Cortera™ Spinal Fixation System

GENERAL DESCRIPTION

The Cortera Spinal Fixation System (Cortera System) is a thoracolumbosacral pedicle screw system intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or the sacral spine. The Cortera System consists of screws, rod-to-rod connectors, lateral offset connectors, rods, locking set screws and associated reusable manual surgical instruments for an open or minimally invasive surgical approach. The screws, rod-to-rod connectors, lateral offset connectors, and set screws are manufactured from titanium alloy (Ti6Al4V per ASTM F136). The rods are available in titanium alloy or cobalt chromium alloy (Co-28Cr-6Mo per ASTM F1537). The implants are available in a variety of sizes to accommodate individual patient anatomy and are provided non-sterile. A variety of these implant configurations were previously covered in K221403.

The Cortera System rods may be used in connection with Streamline Cross Connectors, cleared by FDA in K192800. The Streamline Cross Connectors accept various rod diameters and are appropriate for use with Cortera System 5.5 mm diameter rod-based systems. These cross connectors will keep their original cleared trade name.

INDICATIONS FOR USE

The Cortera Spinal Fixation System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Cortera Spinal Fixation System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Cortera Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. Pediatric pedicle screw fixation is limited to a posterior approach.

The Cortera Spinal Fixation System is intended to be used with an autograft and/or allograft.

CONTRAINDICATIONS

This system is contraindicated for the following:

- Use in the cervical spine.
- Use with bone cement.
- Patients with osteopenia, bone absorption, bone and/or joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance or allergy.

- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness, and/or other medical conditions, which would prohibit beneficial surgical outcome.
- Patients resistant to following postoperative restrictions on movement especially in athletic and occupational activities.
- Spinal surgery cases that do not require bone grafting and/or spinal fusion.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- 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.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- 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.
- Any case not described in the indications for use.
- Reuse or multiple uses.

⚠ WARNINGS

- 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 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.
- The implantation of pedicle screw spinal systems should be performed only 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.
- Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
- The implants of the system are provided non-sterile and must be sterilized prior to use. Refer to the sterilization section below.
- All instruments, except instruments marked as sterile, are provided non-sterile and must be cleaned and sterilized prior to use. Refer to the cleaning and sterilization sections below. Verify that all relevant instrumentation has been properly cleaned and disinfected.
- Inspect all instruments before use and do not use the instrument if it appears modified or damaged.
- Prior to use the surgeon must become familiar with the device system and the surgical procedure. Use surgical instrumentation, accessories, and surgical technique guide provided with this device or associated implant system.
- Single Use/Do Not Re-Use: Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables and transmission of infectious agents.
- The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
- Do not comingle titanium and stainless-steel components within the same construct.
- Risks identified with the use of these devices, which may require additional surgery, include device

component failure, loss of fixation/stabilization, non-union, vertebral fracture, neurological injury, vascular or visceral injury.

- Risk factors that may affect successful surgical outcomes include the following: alcohol abuse, obesity, patients with poor bone, muscle and/or nerve quality. Patients who use tobacco or nicotine products should be advised of the consequences that an increased incidence of non-union has been reported with patients who use tobacco or nicotine products.
- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
- No spinal implant can withstand body loads for an indefinite period of time without the support of bone. In the event that successful fusion is not achieved, bending, breakage, loosening or disassembly of the device will occur.

