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PRIMUS™ SPINAL FIXATION SYSTEM
IMPLANTS AND INSTRUMENTATION

This package insert covers the Primus Spinal Fixation System and Manual Surgical Instruments that are used for the implantation of this system. Specific sections for implants and instrumentation highlight important user information for only those devices.

GENERAL INFORMATION

Implants

Spinal Elements' Primus Spinal Fixation System is comprised of a variety of screws, hooks, rods, and connectors that are used for attachment to the non-cervical spine (T1-S1). System components are available in a multitude of sizes and configurations. A variety of constructs may be assembled to suit the individual pathology and anatomy of the patient. All implant components are made from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or ASTM F1472. Cobalt-Chrome Rods are made from cobalt chromium alloy (CoCr) conforming to ASTM F1537.

Spinal Elements' instruments are manufactured from various stainless steels, aluminums, and polymers. All materials used have a history of use in such instruments. All implants are intended for single patient use only and should not be reused (used in additional patients) under any circumstances. Reuse may result in serious injury or death. Components from this system should not be used in conjunction with components from other systems except those indicated below.

Navigation Instruments

Navigated instruments are manual surgical instruments manufactured from stainless steel, as specified in ASTM F899 or ASTM A564. Navigated instruments are non-sterile and are intended to be used with the Medtronic StealthStation® System.

INDICATIONS FOR USE

The Primus Spinal Fixation System is intended to provide immobilization and stabilization of the spine in skeletally mature patients as an adjunct to fusion for procedures of the thoracic, lumbar, and sacral spine (T1-S1). Screws may be placed from the thoracic spine through the sacral spine and into the ilium. This system is intended for anterior/anterolateral non-pedicle fixation, posterior non-pedicle fixation, and posterior pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

The Spinal Elements Primus Spinal Fixation System may be used in conjunction with the Spinal Elements Overwatch System. In order to achieve additional levels of fixation, the Primus or Overwatch Fixation Systems may be connected to the Lotus Posterior Cervical/Thoracic rod connectors. Transition rods with differing diameters may also be used to connect the Lotus Posterior Cervical/Thoracic Spinal System to the Primus or Overwatch Spinal Systems. Refer to the Lotus Posterior Cervical/Thoracic Spinal System package insert for a list of Lotus indications for use.

When used for posterior non-cervical pedicle screw fixation in pediatric patients the Primus and Overwatch implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Spinal Elements' fenestrated screws are intended to be used with saline or radiopaque dye.

These devices are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Spinal Elements Navigated Instruments are intended to be used during the preparation and placement of Spinal Elements Primus screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

CONTRAINDICATIONS

1. Patients with known or probable intolerance to the materials used in the manufacture of this device.

2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement especially in athletic and occupational activities.
4. Use with components from other systems.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
7. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
8. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
10. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not needing bone graft and fusion.
12. Any case not described in the indications for use.
13. Reuse or multiple use.
14. Any contraindications to the compatible Medtronic StealthStation System are applicable to the Primus Spinal Fixation System.

WARNINGS and PRECAUTIONS

Implants are provided both sterile and non-sterile. Implants provided sterile are sterilized through gamma irradiation. Do not re-sterilize implants provided sterile. Do not use sterile devices beyond their expiration date or if the packaging is damaged/ compromised. Devices provided non-sterile must be cleaned and sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert. Implants that have come in direct contact with a patient or bio-contaminants should be disposed of in accordance with biohazard regulations.

Some instruments may be sharp, depending on their intended use. Care should be taken in handling such instruments to avoid injury to the user or patient.

The safety and effectiveness of pedicle screw systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grade 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocations, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

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 or in cases that develop into a non-union 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.

Precaution: Implantation of pedicle screw spinal systems should be performed only by experienced surgeons with training in the use of spinal devices. 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 Primus modular screws may be assembled and disassembled during the procedure, when used in the same patient. It is recommended that the Primus modular tulips be assembled only once. If screws or tulips are used intraoperatively but not used in the final construct, the screws or tulips must be discarded. The Primus 6.0mm diameter rods will not mate with previously cleared Mercury/Overwatch tulips. These devices are single use and should not be reused. 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.

Note: Components of this system should not be used in conjunction with other systems unless specifically specified in this package insert.

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

1. Spinal Elements' Navigated Instruments are validated for use with the StealthStation S7 and S8 system and software version v2.1.0. Do not attempt to use Spinal Elements' Navigated Instruments with other models and software versions.

