Boomerang™ Anterior Cervical Plate System
Instruction for Use

Rx only

Implants

NON STERILE

ChoiceSpine, LLC
400 Erin Drive
Knoxville, TN 37919
USA

General Description:

The ChoiceSpine Boomerang Anterior Cervical Plate system is intended for anterior screw fixation to the cervical spine. The system consists of a variety of bone plates and screws made from titanium alloy (T-6Al-4V ELI) per ASTM F136 and a set of instruments made from stainless steels (455, 465 and 17-4) per ASTM A564 and ASTM F899. The system components are provided non-sterile and must be steam sterilized by the user prior to use.

Indications for Use:

The ChoiceSpine Boomerang Anterior Cervical Plate System is intended for anterior cervical fixation (C2-T1) 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, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

WARNING: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine

Contraindications:

Contraindications include, but are not limited to:

- Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
- Signs of local inflammation
- Morbid obesity
- Pregnancy
- Grossly distorted anatomy due to congenital abnormalities
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
- Rapid joint disease, bone absorption, osteopenia, osteomalcia, 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
- Suspected or documented metal allergy or intolerance
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- 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
- Any time implant utilization would interfere with anatomical structures or expected physiological performance
- Any case not needing a bone graft and fusion or where fracture healing is not required

Warnings and Precautions:

The ChoiceSpine Boomerang Anterior Cervical Plate 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 ChoiceSpine Boomerang Cervical Plate 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. A suitable bone graft/interbody device must be part of the spinal fusion procedure in which The ChoiceSpine Boomerang Anterior Cervical Plate System is used. Use of this product without a bone graft may not be successful. The spinal implant cannot withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device will eventually occur.

Based on fatigue testing results, when using the Boomerang Anterior Cervical Plate, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

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

Additional warnings and precautions should be followed as directed by the surgical technique guide.

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. Due to the short plate lengths offered in the ChoiceSpine Boomerang Anterior Cervical Plate System, bending/contouring of the plate is not necessary and should not be attempted.

The surgeon should follow established practices and specific instructions for implantation of the system components. 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 Boomerang 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, ensure that the propeller-shaped screw cover has been rotated to the locked position. A suitable bone graft/interbody device 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 ChoiceSpine Boomerang Anterior Cervical Plate System must not be used with components from any other system or manufacturer.

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 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, interference with roentgenographic, CT, and/or MR imaging will 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

How Supplied:

NON STERILE The ChoiceSpine Boomerang Anterior Cervical Plate 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 and implants are supplied to the health care facility clean but non-sterile. Implants are single use only but need to be sterilized before use. Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Implants that have been implanted and then removed must be discarded. Cleaning and disinfecting of instruments can be accomplished by using alkali aldehyde-free solvents at high temperatures. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

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.

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. All products should be treated with care. Improper use and handling may lead to damage and possible improper functioning of the device.

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.

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 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 & 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 & around cracks, crevices, & 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, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & 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 & sonicate for ten (10) minutes.
9. Remove instrument(s) from cleaner & thoroughly rinse using reverse osmosis/deionized (RO/DI) water for at least one (1) minute.
10. Dry instrument(s) using a clean, soft towel & 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 & around cracks, crevices, & 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, & hard to reach areas.
5. Use a sterile syringe to flush detergent through & around cracks, crevices, & hard to reach areas.
6. Remove instrument(s) from detergent & 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 & 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.
  DO NOT use instrument(s) that is/are discolored, have loose screws/pins, are out of alignment, cracked, show excessive wear, or have other irregularities.

- Lubricate instruments to protect them 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 are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. Instruments are recommended to be steam sterilized by the hospital using the following process parameters (Alternative methods or cycles may be used, but should be validated according to hospital practices and procedures):

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.

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.

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 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.

Device Retrieval Efforts:

Should it become necessary to remove any or all of the Boomerang Anterior Cervical Plate components, please call ChoiceSpine 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:

See www.choicespine.com/patents for details.

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

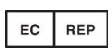
For additional Product information please contact:
ChoiceSpine, LLC
Customer Service Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333 or fax: 865-588-4045
customerservice@choicespine.com

Product Complaints:

Any dissatisfaction with the product quality, labeling, or performance should be reported to ChoiceSpine immediately by the customer or health care provider. Furthermore, ChoiceSpine should be notified immediately of an implant malfunction 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.

Some components may not be currently available. Please contact your ChoiceSpine representative for additional information.

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