Diamond™ Cervical Plate System
PACKAGE INSERT

CAUTION: Federal law (USA) restricts these devices to the sale by or on the order of a physician. Implants and disposable instruments single use only.

Description:
The Diamond™ Cervical Plate System is a plate and screw system composed of medical grade titanium (Ti-6A-l4V ELI) and nitinol (NiTi) components. 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.

Indications for Use:
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
- Spondylolisthesis
- Spinal Stenosis.

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.

Contraindications include, but are not limited to:

- An active infection
- Suspected or documented allergy to titanium or nitinol (nickel and titanium alloy) materials

Precautions:

- A successful result is not always achieved in every surgical case. Surgeons should not implant the Diamond™ Cervical Plate until receiving adequate training regarding surgical technique. Inadequate training may result in poor patient outcomes and/or increased rates of adverse events. See the Diamond™ Cervical Plate Surgical Technique Manual for more information on proper implantation technique.
- Fatigue testing of the Diamond™ Cervical Plate cannot guarantee device performance in patients. Patient selection is important to minimize device failure.
- 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.
- Titanium and stainless steel components should not be used together.

Possible Adverse Effects:
Possible adverse events or complications associated with the Diamond™ Cervical Plate System may include, but are not limited to:

- Implant breakage
- Implant migration
- Revision, removal or supplemental fixation of original implant
- Failure to relieve symptoms
- Dysphagia
- Nerve damage leading to decrease or loss of sensory and/or motor function, or paralysis

- Pseudarthrosis
- Vocal paresis
- Vertebral body damage
- Degeneration at adjacent level
- Anesthesia or other drug reactions
- Incision related issues
- Bleeding, significant blood loss
- Pneumonia
- ARDS
- Atelectasis
- Thrombophlebitis
- Emboli
- Heart attack
- Stroke
- Nerve or soft tissue damage
- Death

Material Specification: The material used for the Diamond™ Cervical plates and screws is a titanium alloy (Ti6-Al-4V-ELI) per ASTM F136. These plates and screws are titanium anodized. The washer contained in the plate is made from Nitinol-SE per ASTM F2063. The instruments are made from stainless steel per ASTM F899. The handles of certain instruments are made from Radel R-5500 per ASTM D6394. No warranties, expressed or implied, are made.

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 AMENDIA.

Sterilization:
Products not clearly marked as sterile should be assumed non-sterile.

For Sterile Implants and Instruments:
Implants and instruments provided sterile will be clearly labeled as such in an unopened sterile package provided by AMENDIA. The contents are considered sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised. Implants supplied sterilized from AMENDIA must **not** be re-sterilized.

For Non-Sterile Implants and Instruments:
Implants and instruments used in surgery not clearly labeled as sterile must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization where applicable.

Only sterile products should be placed in the operative field.

Product Complaints: Any Health Care Professional (e.g. customer or user of this system of product), who has any complaints or who has experienced and dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor. Further, if a Diamond™ Cervical Plate System ever "malfunctions", (i.e. does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Company device ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Manufacturer: AMENDIA, 1755 West Oak Parkway, Marietta, GA 30062, 877-755-3329 (Toll Free), 770-575-5200 (Main), 877-420-1213 (Fax)

Recommended Sterilization Procedures for Diamond™ System Provided Non-Sterile:

Manufacturer: Amendia, Inc.

Method: Manual Cleaning and Steam Sterilization

Device(s): Trays/Implants/Instruments

CAUTIONS:	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.
Limitations on Reprocessing:	Repeated processing has limited effect on **REUSABLE** instruments. End of life is normally determined by wear and damage due to use.

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.

Disinfection:	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 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 Amendia representative for a replacement.
Packaging:	This set of components may be loaded into a dedicated tray, supplied by the manufacturer, for sterilization.
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° 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 Amendia 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.

Amendia
The Elements of Healing

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