2. Spinal Elements is not a navigation software and system provider. Instructions for use and handling of third-party navigation systems are the responsibility of the hospital and navigation company. Refer to the navigation company's software and user guides for navigation guidance. The navigation system should be set up per the manufacturer's instructions.
3. Examine all instruments for damage and deterioration prior to use. Do not use any instruments that are damaged.
4. All instruments must be successfully verified and registered prior to use. Do not use instruments that have not been successfully verified and registered with navigation.
5. Navigation accuracy should be frequently assessed during the procedure. Place the tip of the instrument on an identifiable anatomical landmark and compare it to the location displayed on the screen. Discontinue use immediately if inaccuracy is suspected.
6. Care should be taken to limit bending forces on instruments during navigation as deflection can adversely affect navigation accuracy, cause serious injury to the patient, and damage the instruments. Discontinue use immediately if the instrument becomes damaged during the procedure.
7. Spinal Elements' instruments should only be used with Spinal Elements' implants. Do not attempt to use with other devices.
8. Refer to the Synergy Spine & Trauma Packet Guide for additional information regarding navigation.
9. Screw systems other than those indicated, should not be used with the Medtronic StealthStation System.

MAGNETIC RESONANCE ENVIRONMENT

The Primus Spinal Fixation System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Primus Spinal Fixation System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

POSSIBLE ADVERSE EVENTS

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Loss of fixation (implant migration).
4. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
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. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
13. Soft tissue injury, vascular, or visceral injury.
14. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
15. Non-union (pseudo-arthrosis), delayed union, mal-union.
16. Cessation of any potential growth of the operated portion of the spine.
17. Loss of or increase in spinal mobility or function.
18. Bone loss or decrease in bone density, possibly caused by stress shielding.
19. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
20. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
21. Inability to perform the activities of daily living.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death.

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

PREOPERATIVE MANAGEMENT

1. Verify that the StealthStation model and software version are correct. Spinal Elements' Navigated Instruments are validated for use with the StealthStation S7 and S8 software version v2.1.0.
2. The surgeon should consider for surgery only those patients indicated for the use of this device.
3. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
4. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
5. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
6. Device components 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.

7. All implants and instruments 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.
8. The type of implant to be used for the case should be determined prior to beginning the surgery.
9. All instruments and implants should be processed and sterilized prior to use.

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. Care should be taken during intraoperative forming of the rods. Sharp bends or notches in the rods may decrease their functional strength. Rods should not be repeatedly or excessively bent. Rods should never be reverse bent in the same location. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. If the rods are cut, cut them outside of the operative field. Whenever possible, it is recommended to use precut rods.
5. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
6. When the polyaxial head is at the limit of its angulation, care should be taken to ensure the head can properly accommodate the rod. The head should be perpendicular to the rod upon final-tightening.
7. Care should be taken when tapping or inserting screws. Proper size selection is critical. Incorrectly sized taps or screws may cause nerve damage, hemorrhage, or other possible adverse events listed in this package insert.
8. Always use supplied gauges to verify the sizes of screws to be implanted prior to implantation. Do not rely solely on markings or color coding on the implants.
9. Caution should be taken not to over-tighten implants, instruments, and interfaces between implants and instruments.
10. Before closing the soft tissue, all screws or locking/securing mechanisms should be tightened according to the operative technique.
11. Implants should not be reused under any circumstances.
12. The Primus modular screws may be assembled and disassembled during the procedure, when used in the same patient. The Primus modular tulips should only be assembled once. Implants assembled and not used in the final construct must be discarded.

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 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 the 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 tobacco or utilize nicotine products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as aspirin during the bone graft 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 in 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. The implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) corrosion, with localized tissue reaction or pain; (2) migration of implant position, possibly resulting in injury; (3) risk of additional injury from postoperative trauma; (4) bending, loosening and breakage, which could make removal impractical or difficult; (5) pain, discomfort, or abnormal sensations due to the presence of the device; (6) possible increased risk of infection; (7) bone loss due to stress shielding; and (8) potential unknown and/or unexpected long term effects such as carcinogenesis.

Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
7. Retrieved implants should be properly disposed of and are not to be reused under any circumstance.

SINGLE USE
Primus implants are single-use and should not be reused. If components have been assembled and disassembled during the procedure and are not used in the final construct, the components must be discarded. 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, serious injury, transmission of infectious agents and death.

