DIAMOND™ CERVICAL PLATE SYSTEM

This package insert covers the Diamond™ Cervical Plate 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

The Diamond™ Cervical Plate System is a plate and screw system composed of medical grade titanium per ASTM F136 (Ti-6Al-4V ELI) and nitinol (NiTi) components per ASTM F2063. Titanium fixed, and variable angle screws are available in various diameters and lengths. The titanium plate contains integrated locking washers composed of nitinol. These washers secure the bone screws into the plate. The system is intended to provide mechanical support to the implanted level until biologic fusion is achieved. Various instruments are available to facilitate the implantation of the device. The instruments are made from stainless steel per ASTM F899. The handles of certain instruments are made from Radel R-5500 per ASTM D6394.

INDICATIONS

The Diamond™ Cervical Plate System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Spondylolysis
- Spinal Stenosis.

CONTRAINDICATIONS

1. An active infection
2. Suspected or documented allergy to titanium or nitinol materials

WARNING

THIS DEVICE IS NOT APPROVED FOR SCREW ATTACHMENT OR FIXATION TO THE POSTERIOR ELEMENTS (PEDICLES) OF THE CERVICAL, THORACIC OR LUMBAR SPINE. Never reuse an implant under any circumstances. Even when a removed device appears undamaged, it may contain small defects or residual stresses. These defects and stresses may lead to implant failure. Any retrieved devices should be handled in a manner such that they may not be reused in another surgical procedure.

Note: Titanium and stainless-steel components should not be used together.

Implants and instruments are provided non-sterile. Instruments must be cleaned and sterilized before use. Implants may be processed prior to use and must be 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.

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.

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

LB-006 Rev 20190716
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.

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 (used in additional patients) under any circumstances.
7. Forming or bending of the plates should be kept to a minimum. Bending of the plate near the screw holes should be avoided. Distortion of the screw holes may prevent proper locking of the screw. If bending of the plate is performed, only benders supplied with the system should be used for such bending. Notching of the plate may reduce its fatigue life. Care should be taken to avoid bending the plate multiple times in the same location.
8. If the surgeon experiences difficulty in inserting screws (hard bone, etc.), drilling and/or tapping prior to screw insertion is recommended.
9. A drill guide should be used to limit the angle of drilling and subsequent insertion of screws. Insertion angles greater than what drill guides allow may prevent adequate locking of the screw.
10. 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.
11. Before the closing of the soft tissues, all screws should be secured to the plate by activating the locking mechanism as described.

POSTOPERATIVE MANAGEMENT
1. Anterior cervical plate implant components are for temporary internal fixation during the formation of a spinal fusion. Implants are not meant to support a load for an indefinite period. After the formation of a fusion, the device may be removed.
2. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
3. Postoperative patients should be instructed to limit activity as determined by their surgeon.
4. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.
MAGNETIC RESONANCE ENVIRONMENT
These systems have not been evaluated for safety and compatibility in the MR environment. They have 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.

POSSIBLE ADVERSE EFFECTS
Possible adverse events or complications associated with the Diamond™ Cervical Plate System may include, but are not limited to:
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
20. Failure to relieve symptoms
21. Dysphagia
22. Degeneration at adjacent level

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.

PACKAGING
Packages for each of the components should be intact upon receipt. Damaged packages and products should not be used and should be returned to Spinal Elements.

Recommended Cleaning and Sterilization Procedures for Diamond™ System

Method: Manual Cleaning and Steam Sterilization

Device(s): Trays/Implants/Instruments
**CAUTIONS:**

<table>
<thead>
<tr>
<th>The Diamond™ Cervical Plate System components provided NON-STERILE should be cleaned and sterilized before use, unless the individual packaging states otherwise. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended. Cleaning agents with chlorine or chloride as an active ingredient are corrosive to stainless steel and should not be used. Saline solution has a corrosive effect on stainless steel and should not be used. Use only neutral pH cleaning agents and detergents. Diamond™ implants are single use. Therefore these guidelines are not intended for USED Diamond™ spinal implants or DISPOSABLE, single use instruments. The Diamond™ Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. The Diamond™ Cervical Plate System has not been tested for heating or migration in the MR environment.</th>
</tr>
</thead>
</table>

**Limitations on Reprocessing:**

<table>
<thead>
<tr>
<th>Repeated processing has limited effect on REUSABLE instruments. End of life is normally determined by wear and damage due to use.</th>
</tr>
</thead>
</table>

**INSTRUCTIONS**

**Point of use:**

Use clean flowing water and disposable wipes to remove excess soil. Reprocess instruments as soon as possible to prevent body fluid and tissue from drying on instruments prior to cleaning.

**Preparation for decontamination:**

Disassemble all components to provide maximum exposure for cleaning.

**Cleaning - Automated**

Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated system may be used as a follow-up method to manual cleaning.

**Cleaning - Manual**

1. Disassemble all components before cleaning.
2. Completely submerge instruments in enzyme solution and allow to soak for a minimum of 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, and appropriately sized soft-bristled brush (e.g. pipe cleaner brush).
3. Remove the devices from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
4. After manual cleaning, and all visible blood, soft tissue, and bone have been removed ultra-sonic cleaning may be used. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for a minimum of 10 minutes at 45-50 kHz.
5. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas. Use de-ionized water for final rinse of all components.
6. Repeat the sonication and rinse steps above until all visible contamination has been removed.
7. Thoroughly and promptly, remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe. Allow the tray and components to dry for a minimum of 15 minutes. The tray and components must be thoroughly dry prior to sterilization cycle.
**Disinfection:**
Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments.

**Maintenance, inspection, and testing:**
Carefully inspect each device to ensure that all visible blood and soil have been removed. Inspect lumens to confirm that all foreign material has been removed. Visually inspect for damage and/or wear. Note: If any damage or wear is noted that impairs the function of the instrument, contact your Spinal Elements representative for a replacement.

**Sterilization:**
Visually inspect all components for any remaining debris prior to sterilization. The Diamond™ Cervical Plate System components provided NON-STERILE should be autoclave sterilized using the sterilizer manufacturer’s instructions and the institution’s procedures for ensuring sterility. The sterilization cycle should occur in a calibrated autoclave.

Diamond™ Cervical Plate System components should be sterilized utilizing a pre-vacuum steam autoclave for a minimum of 5 minutes at 270°F (132°C). The 5 minute, 270°F pre-vacuum steam 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).

**Drying:**
A minimum drying time of 20 minutes, after sterilization, is recommended. Drying times may vary according to load size and should be increased for large loads. Dry, thoroughly and promptly, after both cleaning and sterilization.

**Storage:**
Store components in a clean, dry, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and extremes in humidity and temperature.

The instructions provided above have been validated by Spinal Elements as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the re-processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

<table>
<thead>
<tr>
<th>REF</th>
<th>Catalog Number</th>
<th>MAT</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Batch Code</td>
<td>QTY</td>
<td>Packaged Quantity</td>
</tr>
<tr>
<td></td>
<td>Manufacturer</td>
<td></td>
<td>Date of Manufacture</td>
</tr>
<tr>
<td></td>
<td>Caution, Consult Accompanying Documents</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NON-STERILE</th>
<th>Device Not Sterile</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Instruction for Use are provided electronically at ifu.spinalelements.com</td>
</tr>
</tbody>
</table>

© 2019 Spinal Elements Inc.
Patents: patent.spinalelements.com

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