PRECAUTIONS

- Do not bend the Guidewire. Bending the Guidewire could cause it to kink and/or break.
- Do not advance or remove the Guidewire while placing instruments over the Guidewire during the procedure to prevent unintentional advancement of Guidewire.
- Guidewires should be monitored using fluoroscopic imaging to avoid advancement through the vertebral body in order to prevent damage to underlying structures.
- Select the proper sized Tap. Over-tapping can result in construct instability and screw loosening.
- To maintain the polyaxial characteristics of the pedicle screw, avoid bottoming and/or impinging the tulip head against bony elements.
- Ensure proper rod orientation before bending the rod. Ensure the rod inserter engagement feature and bullet tip is fully cleared beyond the Rod Bender roller.
- Avoid creating a sharp bend or overbending the rod, as this may lead to premature material fatigue of the implant. Do not bend the rod in the reverse direction if the rod has already bent, as this may introduce micro fractures that compromise its strength.
- Avoid creating a notch in the rod by using the Ø6.0 rod benders with the Ø6.0 rod and the Ø5.5mm benders with the Ø5.5mm rod. Failure to match the correct diameters may lead to premature material fatigue of the implant.
- Verify the superior and inferior rod overhang. Inadequate overhang may cause improper set screw placement resulting in an unstable construct.
- Inability to identify the entirety of each MIS Rod through-hole with fluoroscopy may cause improper Set Screw placement or inadequate rod overhang, resulting in an unstable construct.
- Reduction instrumentation provided within the Cortera MIS Spinal Fixation System is intended to

aid in the reduction of vertebral spondylolisthesis. Cortera MIS reduction instrumentation should not be used to forcefully contour a rod in situ into a tulip head in a previously fused or otherwise immobile spinal level(s).

- Do not final tighten under compression or distraction as the rod may not be normalized to the tulips, resulting in lack of construct stability.
- The Compressor and Distractor must be removed prior to final Set Screw locking. Additional forces and friction occur between the Compressor and the Final Driver when tightening a Set Screw. This may result in insufficient torque for final Set Screw locking with the Compressor in place.
- The Final Driver must be used in combination with the Torque-Limiting Handle to complete final Set Screw locking.
- Failure to tighten Set Screws using the recommended instrument(s) could compromise the mechanical stability of the construct.

MRI SAFETY INFORMATION

The Cortera™ Spinal Fixation System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Cortera™ Spinal Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

INSTRUCTIONS FOR USE

For additional instructions regarding the proper use and application of all implants and instruments, please refer to the Cortera™ Spinal Fixation 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.

POSSIBLE ADVERSE EFFECTS AND COMPLICATIONS

No surgical procedure is completely free of risk from complication and often risk factors can be managed to avoid surgery-related problems. The surgeon must discuss all known risks with the patient where patient compliance is essential both preoperatively and postoperatively. The following complications and adverse reactions are known to be potential risks of spine surgery.

- Pain, discomfort, or abnormal sensations
- Dural leak
- Bone fracture

- Allergic reaction
- Cutting of skin or gloves of operating staff
- Vascular or visceral injury
- Neurological injury
- Infection
- Hemorrhage
- Revision surgery
- 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.

CLEANING & REPROCESSING

Non-Sterile Instruments:

- Instruments must be cleaned and sterilized per the below instructions prior to introduction into a sterile surgical field. or (if applicable) return of the product to the manufacturer.
- To minimize corrosion and prolong the usable life of instruments used during surgery, remove gross traces of blood and residues then thoroughly clean and dry immediately after use. Do not allow soils to dry.
- Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
- Prior to and during use, including reprocessing, inspect instruments for:
- Damage such as but not limited to, wear, discoloration, corrosion, cracking, fracture, or unrecognizable markings.
- Proper function including but not limited to, sharpness, movement of hinges and couplings, joint stability, and legible markings.

- Instruments that show signs of damage or an inability to function should not be used and should be returned to the manufacturer.

