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## **CERVICAL SPINE IMPLANTS AND INSTRUMENTATION MOSAIC CERVICAL INTERBODY SYSTEM AND INSTRUMENTATION**

### **GENERAL INFORMATION**

Spinal Elements' Mosaic Cervical Interbody System is composed of a device body and fixation screws. The body is a generally box-shaped device with various holes located throughout its geometry and teeth on its external surfaces. The box-shaped body has projections (or flanges) that encompass screw holes. Screws pass through screw holes and affix to bone to help prevent implant migration.

Devices are available in a multitude of sizes. Device bodies are made from either titanium alloy (Ti-6Al-4V) conforming to ASTM F 136 or ISO 5832-3 or polyetheretherketone PEEK-Optima®) conforming to ASTM F 2026. Screws are made from Ti-6Al-4V per ASTM F 136 or ISO 5832-3. All implants are intended for single use only and should not be reused 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.

### **INDICATIONS**

The Mosaic device is an interbody fusion device intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to being treated with these devices.

The implant is designed to accommodate two, three, or four screws. The maximum number of screws should be used to ensure adequate fixation of the implant.

### **CLEANING AND MAINTENANCE**

1. Inserters and Spring-Loaded Awls should be disassembled before cleaning by compressing the button and removing the external shaft from the handle.
2. Follow the cleaning instructions listed in the Manual Surgical Instruments section of this insert. Pay special attention to the lumens of the external shafts of disassembled instruments and all guide sleeves.
3. An instrument lubricant should be applied to the ratchet teeth on the internal shaft of inserters and to the ratcheting mechanism of the Mosaic Gun after cleaning.
4. An instrument lubricant should be applied to all hinged instruments after cleaning.

### **INTRAOPERATIVE MANAGEMENT**

1. Flanged trials should be used prior to placement of the device body to ensure proper fit.
2. The device body should be attached to the corresponding inserter such that it is fully seated on the inserter.
3. The device body should not be axially rotated with the inserter once it has been implanted. This may lead to damage of the implant and/or the inserter.
4. If the surgeon experiences difficulty in inserting screws (i.e. hard bone, etc), drilling and/or tapping prior to screw insertion is recommended.
5. A drill guide should be used to limit the angle of drilling and subsequent insertion of screws. Insertion angles greater than what the drill guides allow may prevent adequate locking of the screw.
6. To help prevent screws from disassociating from the plate postoperatively, the screw locking mechanism of each screw should be engaged. The screw locking mechanism is activated by the clockwise rotation of the inset screw within the bone screw by the Breakaway Driver until an audible "click" is heard, indicating that the locking mechanism has been activated. To ensure that the locking mechanism has been activated, it is recommended to continue rotating the inset screw until a second audible "click" is heard.
7. Before the closing of the soft tissues, all screws should be secured to the device body by activating the locking mechanism as described.

## MANUAL SURGICAL INSTRUMENTS

### GENERAL INFORMATION

Spinal Elements' instruments are manufactured from various stainless steels, aluminums, and polymers. All materials used have a history of use in such instruments.

### WARNINGS

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.

### CLEANING AND MAINTENANCE

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.

Follow the instructions listed below for all instruments prior to sterilization.

1. Do not subject implants to cleaning.
2. Disassemble all instruments that come apart for cleaning. See system specific cleaning instructions to determine which instruments should be disassembled.
3. Rinse 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.
4. Prepare EnzyCare2® (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. A syringe, wire guide, and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other hard to reach areas.
5. 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. Flush all hard to reach areas.
6. Prepare Renu-klenz® (or equivalent neutral pH detergent) according to manufacturer recommendations using warm tap water. Fully immerse devices in the detergent solution and allow to soak for a minimum of 10 minutes. After the soak, scrub devices with a soft bristle brush paying particular attention to hard to reach areas. A syringe, wire guide, and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other hard to reach areas.
7. Remove from the detergent solution and rinse with RO/DI water for a minimum of three minutes to remove any residual detergent. Flush all hard to reach areas.
8. Prepare Renu-klenz® (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.
9. 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. Flush all hard to reach areas.
10. Repeat Steps 7 and 8.
11. Dry devices using a clean lint-free cloth. Pressurized air (20psi) may be used to assist in drying.
12. Visually examine devices to ensure all visible soil has been removed.
13. Once instruments pass visual inspection, reassemble devices that come apart for cleaning.
14. 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.

### GENERAL INSTRUCTIONS FOR USE

### 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 patient that has had prior fusion surgery at the levels to be treated.
7. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.

8. 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.
9. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
10. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
11. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
12. Any case not described in the indications for use.
13. Reuse or multiple use.

## **WARNINGS**

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

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.

Implantation of devices should be performed only by experienced spinal surgeons with specific training in the use of this 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 the 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. The use of allograft material may not give as good a result as pure autograft.

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, warnings, and precautions given in this document must be conveyed to the patient.

## **MAGNETIC RESONANCE ENVIRONMENT**

The Mosaic Cervical Interbody System 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 device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## **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. Damaged implants and/or instruments should not be used. All implants and instruments should be inspected prior to use. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. The type of implant to be used for the case should be determined prior to beginning the surgery.
7. All parts should be sterilized before 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. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.

5. Caution should be taken not to over-tighten threaded components, including instruments, implants, and interfaces between implants and instruments.
6. 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.
3. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.

### **POSSIBLE ADVERSE EFFECTS**

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.
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, vertebral endplate 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-arthritis), 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. Inability to perform the activities of daily living.
19. Death.

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

### **SINGLE USE**

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.

### **CLEANING AND MAINTENANCE**

#### *Implants:*

Implants are single use devices and should not be cleaned. Implants exposed to bio-contaminants should be disposed of. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation.

#### *Instruments:*

Instruments 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. Follow directions from the manufacturer of lubricating and cleaning agents regarding handling, concentration, and use of such agents.

### **STERILIZATION**

All 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

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

Sterilization parameters were validated per *ANSI/AAMI/ISO 17665-1: 2006. 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-AAM ST 79 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. These parameters were validated to a sterility assurance level (SAL) of 10<sup>-6</sup>. This sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. 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

 Catalog Number

 Material

 Batch Code

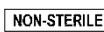
 Packaged Quantity

 Manufacturer

 Date of Manufacture

 Caution, Consult  
Accompanying  
Documents

 Do Not Re-Use

 Device Not Sterile

 Prescription Only

 Instruction for Use are provided electronically at [ifu.spinalelements.com](http://ifu.spinalelements.com)

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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.**