INSTRUCTIONS FOR USE - IMPLANTS
Femoral Trochanteric Nail System – Neonail

Attention! Read, follow and keep these instructions as a reference of use.

This medical device requires specializes surgical procedure. It should only be performed by qualified surgeons with specific training, including diagnosis, preoperative planning and surgical protocol. The use of the product without knowledge of appropriate techniques and/or procedures and inadequate conditions, including the surgical environment, may harm the patient leading to unsatisfactory results.

INDICATIONS

The Femoral Trochanteric Nail System – Neonail is indicated for the treatment of stable and unstable fractures as well as for stabilization of bones and correction of bone deformities in the intracapsular, trochanteric, subtrochanteric and shaft regions of the femur.

TECHNICAL SPECIFICATIONS AND CHARACTERISTICS

An intramedullary nail is a metal rod implanted into the medullary cavity of a bone to treat fractures that occur in long bones of the body. Femoral Trochanteric Nail System – Neonail consists of metal rods, bone screws, and end caps. The rods are cannulated and are provided with screw holes to accommodate screws of various diameters and lengths. The rods are available in a range of sizes used for specific anatomic locations and fracture configurations.

Intramedullary Nails, Screws, and End Caps are made of titanium alloy according to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).

Nails, screws, and end caps are colored by the anodizing process. The color changes are obtained as titanium oxide is deposited via an electrical current. They also receive a passivation treatment that protects the layer of oxide on the surface of the implant to create an additional film coating for maximum corrosion resistance.

PRESENTATION

Femoral Trochanteric Nail System – Neonail implants are available in envelopes (surgical grade paper and plastic film).

The packaging is properly sealed, labeled and includes a package insert with instructions.

FEMORAL TROCHANTERIC NAIL SYSTEM – NEONAIL implants are NON STERILE and must be sterilized before each use, as per instructions under "Sterilization".

Note: FEMORAL TROCHANTERIC NAIL SYSTEM – NEONAIL implants are to be used ONLY ONCE and ITS REPROCESSING IS FORBIDDEN.

HANDLING

Please read, follow and keep these Instructions for Use for future reference.

The product must be used only for its intended purpose.

Surgical techniques may vary depending on the surgeon's choice, who also selects the method, type and dimensions of all products used, as well as the criteria to assess the surgical results.

Implants should be sterilized before use, as per recommendations under "Sterilization".
Implants should be handled exclusively in adequate places and with appropriate care. Only skilled professionals can handle and implant the nails and screws.

Implants should be applied and adapted according to the exact requirements and adequate surgical techniques.

Implants can only be used with the appropriate tools.

Before using the product, the surgeon must carefully study all recommendations, warnings and precautions.

We suggest surgeons, their teams and surgical nurses get together, right before the surgery, and check all materials that will be used (quantity) and if all necessary tools (essential and auxiliary ones) are available. We do not recommend procedures that ignore such previous inspection.

Before using the implant, check its integrity, as well as the integrity of all necessary tools, they are not supposed to show scratches or damages.

All products should be handled with care. The inadequate handling may damage and/or impair the adequate functioning of the product. The product should not be subjected to mechanical shocks such as impacts, falls, etc. as they may introduce internal tensions that will shorten the implant's useful life.

The products must be appropriately sterilized.

Any complication or other effect that may present itself due to an incorrect indication or surgical technique, inadequate selection of material, lack of proper asepsis, etc., is the surgeon's responsibility and the supplier or manufacturer cannot be held responsible in such cases.

NEOORTHO cannot be held responsible for any adaptation done during surgery, or in connection with the material it provides and hereby formally contraindicates any attempt to adapt such material and reminds surgeons about the ethical and legal consequences related to such adaptations.

If a component is missing (container, box, tray, etc.) IT CANNOT BE REPLACED BY A DIFFERENT (NOT RECOMMENDED) MATERIAL, which may result in a serious problem to the patient and surgeon. We recommend the cancelling of the surgery.

The product selection must be in accordance with the chosen technique and individual patient's needs and must also take into consideration the pathology and the surgical site.

We also suggest radiological control, before the surgery, to check the exact location of the desired segment as well as trans-surgery radiological control to help in the correct positioning of the implants and immediate after-surgery control, documenting the implant's placement and stability at the chosen site.

IMPLANT TRACEABILITY

The manufacturer is responsible, together with distributors, suppliers and hospitals, for the traceability of FEMORAL TROCHANTERIC NAIL SYSTEM – NEONAIL implants.

