9401879-EN (Rev S)	Reline™ SYSTEM
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For symbols glossary, please refer to www.nuvasive.com/eIFU

ENGLISH

WITHIN THE UNITED STATES ONLY

IMPORTANT INFORMATION ON Reline™ SYSTEM

DESCRIPTION

The NuVasive Reline™ System consists of variety of screws, hooks, rods, lock screws, transverse connectors, rod-to-rod connectors and iliac connectors manufactured from Ti-6Al-4V ELI per ASTM F136 and ISO 5832-3, Grade 4 CP Ti per ASTM F67, or cobalt chromium per ASTM F1537. Reline implants also mate with the appropriate size patient-matched SCRIPT™ Rods. SCRIPT™ Rods are manufactured from titanium alloy, cobalt chromium alloy, stainless steel, or commercially pure titanium, as specified in ASTM F136, F1295, F1472, F1537, F138, and F67.

SCRIPT™ Rods are available in diameters ranging from 4.75-6.35mm. The rods are patient-matched to accommodate the curvature of the patient's spine. SCRIPT™ Rods must only be used in the patient for whom it was designed.

INDICATIONS

When used as a pedicle screw fixation system in skeletally mature patients, the NuVasive Reline™ System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the posterior thoracic, lumbar, and sacral spine:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
2. Degenerative spondylolisthesis with objective evidence of neurologic impairment
3. Fracture
4. Dislocation
5. Scoliosis
6. Kyphosis
7. Spinal tumor and/or
8. Failed previous fusion (pseudoarthrosis)

The NuVasive Reline™ System is also indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft, having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum), with removal of the implants after attainment of a solid fusion.

When used as an anterolateral non-pedicle screw system in the thoracic and lumbar spine, the NuVasive Reline™ System is also intended for the following indications:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
2. Spinal stenosis,
3. Spondylolisthesis,
4. Spinal deformities,
5. Fracture,
6. Pseudoarthrosis
7. Tumor resection and/or
8. Failed previous fusion

When used for posterior non-cervical screw fixation in pediatric patients, NuVasive Reline™ System is indicated as an adjunct to fusion to treat:

1. Adolescent idiopathic scoliosis
2. Progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including infantile and juvenile idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis
3. Spondylolisthesis
4. Spondylolysis
5. Pseudarthrosis
6. Failed prior fusion and
7. Fracture caused by tumor and/or trauma in pediatric patients

Pediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

In order to achieve additional levels of fixation, the Reline™ System rods may be connected to the Armada System.

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. 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 associated with general surgical procedures of this type 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

Residual risks to the patient associated with the use of the Reline™ system are:

- Cleaning and sterilization failures, sterile barrier compromise, implant and/or instrument corrosion, and unretrieved instrument fragments which may cause or contribute to infections, wound dehiscence, and immunological reactions. In some instances, treatment of these events may require surgical intervention including revision surgery.
- Sensitization may occur in the event a patient is allergic or has hypersensitivity to a material used in the system implants or instruments. In rare events, the severity of the subsequent immunological response could necessitate revision surgery.
- Instrument and/or implant malfunctions (including instrument-implant mating, instrument or implant mechanical strength issues, and construct assembly failures) and use errors in both determining the correct size, and while implanting the definitive implant can potentially result in change of surgical plan, user inconvenience, and surgical delays, which expose the patient to additional anesthesia and blood loss.
- Risks inherent to invasive surgical procedures associated with site access and preparation, implant selection and placement, and achievement of correction which cannot be eliminated. These risks include early or late infections, pain, loss of correction, new or worsened deformity, tissue damage (including hematoma), wound dehiscence, and minor nerve injuries (such as numbness or mild weakness). While rare, these risks also include the following: bone fractures (including pedicle breach/fracture, vertebral body fracture, endplate fracture), serious nerve damage or neurologic deficit (numbness, weakness, or loss of function), vascular injury, visceral injury to adjacent organs, dural tear (with the potential for cerebrospinal fluid leakage), and screw misposition; many of these events may necessitate revision surgery. The probability of some events may be increased due to instrument or implant failures which, when functioning as designed, serve to mitigate common surgical risks.
- Post-operative implant malfunctions including anchor failure, implant fracture, and loosening of components which may result in loss of correction, pain, new or worsened deformity, and though rare, nerve damage and/or neurological deficit, any of which may necessitate revision surgery.
- Local tissue discoloration (i.e., metallosis), local acute inflammatory response, or other harms associated with exposure to wear debris and metal micro and nanoparticles (including risks associated with metal toxicity).
- In the improbable event a patient receives an MRI after implantation with the Reline™ system, implant heating may occur which could result in tissue damage and necessitate the need for revision surgery.

