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.

BASIC STRUCTURE
The X90 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 always be made to take into account the pathology and anatomy of an individual patient.

MATERIAL
All components are made of Ti6Al4V ELI, a titanium based alloy which complies with ASTM F136.

INDICATIONS FOR USE
The X90 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 X90 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).

LEVELS OF FIXATION
Levels of fixation are for the thoracic, lumbar and sacral spine.

GENERAL CONDITIONS OF USE
The implants must be implanted only by experienced surgeons having undergone appropriate training in spinal surgery. Their use in implantation 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. X90 implants must not be used together with implants from a different source, a different manufacturer or made from a different material. Under no circumstances may the implants be reused.

CONTRAINDICATIONS
Contraindications for the X90 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.
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, osteomalacia, 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.

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.

PRECAUTIONS
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.

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, contra-indications, 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.

⚠️ 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.
The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative 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 condition 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 rod(s) 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 X90 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.

**PACKAGING, LABELING AND STORAGE**

The implants are supplied NON-STERILE. They must be cleaned and 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 implants 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 PROCEDURES**
Ultrasound clean for five minutes using distilled water.

⚠️ Caution: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided. Verify that the instruments are in operating condition.

Sterilization: The X-Spine X90 Pedicle Screw System components are provided non-sterile. To achieve a sterility assurance level of 10^-6, a 20 minute full cycle exposure at 132° C using pre-vacuum air removal, four pulses, no dry time, in a double-wrapped case configuration.

**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 X90 Pedicle Screw System should only be considered when the following preoperative, intraoperative and postoperative conditions exist.

**PREOPERATIVE**
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 X90 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.

**INTRA-OPERATIVE**
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 conformation 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 pre-operative radiographic images and on the intra-operative 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 probe, the curved tester is used to confirm continuity of the cortical walls of the pedicle. The straight tester can also be used to palpate the inner surface of the pedicle canal to check for defects of perforations of the cortical walls.

6. Screw Driving
The pedicle screws are inserted using the X90 screw driver. The screw driver head is inserted into the hexagonal opening and secured to the driver by engaging the outer sleeve of the screwdriver to the rotating cup. The pedicle screw is inserted into the vertebral body to the desired depth. The pedicle screw should parallel the endplates and extend 50% to 80% into the vertebral body when fully seated. The distal tip of the X90 pedicle screw has a self-tapping flute and generally does not require tapping. Varying sizes of taps with quick connect capabilities are included for time 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 X90 screws and rod bending, the rod is placed in the X90 screw cup. A rod gripper is provided for this purpose. The cup is rotated clockwise to the provisional locking detent using the pre-locking instrument. The detent should be felt by the surgeon and the rod will be loosely captured in the screw cup, allowing for lateral movement for compression or distraction.

10. Rod Persuasion
   A rod persuader instrument is included to assist in rod replacement into the X90 screw cup. The persuader instrument contains a forked head which slides medially or laterally under a corresponding collar of the X90 screw cup. Clockwise rotation of the persuader handle directs the rod downward into the X90 screw cup. The final rotation of the persuader will automatically rotate the cup into the loose capture position.

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 X90 screws. When the desired amount of distraction or compression has been achieved, final tightening of the X90 screw cup is performed. Screw unlocking, if desired, is the reversal of the locking procedure.

12. Final Tightening and Counter Torque
   After desired compression or distraction has been performed, the anti-torque sleeve is used to stabilize the rod and screw cup interface while rotating the cup clockwise until the cup reaches the final positive stop, using the Final locking wrench. Complete cup rotation should be confirmed by visualizing the linear indicators engraved on the upper surface of the cup. Positioning of the linear indicators parallel to the rod indicates complete locking.

13. Cross Bar Connector Placement
   After final tightening of the X90 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 clock-wise, is used to tighten each locking clamp onto the rods.

**POSTOPERATIVE**
The physician’s post-operative 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. 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 X-Spine X90 components should ever be reused under any circumstances.