Silverbolt® MIS Mainframe HA Screw System
Instruction for Use

Rx only

STERILE R

IMPLANTS

2797

ChoiceSpine, LLC
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USA

General Description:
The ChoiceSpine Silverbolt MIS Mainframe HA Screw System is a temporary posterior, non-cervical implant to correct spinal disorders and provide stabilization of the spine to permit the biological process of spinal fusion to occur.

This System consists of:
1. Pedicle Screws, with Caps/Set Screws
2. Rigid and Semi-Rigid Rods
3. Instruments used to implant the device
4. Sterilizer cases

Implantable portions of the ChoiceSpine Silverbolt MIS Mainframe HA Screw System 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 5832-3. ChoiceSpine Spinal Screw System components should not be used with components from other spinal systems. Standard techniques of spinal fusion are an integral part of the implementation of this system as described in the Surgical Technique Guide.

Indications for Use:
The ChoiceSpine Silverbolt MIS Mainframe HA Screw System is intended for temporary, posterior noncervical pedicle 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 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 implanting the ChoiceSpine Silverbolt MIS Mainframe HA Screw System 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 system is 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 System when used as an adjunct to fusion. The choice and nature of the graft is the decision of the surgeon. Use of the System 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.
- The surgeon is expected to follow the instructions made available in training manuals and literature relative to implantation of the system.
- The surgeon is expected to follow and exercise extreme care in the placement of implants, particularly in regard to neutral elements.
- Radiographs should be made if there is any question as to the location of the intended or actual placement of the implant.
- Components of other manufacturer's spinal system should **NOT** be used with the system.

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 system.

Postoperative:
- The patient is expected to follow the detailed instructions of the operating surgeon. When used as an adjunct to fusion, the patient and the surgeon must understand that the implant is not expected to support the spine if fusion does not occur.
- When used as an adjunct to fusion, there is a risk of failure of the implant if 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. There 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 support spinal structure.
- When used as an adjunct to fusion, 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.

Potential Complications and Adverse Effects:
The complications and adverse effects of this system are similar to other systems and may include the following:
- Loosening, disassembly, bending, or breakage of the components, possibly requiring further surgery.
- Foreign body reaction due to implant material or wear debris.
- Infection.
- Cessation of growth of the fused portion of the spine
- Non-union or pseudoarthrosis, possibly requiring further surgery
- Infection
- Prominence of the component parts under the overlying skin
- Loss of neurological function by several mechanisms, including direct compression of components 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

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.

When used as an adjunct to fusion, the safety and effectiveness of pedicle screw spinal 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.

When used for semi-rigid stabilization of the spine, the safety and effectiveness of pedicle screw spinal systems have been established only for those spinal conditions with significant mechanical instability or deformity for which they are indicated. These conditions are instabilities of the thoracic, lumbar, and sacral spine such as degenerative disc disease, recurrent disc herniation, degenerative spondylolisthesis, degenerative lumbar spinal stenosis, iatrogenic instability following decompression, and for adjacent level degeneration prophylaxis. The safety and effectiveness of these devices for any other conditions are unknown.

When used as an adjunct to fusion, the device is not intended or expected to be the only mechanism of support of the spine, and 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. In such cases, 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.

The Silverbolt MIS Mainframe HA Screw System has not been evaluated for safety and compatibility in the MR environment. The Silverbolt MIS/Mainframe Spinal Screw Systems has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Silverbolt MIS Mainframe HA Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 by 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.

How Supplied:
STERILE R The Silverbolt MIS Mainframe HA Screws are supplied "Sterile" (gamma radiation) with SAL of 10^{-6} and intended for single use only. The sterility can only be assured if the packaging is intact. Do not use this device if the sterile packaging has been opened or damaged. Contact your local sales representative or distributor for replacement. Remove all packaging material prior to use.

Only sterile implants should be used in surgery. Refer to the Silverbolt MIS/Mainframe Spinal System IFU for recommended cleaning and sterilization instructions for the system implants and instruments provided non-sterile.

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.

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.

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.

Device Retrieval Efforts:
Should it become necessary to remove any or all of the Silverbolt MIS Mainframe HA Screw 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 Silverbolt MIS Mainframe HA Screw System Surgical Technique Manual is available by contacting ChoiceSpine Customer Service.

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. The products discussed herein may be available under different trademarks in different countries. All copy rights and pending and registered trademarks are property of ChoiceSpine.

For more information on a specific product or trademark, please contact your local ChoiceSpine representative.

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

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

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EC REP
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Westervoortsedijk 60
6827 AT Arnhem
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