During the manufacturing, the implants are laser-engraved with the, for instance, manufacturer's logo, batch number, product reference number and product dimensions, so that one of the implants' traceability phases is completed.

In FEMORAL TROCHANTERIC NAIL SYSTEM – NEONAIL implants, traceability is ensured by engraving on the implant's body (inviolable marking) of the following information:

- Manufacturer's logo;
- Batch number.

Implants with insufficient space to accommodate all applicable information are engraved with all relevant information possible, in the following order: batch number, manufacturer's name or logo; material identification; product reference code and other optional pieces of information.

If product marking may affect its performance, the implant is too small or its physical properties do not allow a legible marking, the required information is to be provided on the label or instruction for use, in order to ensure the product's traceability.

In case of an adverse effect, related to the product, the PATIENT, who holds all information related to his/her respective implant, will visit the SURGEON (responsible for the procedure) for a clinical assessment. Once the problem is diagnosed and related to the product, the HOSPITAL, in charge of providing all data related to the product, surgery, materials and sterilization, will get in touch with the DISTRIBUTOR to report the occurrence. The DISTRIBUTOR will request a Cause Analysis from the MANUFACTURER.

STERILIZATION

FEMORAL TROCHANTERIC NAIL SYSTEM – NEONAIL is NON-STERILE and is to be used ONLY ONCE and must be sterilized before it is used.

WE RECOMMEND STEAM AUTOCLAVE ONLY TO STERILIZE IMPLANTS.

The product must be removed from its packaging and placed in its appropriate box (container, box, tray) before undergoing the sterilization process. We recommend two layers FDA-cleared wrap to be used in order maintain sterility for the intended sterilization cycle.

Please use a hospital autoclave, as per adequate standard procedure. We recommend the following sterilization parameters:
Sterilization temperature: 132°C
Sterilization cycle: 4 minutes
Drying time: 20 minutes

The sterilized material must not stay inside the autoclave. We recommend its immediate use, right after the sterilization process, as there is the imminent risk of recontamination when the material is exposed to a, hot and humid, environment.

Do not allow contaminated products to touch sterilized products, in order to avoid the risk of cross-infection.

WE DO NOT RECOMMEND IMPLANT STERILIZATION USING ETHYLENE OXIDE, GAMMA RADIATION OR DRY HEAT (STERILIZER).

IMPLANTS MUST NOT BE SUBMERGED IN GLUTARALDEHYDE OR SIMILAR PRODUCTS.

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CONTRAINDICATIONS

Contraindication: any health condition, related to a disease or to the sick individual, that serves as a reason to withhold a certain medical treatment (relative contraindication) or even not undertake such course of action (absolute contraindication). If such condition is not observed, the patient's health may be considerably affected by severe harmful effects.

Contraindications (relative or absolute) must be taken into consideration when the surgeon is deciding on best course of treatment. The selection of a certain device should include a general assessment of the patient's health. The circumstances below may reduce the changes of a successful procedure:

Relative contraindications:

- Any abnormality that may affect the normal bone remodeling process, including, but not limited to: severe or mild osteoporosis; bone absorption, primary tumors or metastasis tumors; metabolic anomalies affecting the osteogenesis, immunosuppression cases, chronic inflammatory cases and septic cases.
- Previous history of infection.
- Blood circulation problems affecting the fracture's site.
- Obesity may impair (posterior) implant fixation.
- Pregnancy (depends on the doctor's assessment). There are no reports of complications related to implants in pregnant women, except the ones related to the surgical procedure per se.
- Open bone wounds and/or experiencing soft-tissue structure deficiency.
- In the presence of senile psychosis, mental disorders, dementia or abuse of illicit substances. Under these conditions the patients may ignore certain limitations and necessary precautions in relation to the implant, which could result in implant-failure and other complications.

Absolute contraindications:

- Active-acute infection at the site.

ADVERSE EFFECTS

The surgical procedure to place the FEMORAL TROCHANTERIC NAIL SYSTEM – NEONAIL implants, as well as other surgical procedures, may cause some discomfort and edema (swelling) at the surgical site, including some complications:

- Incision scar, size compatible with surgical need (to implant the device).
- Site or systemic infection, deep and/or superficial.
- Delayed union or non-union.
- Fixation loss or unsuccessful fixation.
- Device migration or mobilization.
- Mechanical loosening, torsion, dismembering, breaking of components – which may be the result of defective fixation, lack of consolidation or hidden infection.
- Risk of lesion by accidental trauma during the after surgery period.
- Superficial or muscular sensibility in patients with inadequate tissue coverage at the operation site.
- Pain, discomfort or abnormal sensations as a result of the device's presence.
- Sickness and Death: in all surgical procedures there is an incidence of sickness and death and the patient must be informed, by the doctor, before the surgery about such incidence.

