INSTRUCTIONS FOR USE

INSTRUMENTS

(K221021 - Femoral Trochanteric Nail System – Neonail)

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

The use of these instruments requires specialized surgical procedure. It shall be carried out only by qualified surgeons with specific training, including diagnosis, pre-operational planning and surgical protocol. The product use without knowledge about the adequate techniques and/or procedures and in inadequate conditions, including the surgical environment, may harm the patient, leading to non-satisfactory results.

GENERAL INFORMATION

The NEOORTHO Instruments are designed and manufactured in order to be durable and reusable. They are available in different dimensions and formats specific for each system, aiming to fulfill the medical needs.

The NEOORTHO Instruments shall be used only as planned and described in these instructions for use, by qualified and adequately trained personnel and maintenance and repair shall only be carried out by authorized specialized technicians.

MAIN DIFFERENCES BETWEEN THE MODELS

The basic differences of the NEOORTHO Instruments are their length and diameter, thus serving the different patient's characteristics.

ATTENTION!

NEOORTHO and the seller of this product do not accept any liability regarding direct or consequential damage or injury, caused by improper use or manipulation, particularly due to non-compliance with these instructions for use or inadequate maintenance or reprocessing.

The NEOORTHO Instruments are delivered **not sterilized**. Sterilize them in a hospital autoclave according to the standard procedure described in item "Sterilization" before use.

The non-sterile Instruments can be sterilized and reused, and the procedures in the pre-washing or de-scaling processes, as well as decontamination, washing, rinsing, drying, sterilization and final inspection shall be followed.

INDICATION / INTENDED PERFORMANCE

The NEOORTHO Instruments are made of stainless steel, aluminum, polymer and carbon fiber.

The NEOORTHO Instruments are **non-sterile** medical instruments, which have been manufactured for use in surgical procedures.

HANDLING

We recommend the surgeons together with their teams and technicians, before starting the surgery, to check the material to be used (regarding quantity) and the complete set of main and auxiliary instruments. We do not recommend starting the procedure without such prior care.

Before use, the integrity and the functionality of the instruments shall be observed and they shall not be scratched.

The products shall be correctly cleaned and sterilized.

Any complication or other effects, which might occur due to reasons, such as incorrect indication or surgical technique, inadequate selection of material, lack of asepsis, etc., is the surgeon's responsibility and cannot be transferred to the product manufacturer or suppliers.

NEOORTHO shall not be held liable for any adapting carried out during the surgical act with the material it supplies, and formally contraindicates any attempt of adapting, reminding the ethical and legal consequences that might result from such adapting.

The absence of one of the components of the box (container, box, tray), CANNOT BE REPLACED BY MATERIAL OTHER THAN THE RECOMMENDED, which may lead to a great inconvenience for the patient and the surgeon, causing the cancelation of the surgical act, as well.

CLEANING

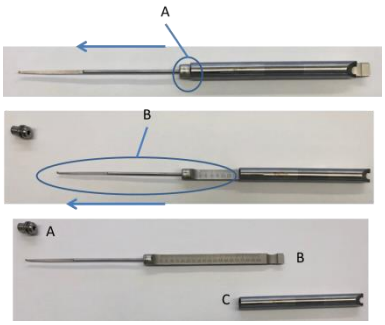
NEOORTHO instruments are not supplied sterile. Before sterilization, instruments must be thorough cleaned using the following procedures.

Caution: We do not recommend sterilization of the instruments by ethylene oxide, gamma radiation or dry heat (oven). The instruments shall not be placed in glutaraldehyde or similar solutions.

The instrument 908.081 Depth Measurer 4.5-6.5mm requires disassembly prior to cleaning. The disassembling, cleaning and reassemble should be performed at the hospital central processing department.

How to disassemble the product for cleaning:

Pull the part A forward in order to disconnect it. After that, pull the part B forward until it is removed from the part C.



Disassemble of 908.081 Depth Measurer 4.5-6.5mm

Prior to reassemble the instrument, a visual inspection should be performed for assessing wear and tear of components.
Inspection
- Inspect the instruments using 8 times image intensifier lens.
- Look for dirt and stains on the product during and after drying.
- Observe absence of moisture after drying.
- Observe the integrity of the surface, clear cannulated areas, perfect fittings.

How to assemble the product once the cleaning is done:

Introduce the part B into the part C. After that, introduce the part A through part B and connect it to part C.

Note: The cleaning bath has 24-hour effectiveness. For very dirty devices, replace it several times.

Clean the instruments to remove organic matter from the instruments without direct manual contact. Cleaning should be started as soon as possible after use.

It is recommended to use personal protection equipment (gloves, masks, goggles, aprons, caps, among other PPE).

It is also recommended to use enzymatic solution at concentration and time of exposure as determined by the manufacturer of such chemical solutions.

