X-spine Systems, Inc.
Fortex™ Pedicle Screw System

⚠ **IMPORTANT NOTE:**

The user acknowledges that he/she has read and agreed to the conditions in this insert, which are to be considered as contractual.

GENERAL INFORMATION

The Fortex Pedicle Screw System consists of rods, pedicle screws, cross bar connectors and hand instruments. Various forms and sizes of these implants are available so that adaptations can be made to take into account the pathology and anatomy of an individual patient. The system components are made of Ti6Al4V ELI, a titanium-based alloy which complies with ASTM F136, and Co28Cr6Mo, a cobalt chromium alloy which complies with ASTM F1537.

INDICATIONS FOR USE

The Fortex Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the Fortex Pedicle Screw System is intended to provide immobilization and stabilization of the spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

CONTRAINDICATIONS

Contraindications for the Fortex Pedicle Screw System are similar to those of other systems of similar design, and include, but are not limited to:

1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures.
2. Morbid obesity.
3. Pregnancy.
4. Grossly distorted anatomy due to congenital abnormalities.
5. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
6. Rapid joint disease, bone absorption, osteopenia, osteomalcia, or osteoporosis. Osteopenia or osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
7. Suspected or documented metal allergy or intolerance.

8. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
9. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions.
10. Any time implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not needing a bone graft and fusion or where fracture healing is not required.
12. Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery such as the presence of tumors, congenital abnormalities, elevation of white blood cell count (WBC), or a left shift in the WBC differential count.

PRECAUTIONS

The implants must be implanted only by experienced 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. The use of implants must be decided upon with regard to the surgical and medical indications, the potential risks, and limitations related to this type of surgery. The surgeon and patient should demonstrate knowledge of the contraindications, side effects, precautions, metallurgic and biological characteristics of the implants to be used. Fortex implants must not be used together with implants from a different source, a different manufacturer or made from a different material.

As with all orthopedic and neurosurgical implants, none of the Fortex system components should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.

Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre and post-operative patient management are considerations essential to a successful surgical outcome. Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).

Patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients should be advised of this fact and warned of the potential consequences.

If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g. substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device. In some cases, progression of degenerative disease may be so advanced at the time of

implantation that the expected useful life of the appliance may be substantially decreased. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

Due to the presence of implants, interference with roentgenographic, CT and/or MR imaging may result. The Fortex Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. The Fortex Pedicle Screw System has not been tested for heating or migration in the MR environment. It must be noted that there are several different manufacturers and generations of MRI systems available, and X-spine cannot make any claims regarding the safety of X-spine implants and devices with any specific MR system.

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. If requested, additional information, including surgical technique manuals, may be obtained through corporate sales representatives.

⚠ 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 (Grade 3 and 4) of 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.

Benefits of spinal fusion utilizing any pedicle screw fixation system has not been adequately established in patients with stable spine. 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.

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.

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, they must 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 must not be implanted.

Mixing Metal; some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, screws, etc., which come in contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, the components of Fortex should not be used in conjunction with components from any other manufacturer's spinal system.

Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before attempted clinically. Any decision by a surgeon to remove the internal fixation device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Implant removal should be followed by adequate postoperative management to avoid fracture.

INSTRUCTIONS FOR USE

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 X-Spine Fortex Pedicle Screw System should only be considered when the following preoperative, intraoperative and postoperative conditions exist.

<u>Preoperative</u>:

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. 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.

4. 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.
5. 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. The X-Spine Fortex System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. All components and instruments should be cleaned and sterilized prior to use. Additional sterile components should be available in case of unexpected need.

