INSTRUCTIONS FOR USE - IMPLANTS

INTRAMEDULLARY NAIL AND SCREWS FOR FEMUR – 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 Intramedullary Nail and Screws for Femur - NEONAIL was developed to be used during surgeries to fixate femoral fractures usually caused by trauma, promoting stabilization, correction and fixation, which may include the following:

- Open and closed femora fractures
- Pseudo arthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Ipsilateral femur fractures
- Fractures distal to hip joint
- Nonunion and malunion Fractures

TECHNICAL SPECIFICATIONS AND CHARACTERISTICS

The Intramedullary Nail and Screws for Femur - NEONAIL comprises Femur Nail, Candelabrum Star Head Screws, Condylar Screw, End Cap and End Cap Standard.

The Femur Nail, Candelabrum Star Head Screws, Condylar Screw, End Cap and End Cap Standard are all manufactured in Ti-6Al-4V alloy, as per ASTM F136 – *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*.

The Intramedullary Nail and Screws for Femur – NEONAIL is available in different dimensions, providing better adaptation to each patient's needs.

PRESENTATION

Intramedullary Nail and Screws for Femur - NEONAIL are available in envelopes (surgical grade paper and plastic film) containing one (01) unit (nails). The screws of the Intramedullary Nail and Screws for Femur – NEONAIL are available in blisters (surgical grade paper and rigid plastic film).The packaging is properly sealed, labeled and includes a package insert with instructions.

Implants provided are NONSTERILE and must be sterilized before each use, as described in "**Sterilization**" section.

Intramedullary Nail and Screws for Femur - NEONAIL is intended for ONE USE ONLY and shall not be reused meaning that, once a unit comes in contact with body fluids or tissues, or it falls to the floor, it is contaminated and shall be immediately discarded. Only intact implants can be re-sterilized.

Intramedullary Nail and Screws for Femur - NEONAIL must be implanted using specific and exclusive tools. The necessary tools must be purchased separately and ARE NOT INCLUDED in the product as they are not part of the implants – tools are available in individual packages. NEOORTHO implants must only be handled with the help of NEOORTHO tools. The tools have separated registration.

HANDLING

Please read, follow and keep these instructions as a reference of use.

Use the product only for the purpose it was intended.

The surgical techniques vary according to the surgeon's choice and it's his responsibility to choose the methodology, type, size, design and dimension of the products to be used, as well as the criteria for evaluating the results of surgery.

Sterilize the implants following the instructions of the **"Sterilization"** item.

Manipulate the implants only in appropriate environments with due care. Only trained professionals should handle and deploy the plates and screws.

The implants must be applied and adapted in accordance with the requirements and suitable surgical techniques.

The implants must only be used with their NEOORTHO instrumental.

Before using the product, the surgeon should read carefully the recommendations, warnings and precautions.

We recommend that surgeons with their staff, before starting the surgical procedure, check the material to be used (correct quantity) and the complete presence of instrumental and auxiliary instruments. It is not indicated the beginning of the procedure without such care.

Before use, it is necessary to check the integrity of the implants and instruments. They must not have bruises.

The products must be correctly clean and sterilized.

Any complication or other effects that might happen because of wrong indications or techniques, inappropriate choice of material, lack of asepsis, etc., is the surgeon's responsibility and cannot be transferred to the manufacturer or supplier of the product.

NEOORTHO is not responsible for any adaptation of its material and not advise other indications of use or adaptations of use during the surgical procedure. NEOORTHO reminds the ethical and legal consequences that may result from such adjustments.

The lack of one of the components in the container, box or tray **CANNOT BE REPLACED BY ANY MATERIAL OTHER THAN THE RECOMMENDED**, which can cause great inconvenience to the patient and the surgeon, even causing the cancellation of the surgery.

The product selection must be in accordance with the techniques and the patient's needs, taking into consideration the kind of pathology and where the product will be used.

The characteristics of adequate bone support are related to the experience of the professional that, by opting for the use of the implants of the Intramedullary Nail and Screws for Femur - NEONAIL, should perform the analysis of the patient, observing the restrictions imposed in the "Contraindications" item in these Instructions for Use.

IMPLANT TRACEABILITY

The manufacturer is responsible, together with distributors, suppliers and hospitals, for the traceability of Intramedullary Nail and Screws for Femur - 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 Intramedullary Nail and Screws for Femur - 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

Intramedullary Nail and Screws for Femur - NEONAIL implants are NONSTERILE, are intended for ONE USE ONLY and shall be sterilized before use.

Product sterilization facilities must observe all hospital, technical and sterilization standard procedures and such standards shall be checked before the sterilization of Intramedullary Nail and Screws for Femur - NEONAIL (autoclave biological and physical tests).

WE ONLY RECOMMEND STEAM AUTOCLAVE TO STERILIZE IMPLANTS.

Please use a hospital autoclave according to standard procedure. The product must be removed from its packaging and placed in its appropriate container before undergoing the sterilization process. We recommend 2 layers of an FDA-cleared wrap and the following sterilization parameters:

Sterilization temperature: 132°C

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Sterilization cycle: 4 minutes
Drying time: 20 minutes

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

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

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

IMPLANTS ARE NOT TO BE SUBMERGED IN GLUTARALDEHYDE (OR SIMILAR PRODUCTS).

