Fixcet® Spinal Facet Screw System

GENERAL INFORMATION

The Fixcet Spinal Facet Screw System is designed to provide bilateral, transfacet fixation of the spinal facet joint in the lumbar spine. The partially-threaded screws are design to transfix the facet articular process in the spine to enhance spinal fusion and stability. Various forms and sizes of these screws are available, to accommodate the individual patient anatomy. All components are made of Ti6Al4V ELI, a titanium-based alloy which complies with ASTM F136.

INDICATIONS FOR USE

The Xtant Medical Fixcet Spinal Facet Screw System is intended for posterior fixation to the lumbar spine (L1 to S1 inclusive). The system is intended for bilateral, transfacet fixation of the facet joint in order to provide stability for fusion. The system is indicated for posterior surgical treatment of any or all of the following at the L1 to S1 (inclusive) spinal levels:

- Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies),
- Degenerative disease of the facets with pain and/or instability on plain flexion and extension lateral radiographs where there is movement of the vertebral bodies relative to each other of more than 4mm,
- Trauma (i.e., fractures and/or dislocations),
- Spondylolisthesis,
- Spondylolysis,
- Pseudoarthrosis and/or failed previous fusions.

CONTRAINDICATIONS

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 case not needing a bone graft and fusion or where fracture healing is not required.
11. 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.
12. Use with components from other systems.
13. Any case not described in the indications for use.
14. Reuse or multiple uses.

⚠ WARNINGS:

1. System implants and instruments are provided non-sterile and must be sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.
2. As with all orthopedic and neurosurgical implants, none of the system components should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.
3. The Fixcet Spinal Facet Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Fixcet Spinal Facet Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PRECAUTIONS

When properly used, facet screws will provide temporary stabilization as an adjunct to spinal bone grafting processes. After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer or to support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient. This decision should consider the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

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.

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. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery. Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions, etc. which may have an impact on the performance of the system.

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.

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.

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.

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.

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.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. The type of implant to be used for the case should be determined prior to beginning the surgery.
7. All parts must be clean and sterile before use.

INTRAOPERATIVE MANAGEMENT

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to these structures will cause loss of neurological function.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
4. Caution should be taken in handling the implants; Damage to the implants may affect their performance.
5. Implants should not be reused under any circumstances.

INSTRUCTIONS FOR USE

For additional instructions regarding the proper use and application of all Fixcet implants and instruments, please refer to the Fixcet Surgical Technique Manual (available at no charge upon request).

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity.
3. Rigid external orthosis/bracing should be utilized until fusion is confirmed clinically and radiographically.
4. During 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.
5. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.

POTENTIAL COMPLICATIONS AND ADVERSE EFFECTS

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 Fixcet Spinal Facet Screw System implants and instruments are provided clean and 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 (pressure 41.9 psia, 205.5 kPa), pre-vacuum air removal (3 pulses), 270^{o} F (132^{o} C), 4-minute exposure time, 30-minute dry time, in a double–wrapped case configuration. Note: Most sterilizers automatically control pressure to ensure saturated steam and may not be adjusted by the user.

Use FDA cleared sterilizers and sterilization packaging materials/accessories (wraps, biological indicators, chemical indicators, etc.) for both non-sterile implant components and instruments.

Do Not stack instrument trays during sterilization.

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 and trays 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.

Table 1 – Instructions for Cleaning System Instruments

Step	Agent	Time (mm:ss)
	Instructions	
1. Initial Clean	Enzol Enzymatic Detergent Solution (or equivalent)	3:00
	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 three (3) minutes. While submerged, use a soft bristle brush that is intended for use with surgical instruments, 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. A cannula cleaner stylet is provided to be pushed thru cannulated instruments to clear out contaminants.	
2. Rinse	Deionized water	1:00
	Thoroughly rinse each instrument with deionized water including all channels to remove detergent for one (1) minute.	
3. Ultrasonic Clean	Enzol Enzymatic Detergent Solution (or equivalent)	10:00
	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 ten (10) minutes.	
4.	Deionized water	1:00

Ultrasonic Rinse	Thoroughly rinse each instrument with deionized water including all holes and cannulations to remove detergent for one (1) minute.	
5. Inspection	Unaided eye	
	Inspect each instrument for evidence of organic material. Repeat the ultrasonic clean and rinse steps if needed.	

4. If instruments are not dry, use filtered pressurized air or lint-free wipes to dry.

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.

REF

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