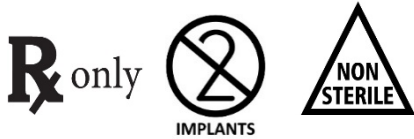





FALCON™ Anterior Cervical Plate System Instruction for Use



 ChoiceSpine, LLC
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USA

Important Note to Operating Surgeon:

The ChoiceSpine FALCON Anterior Cervical Plate System is designed to provide stability as an adjunct to fusion. For best results, a detailed, preoperative diagnostic with meticulous surgical technique as well as adapted postoperative care are essential. Spinal fixation should only be undertaken after the surgeon has had hands on training and has become thoroughly knowledgeable about spinal anatomy and biomechanics. A surgical technique is available and describes in detail the important aspects of this surgical procedure. It is most important that the patient and the surgeon are fully aware of the risks and complications inherent to this type of surgery. The patient should be made aware of the implant limitations and the potential adverse effects of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed. Postoperative evaluation of the fusion and implant status is necessary. The surgeon may remove the implant once a solid fusion is obtained (confirmed by clinical and radiographic examination). The patient must be informed of the potential for this second surgical procedure and the associated risks.

General Description:

The ChoiceSpine FALCON Anterior Cervical Plate System is an anterior cervical spinal fixation system consisting of plates and screws, manufactured from titanium alloy (Ti6Al4V ELI; ASTM F136). The plates are available in multiple lengths, suitable to 1-, 2-, 3-, and 4-level surgeries, in order to accommodate different anatomies. The plates incorporate a screw-retention mechanism, or clip, made of Nitinol alloy (NiTi; ASTM F2063) to prevent screw back-out. The screws, which serve as fixation devices of the plates, are available in diameters of 4.0mm and 4.5mm in either a fixed- or variable-angle design that has a self-tapping feature. A self-drilling version of the 4.0mm diameter screw is also available. A complete instrument set has been specifically designed to implant the FALCON Anterior Cervical Plate System components. It is essential that only these instruments be used with this system.

Indications:

The ChoiceSpine FALCON Anterior Cervical Plate System is intended for anterior fixation of the cervical spine (levels C2 to C7) and is designed to provide stabilization as an adjunct to spinal fusion at these levels. Indications for the use of this device includes: failed previous fusion, pseudoarthrosis, tumor, deformity, spinal stenosis, trauma, spondylolisthesis, or degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies.

WARNING: The ChoiceSpine FALCON ACP System is not intended for screw attachment or fixation to the posterior element (pedicles) of the cervical, thoracic or lumbar spine.

Contraindications:

Use of any implant system and spinal fixation surgery are contraindicated in the presence of existing or recent active infection near or at the proposed implantation site.

Any conditions that preclude the possibility of fusion are relative contraindications. These include but are not limited to:

- Cancer
- Fever

- Mental illness
- Alcoholism or drug abuse
- Osteoporosis or osteopenia
- Neurotrophic disease
- Obesity
- Pregnancy and foreign body sensitivity

In addition, patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Based upon the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions which may impact the performance of the system. See also the WARNING and POSSIBLE ADVERSE EVENTS/COMPLICATIONS section of this insert. The following are specific warnings and adverse events that should be understood by the surgeon and explained to the patient. They are specific metallic internal fixation devices. General surgical risk should be explained to the patient before surgery.

Warnings:

The ChoiceSpine FALCON Anterior Cervical Plate System Implants have not been tested for safety and compatibility in the MR environment. ChoiceSpine FALCON Anterior Cervical Plate System Implants have not been tested for heating, migration, or image artifact in the MR environment. The safety of the ChoiceSpine FALCON Anterior Cervical Plate System Implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Possible Adverse Effects/Complications:

The potential risks identified with the use of this system, which may require additional surgery include:

- Implant loosening or fracture
- Pseudoarthrosis, non-union or delayed union
- Vertebral fracture
- Neurologic, vascular, or visceral injury
- Bone density decrease due to stress shielding
- Infection
- Nerve damage due to surgical trauma
- Metal sensitivity or allergic reaction to a foreign body
- Pain, discomfort, or abnormal sensation due to the presence of the implant
- Paralysis
- Death

Implant Selection

The Choice FALCON Anterior Cervical Plate System components are available in a variety of sizes so that the proper sizing of the implant for a specific patient can be made. Selection of the correct size of implant appropriate to the patient is extremely important. As such, an appropriate range of sizes must be available at the time of operation.

How Supplied:



The FALCON Anterior Cervical Plate System devices are provided clean but non-sterile and must be sterilized prior to use. Implants are intended for single use only. Instruments can be reprocessed using the recommended cleaning instructions.

Cleaning and Decontamination:

All instruments must first be cleaned using methods recommended in this document or established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using methods recommended in this document or established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

These devices are packaged in a convenience caddy/case. All devices must be removed from the case, inspected and cleaned via one of the appropriate methods below. Where applicable, instruments should be disassembled prior to cleaning and reassembled prior to sterilization. All devices must be placed back into the caddy and case prior to steam sterilization.

Recommended Cleaning:

The terms "Steris 444", "Enzol™" and "Prolystica™" are tradenames of ultrasonic equipment and detergents utilized on the recommended cleaning instructions. Any ultrasonic washer or equivalent ultrasonic detergent can be utilized when used in accordance to the manufacturer's instructions and labeling. When appropriate, disassemble instruments prior to cleaning.

