CERVICAL PLATE

INSTRUCTIONS FOR USE

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

DEVICE DESCRIPTION

The Cervical Plate spinal internal fixation device made from titanium alloy (all components are made from ASTM F-136). It is provided in a variety of sizes ranging from 20mm to 110mm in length, and accommodating fusion of one to four levels of the cervical spine. Two screws may be affixed to each vertebral body associated with the spinal fusion.

All plates, regardless of length have a nominal thickness of 1.85mm and width of 18mm. Screws are provided in 4.0mm and 4.5mm diameters and in fixed and variable angle styles.

Screws are prevented from backing out of the plate by attaching a separate locking mechanism. The mechanism is either a lock washer, consisting of a set screw attached to a washer, or a lock cover, which is a solid screw whose head captures both bone screws at the level of application.

INDICATIONS

The Cervical Plate is intended for anterior screw fixation to the cervical spine (C2-C7) *for immobilization and stabilization as an adjunct to fusion in skeletally mature patients* for the following indications:

- Degenerative disc disease (DDD, defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Spondylolisthesis
- Spinal stenosis
- Tumors (primary and metastatic)
- Failed previous fusions
- Pseudoarthrosis
- Deformity (i.e. kyphosis, lordosis, and/or scoliosis).

CONTRAINDICATIONS

-Severe osteoporosis
- Any indication where fusion is not required

WARNINGS

• Use as indicated. The safety and effectiveness when implanted in the spine for any other indications has not been established.
• Do not use this device with components from another system.
• Do not implant this device in a manner in which it is in contact with dissimilar metals, as accelerated corrosion may occur.

PRECAUTIONS

• Use of the Cervical Plate should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics; has had experience with anterior cervical fusion procedures and anterior cervical fixation; and has had hands-on training in the use of this device.

• The surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
• The Cervical Plate is supplied non-sterile. It must be sterilized before use.
• Implant components can break when subjected to the increased loading associated with delayed union or nonunion.
• Patients with previous spinal surgery at the level to be treated may have different outcomes compared to those without previous surgery.

The following potential adverse events (singly or in combination) could also result from the implantation of the Cervical Plate:

1. Dysphagia or dysphonia.
2. Decrease in bone density due to stress shielding.
3. Degenerative changes or instability of segments adjacent to fused vertebral levels
4. Fracture of bony structures.
5. Implant material sensitivity, or allergic reaction to a foreign body.
6. Infection, early or late.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, radicular pain, tethering of nerves in scar tissue, muscle weakness, headaches, dural tears, and paraesthesia.

8. Nonunion, delayed union.
9. Discomfort, or abnormal sensations due to the presence of the device.
10. Paralysis.
11. Spinal cord impingement or damage.
12.Vascular damage could result in catastrophic or fatal bleeding, airway compromise or stroke.
13. Early or late loosening of any or all of the components.
14. Disassembly, bending, and/or breakage of any or all of the components.
15. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
16. Change in mental status.
17. Death.

Additional surgery may be necessary to correct some of these anticipated adverse events.

INFORMATION FOR PRESCRIBERS
• Correct selection of the appropriate implant size is important.
• Surgical implants must never be reused or re-implanted. Even though the device appears undamaged, it may have defects and internal stresses that may lead to early breakage.

HOW SUPPLIED
The Cervical Plate is supplied non-sterile.

RECOMMENDATIONS FOR STEAM STERILIZATION:
The individual products are recommended to be steam sterilized by the hospital in a gravity-displacement autoclave cycle at 270∞F (132∞C) for a minimum of 3 minutes exposure time with a 1 minute drying time.

Using a prevacuum cycle, an exposure time of 4 minutes at 132°C (270 °F) should be the minimum used, followed by a drying time of at least 20 minutes. Please note that drying times will be variable for different conditions, steam quality, total mass in the sterilizer, and varying cool down time. The user should perform inspections to confirm that products have been appropriately dried, and adjust drying time if required. Only FDA-cleared wraps should be used. Additionally the user should adhere to their standard sterilization validation procedures

The fully loaded implant and instrument trays are recommended to be steam sterilized by the hospital using an FDA cleared wrap in a gravity-displacement autoclave cycle at 270∞F (132∞C) for a minimum of 15 minutes of exposure with a 30 minute drying time.

These sterilization recommendations follow the guidelines for sterilization per ANSI/AAMI ST79.

Remove all packaging materials prior to sterilization.

Use only sterile products in the operating field.

CLEANING AND DECONTAMINATION
Any instruments and implants that have been taken into a sterile field must be decontaminated and cleaned before re-sterilizing and re-introducing them into a sterile surgical field.

- Remove all gross visible soil with a damp gauze pad or wipe.
- Prepare an enzymatic cleaning solution per the manufacturer's instructions. Immerse the instruments in the cleaning solution.
-No instruments require disassembly. However, the awls and drill guides should be inspected carefully, as tissue may become lodged between the sleeve and the awl or in the barrels of the drill guides. Tissue may be removed by extending the awl tip from the sleeve. Additionally, multiple flush ports are located in the awl sleeve to facilitate cleaning. The drill guide barrels may be flushed and/or scrubbed with a small diameter nylon brush.
- Ultrasonically clean the instruments for while immersed in the cleaning solution for at least 15 minutes.
-Transfer the instruments to fresh enzymatic cleaning solution. Thoroughly scrub the instruments with a soft bristle cleaning brush while immersed in the solution. Scrubbing must also include any lumens with an appropriate sized round brush.
-Thoroughly clean the instruments.
-Rinse all instruments with warm running water and dry with a clean cloth and/or allow to air dry.

-Verify that all instruments are visually clean. If not, repeat the cleaning process from the beginning until they are clean.

Please note that certain cleaning solutions, such as those containing formalin, glutaraldehyde, caustic soda, bleach, or alkaline cleaners may damage some device, particularly some instruments and instrument trays. These solutions should not be used.

MRI COMPATIBILITY:
"The Teslake Cervical Plate has not been evaluated for safety and compatibility in the MR environment. The Teslake Cervical Cage has not been tested for heating or migration in the MR environment."

PACKAGING:
The implants are delivered in packages. These must be intact at the time of receipt.

The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially-designed storage boxes.

SURGICAL TECHNIQUE MANUAL:
To view or download the surgical technique manual, please visit www.teslake.com.

MANUFACTURED BY:
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