

**X-spine Systems, Inc.**  
**Spider® Cervical Plating System**

**GENERAL DESCRIPTION**

The Spider® Cervical Plating System consists of screws and plates offered in various sizes so that adaptations can be made to take into account pathology and individual patient anatomy. The implants are manufactured from titanium alloy (Ti 6Al 4V ELI) as described by ASTM F136. The Spider System implants are intended for single use only and are provided non-sterile. The products need to be steam sterilized by the hospital prior to use.

**INDICATIONS FOR USE**

The Spider® Cervical Plating System is intended for anterior fixation of the cervical spine. The system is indicated for use in temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with the following: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal tumors, deformity (e.g., kyphosis, lordosis, scoliosis), pseudoarthrosis, and/or failed previous fusion.

**CONTRAINDICATIONS**

1. Patients with probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities.
4. Use with components from other systems, or in any case requiring the mixing of metals from different components.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
7. Rapid joint disease, bone absorption, osteopenia. 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.
8. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
10. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

11. Any case not described in the indications for use.
12. Reuse or multiple uses.

## **WARNINGS**

1. This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
2. Implants and instruments are provided non-sterile and must be sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.
3. As with all orthopedic and neurosurgical implants, none of the Spider System implants should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.
4. The system has not been evaluated for safety and compatibility in the MR environment. The safety of the system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
5. Internal fixation devices cannot withstand activity and load levels equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed do not subject this device to the stress of full weight bearing, or implant failure may result.
6. Always orient the Spider Cervical Plating as close as possible to the spinal midline.

## **PRECAUTIONS**

Potential risks associated with the use of this system, which may require additional surgery, include; device component neurological injury, and vascular or visceral injury. Discard all damaged or mishandled implants. Never reuse an implant, even though it may appear undamaged.

Contouring and bending of a system component may reduce its fatigue strength and cause failure under load. If spinal screws are bent or otherwise damaged during insertion or adjustment, the screw should be explanted and replaced.

The Spider System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Further, the proper selection and compliance of the patient will greatly affect the results. The surgeon should consider the patient conditions (e.g., smoker, malnutrition, obesity, alcohol and drug abuse, poor muscle and bone quality), which may impact system performance.

The Spider System is only a temporary implant used for the correction and stabilization of the cervical spine. The system is also used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the Spider System is utilized. Use of this product without a bone graft or in cases that develop into a nonunion will not be successful. The spinal implant cannot stand body loads without the support of bone. In this event, bending, loosening, disassembly and or breakage of the device will eventually occur.

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/or breakage, which could make removal impractical or difficult, (5) Pain, discomfort, or abnormal sensations due to the presence of the device, (6) Possible increased risk of infection, and (7) bone loss due to stress shielding. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

### **INSTRUCTIONS FOR USE**

For additional instructions regarding the proper use and application of all Spider implants and instruments, please refer to the Spider System Surgical Technique Manual (available at no charge upon request).

A successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise 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 the Spider System should only be considered when the following preoperative, intra-operative and postoperative conditions exist.

### **PREOPERATIVE MANAGEMENT**

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those mentioned in the contraindications should be avoided.
3. . Device components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion. 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.
4. 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.

## **INTRAOPERATIVE MANAGEMENT**

1. The vertebral levels to be fixated should be well visualized with a linear anterior surface so that the plate will mount flush with the anterior cervical spine. The Spider Cervical Plate comes with a standard lordotic curve. When the configuration of bone cannot be fitted with an available temporary fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent more than absolutely necessary. The components should not be reverse bent at the same location.
2. The appropriate sized plate should be selected with the plate holes directly anterior to the vertebrae to be fused.
3. Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae.
4. The Spider Plate incorporates resilient locking arms with tabs which seat on a corresponding locking surface of the placed bone screw head. After placement of the screw, the resilient arm should be visualized with the locking tab positioned over the lateral portion of the screw head. Fixed and variable screw head types are provided.
5. Removal of screws, if desired, is accomplished by laterally moving the resilient arm away from the screw head using the included screw removal instrument. With lateral pressure on the resilient arm the locking tab will move lateral to the screw head, allowing for screw removal using the standard 2.5 mm hex screwdriver.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat from the curing process may cause neurological damage and bone necrosis.

## **POSTOPERATIVE MANAGEMENT**

The physician's post-operative directions and warnings to the patient and the corresponding patient compliance are essential.

1. 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. Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent restriction in body motion. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
2. 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 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).
3. During explantation, care should be taken to avoid damaging the implant and surrounding tissue as little as possible. The explanted device should be cleaned and disinfected using the instructions provided for cleaning/disinfection of instruments. Information on the procedure and patient should be retained to assist in any investigation.
4. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.

