Silverbolt® MIS/Mainframe Spinal Screw System Instruction for Use

℞ only

NON STERILE

IMPLANTS

CE 2797

ChoiceSpine, LLC
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USA

General Description:
The ChoiceSpine Silverbolt MIS/Mainframe Spinal Screw Systems are posterior, non-cervical implants to correct spinal disorders and provide stabilization of the spine to permit the biological process of spinal fusion to occur.

These Systems consist of:

1. Spinal Screws, with Caps/Set Screws: Screws are available with polyaxial or fixed heads, in either cannulated or solid configuration. Cannulated screws are offered in diameters from 5.5mm to 8.5mm, and in lengths from 25 to 80mm. Solid screws are offered in diameters from 4.0mm to 8.5mm, and in lengths from 25 to 80mm.
2. Rods: Rigid rods are available in a choice of smooth-, or ball-end, and in either straight or curved forms. Rods are 5.5mm in diameter and are offered in lengths ranging from 30mm to 200mm. Straight, smooth-end rigid rods are also available up to and including 600mm lengths which can be cut to size and contoured as desired. Multi-level rods are 5.5mm in diameter and are available in lengths ranging from 30mm to 85mm. Multi-level rods are designed for percutaneous creation of single or multi-level constructs.
3. Instruments used to implant the device: Manual instrument sets are available for both conventional and minimally invasive/percutaneous approaches.
4. Sterilizer trays: Sterilization trays are provided for all instruments and implants.

Implantable components of the Silverbolt MIS/Mainframe Spinal Screw Systems are made from surgical implant grade titanium alloy described by ASTM Standard F-136 (Ti-6AL-4V ELI) and commercially pure titanium grade 2 as described by ASTM Standard F-67 (CP Ti, Grade 2) or ISO 5832-2 or ISO 5832-3. Silverbolt MIS/Mainframe Spinal Screw Systems components should not be used with components from other spinal systems.

Implantable components of the Silverbolt MIS/Mainframe Spinal Screw Systems are intended for single use only. Do not reuse. Standard techniques of spinal fusion are an integral part of the implementation of this system as described in the surgical technique guide for each system.

Indications for Use:
Silverbolt MIS/Mainframe Spinal Screw Systems
The Silverbolt MIS/Mainframe Spinal Screw Systems are intended for, posterior noncervical spinal fixation to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities and deformities of the thoracic, lumbar, and sacral spine. The indications for use are as follows:

- Degenerative Disc Disease (DDD) defined as by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.
- severe spondylolisthesis (grades 3 and 4) at L5-S1
- degenerative spondylolisthesis
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- tumor
- pseudoarthrosis
- failed previous fusion

Contraindications:
The contraindications of this system are similar to other systems of similar design. Contraindications include the following conditions:

ABSOLUTE CONTRAINDICATIONS
- Active posterior infection
- Allergy to titanium

RELATIVE CONTRAINDICATIONS
- Fever
- Pregnancy, unless internal fixation of the spine is indicated for unstable fracture.
- Signs of infection in the area to be implanted
- A patient unwilling or unable to follow instructions

Instructions for Use:
The surgeon using the Silverbolt MIS/Mainframe Spinal Screw Systems is expected to be fully educated and trained in the techniques and methods to place the system. A successful result may not occur in every event in which the Systems are implanted. Failure rates in spinal fusion procedures are published and spinal fusion failure is an accepted risk of the procedure. This is particularly true for patients who choose to smoke tobacco products, patients in malnourished or obese states, or who abuse alcohol products.

Proper selection of patients and good compliance of patients with pre-surgical instructions are an integral part of the realization of a successful surgical procedure. All patients contemplating implantation of this device should be apprised of the risks associated with the procedure as well as the limitations regarding activities that the patient will face following surgery.

Bone grafting is an integral part of placement of the systems. The choice and nature of the graft is the decision of the surgeon.

Complications and Adverse Reactions:
The complications and adverse effects of these Systems are similar to other systems and may include the following:

- Loosening, disassembly, bending, or breakage of the components, possibly requiring further surgery.
- Non-union or pseudoarthrosis, possibly requiring further surgery.
- Infection.
- Prominence of component parts on the overlying skin.
- Loss of neurological function by several mechanisms, including direct compression of component parts, stretching of the spinal cord by component parts, vascular spinal cord compromise, or other mechanisms.
- Loss of normal spinal contours.
- Excessive blood loss during implantation.
- Erosion of blood vessels by implantation.
- Death.

* Loss of normal spine motion is an expected result and does not constitute an adverse effect.

Precaution:
The implantation of spinal screw systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Warnings:
Implants must not be reused. Any implant, once used, should be discarded; even though it may appear undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

The safety and effectiveness of spinal screw systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grade 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

The safety and effectiveness of Silverbolt MIS/Mainframe Spinal Screw Systems components, when used with components of other spinal systems, has not been established. Silverbolt MIS/Mainframe Spinal Screw Systems components should not be used with components from other spinal systems.

The safety and effectiveness of the Systems for the indication of spinal stabilization without fusion have not been established.

The device is not intended or expected to be the only mechanism of support of the spine. Regardless of the etiology of the spine pathology for which the implantation of this device was chosen, it is the expectation and requirement that a spinal fusion or arthrodesis be planned and obtained. Without solid biological support provided by spinal fusion, the device cannot be expected to support the spine indefinitely and will fail in any of several modes. These modes may include bone-metal interface failure, rod or screw failure, or bone failure.

