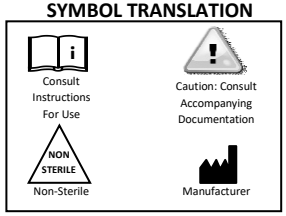
Facet Fixx® System

SYMBOL TRANSLATION



BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION

This booklet is designed to assist in using the Facet Fixx® System. It is not a reference for surgical techniques.

CAUTION

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

GENERAL DESCRIPTION

The Facet Fixx® System is a posterior facet spinal fixation system consisting of screws with and without washers manufactured from Titanium alloy Ti-6AL-4V per ASTM F136. The screw is offered in various diameters, lengths, and partially or fully threaded configurations. The Facet Fixx® system provides instruments to facilitate the proper placement of the implant. The device is designed to provide mechanical support and stability to the implanted level until fusion is achieved.

INDICATIONS FOR USE

The Facet Fixx® System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. For transfacet fixation, the screws are inserted through the inferior articular process across the facet joint and into the pedicle. For translaminar facet fixation, the screws are inserted through the lateral aspect of the spinous process, through the lamina, through the inferior articular process, across the facet joint and into the pedicle.

The Facet Fixx® System is intended for bilateral facet fixation, with or without bone graft, at single or multiple levels from C2 to S1 inclusive. The Facet Fixx® System is indicated for treatment of any or all of the following:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origins confirmed by history and radiographic studies
- Degenerative disease of the facets with instability
- Trauma (i.e. fracture or dislocation)
- Spondylolisthesis
- Spondylolysis
- Pseudoarthrosis and failed previous fusion which are symptomatic or which may cause secondary instability or deformity

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice to implant the Facet Fixx® Device must be carefully weighed against the patients overall evaluation. Circumstances listed below may reduce the chance of a successful outcome. Contraindications include, but not limited to:

1. Allergy or sensitivity to Titanium or Titanium Alloy.
2. Active or suspected infection.
3. Patients who are immune-compromised.
4. Any condition that may affect the process of normal bone remodeling, including, but not limited to osteoporosis, bone absorption, osteopenia, or certain metabolic disorders affecting osteogenesis.
5. Morbid obesity.
6. Signs of local infection or inflammation.
7. The Facet Fixx® System is also contraindicated where an anatomical deficit exists leaving an absence or destruction of any portion of the facet joint, pars defect, or in conjunction with procedures which require removal of any portion of the facet joint.
8. Alcoholism or heavy smoking.
9. Pregnancy.
10. Any case requiring the mixing of metals from two different systems.
11. Any patients exhibiting disorders which would cause the patient to ignore the limitations of the rigid fixation screw implants.
12. Conditions not described in the Indications For Use section.

WARNINGS AND PRECAUTIONS

1. The safety and effectiveness of the Facet Fixx® System has been established only for those spinal conditions listed in the Indications For Use section. The safety and effectiveness of these devices for any other conditions are unknown.
2. The Facet Fixx® System implants are used only to provide temporary internal fixation during the bone fusion process with or without the assistance of a bone graft. A successful result may not be achieved in every instance of use with these devices.
3. Without solid bone fusion, these devices cannot be expected to support the spine indefinitely and may fail due to the bone-metal interface, or bone failure.
4. The benefit of spinal fusions utilizing any facet screw fixation system has not been adequately established in patients with stable spines.
5. The implants are provided non-sterile and must be cleaned and sterilized before use.
6. These implants are for **SINGLE USE ONLY.** Under no circumstances should they be reused. While the device may appear to be undamaged, it may have small defects or internal stress patterns, as a result of the prior implantation or removal that could lead to fatigue failure. Additionally, please note that a removed implant has not been designed or validated so as to allow for decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process. The company accepts no responsibility for products which have been reused.
7. Based on testing results, use of these systems is significantly affected by the surgeon's proper patient selection, preoperative planning, surgical technique, selection and placement of implants, and complete compliance of the patient.
8. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level and patient condition, which may impact the performance of the system when using this device.
9. Potential risks identified with the use of these devices, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, vascular or visceral injury.
10. Patients who smoke should be advised of the consequences of the fact that an increased incidence of non-union has been reported with patients who smoke.
11. Other significant risks to spinal surgery include alcohol abuse, obesity, and/or patients with poor bone, muscle and/or nerve quality.
12. It is recommended that the implants of the Nexxt Spine product lines should not be used with any other company's spinal systems.
13. Titanium and stainless steel components must not be used within the same construct.
14. To prevent unintended guidewire advancement, do not use a kinked or bent guidewire.
15. The implantation of the Facet Fixx® System should be performed only by experienced spinal surgeons with specific training in the use of this facet screw spinal system due to the nature of this technically demanding procedure and potential risk of serious injury to the patient.
16. The Facet Fixx® System has not been evaluated for safety and compatibility in the MR environment. The Facet Fixx® System has not been tested for heating or migration in the MR environment.