Intraoperative:

1. Patient Positioning

   The patient is positioned on the operating table in the prone position. The patient should be positioned to minimize intra-abdominal pressure to avoid venous congestion and excess intra-operative bleeding and allow adequate ventilation under anesthesia. The patient's hips should be extended to preserve lumbar lordosis for fusion and instrumentation of the lumbosacral junction.
2. Exposure

   The surgical approach is carried out though a standard midline incision to the spinal column over the anatomic position of the spinous process. The exposure of the spinous process should extend one additional level. The spinal column is then exposed in routine fashion by the surgeon and decompression is carried out as needed.
3. Decortication

   Vertebral decortication and placement of bone grafts are usually done after pedicle screw preparation just prior to insertion of the pedicle screw. Meticulous fusion techniques are critical for success of the procedure.
4. Pedicle Probing

   After confirmation of the position of the pedicle canal via radiography and creation of a cortical defect using the bone awl, the pedicle probe is gently pressed into the pedicle canal. The pedicle entry point is intersected by the vertical line that connects the lateral edges of bony crest extension of the pars inter-articularis, and the horizontal line that bisects the middle of the transverse process. Anatomical variation in individual patients may cause slight differences in the entry site. These differences should be considered carefully and noted on the preoperative radiographic images and on the intraoperative images. A small rongeur or a burr may be used to decorticate the pedicle entry point. The bone awl may be used to make an entry hole through the cortex at the pedicle entry point. The probe is passed through the pedicle canal until the probe is 2/3rds of the distance to the anterior cortex of the vertebral body. The pedicle probe incorporates centimeter graduations and is used to determine the appropriate screw length. The length of the pedicle screw to be used can be determined relative to this measurement. Caution should be taken not to violate the anterior wall of the vertebral body or cortical walls.

5. Pedicle Testing

   After use of the pedicle probe, the curved sounding probe is used to confirm continuity of the cortical walls of the pedicle. The straight sounding probe can also be used to palpate the inner surface of the pedicle canal to check for defects or perforations of the cortical walls.

6. Screw Driving

   The pedicle screws are inserted using the Fortex screw driver assembly. The screw driver head is inserted into the hexagonal opening and secured to the driver by engaging the locking outer slide into the screw head. The pedicle screw is inserted into the vertebral body to the desired depth. The pedicle screw should be parallel to the endplates and extend 50% to 80% into the vertebral body when fully seated. The distal tip of the Fortex pedicle screw has a self-tapping flute and generally does not require tapping. Varying sizes of taps with quick connect capabilities are included for instances when tapping may be required due to high bone density.

7. Rod Selection

   After the pedicle screws have been placed in the pedicles, the correct length of the rod is selected. The rods are provided in various pre-cut lengths. The rod should extend approximately 5 mm beyond the outer edges of the proximal screw bodies of the most superior and the most inferior pedicle screws.

8. Rod Bending

   After the appropriate length of rod has been selected, lordosis may be bent into the rod via the rod bender. A simple lordosis bend is typically sufficient and the amount of lordosis is based on the patient's anatomy and the amount of reduction to be achieved.

9. Rod Placement and Loose Capture

   After insertion of the Fortex screws and rod bending, the rod is placed in the Fortex screw housing. A rod gripper is provided for this purpose. The setscrew is placed by rotating clockwise using the cap-introducer instrument.

10. Rod Persuasion

    A rod persuader instrument is included to assist in rod placement into the Fortex screw housing. The persuader instrument slides over the collar of the Fortex screw housing, where keyed tabs on the instrument engage with matching slots on the screw cup. Clockwise rotation of the persuader handle directs the rod downward into the Fortex screw housing.

11. Distraction and Compression

    Distraction is accomplished using the distractor, and compression is accomplished using the compressor. The spreader or compressor fit onto the rod adjacent to one or more loosely captured Fortex screws. When the desired amount of distraction or compression has been achieved, final tightening of the Fortex screw housing is performed. Screw unlocking, if desired, is the reversal of the locking procedure.

12. Final Tightening and Counter Torque

    After desired distraction or compression has been performed, the anti-torque sleeve is used to stabilize the screw housing while rotating the setscrew clockwise using the final locking cap driver. Tightening should be confirmed by audible clicking of the torque handle.

