ANTERIOR CERVICAL PLATE SYSTEM

GENERAL DESCRIPTION
The Choice Spine Classic Anterior Cervical Plate (ACP) System is intended for anterior screw fixation to the cervical spine. The system consists of a variety of shapes and sizes of bone plates and screws. The components are manufactured from titanium alloy (Ti-6Al-4V ELI as described by ASTM F136). The Choice Spine Classic ACP System components are provided clean and non-sterile. The products must be steam sterilized by the hospital prior to use.

INDICATIONS FOR USE
The Choice Spine Classic ACP System is indicated for use in the temporary stabilization of the anterior cervical spine (levels C2 to C7) during the development of cervical spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

CONTRAINDICATIONS
Contraindications for the Choice Spine Classic ACP System are similar to those of other systems of similar design, and include, but are not limited to:
1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
2. Morbid obesity.
4. Grossly distorted anatomy due to congenital abnormalities.
5. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
6. Rapid joint disease, bone absorption, osteopenia, osteomalacia, or osteoporosis. Osteopenia or osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
7. Suspected or documented metal allergy or intolerance.
8. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
9. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions.
10. Any time implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not needing a bone graft and fusion or where fracture healing is not required.

WARNINGS AND PRECAUTIONS
The Choice Spine Classic ACP System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Further, the proper selection and compliance of the patient will greatly affect the results. The surgeon should consider the patient conditions (e.g., smoker, malnutrition, obesity, alcohol and drug abuse, poor muscle and bone quality), which may impact system performance.
The Choice Spine Classic ACP System is only a temporary implant used for the correction and stabilization of the cervical spine. The system is also used to augment the development of a spinal fusion by providing temporary stabilization. This system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the Choice Spine Classic ACP System is utilized. Use of this product without a bone graft or in cases that develop into a nonunion will not be successful. The spinal implant cannot stand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device will eventually occur.

The Choice Spine spinal systems have not been tested for safety and compatibility in the MR environment. The Choice Spine spinal systems have not been tested for heating or migration in the MR environment.

**Preoperative:**
A successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are critical considerations in achieving a successful result.

Only patients that meet the criteria described in the indications should be selected. Patient conditions and/or predispositions such as those mentioned in the contraindications should be avoided.

Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.

The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.

All components and instruments must be cleaned and sterilized prior to use. Additional sterile components should be available in case of unexpected need.

Prior to surgery, the patient must be informed of all potential risks and adverse effects contained in the present instructions for use.

**Intraoperative**
The vertebral levels to be fixated should be well visualized with a linear anterior surface so that the plate will mount flush with the anterior cervical spine. The Choice Spine Classic Anterior Compact Plate comes with a standard lordotic curve. When the configuration of bone cannot be fitted with an available temporary fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent more than absolutely necessary. The components should not be reverse bent at the same location. Bending near the screw holes should be avoided.

The surgeon should follow established practices and specific instructions for implant of the system. Whenever possible or necessary, an imaging system should be utilized to verify proper component placement.
Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.

Always orient the Anterior Cervical Plate as close as possible to the spinal midline.

The appropriately sized plate should be selected with the plate holes directly anterior to the vertebrae to be fused.

Before closing the soft tissues, all of the set screws should be tightened firmly. Recheck the tightness of all set screws after finishing to make sure that none loosened during the tightening of the other set screws. Failure to do so may cause loosening of the other components.

Caution should be taken not to over-tighten threaded components.

Bone grafts must be placed in the area to be fused. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat from the curing process may cause neurological damage and bone necrosis.

Some degree of corrosion occurs on all implanted metal and alloys. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.

Different manufacturers use different materials, varying tolerances and design configurations. Components of the Choice Spine Classic ACP System must not be used with components from any other system or manufacturer.

This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

**Postoperative**

The physician’s post-operative directions and warnings to the patient and the corresponding patient compliance are extremely important.

Detailed instructions on the use and limitations of the device should be given to the patient. The patient should be instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent restriction in body motion. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.

