HydraLok®
Polyaxial Pedicle Screw System

GENERAL DESCRIPTION
The HydraLok® System is a top-loading spinal fixation system including screws, rods, and connectors for fixation to the thoracic, lumbar and sacral spine. Various sizes of the implants are provided. The components are manufactured from titanium alloy (Ti-6Al-4V ELI as described by ASTM F136). The HydraLok System components are provided clean and non-sterile. The products must be steam sterilized by the hospital prior to use.

INDICATIONS FOR USE
The HydraLok System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine including degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kypohsis, spinal tumor and failed previous fusion (pseudoarthrosis).

In addition, when used as a pedicle screw fixation system, the HydraLok System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra, who are receiving fusion by autogenous bone graft only having the device attached to the lumbar and sacral spine (L3 and below), who are having the device removed after the development of a solid fusion.

CONTRAINDICATIONS
Contraindications for the HydraLok System are similar to those of other systems of similar design, and include, but are not limited to:

- Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
- Morbid obesity
- Pregnancy
- Grossly distorted anatomy (e.g., congenital abnormalities) and bone abnormalities (e.g., bone absorption, osteopenia, or osteoporosis) preventing safe screw fixation
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
- Suspected or documented metal allergy or intolerance

WARNINGS AND PRECAUTIONS
The HydraLok System should only be implanted by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. In addition, based on the fatigue test results, 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.

The Choice Spine spinal systems have not been tested for safety and compatibility in the MR environment. The Exactech spinal systems have not been tested for heating or migration in the MR environment.

Due to the presence of implants, image artifacts with roentgenographic, CT, and/or MR imaging may result.

Preoperative

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.

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 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 (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological 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.

Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.

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.

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

Contouring or bending of a screw may reduce its fatigue strength and cause failure under load. 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. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured should not be implanted.

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

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.

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

Postoperative
The physician's post-operative 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. 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.

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).

Any decision to remove the implants should take into consideration the risk to the patient of additional surgeries, as well as the difficulty of removal.

Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the HydraLok System components should be reused under any circumstances.

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:

- Early or late loosening of the components
- Disassembly, bending or breakage of any or all of the components
- Foreign body (allergic) reaction to the implants
- Infection
- Non-union (pseudoarthrosis)
- Loss of neurological function
- Excessive blood loss
- Misalignment of anatomical structures or loss of spinal mobility
- Reduction in bone density due to different distribution of mechanical stresses
- Cessation of any potential growth of the operated portion of the spine
- Death

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

PACKAGING
Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to Choice Spine.

IMPLANT PROCESSING
These recommendations are for processing non-sterile HydraLok System components. The information applies to unused and non-contaminated implants only. Explanted implants must never be reprocessed and should be handled according to hospital protocol upon removal. Any implant that has not been used, but has become contaminated, should be handled according to hospital protocol. Choice Spine does not recommend the reprocessing of contaminated implants.

The HydraLok System components are provided non-sterile and must be sterilized prior to use. The sterilization parameters are only valid for devices that are adequately cleaned.

Processing
The following cleaning guidelines are intended to supplement those supplied by equipment and solution manufacturers and local policies.

Operate equipment in accordance with the equipment manufacturer's instructions and in consideration of any limitations of use. This includes characteristics of certain types of components that require special handling or which may not be adequately cleaned by the equipment. Select, prepare and use cleaning solutions in accordance with the equipment manufacturer's instructions. Special attention should be paid to specifications for detergent concentration, water temperature, water quality and maintenance schedules.

In order to prevent damage to implants, use only neutral enzymatic detergents (pH 7 – 9).

During ultrasonic cleaning combine only items made of similar metals in order to avoid ion transfer, which may result in etching and pitting.

Ensure rinsing processes remove all cleaning residues. Removal of cleaning residues is an essential prerequisite for effective steam sterilization.

Ensure cleaning equipment achieves and maintains the proper process parameters (e.g. time, temperature, water pressure, fluid flow rates, concentration and delivery of accessory solutions etc.).

Manual - Ultrasonic Method
Equipment: Ultrasonic cleaner, cleaning brush, enzymatic detergent (neutral pH), running water (tap, purified)

1. Pre-rinse under warm running water for a minimum of two (2) minutes.
2. Completely immerse in an ultrasonic cleaning bath filled with a neutral (pH 7 – 9) enzymatic detergent solution (e.g. Enzol®) prepared according to the manufacturer's instructions.
3. Ultrasonicate for a minimum of ten (10) minutes at or below 35 ºC (95 ºF).
4. If necessary, clean implant with a cleaning brush.
5. Rinse for at least two (2) minutes under purified running water to remove cleaning residue.
6. Carefully dry using an absorbent, non-shedding cloth or industrial hot dryer, or place into a drying cabinet until all moisture is removed.

Automated Method
1. An automated cleaning process of equal effectiveness to the manual cleaning method may be used. Follow instructions provided by the washer manufacturer and detergent manufacturer as well as local policies.
2. Arrange items in the washer such that all surfaces are exposed to the action of the automated washer.
3. Sequencing, number and type of stages may vary among washer manufacturers. Washers may use a single chamber for rinsing, cleaning and drying or may use multiple chambers, one for each cycle. Typical wash cycles may include the following: cool water rinse, enzymatic soak, detergent wash, ultrasonic cleaning, sustained hot water rinse and drying. It is recommended to perform a neutralizing rinse after use of strong alkaline or acidic cleaning solutions. Use purified water for the final rinse.

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
Equipment: Prevacuum steam autoclave, purified water, sterilization wrap.

1. **Assemble components into their respective tray positions and place lid on tray.**
   Proper positioning of items is essential for adequate steam penetration and aeration during processing. Steam must contact all implant surfaces in order to ensure effective sterilization.

2. **Wrap entire tray in sterilization wrap material and apply label to indicate contents.**
   Sterilization wraps must allow adequate steam penetration, aeration and protection against microbial penetration. Sterilization wraps should be approved for clinical use. In the United States only sterilization wraps cleared for marketing by the Food and Drug Administration (FDA) should be used, such as KimGuard® One-Step® KC100.

3. **The following are the recommended sterilization parameters:**

Method	Cycle	Temperature	Exposure Time	Drying Time
Steam	Pre-Vacuum	132ºC (270ºF)	4 minutes	60 minutes
Steam	Pre-Vacuum	134ºC (273ºF) *See below.	3 minutes	60 minutes

**The 134°C / 3-minute sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as*

sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

- Ensure autoclave equipment achieves and maintains the proper time, temperature, and pressure.
- Operate equipment in accordance with the equipment manufacturer's instructions.
- When sterilizing multiple device sets in one autoclave cycle ensure the maximum load stated by the equipment manufacturer is not exceeded.
- Use purified water for steam sterilization.

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.

Limitations and Restrictions

Repeated sterilization according to these instructions has a minimal effect on Exactech 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 Choice Spine implants. Any deviations from these procedures must be evaluated for efficacy by the sterilizing facility.

CAUTION

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

INFORMATION

"**Patent Coverage: See www.choicespine.com/about-us/patents/**"

For product complaints please contact
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