X-spine™ Surgical Technique

X-spine Systems SPIDER™
Cervical Plating System

X-spine™
X-treme Innovations
General Description
The X-Spine Spider™ Cervical Plating System is intended for anterior screw fixation to the cervical spine. The SCP system consists of a variety of shapes and sizes of bone plates and screws. The components are manufactured from titanium alloy (Ti 6Al 4V ELI) as described by ASTM F136. Components of the X-Spine SCP System should not be used with components from any other system or manufacturer. The X-Spine SCP System components are provided non-sterile. The products need to be steam sterilized by the hospital prior to use.

Indications for Use
The SCP system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with 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., fractures or dislocations), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

Warnings
1. This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

2. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct. The X-Spine SCP System should not be used with components from any other system or manufacturer. As with all orthopedic implants, the X-Spine SCP System should not be reused after use in an implant or prior to sterilization.

3. Always orient the Spider Cervical Plating as close as possible to the spinal midline.

Precautions
The X-Spine SCP 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.

Due to the presence of implants, interference with roentgenographic, CT, and/or MR imaging will result.

The X-Spine SCP 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 X-Spine SCP 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 withstand body loads without the support of bone. In this event, bending, loosening, disassembly and or breakage of the device will eventually occur.

Please refer to the Package Insert for a comprehensive listing of warnings and precautions.
This publication recommends procedures for using X-spine products and instruments. The guidance it offers is for surgeon consideration, but, as with any technical guide, the surgeon must evaluate the specific requirements of the patient, making appropriate adjustments as needed.

1. Site Preparation

The anterior cervical spine is exposed via the standard surgical approach of Cloward. Interbody bone grafting is performed at the desired disk levels. The ventral cortical surface must be free of osteophytes and smooth in profile prior to plate placement.

2. Sizing

A plate is selected such that the screw sockets are located in the mid-portion of the vertebra. The plate should be centered in the midline and confirmed using anatomical landmarks and AP radiography.

Sizing may be determined by using the Neuro Caliper instrument. Plate sizing corresponds to the overall plate length, not screw socket distance. A Plate Holding Instrument is provided to assist in plate placement.
3. Plate Bending
The SPIDER plate comes with a standard lordotic curve. If additional lordosis is required, the Plate Bending Instrument may be used. The plate should be bent within the Bending Zone. To increase the lordotic curve further, bend the plate at multiple locations across the Bending Zone.

**CAUTION** - Once bent, avoid reverse bending the plate in the same location. This may result in plate weakening and premature fatigue fracture.

**CAUTION** - Avoid bending the plate in the region of the locking mechanism. This may result in screw locking mechanism malfunction.

4. Fixation Pin Placement
Fixation Pins may be placed in the screw sockets as needed. The Fixation pins may be inserted and extracted with the Fixation Pin Inserter.

**CAUTION** - The Fixation Pins should be oriented so that the flats are medial and lateral.
5. Bone Awl

The bone awl instrument is used to penetrate the cortical bone via each screw socket. Optionally, fixation pins may be placed through the screw sockets to temporarily hold the plate in the midline.

6. Drilling

The SPIDER Cervical Plating System is designed to be used with the self-drilling screws provided. Self-drilling screws preserve cancellous bone for screw purchase and generally result in improved screw fixation compared with drilled screws. In cases where there is unusually hard bone present, drilling can be performed. If drilling is desired, the drill guide instruments are used to guide the drill bit through each screw socket.

Drill bits are provided in 12, 14, and 16mm lengths, corresponding to the available screw lengths. The drill bits have a standard AO quick-connect coupling. A ratcheting handle for hand-drilling is provided.

CAUTION - Excessive angulation force on any drill guide should be avoided. Over-angulation of the drilled hole beyond 7.5 degrees may result in failure of the screw to engage the plate and/or locking mechanism.
OPTION 1: Variable Single Barrel Drill Guide

The Variable Single Barrel Drill guide allows for approximately 15 degrees of total drill angulation with respect to the plate. It has a soft-stop mechanism to indicate over-angulation. It is important not to force the guide past 7.5 degrees in any direction. The drill guide tip has flats on the lateral sides (with the handle in the rostral or caudal position). The flats allow for the drill guide to engage the screw socket without impacting the locking arm, which should be avoided. The Variable Single Barrel Drill Guide is intended to be used with variable (blue or yellow) screws.

OPTION 2: Fixed Single Barrel Drill Guide

The Fixed Single Barrel Drill guide has a hard-stop mechanism to prevent significant angulation of the guide with respect to the plate. The drill guide tip has flats on the lateral sides (with the handle in the rostral or caudal position). The flats allow for the drill guide to engage the screw socket without impacting the locking arm, which should be avoided. The Fixed Single Barrel Drill guide is intended to be used with fixed (magenta or green) screws.

OPTION 3: Double Barrel All-In-One Drill Guide

The Double Barrel All-In-One Drill Guide instrument may be used as an alternative to the Variable Single Barrel Drill Guide instrument. The Double Barrel All-In-One Drill Guide instrument has a tip which is dimensioned to be engaged into the slotted area adjacent to the screw sockets. The Double Barrel All-In-One Drill Guide instrument allows for the placement of the Bone awl, Thread Tap, and Hex Driver through the guide while it is engaged in the plate. Each barrel contains a removable Drill Insert which must be removed to allow the use of the instruments through the guide.
7. Thread Tapping
The provided screws are fluted for self tapping. For unusually hard bone, a 4 mm threaded tap is provided.

8. Screw Selection
Screws are available in 12, 14 and 16mm lengths and the following Diameters:

- 4.00mm Variable: Blue
- 4.25mm Variable: Yellow
- 4.00mm Fixed: Magenta
- 4.25mm Fixed: Green

9. Screw Angulation
CAUTION- Angulating the variable screws greater than 7.5 degrees in any one direction may prevent the screw from engaging the plate and/or locking mechanism properly.
10. Screw Placement

The Hex Driver instrument is used to drive the screws into bone. The Hex Driver tip is designed to self-retain the screw. As the screw is tightened into bone, the screw head will pass through the resilient locking arm. An audible and tactile click should be noted as the screw engages the locking mechanism. Positioning of the locking tab in front of the screw shoulder should be visually confirmed.

**CAUTION** - Placement of high torque force during screw tightening may result in plate damage, stripping of bone and weakening of the bone/screw interface. If screw stripping or other compromise of the bone/screw interface occurs, placement of a wider and/or longer screw is advised, within anatomical limitations. If screw replacement fails to establish adequate strength, repositioning of the plate is advised. Following plate placement, radiography is recommended to confirm appropriate positioning.

11. Screw Removal

If a screw needs to be removed, the screw removal tool is placed into the slotted area adjacent to the screw socket. The Screw Removal Instrument should fully engage the plate and by doing so will retract both locking arms of a screw socket pair. The Screw Removal Instrument has a built-in 15 degree angulation with respect to the plate. This allows for clearance of the hex-driver. The Hex Driver can then be used to withdraw the screw.
SPIDER® Plating System
Instruments

- Spider Fixation Pin Impactor – #N60001054
- Spider Drill – #N60000175,176,177
- Spider Tap – #N60000170
- Spider Screw Removal Device – #N60000190
- Spider Awl – #N60000165
- Spider Single Barrel Drill Guide – #N60000180 & #N60001050
- Spider Double Barrel Drill Guide – #X009-0001
- Spider Plate Holder – #N60000089
- Spider Drill – #N60000175,176,177
WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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Products Patented and Patents Pending
All products are not currently available in all markets.

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