13. Cross Bar Connector Placement

    After final tightening of the Fortex screws, a cross bar connector is used if desired. The cross bar

connector assembly consists of one jointed transverse body and two integrated rod locking clamps. There are multiple sizes of cross bar connectors provided to allow for anatomic variation. Once the desired location of the cross bar has been determined, the appropriate cross bar connector size is selected. The connector is placed with each clamp pressed lightly onto each rod. The cross bar connector hex driver and anti-torque sleeve, rotated clockwise, is used to tighten each locking clamp onto the rods.

Postoperative:

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

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 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. If required, the device may be disassembled for 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. 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 Fortex components should ever be reused under any circumstances.

POTENTIAL COMPLICATIONS AND ADVERSE SIDE 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 the components.
2. Disassembly, bending or breakage of any or all of the components.
3. Foreign body (allergic) reaction to the implants.
4. Infection.
5. Non-union (pseudarthrosis).
6. Loss of neurological function, including paralysis (complete or incomplete), radiculopathy, dysesthesia, hyperesthesia, anesthesia, paresthesia, development or continuation of pain,

numbness, neuroma, tingling sensation, dural tears, neuropathy, neurological deficits (transient, permanent, or delayed), reflex deficits, bilateral paraplegia, and/or arachnoiditis.

7. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, or wound dehiscence.
8. Misalignment of anatomical structures or loss of spinal mobility.
9. Bone graft donor complications including pain, fracture or wound healing problems.
10. Atelectasis.
11. Cessation of any potential growth of the operated portion of the spine.
12. Vascular damage resulting in excessive bleeding.
13. Loss or impairment of bowel, sexual, and/or bladder function and other types of urological compromise.
14. Fracture, damage, degenerative changes or instability of any bone above and/or below the level or surgery.
15. Gastrointestinal system compromise.
16. Bone loss due to resorption or stress shielding.
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. All the legal information required for this type of implant is given on the label of each package. The implants may be delivered as a complete set: Implants and instruments are contained within specially designed trays or in boxes 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 Fortex Pedicle Screw System implants and instruments are provided 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, pre-vacuum air removal, 270^{o} F (132^{o} C), 4-minute minimum exposure time, 30-minute minimum drying time, in a double-wrapped case configuration.

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 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. No instruments within this system require disassembly as part of the cleaning process.
3. The following table describes the required steps for thoroughly cleaning the system instruments:

Step	**Agent**	**Minimum Time (mm:ss)**
	Instructions	
1. Initial Clean	Enzol Enzymatic Detergent Solution (or equivalent)	10:00
	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 a minimum of ten (10) minutes. Use a soft bristle brush (Spectrum™ M-16 or equivalent) 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	3:00
	Thoroughly rinse each instrument with deionized water including all channels to remove detergent for a minimum of three (3) minutes.	
3. Inspection	Unaided eye	1:00
	Inspect each instrument for evidence of organic material. Particular attention should be taken to remove all debris from instruments with cannulations, holes, and features that may be shielded from brushing action. Subject instruments to ultrasonic cleaning if organic matter is present after the initial cleaning step.	
4. Ultrasonic	Enzol Enzymatic Detergent Solution (or equivalent)	10:00

Clean (if required)	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 a minimum of ten (10) minutes.	
5. Ultrasonic Rinse	Deionized water	3:00
	Thoroughly rinse each instrument with deionized water including all holes and cannulations to remove detergent for a minimum of three (3) minutes.	
6. Inspection	Unaided eye	1:00
	Inspect each instrument for evidence of organic material. Repeat the ultrasonic clean and rinse steps if needed.	

4. Upon completion, visually inspect each instrument for contamination such as remaining soil and moisture or wetness. If soil remains, repeat the cleaning process. If wetness remains, use filtered pressurized air or lint-free wipes to dry.

INSPECTION

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
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.

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

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