Implants that come in direct contact with the patient or bio-contaminants should be discarded. Separate inserts for implants from the instrument tray prior to and during any processing.

SHELF LIFE
The product expiration date is indicated by the hourglass symbol on the product label. Product should not be used beyond the expiration date. Caution: Do not use sterile devices if the packaging providing the sterile barrier has been compromised.

CLEANING AND MAINTENANCE

All devices must be free of packaging material prior to sterilization. All instruments must be free of bio-contaminants prior to sterilization. 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. 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.

AUTOMATED CLEANING INSTRUCTIONS
All devices must be processed manually prior to automated cleaning. Follow the instructions below for the manual and automated washing.

PRE-AUTOMATED WASHER: MANUAL CLEANING
1. Disassemble all instruments that come apart for cleaning.
2. Rinse under running tap water to remove gross contamination. Use a syringe, wire guide and/or pipe cleaner (as appropriate to the presented cleaning challenge) to push debris out of lumens/cannulations or other hard to reach areas. Pay special attention to lumens of the external shafts of disassembled instruments.
3. Prepare Enzol® (or equivalent neutral or mild pH enzymatic cleaner) according to manufacturer recommendations using warm tap water. Fully immerse devices in the enzymatic cleaner solution and allow to soak for a minimum of 1 minute. While soaking, actuate the instruments through a full range of motion (as appropriate) to allow complete penetration of the cleaning solution. Instruments that do not disassemble may require additional soaking.
4. After the soak, remove the instruments and wipe any soil or debris using a disposable towel. Then, place the instruments into a fresh batch of enzymatic cleaning solution using warm water. Scrub the entire surface of the devices with a soft bristle brush paying particular attention to hard to reach areas such as mated surfaces. A syringe, wire guide, and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other hard to reach areas. A minimum of 60ml of detergent should be used when flushing lumens and cannulations. Ensure no soil is visible in the rinse stream.
5. Remove from enzymatic cleaner solution and rinse with reverse osmosis or de-ionized (RO/DI) water for a minimum of 30 seconds to remove any residual cleaner solution. Thoroughly and aggressively flush lumens, holes and other hard to reach areas with a minimum of 60ml of water.
6. Prepare Prolystica® (or equivalent neutral pH detergent) according to manufacturer recommendations using warm tap water in an ultrasonic bath. Fully immerse into the sonication bath and sonicate for a minimum of 10 minutes.
7. Remove from the detergent solution and rinse by agitating and actuating in RO/DI water for a minimum of 30 seconds to remove any residual detergent and until no sign of soil is seen in the rinse stream. While rinsing, thoroughly and aggressively flush lumens, holes and other hard to reach areas with a minimum of 60ml of water.

AUTOMATED CLEANING
8. Transfer the instruments into the washer for processing. Position the instruments to allow for proper drainage. Process per the cycle below. These are minimum validated parameters:

Phase	Recirculation Time	Water Temp	Detergent Type (if applicable)
Pre-wash	2 minutes	Cold tap water	N/A
Enzyme Wash	2 minutes	Hot tap water	Enzol or equivalent per manufacturer's instructions
Wash	2 minutes	65.5°C	Prolystica or equivalent per manufacturer's instructions
PURW Rinse	2 minutes	43°C	N/A
Drying	15 minutes	90°C	N/A

9. If needed, dry devices using a clean lint-free cloth. Pressurized air (20psi) may be used to assist in drying.
10. Visually examine devices to ensure all visible soil has been removed.
11. Once instruments pass visual inspection, reassemble devices that come apart for cleaning.
12. After cleaning, an instrument lubricant (i.e. Steris Hinge-Free® or equivalent) should be applied to moving devices to maintain fluid movement between components. Pay special attention to the instruments called out in system specific sections.

