1. Caution should be taken in handling the devices. Damage to the devices may affect their performance.
2. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments may cause injury to the patient or operative personnel.
4. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower endplates being fused.
5. Bone cement should not be used; the safety and effectiveness of bone cement has not been determined for spinal fusion applications. Bone cement will make removal of the implant difficult or impossible.
6. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
7. Devices should not be reused under any circumstances.

POSTOPERATIVE MANAGEMENT

None

SINGLE USE

The single-use device is intended for single-use only. Single-use devices should not be reused. The reuse of the device could result in infection, cross-contamination from contact with blood, bone, tissue or other body fluids may lead to patient or user injury and/or failure of the device to perform in a safe manner as intended. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, serious injury, transmission of infectious agents and death.

SHELF LIFE

The product expiration date is indicated by the hourglass symbol on the product label. Use the device prior to the Use By date noted on the package. Caution: Do not use sterile devices if the packaging providing the sterile barrier has been compromised.

STERILIZATION

The Luna® Graft Injector is supplied sterile through gamma irradiation in peel open packages and are for single use only. The devices should not be re-sterilized. Do not use device if the package is damaged, opened, accidentally contaminated, or past the Use By date listed on the package.

PYROGEN INFORMATION: Meets pyrogen limit specification of < 20 endotoxin units/device**.**

LUNA® XD ACCESSORY INSTRUMENT SET

GENERAL INFORMATION

The Luna® XD Accessory Instrument Set is comprised of reusable surgical instruments that are intended to facilitate the delivery of the Luna XD Implant. The instruments are comprised of stainless steel, anodized aluminum, radel, and silicone components. The perforated instrument tray is comprised of anodized aluminum and has various silicone brackets and stainless steel hardware to hold the instruments in place during handling and storage. The reusable instrument set consists of the Luna

XD Sizing Paddles, SureGuide Graft Access System, Inserter Introducer, Inserter Ejector and Luna XD Extraction System. These instruments are designed to assist placement and removal of the Implant within the disc space to facilitate fusion when used in conjunction with posterior fixation and autogenous bone graft.

WARNINGS
Devices are provided non-sterile and must be cleaned and sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.

Unwrapped instrument trays DO NOT maintain sterility. Utilize an FDA-cleared sterilization wrap.

Universal Precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling instruments with sharp points or cutting edges to prevent cutting surgical gloves. Care should be taken to avoid penetrating or cutting injuries.

Follow instrument layout guide for placing instruments in their proper locations within the instrument tray. Insert the instruments completely into their respective silicone brackets for full security. Failure to do so can compromise the steam sterilization processing.

Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft bristled, nylon brushes and pipe cleaners should be used. Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on used devices. The effectiveness of subsequent decontamination processes depends on prior removal of gross soil as it may be impaired by dried or coagulated protein. Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used. Instruments must not be placed or soaked in Ringers Solution. Instruments should only be lubricated with biocompatible, water-soluble instrument milk that is compatible with steam sterilization (Miltex® or equivalent). Silicone lubricants should not be used because they coat microorganisms, prevent direct contact of the surface with steam, and are difficult to remove.

Instruments must be removed from instrument tray for recommended manual cleaning procedures. Instrument trays and lids must be cleaned separately. Stacking of instrument trays will adversely affect sterilization and drying effectiveness. DO NOT STACK trays in the autoclave chamber. DO NOT load instrument trays into the autoclave chamber on sides or upside down with the lid side on the shelf or cart. Load trays on cart or shelf so that the lid is always facing upward. This will allow for proper drying. The instrument trays are designed to drain in this position. DO NOT load any instruments into the instrument tray that are not intended for use with the Luna XD Accessory Instrument Set. This will adversely affect sterilization and drying effectiveness.

The associated reusable instruments of the Luna XD Interbody Fusion System—Sizing Paddles, SureGuide Graft Access Tube, Ejector Tool and Extraction System—are supplied non-sterile and must be steam sterilized at the surgical facility.

POSSIBLE ADVERSE EFFECTS
Potential risks associated with the use of the Luna XD Accessory Instruments are similar to those associated with any surgical instrument with the same intended use. The most frequent risks are:

1. Bleeding
2. Damage to the surrounding soft tissue
3. Infection

Additional risks associated with the use of the Luna XD Accessory Instruments, other than those described for surgery in general, may be instrument malfunction, such as:

1. Bending
2. Fragmentation
3. Loosening and/or breakage (whole or partial)
4. Breakage in the patient may increase surgical time since the instrument pieces should not be implanted.

CLEANING AND MAINTENANCE

CLEANING AND MAINTENANCE
Devices must be free of packaging material prior to cleaning. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Only neutral pH cleaners or detergents labeled for use in cleaning medical devices should be used for cleaning components. Only lubricants that are

intended for use on surgical instruments should be used to lubricate instruments. Check the action of moving parts to ensure smooth operation throughout the intended range of motion. Follow directions from the manufacturer of lubricating and cleaning agents regarding handling, concentration, and use of such agents.

