ChoiceSpine®
Propelling Spinal Surgery

TYPHOON™ Facet Screw Fixation System
Instruction for Use

℞ only

IMPLANTS

NON STERILE

ChoiceSpine, LLC
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USA

Important Note to the Operating Surgeon:
The TYPHOON Facet Screw Fixation 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 post operative 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. Post operative 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 TYPHOON Facet Fixation System is a posterior Facet spinal fixation system consisting of screws and washers, manufactured from titanium alloy (Ti6Al4V ELI; ASTM F136). The bone screws are designed to transfix the facet articular process in the spine to enhance spinal fusion and stability. The self-tapping screws are 4.5mm and 5.5mm in diameter the 4.5mm screws are supplied in length ranging from 20mm to 60mm and the 5.5 mm screws range in length from 25mm to 60mm.

Washers:
Washers are available to increase the load bearing area of the screw in contact with the bone. These washers are designed to angulate about the head of the bone screw to provide optimal bony contact over the range of screw trajectories.

Indications for Use:
The TYPHOON Facet Screw Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from L1 to S1 inclusive.

The TYPHOON Facet Screw System is indicated for treatment of any or all of the following: degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by patient history and radiographic studies; degenerative disease of the facets with instability; Spondylolisthesis; Spondylolysis; Pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity; and trauma, including spinal fractures and/or dislocations.
When properly used, facet screws will provide temporary stabilization as an adjunct to spinal bone grafting processes. After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer, or support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient. The decision should consider the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

Postoperative Mobilization:
Until x-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended.

Instructions to the patient to reduce stress on the implants are equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

Contraindications:
Contraindications for the TYPHOON Facet Screw Fixation 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. Absence of posterior spinal elements including the pedicle, pars interarticularis, facet joints, spinous process and the majority of the lamina
3. Conditions, such as morbid obesity, which may put excessive stress on the bone and implants
4. Severe osteopenia or osteoporosis may prevent adequate fusion
5. Pregnancy
6. Use of these implants is relatively contraindicated in patients whose activity level, metal capacity, mental illness, alcohol abuse, occupation or lifestyle may interfere with their ability to follow post-operative instructions

Cautions, Warnings, and Possible Adverse Effects:

Cautions:
- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components should NOT be used together.
- Do not use components of the TYPHOON Facet Screw Fixation System with components from any other manufacturer.
- The TYPHOON Facet Screw Fixation System implants are single use devices and should never be reused under any circumstances
- Refrain from handling the devices as much as possible before implantation, and always handle with the utmost care. The devices, in their original packaging must be stored in a clean and dry place away from radiation or extreme temperatures. Should these requirements not be followed, reduced mechanical properties may occur which could lead to device failure in some cases.

Precautions:
- The implantation of the TYPHOON Facet Screw Fixation System should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patent.
- Before use, instruments should be visually inspected, and function should be tested to ensure instruments are functioning properly.
- 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.

Warnings:
- The safety and effectiveness of facet screw fixation spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation.
- This device system is not intended to be the sole means of spinal support. It is used 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. The proper selection and compliance of the patient will greatly affect the results.
- 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 TYPHOON Facet Screw Fixation System Implants have not been tested for safety and compatibility in the MR environment. The TYPHOON Facet Screw Fixation System Implant have not been tested for heating, migration, or image artifact in the MR environment. The safety of the TYPHOON Facet Screw Fixation System Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Preoperative:
1. Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the device and the potential adverse effects of the surgery.
2. Only patients that meet the criteria described in the Indications for Use should be selected.
3. Patient conditions and/or predispositions such as those mentioned in the contraindications should be avoided.

4. 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.

Intraoperative:

1. The surgeon must be fully conversant with all aspects of the surgical technique.
2. Proper function of the surgical instruments specific to the TYPHOON Facet Screw Fixation System should be verified prior to every surgical procedure.
3. The appropriate type and size of implant for the patient and the positioning of the implant are important.

Postoperative:

1. Patients must be informed of the precautions to be taken in their everyday life to enhance a maximum implant service life.
2. Regular post-operative follow-up is recommended to detect early signs of implant failure and consider necessary action.

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
- neurovascular compromise including paralysis or other types of serious injuries
- gastrointestinal and/or reproductive system compromise, including sterility
- cessation of growth of the fused portion of the spine
- death

How Supplied:

The TYPHOON Facet Screw Fixation System devices are provided 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 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.

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 in 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 1oz 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 instruments and inspect for soil, repeat cleaning 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:
The TYPHOON Facet Screw Fixation System 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:

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 implants 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 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 TYPHOON Facet Screw Fixation System components, please call ChoiceSpine at the number below to receive instructions regarding data collection, including histopathological, mechanical, and adverse event information.

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 post operative 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.

Surgical Technique Manual:
The TYPHOON Facet Screw Fixation 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
salessupport@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