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 affects the normal process of bone healing, including, but not limited to: moderate and severe 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 (according to medical evaluation). There are no complications described for the use of devices in pregnant patients, except those from the surgical procedure itself.
- Bone open surgical wounds and/or with deficiency of soft tissue structure.
- 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 / COMPLICATIONS

The insertion procedure of Intramedullary Nail and Screws for Femur - NEONAIL components, 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 procedure (to implant the device).
- Local or systemic infection, deep and/or superficial.
- Delayed union or non-union.
- Fixation loss or unsuccessful fixation.
- Device migration or displacement.
- Mechanical loosening, torsion, dismembering, broken components – as a result of a faulty fixation, lack of consolidation or hidden infection.
- Risk of lesion resulting from an accident during the post-surgery period.
- Superficial or muscular sensitiveness in patients with inadequate tissue coverage at the surgery's site.
- Pain, discomfort or abnormal sensations owing to 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 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.

The use of this material should only be performed within the guidelines and parameters technically acceptable in the country.

We recommend the issuing of an identification card for the patient informing that he/she has a metallic prosthesis.

Titanium used in the implants of the Intramedullary Nail and Screws for Femur - NEONAIL meets the chemical, mechanical and metallurgical specifications according to the standards ASTM F136 and ASTM F67. Titanium is a PARAMAGNETIC metal and, thus, allows the patient to undergo MRI, CT or X-rays, without risk of displacement of the implants.

The titanium used in the manufacture of implants is a biocompatible metal and up to now there is no history of cases of cytotoxicity, carcinogenicity, genotoxicity, toxicity or allergy in relation to that material.

Because other manufacturers employ different materials and have different tolerances and specifications for manufacturing, NEOORTHO warns that the Intramedullary Nail and Screws for Femur - NEONAIL implants cannot be used with components from any other manufacturer, avoiding the occurrence of galvanic corrosion (corrosive process resulting from the electrical contact between different materials placed in direct contact in the presence of an electrolyte medium).

During the plate conformation, it is necessary to observe if there is metal fatigue due to excessive conformation. If it occurs, the plate must be discarded and replaced.

For the torque application on the screws, bone quality and the skill and experience of the professional should be noted. If the thread is damaged because of bone quality and the torque that was applied, the screw must be replaced by the correspondent emergency screw.

Injuries and falls that might happen can hardly move or displace the implants.

In case of surgery to be performed during pregnancy, it is the medical staff responsibility to evaluate the patient conditions and the decision whether or not the surgical procedure.

We suggest radiological pre-operative control to verify the location of the desired segment, as well as trans-operative radiological control to assist in the correct positioning of implants and immediate postoperative control, documenting the placement and stability of the implant site.

It is the surgeon's choice the need for removing the implants after achieved the desired goal.

In case it is necessary to remove the implants, the surgical procedure of removal is the inverse of the procedure of implantation. The removed implant must be immediately discarded, observing the instructions of the item "**Disposal of Materials**".

The implant removed must NEVER be reused.

In case of infection, the necessity of removing the implant should be analyzed by the surgeon. It is known that in infections of low virulence, the implants of titanium do not interfere in the treatment and/or in the control of the process. When the removal of the implant is necessary in order to control the infection, it may be considered the possibility of a re-implantation at a later time, after the complete healing of the infection.

The NEOORTHO implants should be handled only by specialized personnel and nursing, in the phases of sterilization and implantation. This material, despite its ease of handling and placing, does not relieve the previous experience of the surgical team with this type of procedure.

AFTER SURGERY CARE

Instruct the patient on the need for post-surgical professional monitoring, noting the importance of the patient's postoperative guidelines and restrictions.

Patients should be advised to follow a program of supportive therapy with the intent to assist the treatment.

The patient should be instructed regarding the appropriate and restricted activities.

The patient should also be instructed to report the physician of any unusual changes in the surgical site. The physician should monitor the patient if a change is detected at the site.

STORAGE

The Intramedullary Nail and Screws for Femur - NEONAIL must be kept, after sterilization, in their sterilization box (container, box, and tray) in a dry, cool place, without contact or presence of humidity and must be used immediately after the sterilization process to avoid the risk of their contamination.

The implant must be stored in such a way to keep its configuration and it's finishing of surface and not causing any damage to its package.

It is recommended to store the implants separately from the instruments.

Store preferably in shelves of metal or glass frame, thus enabling the daily cleaning and hygiene that may assure that the storage environment is free of dust and weather conditions that may affect the perfect conservation of the stored product.

Do not store the implants in high shelves, next to lamps (so it does not resect the package or fade the label). They cannot be stored directly on the ground.

They cannot be stored in areas where contaminant substances, such as insecticides, pesticides or cleaning materials, are used.

All products must be handled carefully. The inadequate handling can damage and/or harm the adequate functioning of the product. The product may not suffer mechanical shock, such as fall, hit, since it can induce internal tensions that will compromise the shelf-life of the implant.

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


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.

For further information, please visit: www.neoortho.com.br