POTENTIAL 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:

- Implant breakage, failure, loosening, or migration
- Bone fracture or fracture to the spinous process or facet joint
- Allergic reaction to the implant material
- Pseudoarthrosis
- Pain
- Revision surgery
- Bleeding
- Infection, early or late
- Tissue or nerve damage
- Spinal fluid leakage
- Scar formation
- Complications due to the use of bone grafting, including donor site complications.

CLEANING AND DECONTAMINATION

All implants and instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Refer to the Nexxt Spine ***Reprocessing Instructions for Reusable Instruments*** document available at www.NexxtSpine.com/Resources/Indications-For-Use or by calling 317-436-7801 for a copy of the detailed cleaning instructions.

STERILIZATION

Unless specifically labeled sterile, the implants and instruments are supplied NON-STERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap is recommended. The following validated steam autoclave cycle is recommended:

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

INSTRUCTIONS FOR USE

The Facet Fixx® System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Refer to Facet Fixx® System Surgical Techniques for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Nexxt Spine customer service by phone, 317-436-7801.

INSTRUCTIONS:

PREOPERATIVE

1. Preoperative instructions to the patient are essential. The adverse effects, warnings, precautions and limitations should be understood by the surgeon and explained to the patient prior to the surgery.
2. Only patients that meet the criteria described in the indications should be selected.
3. Correct selection of the implant is extremely important. An adequate inventory of sizes should be available at the time of surgery.
4. Patient conditions and/or predispositions such as those mentioned in the Contraindications, Precautions and Warnings should be avoided.
5. The surgeon should be familiar with the use and handling of all components and instruments of the system prior to surgery.
6. Proper function of the surgical instruments and components should be verified prior to every surgical procedure. All instruments and components must be sterilized before use.

INTRAOPERATIVE

1. The primary goal of this surgery is to arthodese selected vertebrae. Adequate exposure, bony preparation, and grafting are essential to this result.
2. The placement of the Facet Fixx® System devices should be checked radiographically.
3. Care should be taken when positioning the implants to avoid neurological damage. Extreme caution should be used around the spinal cord and nerve roots.

POSTOPERATIVE

1. Adequately instruct the patient on postoperative care, use and limitations and potential complications. Successful healing depends on postoperative care and the patient's ability and willingness to follow instructions.
2. The patient must be made aware of the limitations of the implant and that physical activity and load bearing may cause premature loosening, bending or fracture of the internal fixation device. The patient should be warned to avoid falls, sudden jolts, mechanical vibrations, and lifting, twisting motions and restrict any type of sport participation. An active, debilitated, or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.
3. If a nonunion develops, or if the implants loosen, fracture, corrode, migrate, cause pain, or stress, the device(s) should be evaluated, revised and/or removed. Patients with evidence of these conditions should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity, revision or removal considered.
4. Periodic X-rays for at least the first year postoperatively are recommended to detect any evidence of nonunion, changes in position, loosening, bending or cracking of components.
5. Any retrieved devices must never be reused under any circumstances.

PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Nexxt Spine immediately. Nexxt Spine should be notified immediately of any product malfunction by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

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