## **POSSIBLE ADVERSE EFFECTS AND COMPLICATIONS**

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants.
4. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
5. Infection.
6. Dural tears, persistent CSF leakage, meningitis.
7. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
8. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
9. Loss of bladder control or other types of urological system compromise.
10. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
11. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
12. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
13. Non-union (pseudarthrosis), delayed union, mal-union.
14. Cessation of any potential growth of the operated portion of the spine.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Death.

## **PACKAGING, LABELING, AND STORAGE**

The implants are supplied clean and NON-STERILE. They must be sterilized (see below). The implants are delivered in packages. These must be intact at the time of receipt. The implants may be delivered as a complete set: Implants and instruments are contained within specially designed trays which can be sterilized directly. Use care in handling and storage of the implant components. Cutting, sharply bending, or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environments such as salt, air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if instruments or implants have been damaged during the storage processes.

## **STERILIZATION**

All Spider System implants and instruments are provided clean and non-sterile and must be sterilized before use. All implants and instruments must be free of packaging material and bio-contaminants prior to sterilization. To achieve a sterility assurance level of not less than  $10^{-6}$ , all non-sterile implants and instruments should be autoclave sterilized using the following validated cycle parameters:

*Saturated steam method, (pressure 41.9 psia, 205.5 kPa) pre-vacuum air removal (3 pulses), 270° F (132° C), 4-minute exposure time, 30-minute drying time, in a double-wrapped case configuration. Note: Most sterilizers automatically control pressure to ensure saturated steam and may not be adjusted by the user.*

Use FDA cleared sterilizers and sterilization packaging materials/accessories (wraps, biological indicators, chemical indicators, etc.) for sterilization of instruments.

Do not stack instrument trays during sterilization.

## **CLEANING OF INSTRUMENTS**

 Caution: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided. Cleaning must be performed by personnel trained in the general procedures involving contaminant removal. Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated system may be used in addition to the following manual cleaning procedure.

1. Thoroughly clean all instruments and trays prior to use and as soon as possible after use (within a maximum of 2 hours post-operation) with intensive rinsing under cool tap water (<40°C) to remove gross soil. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent (Enzol® Enzymatic Detergent or equivalent) to delay drying.
2. Loosen and disassemble instruments with removable parts in accordance with **Table 1** below.

**Table 1 – Instrument Requiring Disassembly for Cleaning**

<b>Part Number</b>	<b>Instrument Name</b>	<b>Disassembly Instructions</b>
X009-0001	Double Barrel Drill Guide Assembly	Ensure that the two (2) removable drill inserts have been properly removed from the guide assembly prior to cleaning.

3. **Table 2** below describes the required steps for thoroughly cleaning the system instruments.

**Table 2 – Cleaning Parameters**

Step	Agent	Time (mm:ss)
Instructions		
1. Initial Clean	Enzol Enzymatic Detergent Solution (or equivalent)	3:00
	Add one (1) ounce (30 mL) of Enzol to one (1) gallon (3.8 L) of tap water. Soak instruments immediately after use and flush detergent through all channels until evidence of organic material is removed. Soak for three (3) minutes. While submerged, use a soft bristle brush that is intended for use with surgical instruments to gently remove visible debris. Pay close attention to threads, crevices, lumens and hard to reach areas. If organic material is dried-on, extend soak time and use two (2) ounces (60 mL) of Enzol per one (1) gallon (3.8 L) of warm tap water.	
2. Rinse	Deionized water	1:00
	Thoroughly rinse each instrument with deionized water including all channels to remove detergent for one (1) minute.	
3. Ultrasonic Clean	Enzol Enzymatic Detergent Solution (or equivalent)	10:00
	Prepare a fresh solution by adding one (1) ounce (30 mL) of Enzol and one (1) gallon (3.8 L) of warm tap water to a sonication unit (Branson Bransonic® Ultrasonic Cleaner or equivalent). Fully immerse the instruments in the solution and sonicate for ten (10) minutes.	
4. Ultrasonic Rinse	Deionized water	1:00
	Thoroughly rinse each instrument with deionized water including all holes and cannulations to remove detergent for one (1) minute.	
5. Inspection	Unaided eye	
	Inspect each instrument for evidence of organic material. Repeat the ultrasonic clean and rinse steps if needed.	

4. If instruments are not dry, use filtered pressurized air or lint-free wipes to dry.

## INSPECTION

1. Carefully inspect each instrument and tray to ensure all visible blood and soil has been removed. Repeat cleaning if necessary.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your X-spine Systems representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your X-spine Systems representative for a replacement.

### Manufacturer:



#### X-spine Systems, Inc.

452 Alexandersville Rd.  
Miamisburg, OH 45342 USA  
Phone: (800) 903-0640  
Fax: (937) 847-8410

### Authorized Representative:



#### EMERGO EUROPE

Prinsessegracht 20  
2514 AP The Hague  
The Netherlands



**CAUTION:** Federal Law (USA) restricts these devices to use by or on the order of a physician.

**CE** 0086

REF

Part Number  
N60000225-EN Rev L  
08/2017