Cleaning instructions are provided in accordance with recognized standards and regulations and are intended to supplement a hospital's existing device cleaning and disinfecting protocol. Contaminated devices should be wiped clean of visible soil at the point of use prior to transfer to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaned promptly after use per the instructions provided in this insert to minimize drying and ensure an effective cleaning.

POINT-OF-USE PREPARATION FOR REPROCESSING

1. Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.
2. Soaking in proteolytic enzyme solutions or other pre-cleaning solutions facilitates cleaning. These enzymatic solutions break down protein matter and prevent blood and protein-based materials from drying on instruments. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed.
3. For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.
4. Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

CLEANING AGENTS AND EQUIPMENT

1. Detergents: Mild enzymatic detergent (Enzol, Klenzyme or equivalent) should be used for gross soil removal. Neutral pH detergent (ValSure, Neutrad or equivalent) should be used with ultrasonic cleaners. Always refer to the manufacturer's recommendations for detergent preparation.
2. Water: Warm (38-49°C) tap water should be used for rinsing and cleaning. The quality of tap water should be considered as water hardness can leave deposits on instruments that may result in ineffective cleaning and decontamination. Reverse osmosis/deionized (RO/DI) water should be used for final rinsing.
3. Ultrasonic Cleaners: Ultrasonic cleaners are designed for fine cleaning of medical devices, not for disinfection or sterilization. They are used to remove soil from joints, crevices, cannulations and other difficult-to-access locations. Follow the manufacturer's recommendations. Be aware that loading patterns, water temperature, and other external factors may change the effectiveness of ultrasonic cleaning equipment.
4. Cleaning Tools: General purpose cleaning brushes, pipe cleaners, nonabrasive low-lint cloths, ultrasonic cleaner. Note: Brushes and pipe cleaners should have a tight fit but be able to move back and forth in the area being cleaned.
5. Lubricants: Biocompatible instrument milk (Miltex® or equivalent) should be used for lubricating instruments with moving parts.

MANUAL CLEANING INSTRUCTION

Follow the instructions listed below for manual cleaning prior to sterilization.

1. Rinse the Instruments under running tap water to remove gross soil. Actuate instruments while rinsing. Detach all handles and rinse under running tap water.
2. Prepare enzymatic detergent (Enzol, Klenzyme or equivalent) per manufacturer's recommendation at 1oz. per gallon of lukewarm tap water.
3. Fully immerse the instruments and detached handles and allow them to soak in the prepared detergent solution for a minimum of 10 minutes.
4. Following the soak time, brush the instruments with a soft-bristled brush. Use a lumen brush on the tubular instruments. Agitate the instruments in the solution while brushing.
5. Rinse the instruments under running tap water at 38-49°C and thoroughly flush all lumens, holes and other difficult-to-reach areas with a syringe.
6. Place the instruments in a warm (38-49°C) tap water bath and agitate for at least one (1) minute. Using fresh tap water at 38-49°C, repeat this step for a total of 3 rinses.
7. Prepare a neutral pH detergent (ValSure, Neutrad or equivalent) in a sonicator according to the manufacturer's recommendations at ½ oz. per gallon of warm (38-49°C) tap water.
8. Fully immerse the instruments and allow them to sonicate for twenty (20) minutes.
9. Thoroughly rinse the instruments under running reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry the instruments using clean, lint-free cloths.

INSPECTION, MAINTENANCE, TESTING AND LUBRICATION

1. Carefully inspect each instrument to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
2. Visually inspect for completeness, damage and/or excessive wear. If damage or wear is noted that may compromise the function of the instrument.
3. Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
4. The rotating and articulating instruments should be lubricated with an instrument product (e.g. Instrument Milk or equivalent lubricant) specifically designed for compatibility with steam sterilization.

STERILIZATION

Non-sterile instruments should be autoclave sterilized using the following validated cycle parameters.

Moist heat/steam sterilization is the recommended method for these reusable devices.

The instrument tray may be wrapped in standard, medical grade, steam sterilization wrap using the AAMI double wrap method or equivalent.

Sterilizer manufacturer recommendations should always be followed. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.

Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contract with all surfaces.

Ethylene oxide or gas plasma sterilization methods should not be used.

	Method	Cycle Type	Sterilization Temperature	Exposure Time	Dry Time
Wrapped	Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes

The sterilization parameters for wrapped instruments were validated per *ANSI-AAMI ST79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* These parameters were validated to a sterility assurance level (SAL) of 10^{-6}. 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 Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

INFORMATION

REF	Catalog Number	MAT	Material
LOT	Batch Code	QTY	Packaged Quantity
	Manufacturer		Date of Manufacture
	Do not resterilize		Do not use if package is damaged
	Caution, Consult Accompanying Documents		Do Not Re-Use
STERILE R	Sterilized using irradiation		Use-by date
NON-STERILE	Device Not Sterile	Rx Only	Prescription Only
MR	MRI Conditional		Keep Dry

ifu.spinalelements.com — Instruction for Use are provided electronically at ifu.spinalelements.com

Patents: patent.spinalelements.com

For additional information regarding any of Spinal Elements' devices, please contact Spinal Elements, Inc. Customer Service at (760) 607-0121.

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