Some complications may require additional surgical intervention.

WARNINGS AND PRECAUTIONS

This medical device requires specialized surgical procedure. It should only be performed by skilled surgeons specifically trained for the procedure, including the diagnostic, pre-surgery planning and surgical protocol. The use of the product without the appropriate knowledge, adequate techniques and/or procedures and under inadequate conditions, including an inadequate operation room, may impair the patient's recovery and lead to non-satisfactory results.

We recommend the issuing of an ID card for the patient, informing he/she has a metallic implant.

We recommend physiotherapists are informed about the implant so that they can continue the adequate physiotherapy/treatment.

This device has not been evaluated for safety and compatibility in the MR environment. It has also not been tested for heating or migration in the MR environment.

In case the patient is pregnant, the medical team should assess the patient's conditions and decide for or against the surgery.

We reinforce the need, for safety reasons, of an after-the-event radiologic control and evolution radiographic control until the bone consolidation is fully achieved.

In case of infection, the decision to remove the implant depends on an assessment by the assistant doctor. It is known that in low-virulence infections, titanium implants do not interfere with the treatment or process control. If the implant needs to be removed to control the infection, the re-implanting may be considered, later on, after the patient is completely free from the infection.

The surgeon is the person who will decide if it is necessary to remove the implant, after achieving the expected results. If he/she decides for the removal, it is necessary to use the same tools used to implant the device.

Removed implants MUST NOT be reused. A removed implant should be discarded as per procedures described in "MATERIAL DISPOSAL".

Implants should be manipulated by skilled medical staff only, during the sterilization and implanting processes. The implants, despite being easy to handle and place, require an experienced surgical team.

AFTER SURGERY CARE

Patients should understand they will need professional care following implant surgery and should comply with after-surgery restrictions and special guidelines.

Patients must follow a support therapy program and all instructions to help the recovery/treatment and the adequate bone healing.

The patient should be informed on the appropriate and restricted activities.

The patient should also know he/she must report to his/her doctor any unusual alteration in the surgical site. The doctor must monitor the patient in case an alteration is detected.

STORAGE

The FEMORAL TROCHANTERIC NAIL SYSTEM – NEONAIL implants should be kept, after the sterilization, in their sterilization box (container, box, tray, etc.) in a dry and cool place, with no moist or contact, and they must be immediately used after the sterilization in order to avoid contamination.

The implant must be stored so that its configuration and finishing is preserved and its packaging is not damaged.

We recommend tools are stored away from implants.

Store them, preferably, on metal or glass shelves, so that daily cleaning and hygiene can guarantee a storage area free of dust and any other agent that may affect the perfect conservation of the stored product.

Do not store implants on high shelves, close to light bulbs (they may damage the packaging or alter the label). Do not store them directly on the floor.

Do not store tools where contaminant substances are used, such as insecticides, pesticides or cleaning materials.

MATERIAL DISPOSAL

All materials used during surgery may pose serious health risks. Removed implants should be adequately disposed by the hospital. Before final disposal, into the environment, we recommend in-force guidelines and legislation are carefully followed.

Final disposal methods and procedures, for orthopedic implants, must ensure their complete de-characterization, so that they are not re-used. We recommend removed implants are cut, bended or shaped in such a way its re-use is simply not possible. Implant de-characterization is the hospital's responsibility, as well as used methods and procedures.

"NON-STERILE PRODUCT – IT CANNOT BE RE-USED"


Manufacturer
Fabricante


Date of manufacture
Fecha de Fabricación


Use by date
Plazo de Validad

Bach Code
Código del Lote

Catalogue number
Código del Producto

Product Size
Tamaño del Product


Do not use if package damaged
No utilizer si el embalaje está dañado

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Keep way from sunlight
Mantener alejado de la luz solar


Keep dry
Mantener seco


Do not re-use
No reutilizar


Non-sterile
No estéril


Consult instructions for use
Ver instucciones del uso
ifu.neoortho.com.br


Caution:Attention while using thje product
Precaución: Atención al operar el producto

Manufactured by:
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Lot and Manufacturing Date: See label.

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