Residual risks to surgical staff associated with the use of the Reline™ system are:

Superficial cuts and lacerations may occur due to accidental user contact with sharp components of the system, such as reduction screw tabs which do not break off uniformly or at the desired location.

WARNINGS, CAUTIONS AND PRECAUTIONS

The subject device is intended for use only as indicated.

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 (grades 3 and 4) of the L5-S1 vertebra, 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 conditions are unknown.

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.

Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.

Pivoting rod-rod connectors must be used in pairs (i.e., two per side).

Ø4.75mm rods are not intended for use as a main rod construct to be placed within a Reline™ pedicle screw tulip but exclusively as a supporting rod in multiple rod technique.

The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

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.

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.

Iliac screws have a single lead thread on the shaft and must be used with single lead taps to help proper purchase in bone.

Be careful when palpating the break point as the Tulip may be sharp.

The Silencer and Gator Reducers are not compatible with Reduction Screws or Reduction Uni-planar Screws and may damage the implant if used. Only the Matador Reducer and Rocker may be used.

K-wire should be removed when screw has reached the posterior wall of the pedicle to avoid kink in tip.

Confirm the K-wire is not advancing as the path is created over the K-wire. Use lateral fluoroscopy to properly manage the K-wire during pedicle preparation to confirm proper placement and avoid anterior advancement of the K-wire.

All lock screws should be final-tightened with the Counter-torque and Torque T-handle. Do not final-tighten through compression instruments (e.g. C/D Rack and Figure 8 Compressor) in the set, as the rod may not be able to normalize to the tulip. Be cautious not to over compress or distract as you can loosen the screws in the spine and potentially pull out the screw.

The bulleted portion of the nose of the rod and the faceted portion of the rod (where the inserter locks down on the rod) must extend fully outside of the most inferior or most superior tulip on the construct. The set screw cannot be locked down on this unusable portion of the rod, as this may compromise the stability of the construct.

Cross connectors are designed specific to the rod diameter and cannot be used on the tapered section of tapered rods. If using cross connectors on tapered rods, only attach them on constant diameter rod sections.

Care should be taken to help ensure that all components are ideally fixated prior to closure.

SCRIPT™ Rods are designed from patient imaging data (X-ray and CT). The patient anatomy may change over time. Using imaging data within 6 months from the date of acquisition is recommended. The surgeon is responsible for determining if anatomical changes occurred between the time of imaging and device implantation and assess if the device matches the patient anatomy.

SCRIPT™ rods are designed as patient-specific implants, and must only be used in the patient for whom it was designed. Only use the SCRIPT™ rod if the patient identification markings on the package match the identification of the patient.

The SCRIPT™ Rod is designed for a specific patient. Any modifications of the patient anatomy can reduce the fit with patient anatomy. The patient should be evaluated for potential anatomical changes prior to performing surgery. If the SCRIPT™ Rod does not perform as intended, alter the rod as necessary, or use a standard Reline™ rod to complete the surgery. Intraoperative bending of the pre-contoured patient-specific rod is acceptable. Do not in any case reverse the bend of an already bent rod at the same point.

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 Reline™ 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 Reline™ System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Compatibility: Do not use the Reline™ System with components of other systems, other than the Armada System. Refer to the *Armada System Instructions for Use* for a list of the Armada System indications for use. 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 Reline™ implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.

For Sterile Implants: Assure highly aseptic surgical conditions, and use aseptic technique when removing the Reline™ implant from its packaging. Inspect the implant and packaging for signs of damage, including scratched or damaged devices or damage to the sterile barrier. Do not use the Reline™ implants if there is any evidence of damage.

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.

POST-OPERATIVE WARNINGS

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration, as well as to other complications. To help ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

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.

The instruments and implants of the system may be supplied as either sterile or non-sterile.

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 implants and 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.

HANDLING OF THE STERILE IMPLANT

- Before removing the implants from the package, make sure that the protective packaging is unopened and undamaged. If the packaging is damaged, the implants have to be considered as NON-STERILE and may not be used.
- Upon removal from the package, compare the descriptions on the label with the package contents (product number and size).
- Note the STERILE expiry date. Implants with elapsed STERILE expiry dates have to be considered as non-sterile.
- Take particular care that aseptic integrity is assured during removal of the implant from the inner packaging.
- Open the packages carefully. Take suitable measures to confirm that the implant does not come into contact with objects that could damage its surfaces. Use only the recommended instruments for implantation of the implants. Damaged implants must not be used

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 confirm 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.

Instruments with a “D” prefix part number (e.g. DXXXXXXX) may be disassembled. Please refer to the additional disassembly instructions for these 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).

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 #9402734 for Non-sterile implants and #9402425 for Sterile implants.