If a non-union develops or the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the device(s).

After the spine is fused, these devices serve no functional purpose and should be removed. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain, (2) Migration of implant position possibly resulting in injury, (3) Risk of additional injury from postoperative trauma, (4) Bending, loosening and/or breakage, which could make removal impractical or difficult, (5) Pain, discomfort, or abnormal sensations due to the presence of the device, (6) Possible increased risk of infection, and (7) bone loss due to stress shielding. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant.
Due to the presence of implants, image artifacts with roentgenographic, CT, and/or MR imaging may result.

Implants must not be reused. Any implant, once used, should be discarded even though it may appear undamaged.

**POTENTIAL COMPLICATIONS AND ADVERSE EFFECTS**

Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and include, but are not limited to:

1. Early or late loosening of the components
2. Disassembly, bending or breakage of any or all of the components
3. Foreign body (allergic) reaction to the implants
4. Infection
5. Non-union (pseudarthrosis)
6. Loss of neurological function, including paralysis (complete or incomplete), radiculopathy, dysesthesia, hyperesthesia, anesthesia, paresthesia, development or continuation of pain, numbness, neuroma, tingling sensation, dural tears, neuropathy, neurological deficits (transient, permanent, or delayed), reflex deficits, bilateral paraplegia, and/or arachnoiditis
7. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, or wound dehiscence
8. Misalignment of anatomical structures or loss of spinal mobility
9. Bone graft donor complications including pain, fracture or wound healing problems
10. Atelectasis
11. Retropulsion of graft
12. Cessation of any potential growth of the operated portion of the spine
13. Injury to the neck, including the esophagus, trachea, carotid artery, larynx, or laryngeal nerves
14. Early or late hoarseness, dysphagia, or dysphonia
15. Vascular damage resulting in excessive bleeding.
16. Loss or impairment of bowel, sexual, and/or bladder function and other types of urological compromise.
17. Fracture, damage, degenerative changes or instability of any bone above and/or below the level or surgery.
18. Gastrointestinal system compromise
19. Bone loss due to resorption or stress shielding
20. Death

Additional surgery may be necessary to correct some of these potential adverse effects.

**PACKAGING**

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to Choice Spine, Inc.

**IMPLANT PROCESSING**

These recommendations are for processing non-sterile Choice Spine Classic ACP System components. The information applies to unused and non-contaminated implants only. Explanted implants must never be reprocessed and should be handled according to hospital protocol upon removal. Any implant that has not been used, but has become contaminated, should be handled according to hospital protocol. Choice Spine does not recommend the reprocessing of contaminated implants.

The Choice Spine Classic ACP System components are provided non-sterile and must be sterilized prior to use. The sterilization parameters are only valid for devices that are adequately cleaned.
**Processing**
The following cleaning guidelines are intended to supplement those supplied by equipment and solution manufacturers and local policies.

Operate equipment in accordance with the equipment manufacturer’s instructions and in consideration of any limitations of use. This includes characteristics of certain types of components that require special handling or which may not be adequately cleaned by the equipment. Select, prepare and use cleaning solutions in accordance with the equipment manufacturer’s instructions. Special attention should be paid to specifications for detergent concentration, water temperature, water quality and maintenance schedules.

In order to prevent damage to implants, use only neutral enzymatic detergents (pH 7 – 9).

During ultrasonic cleaning combine only items made of similar metals in order to avoid ion transfer, which may result in etching and pitting.

Ensure rinsing processes remove all cleaning residues. Removal of cleaning residues is an essential prerequisite for effective steam sterilization.

Ensure cleaning equipment achieves and maintains the proper process parameters (e.g. time, temperature, water pressure, fluid flow rates, concentration and delivery of accessory solutions etc.).