MR **Magnetic Resonance Environment**
Non-clinical testing has demonstrated that the Silverbolt MIS/Mainframe Spinal Screw Systems Posterior Fixation Systems are MR Conditional under a range of exemplar configurations. A patient with these devices implanted in a way substantially and effectively similar to tested configurations can be safely scanned in an MR system under the following conditions:

- System contains only rods, connectors, screws, offsets, and hooks.
- Rods are oriented primarily parallel to the axis of the bore of the magnet and screws are oriented substantially perpendicular to the axis of the bore of the magnet.
- Screws are nominal length 95mm or less.
- Rods and constructs are length 600mm or less.
- 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 device is expected to produce a maximum temperature rise of less than or equal to 11˚C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends radially up to 4.2cm and 7.6cm (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.

NOTE: Mechanical and clinical testing indicates that the majority of axial or compressive load is carried in the anterior column of the spine. When posterior instrumentation is utilized for spinal stability, adequate anterior column support is necessary, either by surgical intervention or existing anatomy. Failure to maintain a stable anterior column when using posterior instrumentation may lead to overstressing of the posterior construct and implant failure. A successful result will not be achieved in every instance of use of this device. Strict adherence by the patient to the instructions of the surgeon is necessary to ensure the optimal result. Known conditions associated with poor or less than optimal results include cigarette smoking, obesity, and alcohol abuse.

Use of the systems should only be considered when the following preoperative, intraoperative, and postoperative conditions exist.

Preoperative:
- Patient should be in the previously described diagnostic categories described under INDICATIONS FOR USE.
- Patient should not be in the contraindication groups listed under CONTRAINDICATIONS.
- Sterilization and handling procedures conforming to accepted standards and the recommendations in this labeling are mandatory.
- The techniques for implanting these Systems should be reviewed by the surgeon prior to use of the system.
- The surgeon should inspect the available components of the Systems prior to surgery to assure that all necessary components are present.

Intraoperative:
- The surgeon is expected to follow the instructions made available in training manuals and literature relative to implantation of the Systems.
- The surgeon is expected to follow and exercise extreme care in the placement of implants, particularly regarding neural elements.
- Radiographs should be made if there is any question as to the location of the intended or the actual placement of the implants.
- Components of other manufacturer's spinal system should **NOT** be used with the Silverbolt MIS/Mainframe Spinal Screw Systems.

Postoperative:
- The patient is expected to follow the detailed instructions of the operating surgeon. The patient and the surgeon must understand that the implant is not expected to support the spine if fusion does not occur.
- There is a risk of failure of the implant if the fusion of the spine does not occur. It should be recognized that this may occur and is a function of biology. More surgery may be required in such an event.
- The surgeon is expected to supply detailed instructions to the patient regarding postoperative activities.
- The potential for multiple complications exists. These are not necessarily due to deficiencies of the implants and may include fracture of the implants due to fatigue, late infection, or sensitivity due to fretting-corrosion, prominence of the implants, and displacement of the implants due to failure of the supporting spinal structure.
- The device is only intended to support the spinal pathology during the period required to achieve spinal fusion. It is well recognized that the device will eventually fail if fusion does not occur.

Intended Clinical Benefit:
- Possibility of a higher fusion rate
- To preserve decompression of neural structures, which provides pain relief, and to prevent movement or motion postoperatively, which can cause pain

How Supplied:

The Silverbolt MIS/Mainframe Spinal Screw Systems 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 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. Process instruments as soon as is reasonably possible after use. It is recommended not to delay cleaning for more than 2 hours.

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 with 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 & around cracks, crevices, & hard to reach areas.
2. Use a soft bristle brush as needed to remove soil, paying close attention to threads, crevices, & 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 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 & 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.

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. Implants and Instruments are recommended to be steam sterilized by the hospital using the following process parameters:

Steam Sterilizer Type: Pre-Vacuum
Temperature: 134°C
Duration: 3 minutes
Drying Time: 60 minutes

All devices are to be wrapped in two-layer of 1-ply polypropylene wrap (Kimguard KC400 or equivalent) using various wrapping techniques per ANSI/AAMI ST79.

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 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. Instrument and Implant disposal should follow local hospital disposal instructions, or the explanted implants may be returned to ChoiceSpine for disposal.

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. The patient 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 Silverbolt® MIS/Mainframe Spinal Screw Systems 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 Silverbolt MIS/Mainframe Spinal Screw System Surgical Technique Manual is available by contacting ChoiceSpine Sales Support.

Product Lifetime:
The intention of the spinal implants included in this submission are to provide short-term stability while fusion occurs. The implant devices are mechanically tested in static and dynamic loading. Dynamic testing to 5,000,000 cycles is intended to represent the number of cycles experienced by a patient over a two-year period based on a moderate activity level. Within two years of implantation, fusion is expected to occur, which would alleviate the need for the implants to withstand loading. The minimum expected fusion expectancy would be one year; therefore, the lifetime range of our devices is one to two years. The device is intended to remain in the patient for the lifetime of the patient if fusion occurs.

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 and Periodic Summary Update Report can be found at https://ec.europa.eu/tools/eudamed
The Basic UDI for this system is 084099610370050HH.

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

For additional product information please contact:
ChoiceSpine, LLC
Sales Support
400 Erin Drive
Knoxville, TN 37919
Telephone : 865-246-3333 ; Fax : 865-588-4045
salessupport@choicespine.com

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.

Some components may not be currently available. Please contact your ChoiceSpine representative for additional information. The products discussed herein may be available under different trademarks in different countries.

EC REP

Emergo Europe B.V.
Westervoortsedijk 60
6827 AT Arnhem
Netherlands

Symbol Legend:

Note: The symbol legend includes all symbols relative to ChoiceSpine portfolio. All the applicable symbols will either appear on the label or the header of the IFU**.**

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