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 device body is comprised of three interlocking components, each with various holes located throughout its geometry and teeth on its external surfaces. The two-shaped hole features (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 ASTM F 1535 or polyetheretherketone (PEEK-Optima®) conforming to ASTM F 2626. Screws are made from Ti-6Al-4V per ASTM F 136 or ASTM F 1535. All implants are intended for single use only and should not be reused under any circumstances. Some may result in serious injury or death.

Indication-in-use statements are made so system this system should not be used in conjunction with components from other system.

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 degenerative origin with degeneration of the annulus fibrosis and/or vertebral endplate) or trauma. The device body and screws 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. Poope EnzymeCare® (or equivalent neutral pH enzymatic cleaner) according to manufacturer recommendations using warm tap water and soap. Fully immerse instruments in the enzymatic cleaner solution and allow to soak at room temperature for at least three minutes. After a minimum of 30 minutes to one hour, or as directed by the manufacturer, the instruments should be removed from the detergent solution and agitated for a minimum of 10 minutes. Algae, scum, debris, and soft tissue should be removed from the surface.
5. Poope Rima-klene® (or equivalent neutral pH detergent) according to manufacturer recommendations using warm tap water and soap. Fully immerse instruments in the detergent solution and agitate for a minimum of 10 minutes. Algae, scum, debris, and soft tissue should be removed from the surface.
6. Rinse from enzymatic cleaner solution and rinse with reverse osmosis-deionized (RODI) water for a maximum of three minutes to one hour or as directed by the manufacturer. Prior to sterilization, place instruments in the detergent solution and agitate for a minimum of 10 minutes. Rinse from detergent solution and rinse with RO water for a minimum of 10 minutes. Algae, scum, debris, and soft tissue should be removed from the surface. Soft tissue injury, vertebral endplate injury, vascular or visceral injury.

Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to surgery. 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. Insect, arachnid, and unidentified Arvus should be disassembled before cleaning by contact with the bone and removing the external shell 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 shells of disassembled and assembled instruments, the threads of the handles, and the inserts.
3. An instrument lubricant should be applied to the ratchet teeth on the internal sliding screw and to the endpling mechanism of the Mosaic Gun after cleaning.
4. An instrument lubricant should be applied to all metal instruments after cleaning.

INTRAOPERATIVE MANAGEMENT

1. Only trials should be used prior to placement of the device body to ensure proper fit.
2. The device body should be fastened to the corresponding insert such that it is fully seated on the insert.
3. The device body should not be axially rotated with the inserted insert once it has been implanted. This may result in improper seating or the insert.
4. If the surgeon experiences difficulty in inserting screws (i.e. hand, 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 screws.
6. To help prevent screws from disassociating from the plate postoperatively, the screws should be driven sufficiently that each screw should be engaged. The screw locking mechanism is activated by the clockwise rotation of the inner surface of each screw. The locking mechanism Driver until an audible “click” is heard, indicating that the locking mechanism has been activated. To avoid rethreading the screws, 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.
8. The surgeon should consider for surgery only those patients indicated for surgery and that have not been damaged or tampered with. Damaged implants and 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.

Patients with components from this device should be determined prior to beginning the surgery.

Postoperative

1. Caution should be taken in handling the implants. Damage to the nerves will cause loss of neurological functions.
2. Damage to the spinal cord would cause loss of neurological functions.
3. Soft tissue injury, vertebral endplate injury, vascular or visceral injury.

Postoperative patients should be instructed to limit activity as determined by their surgeon.

1. Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to surgery. 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.

2. An instrument lubricant should be applied to the ratchet teeth on the internal sliding screw and to the endpling mechanism of the Mosaic Gun after cleaning.

3. 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 screws.

4. To help prevent screws from disassociating from the plate postoperatively, the screws should be driven sufficiently that each screw should be engaged. The screw locking mechanism is activated by the clockwise rotation of the inner surface of each screw. The locking mechanism Driver until an audible “click” is heard, indicating that the locking mechanism has been activated. To avoid rethreading the screws, it is recommended to continue rotating the inset screw until a second audible “click” is heard.

5. Before the closing of the soft tissues, all screws should be secured to the device body by activating the locking mechanism as described.

6. The type of implant to be used for the case should be determined prior to surgery. The surgeon should consider for surgery only those patients indicated for surgery and that have not been damaged or tampered with. Damaged implants and 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.

7. Any medical or surgical condition which would preclude the patient’s participation in the benefits of spinal implant surgery.

8. Rapid joint disease, bone absorption, osteopenia. Osteopenia is a relatively non-inflammatory, osteoporotic condition which may limit the degree of compressible, or deformed, bone.

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 variational force over the operative site or inadequate bone stock.

11. A patient in which improper technique would interfere with anatomical structure or expected physiological performance.

12. Reuse or multiple use.

WARNINGs

Implants are intended for single use only and should not be reused under any circumstances. Some may result in serious injury or death.

Postoperative Management

1. Patients 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. Reuse of a single use device that has come in contact with blood, bone, tissue, or other material may not give as good a result as pure autograft.

3. Infection.

4. Paralysis, malignant vertebral body collapse, or other serious adverse event.

5. Spinal fluid leak (or equivalent neutral pH detergent) according to manufacturer recommendations using warm tap water and soap. Fully immerse instruments in the detergent solution and agitate for a minimum of 10 minutes. Algae, scum, debris, and soft tissue should be removed from the surface. Soft tissue injury, vertebral endplate injury, vascular or visceral injury.

Herniated nucleus pulposus, disc disruption or degeneration at or above, or below the level of the surgery.

6. Any patient having variational force over the operative site or inadequate bone stock.

7. Loss of or increase in spinal mobility or function.

8. Failure to carry out the activities of daily living.


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

SINGLE USE

1. Reuse of a single use device that has come in contact with blood, bone, tissue, or other material may not give as good a result as pure autograft.

2. Use of products without a home grill or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads within the range of the forces involved in lifting, bending, loosening, and/or breakage of the device(s) will occur.

3. Any patient having variational force over the operative site or inadequate bone stock.

4. Soft tissue injury, vertebral endplate injury, vascular or visceral injury.

5. Paralysis, malignant vertebral body collapse, or other serious adverse event.

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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.

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle Type</th>
<th>Sterilization Temperature</th>
<th>Exposure Time</th>
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<tr>
<td>Wrapped</td>
<td>Steam Gravity</td>
<td>270°F (132°C)</td>
<td>15 minutes</td>
<td>45 minutes</td>
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<td></td>
<td>Pre-vacuum</td>
<td>270°F (132°C)</td>
<td>10 minutes</td>
<td>60 minutes</td>
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<td>Rigid Container</td>
<td>Steam Pre-vacuum</td>
<td>270°F (132°C)</td>
<td>4 minutes</td>
<td>30 minutes</td>
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*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 Sterilisation of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilisation Process for Medical Devices and ANSI-AAMI ST 79 – Comprehensive guide to steam sterilisation and sterility assurance in healthcare facilities. These parameters were validated to a sterility assurance level (SAL) of 10^-6. 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

<table>
<thead>
<tr>
<th>REP</th>
<th>Catalog Number</th>
<th>MAT</th>
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<td>NON-STERELE</td>
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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.

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