NEVER use saline solutions, disinfectants, hydrogen peroxide or alcohol to rinse the instruments.
All surgical instruments shall be correctly cleaned after each use, following the steps below:

Note: Processing should be started up to 2 hours after the end of the surgery (otherwise it should be immersed in water with enzymatic detergent to prevent blood drying or incrustation of organic material).

1. Disassemble all possible parts of the instrument and open all joints.
2. Dilute the enzymatic detergent according manufacturer instructions.
3. Immerse the materials into the detergent solution at the basket of the ultrasonic washer, connect parts with lumen to the washer devices, allowing the path to be filled.
4. Leave sonication (35kHz) for 10-15 minutes at a temperature of 40-45 °C.
5. After the end of the cycle, remove materials from the ultrasonic washer and brush all parts of the materials with soft nylon bristle brush (piece by piece). Brush for external surfaces: Double end nylon M16.
Brush for lumens: Use circular brushes - diameter somewhat larger than the diameter of the lumen. The brush should not be forced, but some resistance within the lumen must occur. Lack of resistance indicates that the brush is too small. Select a brush with an overall length greater than the length of the lumen.
6. In case of materials with lumen, inject the detergent solution several times to perform a complete removal of organic matter.
7. Rinse abundantly to remove any detergent residue. Use running water, water spray gun or syringe with water to carry out the abundantly rinsing of materials with lumen. The rinse water should be Critical Water (purified water by reverse osmosis or distillation).
8. Dry the instruments with a clean and dry operating field.
9. Dry all parts with compressed air, surgical compress or automated dryer.
10. Inspect the cleaning of materials using image intensifier lens with at least 8 times.
11. Observe no dirt and stains on the product during and after drying.
12. Observe absence of moisture after drying - only forward dry material for preparation.
13. Observe surface integrity, clear cannulated areas, and perfect fittings.

Note: Never let the instruments dry naturally to prevent staining and corrosion.

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STERILIZATION

This is the procedure, which aims at total elimination of microorganisms, such as: virus, bacteria, microbes, fungi; either in vegetative or spore form.

The NEOORTHO Instruments are delivered NON-STERILE, and shall be sterilized before use.

WE RECOMMEND ONLY THE PROCESS IN VAPOR AUTOCLAVE FOR THE INSTRUMENTS STERILIZATION.

Standard applicable for sterilization in vapor autoclave: EN ISO 17665-1 - Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices.

The product handling does not present any technical particularity to be notified to the Material and Sterilization Center personnel (MSC), provided that the recommendations explained herein are complied with.

The product sterilization location (hospital MSC) shall fulfill all sterilization technical requirements before submission to the sterilization process (biological and physical tests of the autoclave).

The product shall be removed from its packaging and placed in its appropriate box (container, box, tray) for the sterilization process, as follows:

908.928 Trochanteric Femoral Nail Instruments Container
908.982 Extraction Instruments Container
908.989 Modular Flexible Reamers Container
908.917 Monobloc Flexible Reamers Container

After the drying process, the instruments are submitted to sterilization in autoclave. Use a hospital autoclave, according to the adequate standard procedure.

The surgical instruments shall be placed inside the container (perforated on the lid and the bottom part), or on a tray or in a box; provided that they are conditioned in a way to be prepared for the sterilization process. We recommend 2 layers of an FDA cleared wrap (cleared for the indicated cycle).

The following sterilization time is recommended for the NEOORTHO Instruments:

Sterilization temperature: 132°C
Sterilization cycle: 4 minutes
Cooling process: 20 minutes

The surgical instruments shall be placed inside the container (perforated on the lid and the bottom part), or on a tray or in a box; provided that they are conditioned in a way to be prepared for the sterilization process. We recommend 2 layers of an FDA cleared wrap (cleared for the indicated cycle).

Clean the autoclave strictly and periodically, removing the dirt and the excess of rust formed (iron oxide).

DO NOT open the autoclave to avoid quick condensation; i.e., letting all vapor out first, making the Drying Cycle complete on its own.

The sterilized material SHALL NOT remain inside the autoclave. We recommend immediate use after the sterilization, because there is an imminent risk of re-contamination of the material when it is exposed to the environment, hot and humid.

DO NOT allow contact of contaminated products with already sterilized products, this avoiding the risk of crossed contamination.

WE DO NOT RECOMMEND STERILIZATION OF THE INSTRUMENTS BY ETHYLENE OXIDE, GAMMA RADIATION OR DRY HEAT (OVEN).

THE INSTRUMENTS SHALL NOT BE PLACED IN GLUTARALDEHYDE OR SIMILAR.

FINAL INSPECTION

This is the act of checking whether the instruments present any irregularity, deformation or dirt residues.

Carefully inspect each device to make sure that all visible residues of blood and dirt have been removed.