Automated Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through and around cracks, crevices, and hard to reach areas.
2. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, and hard to reach areas.
3. Transfer instrument(s) into a STERIS 444 washer with the following parameters. Incline the instrument(s) to assist in drainage. Motor speed: High.

Phase	Time (min)	Temperature	Detergent
Pre-Wash 1	1:00	Cold Tap Water	N/A
Enzyme Wash	1:00	Hot Tap Water	Enzol® at 1 oz per 1 gal water
Wash 1	2:00	60°C	Prolystica® 2x Conc. Neutral at 1/8 oz per 1 gal water
Rinse 1	1:00	Hot Tap Water	N/A
Drying	7:00	115°C	N/A

4. Remove instrument(s) from washer and visually inspect for soil. Repeat if necessary.

Mechanical Cleaning (Ultrasonic):

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through and around cracks, crevices, and hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, and hard to reach areas.
5. Use a sterile syringe to flush detergent through and around cracks, crevices, and hard to reach areas.
6. Remove instrument(s) from detergent and rinse with cool tap water (< 35°C) for at least one (1) minute.
7. Prepare the ultrasonic cleaner with an Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55°C).
8. Load instrument(s) into the cleaner and sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner and thoroughly rinse using reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel and filtered, pressurized air (20 psi).
11. Visually inspect for soil. Repeat if necessary.

Manual Cleaning:

1. Rinse instrument(s) under cool running tap water (< 35 °C) to remove gross soil. Use a sterile syringe to flush water through and around cracks, crevices, and hard to reach areas.
2. Prepare Enzol® solution of one (1) ounce per one (1) gallon of warm tap water (< 55 °C).
3. Fully immerse instrument(s) in the detergent for at least one (1) minute.
4. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, and hard to reach areas.
5. Use a sterile syringe to flush detergent through and around cracks, crevices, and hard to reach areas.
6. Remove instrument(s) from detergent and thoroughly rinse with reverse osmosis/deionized (RO/DI) water for at least one (1) minute. Use a sterile syringe to aid in rinsing.
7. Dry instrument(s) using a clean, soft cloth and filtered, pressurized air (20 psi).
8. Visually inspect for soil. Repeat if necessary.

Care and Handling:

- All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.
- Refer to ASTM standard F1744-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.
- Before use, instruments should be visually inspected, and function should be tested to ensure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear, or have other irregularities DO NOT use.
- Lubricate instruments to protect instruments during sterilization and storage. This should be done with a water soluble, preserved lubricant after each cleaning. The lubricant should contain a chemical preservative to prevent bacterial growth and be made with distilled water. Excess lubricant should be wiped off prior to storage and sterilization.

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:

ChoiceSpine instruments and implants are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Implants and instruments are recommended to be steam sterilized by the hospital using the following process parameters:

Steam Sterilizer Type: Pre-vacuum

Temperature: 132°C

Duration: 4 minutes

Drying Time: 40 minutes

All devices are to be wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 or equivalent) using various wrapping techniques per ANSI/AAMI ST79.

This steam sterilization cycle is not considered by the FDA to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps or pouches, chemical or biological indicators, and sterilization cassettes) that have been cleared by the FDA for the sterilization cycle specifications (time and temperature).

Alternative sterilization methods or cycles may be used, but should be validated according to hospital practices and procedures.

Single Use Only:

Never reuse an implant. Any implant that has been twisted, bent, or implanted, then removed, even if it appears intact, must be discarded. These devices are provided as single use only.

Storage and Handling:

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

Limitations and Restrictions:

Repeated sterilization according to these instructions has a minimal effect on ChoiceSpine 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 ChoiceSpine implants and instruments. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

Patient Education:

It is essential to provide preoperative instructions to the patient. S/he should be made aware of the potential risks of the surgery and the implant limitations. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Device Retrieval Efforts:

Should it become necessary to remove any or all of the FALCON Anterior Cervical Plate components, please call ChoiceSpine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information

Surgical Technique Manual:

The ChoiceSpine FALCON Anterior Cervical Plate System Surgical Technique Manual is available by contacting ChoiceSpine Sales Support.

Product Complaints:

The customer or health care provider should report any dissatisfaction with the product quality, labeling, packaging or performance to ChoiceSpine immediately. Furthermore, if any of the implants "malfunction" (i.e., do not meet any of their performance specifications or otherwise do not perform as intended) and may have caused or contributed to the death or serious injury of the patient, ChoiceSpine should be notified immediately by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Caution:

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

Information:

See choicespine.com for more information.

See choicespine.com/patents/ for patent information.

For product complaints please contact:

ChoiceSpine, LLC
 Quality/Regulatory Department
 400 Erin Drive
 Knoxville, TN 37919
 Phone: 865-246-3333; Fax: 865-588-4045

For additional product information please contact:

ChoiceSpine, LLC
 Sales Support Department
 400 Erin Drive
 Knoxville, TN 37919
 Phone: 865-246-3333; Fax: 865-588-4045
salesupport@choicespine.com

Symbol Legend:

Symbol	Definition
	Do not reuse
	Caution, consult instructions for use for warnings and precautions
	Consult instructions for use
	Do not use if package is damaged
	Lot number
	Reference number
	Serial Number
	Sterilized by irradiation
	Use by
	Manufacturer
	Date of Manufacture
	Federal law (USA) restricts this device to sale by or on the order of a physician
	Non-Sterile
	European Medical Devices
	Authorized representative in the European Community
	MR Conditional
	Unique Device Identification
	Medical Device