MANUAL CLEANING INSTRUCTIONS

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

1. Screwdrivers and Screw Inserters should be disassembled before cleaning.
   -To disassemble the Primus Polyaxial Screwdriver and Shank Driver, hold the instrument outer shaft in one hand. Depress the button on the outer shaft with the first hand while pulling the inner shaft axially away from the outer shaft with the second hand.
2. Rinse under running tap water to remove gross contamination. Use a syringe, wire guide, and/or pipe cleaner (as appropriate to the presented cleaning challenge) to push debris out of lumens/cannulations or other hard to reach areas. Pay special attention to the lumens of the external shafts of disassembled instruments.
3. Prepare Enzol® (or equivalent neutral pH enzymatic cleaner) according to manufacturer recommendations using warm tap water. Fully immerse devices in the enzymatic cleaner solution and allow to soak for a minimum of 20 minutes. After the soak, scrub devices with a soft bristle brush paying particular attention to hard to reach areas such as mated surfaces. A syringe, wire guide, and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other hard to reach areas. A minimum of 60ml of detergent should be used when flushing lumens and cannulations.
4. Remove from enzymatic cleaner solution and rinse with reverse osmosis/de-ionized (RO/DI) water for a minimum of three minutes to remove any residual cleaner solution. Thoroughly and aggressively flush lumens, holes and other hard to reach areas with a minimum of 60ml of water.
5. Prepare Prolystica® (or equivalent neutral pH detergent) according to manufacturer recommendations using warm tap water in an ultrasonic bath. Fully immerse into the sonication bath and sonicate for a minimum of 10 minutes.
6. Remove from the detergent solution and rinse with RO/DI water for a minimum of three minutes to remove any residual detergent and until no sign of soil is seen in the rinse stream. Thoroughly and aggressively flush lumens, holes and other hard to reach areas with a minimum of 60ml of water.
7. Repeat Steps 5 and 6.
8. Dry devices using a clean lint-free cloth. Pressurized air (20psi) may be used to assist in drying.
9. Visually examine devices to ensure all visible soil has been removed.
10. Once instruments pass visual inspection, reassemble devices that come apart for cleaning.
11. After cleaning, an instrument lubricant (i.e. Steris Hinge-Free® or equivalent) should be applied to moving devices to maintain fluid movement between components. All instruments with hinged or ratcheting mechanisms should be lubricated.

STERILIZATION

Implants and instruments are provided non-sterile and must be sterilized before use. Non-sterile implants and instruments should be autoclave sterilized using one of the following validated cycle parameters.

	Method	Cycle Type	Sterilization Temperature	Exposure Time	Dry Time
Wrapped	Steam	Gravity Displacement	270°F (132°C)	15 minutes	45 minutes
	Steam	Pre-vacuum	270°F (132°C)	10 minutes	60 minutes
Rigid Container	Steam	Pre-vacuum	270°F (132°C)	4 minutes	30 minutes
K-Wire Caddy	Steam	Pre-vacuum	270°F (132°C)	4 minutes	20 minutes

*Note: Rigid containers must have a minimum of 2 filters and require a 30-minute cool down period post sterilization.

Sterilization parameters were validated per *ANSI/AAMI/ISO 17665 Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices* and *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}. These sterilization cycles are not considered by the Food and Drug Administration to be standard sterilization cycles. 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).

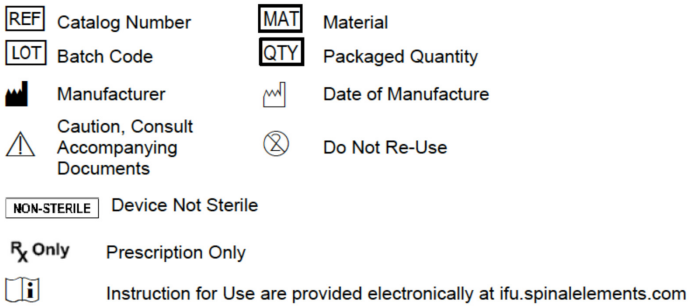
UDI CONSTRUCTION

To compile a unique device identifier (UDI) for reusable, reprocessed devices, the device identifier (GTIN) may be ascertained by searching for the part number in the FDA GUDID at https://accessgudid.nlm.nih.gov/. The production identifier(s) (e.g., lot number, serial number) may be found directly marked on the device.

COMPLAINT HANDLING/REPORTING:

All product complaints relating to safety, efficacy or performance of the product should be reported immediately to Spinal Elements Customer Service Department by telephone (760-607-0121 or 877-774-6255), email (customerservice@spinalelements.com), or letter (3115 S. Melrose Dr. Ste. 200 Carlsbad, CA 92010).
All complaints should be accompanied by name, part number, and lot numbers. The person formulating the complaint should provide their name, address, and as many details as possible. To request a hard copy of the surgical technique guide or this IFU please contact Customer Service at (760) 607-0121.

INFORMATION



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.