Visual inspection is recommended to check the existence of damages and/or wear, because deteriorated instruments, or instruments that present signs of corrosion shall be separated, in order to avoid the corrosion process to spread by contact with the other instruments. It is recommended to always protect the tip of the more delicate instruments.

Check the functioning of the moving pieces (box hinges and blocking) to assure the good functioning of the device along the foreseen movement amplitude.

Check whether the instruments with long and fine pieces show distortion (particularly rotating instruments).

If the instruments are a part of a bigger set, check whether the devices fix easily in the corresponding components.

NEVER store clean instruments in stained surgical boxes or boxes with severe risks, which might be outbreaks of contamination for the instruments. Separate the heavy materials from the delicate and the lighter ones.

WARNINGS AND PRECAUTIONS

Maximum care shall be taken in the processes of cleaning, sterilization, conditioning (storage), transport and handling of the product, in order to avoid mechanical shocks that might alter its anatomy and impair its functionality.

Before starting the surgery, check the product functioning. The product shall not be used, if it presents anatomic alterations.

CONTRAINDICATIONS

There are not any known absolute contraindications for the use of this product. Observe the good cleaning and sterilization practices. The use of this product is contraindicated when, upon the physician's criterion, its use is not in accordance with the best indication for the patient.

SPECIAL APPLICATION WARNINGS

- Always use the product in conformity with the respective application purposes only.
- Always handle the instrument with care, in order to avoid damages on the surfaces or geometrical alterations.
- Avoid making any type of alteration in the instrument design.
- Before starting the operation, make sure all components available for the surgery are perfectly functioning.
- The user shall assure that the reprocessing processes are fulfilled; that the resources and the materials are at the qualified personnel's disposal and that the hospital protocols are fulfilled. The technological progress, and very often the national legislation as well, require that these processes and resources included are duly validated and subjected to adequate maintenance.

POTENTIAL UNDESIRABLE EFFECTS

Incorrect maintenance and cleaning may make the instruments inappropriate for the intended use, provoke corrosion, dismounting, distortion and/or breakage or provoke injuries on the patient or the operation team.

ATTENTION!

In case the instrument breaks, no fragment shall remain in the patient, because this may provoke post-surgery complications, such as allergies, infections or complications with biological nature, related to the release of metallic components, with possible need of another surgery.

STORAGE AND TRANSPORT

After sterilization, the NEOORTHO Instruments shall be kept in their sterilization box (container, box, tray) in a dry and fresh location, without contact or presence of humidity and shall be used immediately after the sterilization process, in order to avoid the risk of their contamination.

The instruments shall be transported and stored in a clean place, free of dust, dry and at room temperature. The transport shall be provided adequately, in order to avoid drop and damages to their original packaging.

The instruments shall be stored in a way to keep their configuration and their surface finishing and not to damage their packaging.

It is recommended for the instruments to be stored separately from the implants.

Store preferably on metal or glass frame stands, thus enabling daily cleaning and sanitization, which can guarantee that the storage environment is free of dust and weather influence, which might affect the perfect preservation of the stored product.

Do not store the instruments on high shelves, close to lamps (in order for the packaging not to dry up or the label to be deleted). They cannot be stored directly on the floor.

The instruments cannot be stored in areas, where contaminating substances are used, such as insecticides, pesticides or cleaning material.

All products shall be handled with care. Inadequate handling may damage and/or prejudice the adequate functioning of the product. The product cannot suffer mechanical shocks, such as drop or knocks, because this may introduce internal stress, which will impair the useful life of the instruments.

MAINTENANCE

Lubricate the hinges, the threads and other moving parts with commercial instrument lubricant with surgical grade and water-based (such as instrument oil), in order to reduce friction and wear. Follow the lubricant manufacturer's instructions.

MATERIAL DISPOSAL

After use, all consumable materials used in the surgery may present risks to the health of those who handle them.

The instruments with defects shall be disposed. Before disposal to the environment, it is recommended to check and fulfill the legislation in force.

The instruments disposal methods and procedures shall assure their complete de-characterization, impeding any possibility of reuse. We recommend that the instruments are cut, bent or deformed, in order to impede their reuse. The hospital institution is fully responsible for the de-characterization of the instruments, as well as for the used methods and procedures.

COMMERCIAL PRESENTATION

The instruments are delivered non-sterile; their packaging (film + film) is composed of Low Density Polyethylene (LDPE) containing 01 unit (primary packaging).

In surgical center environment, the instruments shall be conditioned in specific niches for each instrument, facilitating handling, sterilization and transport. In such conditions, these boxes with instruments and implants shall be sterilized according to the recommendations in item "Sterilization" of these instructions for use.

Better results are obtained using NEOORTHO products.

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

NON STERILE PRODUCT – CANNOT BE REUSED

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Batch and Manufacturing Date: See label.