**Manual - Ultrasonic Method**
Equipment: Ultrasonic cleaner, cleaning brush, enzymatic detergent (neutral pH), running water (tap, purified)

1. Pre-rinse under warm running water for a minimum of two (2) minutes.
2. Completely immerse in an ultrasonic cleaning bath filled with a neutral (pH 7 – 9) enzymatic detergent solution (e.g. Enzol®) prepared according to the manufacturer's instructions.
3. Ultrasonicate for a minimum of ten (10) minutes at or below 35 ºC (95 ºF).
4. If necessary, clean implant with a cleaning brush.
5. Rinse for at least two (2) minutes under purified running water to remove cleaning residue.
6. Carefully dry using an absorbent, non-shedding cloth or industrial hot dryer, or place into a drying cabinet until all moisture is removed.

**Automated Method**
1. An automated cleaning process of equal effectiveness to the manual cleaning method may be used. Follow instructions provided by the washer manufacturer and detergent manufacturer as well as local policies.
2. Arrange items in the washer such that all surfaces are exposed to the action of the automated washer.
3. Sequencing, number and type of stages may vary among washer manufacturers. Washers may use a single chamber for rinsing, cleaning and drying or may use multiple chambers, one for each cycle. Typical wash cycles may include the following: cool water rinse, enzymatic soak, detergent wash, ultrasonic cleaning, sustained hot water rinse and drying. It is recommended to perform a neutralizing rinse after use of strong alkaline or acidic cleaning solutions. Use purified water for the final rinse.

**Inspection**
The implants should be inspected after processing, prior to sterilization. Any implant with damage, corrosion, discoloration, scratches, residue, or debris should be discarded.

**Sterilization**
Equipment: Prevacuum steam autoclave, purified water, sterilization wrap.
1. **Assemble components into their respective tray positions and place lid on tray.**
   Proper positioning of items is essential for adequate steam penetration and aeration during processing. Steam must contact all implant surfaces in order to ensure effective sterilization.

2. **Wrap entire tray in sterilization wrap material and apply label to indicate contents.**
   Sterilization wraps must allow adequate steam penetration, aeration and protection against microbial penetration. Sterilization wraps should be approved for clinical use. In the United States only sterilization wraps cleared for marketing by the Food and Drug Administration (FDA) should be used, such as KimGuard\textsuperscript{®} One-Step\textsuperscript{®} KC100.

3. **The following are the recommended sterilization parameters:**

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Drying Time*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Pre-Vacuum</td>
<td>270°F (132°C)</td>
<td>4 minutes</td>
<td>60 minutes</td>
</tr>
</tbody>
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* Drying times may vary due to differences in packaging materials (e.g. nonwoven wraps), environmental conditions, steam quality, implant materials, total mass, sterilizer performance, and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying.

- Ensure autoclave equipment achieves and maintains the proper time, temperature, and pressure.
- Operate equipment in accordance with the equipment manufacturer’s instructions.
- When sterilizing multiple device sets in one autoclave cycle ensure the maximum load stated by the equipment manufacturer is not exceeded.
- Use purified water for steam sterilization.

**Storage and Handling**
Implants should be stored in the implant sterilization case in clean, dry, well-ventilated conditions away from floors, ceilings, and outside walls. Store and transport sterile implants in such a way as to maintain sterility and functional integrity. Do not use implants if the sterilization wrap is opened, damaged or wet. Implants should remain covered until needed to avoid contamination. Only those to be implanted should be handled.

**Limitations and Restrictions**
Repeated sterilization according to these instructions has a minimal effect on Choice Spine devices.

Sterilization equipment varies in performance characteristics and must be validated accordingly. The sterilizing facility is responsible for the routine validation and monitoring of all equipment, materials and personnel used in their facility to ensure the desired results are achieved. These instructions have been validated as being capable of sterilizing these Choice Spine implants. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

**DEVICE RETREIVAL EFFORTS**
Should it become necessary to remove any or all of the Classic ACP components, please call Choice Spine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information.

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

INFORMATION

For product complaints please contact
Choice Spine, LP
Quality/Regulatory Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; fax: 865-588-4045

For additional Product information please contact
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