TOMCAT™ Cervical Spinal System
Instruction for Use

Rx only | NON STERILE | IMPLANTS | CE 2797

ChoiceSpine, LLC
400 Erin Drive, Knoxville, TN 37919
USA

Important Note to Operating Surgeon:
The TOMCAT Cervical Spinal System is designed to provide biomechanical stabilization as an adjunct to fusion. Spinal fixation should only be undertaken after the surgeon has had hands-on training in this method of spinal fixation and has become thoroughly knowledgeable about spinal anatomy and biomechanics. A surgical technique is available for instructions on the important aspects of this surgical procedure.

Preoperative:
Preoperative instructions to the patient are essential. Only patients who meet the criteria described in the Indications section should be selected for implantation. Patient conditions and/or predispositions such as those addressed in the Contraindications section should be avoided. Care should be used in the handling and storage of the implant components. The implants should not be damaged. Implants should be protected from corrosive elements during storage. The type of construct required for the surgery should be determined prior to beginning the surgery. Implants and instruments must be inspected, cleaned and sterilized prior to use in the operative field.

Intraoperative:
Caution should be used around the spinal cord and nerve roots, particularly when using screws. Damage to the nerves may cause loss of neurological functions. Breakage, slippage, misuse, or mishandling of the instruments or implant components may cause injury to the patient or operative personnel. The implants must be handled carefully so as to avoid notching or scratching the surface. Explanted implants must never be reused.

Post-Operative:
The risks and benefits of a second surgery must be carefully evaluated. The patient must be adequately instructed regarding the risks and limitations of the implant, as well as postoperative care and rehabilitation. The patient should be instructed in the proper use of crutches, canes, external braces or any other weight bearing or assist devices that may be required, and physical activities which would place excessive stresses on the implants or cause delay of the healing process. The patient should also be instructed in the proper methods to ambulate, climb stairs, get in and out of bed and perform activities of daily living, while minimizing rotational and bending stresses.

Description:
The TOMCAT Cervical Spinal System is an anterior cervical spinal fixation system for an effective means of stabilizing the cervical vertebral column (C2-T1) as an adjunct to fusion of vertebral bodies. The TOMCAT System will provide an alternative to the more common cervical plate and cervical interbody spacer Anterior Cervical Discectomy & Fusion (ACDF) surgical procedure. The TOMCAT Cervical Spinal System is a radiolucent and radiopaque intervertebral body fusion device. The interbody is made from PEEK per ASTM F2026 with titanium alloy (Ti-6Al-4V ELI) per ASTM F136, tantalum radiopaque markers per ASTM F560, and nitinol clips per ASTM F2063. This device accepts titanium (Ti-6AI-4V ELI) bone screws that are available in two diameters and multiple lengths.

The system will be composed of a cervical interbody spacer with a zero profile and a hybrid profile design. The hybrid device is implanted anteriorly by inserting two screws, one screw into the anterior face of vertebral body and the other diagonally though the end plate.

The zero profile device implants are implanted anteriorly and stabilized by two diagonally placed screws.

Indications for Use:
The TOMCAT Cervical Spinal System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients. The interbody is used with bone screws provided and requires no additional supplementary fixation. The interbody is inserted between the vertebral bodies into the disc space at one level or two levels from the C2/C3 disc space to the C7/T1 disc space for the treatment of cervical degenerative disc disease. Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history of radiographic studies. The device system is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and /or corticocancellous bone graft, to facilitate fusion. The device is implanted by an anterior approach. The TOMCAT implant must be used with the screws included in the TOMCAT system. This device is to be used in patients who have had six weeks of non-operative treatment.

Contraindications:
Contraindications include, but are not limited to:

- Infection, systemic or localized
- Signs of local inflammation
- Morbid obesity
- Fever or leukocytosis
- Mental illness
- Alcoholism or drug abuse
- Pregnancy
- Severe osteopenia
- Suspected or documented sensitivity allergies to the implant materials
- Presence of congenital abnormalities, vague spinal anatomy, tumors, or any other condition which prevents secure implant screw fixation and/or decreases the useful life of the device
- Any condition having inadequate tissue coverage over the operative site
- Any circumstances not described under Indications for Use
- Patients unwilling or unable to follow post-operative instructions
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft)

Cautions, Precautions, Warnings, and Possible Adverse Effects

Cautions:

- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together.
- Do not use components of the TOMCAT Cervical Spinal System with components from any other system.
- As with all orthopedic implants, none of the TOMCAT Cervical Spinal System implants should ever be reused under any circumstances.

Precautions:

- Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, those with poor muscle and bone quality, and nerve paralysis patients.
- The implantation of spinal systems should be performed only by spinal surgeons fully experienced in the surgical techniques required for the use of such implants. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case. The physician should consider patient weight and patient activity.

Warnings:

- Patient compliance to postoperative precautions will greatly affect surgical outcomes.
- The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. All implants should be examined before use and discarded if damaged.

This device system is not intended to be the sole means of spinal support. Its use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

MR Magnetic Resonance Environment

MR Conditional: (implants only)
Non-clinical testing has demonstrated that the Tomcat devices are MR Conditional.
A patient with the Tomcat can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial gradient field of 19 T/m (1900 G/cm).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

Under the scan conditions defined above, the devices is expected to produce a maximum temperature rise of less than or equal to 2.5°C after 15 minutes of continuous scanning.
In non-clinical testing, the image artifact caused by the device extends radially up to 1.3cm and 1.9cm (respectively) from the device when imaged with a gradient echo pulse sequence in a 1.5T MR system and a spin echo pulse sequence in a 3.0T MR system.

Possible Adverse Effects:
Preoperatively, the patient should be made aware of the following possible adverse effects of spinal implant surgery. Additional surgery may be necessary to correct some of these effects:

- Early or late loosening of the components
- Disassembly, bending, loosening, and/or breakage
- Foreign body reaction to the implants including possible tumor migration
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site which may result in skin breakdown and/or wound complications
- Pressure on the skin from components where there is inadequate tissue coverage over the implant
- Loss of proper spinal curvature, correction, height, and/or reduction
- Infection
- Hemorrhage of blood vessels and/or hematomas
- Bone graft, intervertebral body and/or sacral fracture at, above, and/or below the level of surgery
- Non-union or delayed union
- Loss of neurological function (e.g., bowel or bladder dysfunction), appearance of radiculopathy, and/or development of pain
- Gastrointestinal and/or reproductive system compromise, including sterility
- Cessation of growth of the fused portion of the spine
- Death
- Neurovascular compromise including paralysis or other types of serious injuries

How Supplied:

The TOMCAT Cervical Spinal System instruments and implants are provided clean but non-sterile and must be sterilized prior to use. 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 each 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.

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.

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 & 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. 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.

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. Instruments and implants 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):
All devices must be placed in appropriate caddy/case prior to steam sterilization.

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 implant sterilization case in clean, dry, well-ventilated conditions away from floors, ceilings, and outside walls. Store and transport sterile implant 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.

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 TOMCAT Cervical Spinal System 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 TOMCAT Cervical Spinal 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) may cause or contribute 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.

Summary of Safety & Clinical Performance can be found at https://ec.europa.eu/tools/eudamed

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
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045
salessupport@choicespine.com

EC REP
EMERGO EUROPE
Westervoortsedijk 60,
6827 AT Arnhem
The Netherlands

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