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NUVASIVE® RADIAN® FACET SCREW SYSTEM
INSTRUCTIONS FOR USE

For Symbols Glossary, please refer to www.nuvasive.com/eifu
(doc# 9402624)

DESCRIPTION

The *NuVasive Radian Facet Screw System* consists of broad-headed, partially threaded or fully threaded screws designed to compact or fixate juxtaposed facet articular processes to enhance spinal fusion and stability. The partially threaded screws have a non-threaded portion that facilitates compression of the joint surfaces through a lag technique. The fully threaded screws allow for fixation of the facets without the compression effect offered by the partially threaded screws. Washers may be used to complement the screws by helping to distribute forces and to maintain consistent contact area when the screws are angled relative to the bone surface. The screws and washers are fabricated from anodized titanium alloy (Ti-6Al-4V ELI per ASTM F136/ ISO 5832-3) and are supplied in various sizes.
The *NuVasive Radian Facet Screws* require accessory general instruments for implantation. Instruments required for implantation may include a variety of k-wires, cannulae, drills, taps, and drivers.

INDICATIONS FOR USE

The *NuVasive Radian Facet Screw System* is intended to stabilize the spine as an aid to fusion through immobilization of the facet joints. The *NuVasive Radian Facet Screw System* is indicated for facet fixation, with or without bone graft, at single or multiple levels, from C2 to S1 (inclusive). The *NuVasive Radian Facet Screw System* is indicated for treatment of any or all of the following:

1. Failed previous fusion (pseudoarthrosis)
2. Spondylolisthesis
3. Spondylolsis
4. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
5. Degeneration of the facets with instability; and
6. Fracture

The *NuVasive Radian Facet Screw System* is intended for conventional or percutaneous surgical placement.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Patients with known sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Use with components of other systems.
8. Reuse or multiple uses.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; pulmonary emboli; loss of sensory and/or motor function; impotence; and permanent pain and/or deformity. Rarely, some complications may be fatal.
Potential risks identified with the use of this system, which may require additional surgery, include:

- Bending, fracture or loosening of implant component(s)
- Loss of fixation
- Nonunion or delayed union
- Fracture of the vertebra
- Neurological, vascular or visceral injury
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Bursitis
- Dural leak
- Paralysis
- Death

WARNINGS, CAUTIONS AND PRECAUTIONS

The subject device is intended for use only as indicated.
The implantation of spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.
Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.
These devices can break when subjected to the increased load associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.
Surgical implants must never be reused. An explanted metal implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns that may lead to premature breakage.
Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain, or stress shield bone, even after a fracture has healed. If a device remains implanted after complete healing, it can actually increase the risk of refracture in an active individual. Therefore, these devices are temporary and should be removed after completing their intended function – i.e., aiding in the bone healing process. The surgeon should weigh the risk versus benefit when deciding whether to remove an implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older, and has a low activity level, the surgeon may elect not to remove the implant, thus eliminating the risks associated with a second surgery.
Specific patient's anatomy may present various facet diameters throughout the length of the spine. Therefore, care should be taken by the physician to ensure that the appropriate diameter and length of facet screw is selected based on the specific patient's anatomy.
Before using the *NuVasive Radian Facet Screw System*, the physician should carefully consider the levels of implantation, patient weight, patient activity level, and any other patient conditions that may impact on the performance of the system.
Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.
All components should be final tightened per the specifications in the Surgical Technique. Implants should not be tightened past the locking point, as damage to the implant may occur.
Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage.
The Facet Finder and Obturator are single-use disposable instruments and must be discarded after use.
When using lag screws, increased resistance to screw advancement will be noted (the lag screw compresses the facet complex together) as the washer seats onto the inferior articular facet.
Care should be taken to insure that all components are ideally fixated prior to closure.
Patient Education: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.
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.
MRI Safety Information: The *Radian Facet Screws* have 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 *Radian Facet Screws* in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
Compatibility: Do not use *Radian Facet Screws* with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.
All implants should be used only with the appropriately designated instrument (Reference Surgical Technique).

