NON-STERILE INSTRUMENTS

Neo Medical S.A.
Route de Lausanne 157A
1096 Villette
Switzerland

CE

Important Information on the NEO PEDICLE SCREW SYSTEM™ non-sterile Instruments

PURPOSE

The NEO Pedicle Screw System™ is intended to help provide immobilization, correction and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

DESCRIPTION

The NEO Pedicle Screw System™ comprises a variety of sizes of rods, screws, as well as instruments. They can be locked together into a variety of configurations which are going to be tailor-made for each individual case. All components are made of materials compliant with applicable and current ISO and/or ASTM standards. The system can be used via an open or minimally invasive posterior approach.

The system includes a removal kit which should be used for revision surgery. The procedure for use is described in the surgical technique.

Neo Medical's products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

PROCESSING OF THE NON-STERILE INSTRUMENTS

The cleaning and sterilization process outlined in this Instruction for Use have been validated by Neo Medical S.A. Other reprocessing methods must be validated by the end-user under its sole responsibility before being applied. Furthermore, the end-user must comply with the laws and regulations of countries with stricter reprocessing requirements than those specified in this leaflet (if applicable).

After use all instruments need to be decontaminated and disposed according to local laws and regulations regarding infectious waste.

The following process needs to be followed before the device is used the first time.

1. **Cleaning**
   Immediately before use the instrument must be cleaned using the method specified below.
   Only agents, solutions and detergents proven to be effective may be used. The agents, solutions and detergents specified below are those used by Neo Medical S. A. to validate the present instructions for use. Manual methods are not allowed to clean the non-sterile instruments.

   a) Automated Cleaning
   Materials: Alkazyme® enzymatic solution, Neodisher® MediClean alkaline detergent, osmosed water or the chemical and microbiological equivalent, soft nylon bristle brush, ultrasonic bath, validated washer-disinfector serviced in accordance with prevailing local procedures, single-use towelettes
   - Rinse and brush the device for at least 30 seconds while completely submerging it in a bath of room temperature (15 to 25°C) osmosed water or the chemical and microbiological equivalent.
   - Completely submerge the device in an ultrasonic bath of Alkazyme® enzymatic solution at 0.5 % volume per volume (prepared according to the manufacturer's instructions) for 15 minutes at room temperature (15 to 25°C, ideally 20°C).

Brush all the surfaces of the device with a soft nylon bristle brush for at least 30 seconds (and till visible soil is removed, if the device has been used). Make sure the device is cleaned thoroughly.
- Thoroughly rinse the device with purified water at room temperature (15 to 25°C) for at least 1 minute.
- Load the device into the washer-disinfector, and arranging it so that it can drain.
- Run a washer-disinfector cycle for 10 minutes at temperature of 93°C with MediClean detergent at 0.5 % volume per volume (prepared according to the manufacturer's instruction).
- When unloading, visually inspect the device in a well-lit area to verify that all visible soil has been removed (if the device has been used). If necessary, repeat the cycle and/or clean manually.
- Make sure that the device is completely dry. If necessary, use single-use towelettes to remove any remaining traces of moisture.

2. Inspection

Visually inspect the device in a well-lit area to detect any signs of corrosion, damage or wear. Remove the damaged device, clean it of all biological substances (if necessary) and discard it in accordance with the prevailing laws and regulations.

3. Sterilisation

a) Preparation

The device is placed in the sterilization tray or in specialized device trays and then wrapped in medical quality packaging for standard steam sterilization, according to the double wrapping technique. Also be sure not to allow the device to collide with another device.

b) Cycles

The device must be sterilized by moist steam autoclave using a pre-vacuum cycle (ISO 17665-1). The autoclave must be validated, serviced and calibrated in accordance with local prevailing procedures.

The following cycles have been validated to ensure a sterility assurance level (SAL) of 10^{-6}:

Cycle Type	Temperature	Steam Exposure Time (minimum)	Drying Time (minimum)
Pre-Vacuum	132°C	4 minutes	20 minutes
	134°C	3 minutes	20 minutes
	134°C	18 minutes*	20 minutes

*Steam sterilization parameters recommended by the World Health Organisation (WHO) for instruments subject to risk of TSE/CJD (transmissible spongiform encephalopathy and Creutzfeldt-Jakob disease) contamination.

WARNING

- The Neo MIS Compressor-Distractor Adaptor are designed for single use including the necessary processing (cleaning, disinfection, sterilisation).
- A complete processing is necessary prior to use.
- Highly alkaline (pH > 11) and hypochlorous solutions must be avoided as they promote corrosion of metallic parts.
- The use of metal brushes during cleaning is strictly forbidden as this may damage the surface of the instrument.
- Instruments which show signs of wear or damage must not be used. In particular, if cracks or scratches are visible the instrument must not be used under any circumstances and must be absolutely replaced by a new one.

PRECAUTIONS

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

PACKAGING

Caution: Non-Sterile Instruments should be carefully checked to ensure that there is no damage prior to use. Damaged products must not be used, and should be returned to the local distributor or to NEO MEDICAL S.A.

Caution: Instruments are non-sterile when delivered. The cleaning, disinfection and sterilization process is described in this instruction for use must be conducted before use.

Caution: DO NOT RE-STERILIZE Instruments labeled with the symbol "Do not reuse".

PRODUCT COMPLAINTS

Any health care professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the official distributor of NEO MEDICALS.A.). Further, if any of the implanted spinal system component(s) ever "malfunctions" (i.e., does not meet

any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any NEO MEDICAL S.A. product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX, or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION

For further information refer also to the Neo Pedicle Screw System Instruction for Use. Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact NEO MEDICAL S.A.

EXPLANATION OF SYMBOLS

CE	The device complies with Council Directive 93/42/EEC concerning medical devices		Manufacturer
REF	Catalogue number	LOT	Batch Code
	Consult the Instructions for use		Caution / Warning
	Non-sterile		Do not re-use