Gibralt® Spine System
Instruction for Use

Rx only | Implants | NON STERILE | 2797 | Choice Spine, LLC 400 Erin Drive Knoxville, TN 37919 USA

Description:
The ChoiceSpine Gibralt Spine System is a posterior system intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the cervical, and/or upper thoracic spine. The system consists of a variety of sizes of rods, hooks, poly-axial screws and connecting components, which can be rigidly locked to the rod in various configurations. The Gibralt Spine System components are manufactured from titanium alloy, with rods being available in both titanium alloy and cobalt chrome alloy options.

This system can be used independently or in conjunction with ChoiceSpine 5.5mm or 6.0mm rod-based Thoraco-Lumbar Pedicle Screw Systems. The 5.5mm or 6.0mm rod-based Pedicle Screw systems are not covered by these instructions for use. Reference the instructions for use accompanying the Pedicle Screw System components for complete instructions for use.

Indications for Use:
The ChoiceSpine Gibralt Spine System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1-C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Gibralt Spine System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Gibralt Spine System may be connected to the Gibralt Occipital Spine System with rod-to-rod connectors. The Gibralt Spine System may also be connected to the ChoiceSpine Proliant System, ChoiceSpine Silverbolt and Mainframe Spinal Screw Systems, or ChoiceSpine Hydralok , using rod-to-rod connectors and transitional rods. Refer to the specific system package inserts for a list of their indications for use.

Contraindications:
Contraindications include, but are not limited to:

- Presence of overt infectious process or significant risk of infection (immunocompromise)
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental illness
- Grossly distorted anatomy caused by congenital abnormalities
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count, or a marked left shift in the white blood count differential count
- Suspected or documented metal allergy or intolerance
- Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis. Osteoporosis or osteopenia is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation
- Any patient unwilling to follow postoperative instructions
- Any case not needing a bone graft and fusion
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any case that requires the mixing of metals from two different components or systems
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Presence of any neural or vascular deficit or other compromising pathology, which may be further injured by device intervention
- Any case not described in the indications

Warnings and Precautions:
The Gibralt Spine System should only be implanted by experienced spine surgeons with specific training in the use of this spine system because this is a technically demanding procedure presenting a risk of serious injury to the patient. In addition, the surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions (e.g., smoking, occupation), which may impact on the performance of the system

MR Magnetic Resonance Environment

MR Conditional: (implants only)

Non-clinical testing has demonstrated that the Gibralt Spine System is MR Conditional under a range of exemplar configurations. A patient with the 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.

Preoperative:
A successful result is not always achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise the 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.

Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.

Pre-operative planning prior to implantation of posterior cervical lateral mass and pedicle screw spinal systems should include review of cross-sectional imaging studies (e.g., CT and/or MRI imaging) to evaluate the patient's cervical anatomy including the transverse foramen and the course of the vertebral arteries. If any findings would compromise the placement of lateral mass or pedicle screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

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.

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.

This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful.

No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

Prior to surgery, the patient must be informed of all potential risks and adverse effects contained in the present instructions for use.

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Intraoperative:
The surgeon should follow established practices and specific instructions for implant of the system. 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.

If screws are bent or damaged during insertion or adjustment, they may not be implanted and must be replaced. Rods should only be contoured with the proper contouring instruments. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to ensure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field and whenever possible, use pre-cut rods if available.

The rod-to-rod connecting components must be sized correctly for the diameter of the rods used.

Do not over-tap or use a screw that is either too long or too large. Over-tapping or using an incorrectly sized screw may cause nerve damage, hemorrhage, or other possible adverse events.

Bone grafts must be placed in the area to be fused.

Before closing the soft tissues, all the set screws should be tightened firmly. Recheck the tightness of all set screws after finishing to make sure that none loosened during the tightening of the other set screws. Failure to do so may cause loosening of the other components.

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. Stainless steel and cobalt chrome implants must NOT be used together in building a construct.

Different manufacturers use different materials, varying tolerances and design configurations. Components of the Gibralt Spine System must not be used with components from any other system or manufacturer.

Postoperative:
Postoperative counseling and care are important. It is recommended that regular, long-term postoperative follow-up be undertaken to detect early signs of component failure, and to consider the course of action to be taken if such events occur.

The physician's postoperative 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.

If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as aspirin 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). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by examination.

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 breakage, which could make removal impractical or difficult, (5) pain, discomfort, or abnormal sensations due to the presence of the device, (6) potential increased risk of infection, (7) bone loss due to stress shielding; and (8) potential unknown and/or unexpected long term effects due to wear particles such as carcinogenesis. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.

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 any or all the components
2. Disassembly, bending, and/or breakage of any or all the components
3. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion)
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain; Bursitis
5. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
6. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
7. Infection
8. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis
9. Nerve damage due to surgical trauma or presence of device and temporary or permanent loss of neurologic function, including paralysis
10. Urinary retention or loss of bladder control or other types of urological system compromise
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain
12. Fracture, micro fracture, resorption, damage, or penetration of any spinal bone (including the vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery
14. Non-union (or pseudarthrosis), delayed union or mal-union
15. Loss of or increase in spinal mobility or function
16. Bone loss or decrease in bone density, possibly caused by stresses shielding
17. Graft donor site complications including pain, fracture, or wound healing problems.
18. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise
19. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise
20. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction
21. Development of respiratory problems, (pulmonary embolism, atelectasis, bronchitis, pneumonia)
22. Death

Additional surgery may be necessary to correct some of these potential adverse events.

How Supplied:
NON STERILE The Gibralt Spine System 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 hospital clean but non-sterile and require sterilization before each use. All instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned 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 performed with alkali aldehyde-free solvents at high temperatures. Cleaning and decontamination can include the use of neutral cleaners follow 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 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.

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. 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. 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-layer 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. The use of an FDA cleared wrap is recommended to ensure devices remain sterile prior to implantation.

Storage and Handling:

Implants should be stored in their original, sealed packaging in clean, dry conditions. The packaging should not be exposed to direct sunlight, ionizing radiation, extreme temperatures, or particulate contamination. Prior to use, inspect the packaging and labeling for integrity. If the device has been opened, damaged or adulterated in any way, it must not be used. In order to ensure sterility, please observe aseptic surgical procedures when removing the implant from its packaging.

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. 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 the Gibralt® Spine 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 Gibralt Spine 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 copyrights, and pending and registered trademarks are property of ChoiceSpine. For more information on a specific product or trademark, please contact your local ChoiceSpine representative.

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
Customer Service Department
400 Erin Drive
Knoxville, TN 37919
Phone: 865-246-3333; Fax: 865-588-4045
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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