PRE-OPERATIVE WARNINGS

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the *Radian implants*. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. Refer to Cleaning and Sterilization Instructions below for all non-sterile parts.
5. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

INTRA-OPERATIVE WARNINGS

1. Instructions for Use should be carefully followed.
2. Extreme caution should be exercised at all times around the spinal cord and nerve roots. This is especially true when inserting the screws. Damage to spinal nerves may cause loss of neurological function.
3. The screws and washers should not be scratched or notched, since such actions may reduce the functional strength of the construct.
4. Place the screws as far away as possible from the spinal cord and nerve roots. Damage to spinal nerves may cause loss of neurological function.
5. The placement of the screws should be verified radiographically.
6. Before closing the soft tissues, all the screws should be fully seated onto the facet, and tight. **Caution: The application of excessive torque may cause the thread to strip, reducing fixation or causing loosening.**

POST-OPERATIVE WARNINGS

1. During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.
2. Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration, as well as other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.
3. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required before firm bony union is achieved, the patient must be warned that bending, loosening and/or breakage of the device(s) may occur as a result of early weight-bearing or muscular activity. The risk of bending, loosening or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented, or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls, sudden jolts to the spine, or sudden severe changes in spinal position.
4. To allow maximum opportunity for a successful surgical outcome, the patient or device should not be exposed to mechanical vibrations that may loosen the device. The patient should be warned of this possibility, and instructed to restrict physical activities, especially lifting and twisting motions, and any sort of sports participation. The patient should be advised not to smoke, or consume alcohol, non-steroidals, or aspirin, during the healing process.
5. If a non-union develops, or if the device(s) loosens, bends, and/or breaks, the device should be removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implants. By the mechanism of fatigue, these stresses can cause eventual bending, loosening or breakage of the device(s). The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is achieved.
6. The *NuVasive Radian Facet Screw System* is a temporary internal fixation device. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing, these devices serve no functional purpose and should be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, any of the following complications may occur:
    (a) Corrosion, with localized tissue reaction or pain,
    (b) Migration of implant position resulting in injury,
    (c) Risk of additional injury from postoperative trauma,
    (d) Bending, loosening, and/or breakage, which could make removal impractical or difficult,
    (e) Pain, discomfort, or abnormal sensations due to the presence of the device,
    (f) Bone loss caused by stress shielding.
7. Implant removal should be followed by adequate postoperative management to avoid fracture.
8. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the screws should never be reused under any circumstances.

METHOD OF USE

Please refer to the Surgical Technique for this device.

PACKAGING

Packages for each of the components should be intact upon receipt. Devices should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to NuVasive.
All implants provided non-sterile are single use and should be sterilized per instructions provided below.
Instruments provided non-sterile can be single-use or reusable. Discard single-use instruments after use. Reusable instruments should be reprocessed using instructions provided below.
All instruments provided sterile are intended for single use only. Do not use if package is opened or damaged. This product should NOT be re-sterilized. Discard single-use instruments after use.

CLEANING AND DECONTAMINATION

All non-sterile instruments must first be thoroughly cleaned using the validated methods prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896) before sterilization and introduction into a sterile surgical field. Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. The validated cleaning methods include both manual and automated cleaning. Visually inspect the instruments following performance of the cleaning instructions to ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present at visual inspection, repeat the cleaning steps. Contaminated instruments should not be used, and should be returned to NuVasive. Contact your local representative or NuVasive directly for any additional information related to cleaning of NuVasive surgical instruments.

STERILIZATION

All non-sterile instruments and implants are sterilizable by steam autoclave using standard hospital practices, in addition to NuVasive's validated parameters. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896).

INFORMATION

To obtain a Surgical Technique Manual or should any information regarding the products or their uses be required, please contact your local representative or NuVasive directly at +1-800-475-9131. You may also email: info@nuvasive.com.

This Instructions for Use document is intended for the US market only. For OUS Instructions for Use, please refer to document #9402733 for Non-sterile implants.