CLEANING

Manual Cleaning

1. Disassemble the device(s), if applicable. See surgical technique manual for specific instructions.
2. Rinse soiled device under running, cold tap water for a minimum of two (2) minutes. Remove gross soil using a soft bristle brush or soft, lint-free cloth.
3. Prepare a neutral pH enzymatic solution in warm tap water (approximately 33-43°C or 92-110°F), per the manufacturer's recommended instructions.
4. Soak devices in freshly prepared neutral pH enzymatic solution for a minimum of ten (10) minutes.
5. Rinse device using cool running tap water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels and other hard to reach areas. Actuate joints, handles and other moveable device features under running water to rinse thoroughly.
6. Prepare a neutral pH enzymatic solution in warm tap water (approximately 33-43°C or 92-110°F), per the manufacturer's recommended instructions.
7. Manually clean devices for a minimum of five (5) minutes in freshly prepared neutral pH enzymatic solution. Use a syringe, pipette, or water jet to flush lumens and channels. Use a soft- bristled brush to remove soil and debris. Actuate joints, handles, and other movable device features to expose all areas to detergent solutions. Clean device under water to prevent aerosolization of contaminants.
8. Rinse device using deionized (DI) running water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels. Actuate joints, handles, and other moveable device features to rinse thoroughly under running water.
9. Visually inspect device for residual soil. If present, repeat steps 1-8 above.
10. Gently wipe down the device components with a soft lint-free cloth. Ensure the device is completely dry. Visually inspect the device; it should be clean, dry and residue-free.
11. Reassemble device(s), if applicable, following instructions in the surgical technique manual.

AUTOMATED (MECHANICAL) CLEANING:

<u>Pre-Cleaning</u>

1. Disassemble device(s), as applicable. See surgical technique manual for specific instructions.
2. Rinse the device components under running lukewarm running tap water (22-43°C or 72-110°F) for a minimum of one (1) minute. After rinsing, remove gross soil using a soft-bristled brush or clean, soft, lint-free cloth.
3. Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions.
4. Fully immerse the device components in the fresh, newly prepared neutral pH enzymatic cleaning solution for a minimum of five (5) minutes.

5. After soaking, manually clean the device components for a minimum of two (2) minutes using a soft-bristled brush to remove soil and debris from the device and device lumens. Brush the device while fully immersed to prevent aerosolization of contaminants. After cleaning, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 mL of the cleaning solution.
6. Remove the device components from the cleaning solution and place the device components in a bath of lukewarm tap water (22 – 43°C or 72-110°F) for a minimum of one (1) minute. Ensure that the water immerses the device components. Once the rinse time has elapsed, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 mL of the water.

Automated Cleaning

1. Place the device components in the automated washer.
2. Perform the automated cycle per instructions in the table below.
3. Visually inspect the device; it should be clean, dry and residue-free.
4. Reassemble device(s), if applicable, following instructions in the surgical technique manual.

AUTOMATED (MECHANICAL) CLEANING PARAMETERS			
Cycle	**Time (Minutes)**	**Minimum Temperature**	**Detergent**
Enzyme wash	4:00	Hot water 60°C (140°F)	Enzymatic cleaner (neutral pH) prepared per manufacturer's instructions
Wash	2:00	Hot water	Neutral detergent prepared per manufacturer's instructions
Rinse	2:00	Heated deionized or high purity water 70°C (158°F)	N/A
Dry	15:00	80°C (176°F)	N/A

STERILIZATION

Non-Sterile Instruments and Implants:

Independent testing has shown the following conditions to be effective:

Method	Steam
Cycle	Pre-vacuum (Wrapped)
Temperature	132°C (270°F)
Recommended Exposure Time	4 Minutes
Recommended Dry Time	30 Minutes

- Use of an FDA cleared wrap is recommended to ensure product sterility.

- Steam sterilization (moist heat) is the only method permitted for sterilization. Other sterilization methods are not permitted.
- The values specified here (duration/temperature) can achieve a sterility assurance level (SAL) of at least 10^{-6}.

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 Xtant Medical representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Xtant Medical representative for a replacement.

Manufacturer:

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

XTANT MEDICAL

Cortera™ Spinal Fixation System

Symbol Definitions	
	Reference Number
	Batch Number
	Manufacturer
	Single Use
	Consult instructions for use
	Non-Sterile
	Prescription Only

REF

Part Number
IFU-000001 Rev C
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