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Neo Medical Pedicle Screw System™ and Neo Medical Cage System™ Processing (cleaning, disinfection, and sterilization) of non-sterile instruments

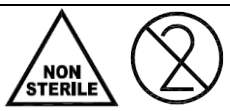
CE

PURPOSE

The Neo Medical 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. The Neo Medical Cage System™ is a titanium alloy Ti6Al4V interbody fusion device intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine.
Both systems are implanted using instruments which are mainly provided single use sterile. This instructions leaflet provides information for proper processing of non-sterile instruments.

DESCRIPTION

The Neo Medical Pedicle Screw System™ and the Neo Medical Cage System™ are mainly used with single use sterile instruments which are described in the system instructions for use and the procedure for use is described in the surgical technique. Some instruments are provided by Neo Medical as non-sterile and some of these are intended to be re-used after appropriate cleaning, disinfection and sterilization procedure. Product labeling clearly indicates which products are non sterile and single use and which products are non sterile reusable via the following symbols.

Non-Sterile / Single use	
Non-Sterile / Reusable	

Please follow these instructions for preparation of the instruments before surgery and, only for reusable instruments, for their reprocessing after surgery.
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.

FUNDAMENTAL POINTS

All instruments labelled as non-sterile are to be cleaned, disinfected, and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile instruments (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the instruments.

The sterility of the instruments falls under your responsibility. Please ensure that only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection, and sterilization, that the used devices (WD, sterilizer) will be maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.

Additionally, please pay attention to the legal provisions valid for your Country as well as to the hygienic instructions of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions (not relevant for USA), which can require the application of cleaning detergents with proven prion efficiency as well as a sterilization with more intensive parameters.

Caution: Non-sterile instruments are provided in a protective packaging designed for maintaining the integrity and cleanliness of the product. However, in no case the product shall be sterilized within this packaging, but needs to be removed from the package and be treated as follows.

CLEANING AND DISINFECTION

Basics

If possible, an automated procedure (WD (Washer-Disinfector)) should be used for cleaning and disinfection of the instruments. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered[1].

The pre-treatment step is to be performed in both cases.

[1] In case of application of a manual cleaning and disinfection procedure a product and procedure specific development and validation of the specific manual procedure under sole responsibility of the user is required.

Pre-treatment

Please remove coarse impurities of the instruments directly after application (within a maximum of 2 h).

Procedure:

1. Rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F).
2. Soak the instruments for the given soaking time the pre-cleaning solution[2] (with activated ultrasound) so that the instruments are completely covered. Pay attention that there is no contact between the instruments.
3. Then, remove the instruments of the pre-cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water.

Pay attention to following points during selection of the cleaning detergent[2]:
- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- compatibility of the cleaning detergent with the instruments (see chapter „material resistance„)

Pay attention to the instructions of the detergent manufacturer regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

[2] In case of application of a cleaning and disinfection detergent for this (e.g. in consequence of personnel´s safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material, and be compatible with the instruments (see chapter „material resistance„). Please consider, that a disinfectant used in the pre-treatment step serves only the personnel`s safety, but cannot replace the disinfection step later to be performed after cleaning.

Automated cleaning/disinfection (WD (Washer-Disinfector))

Pay attention to following points during selection of the WD:
- WD according to EN ISO/ANSI AAMI ST15883 and with fundamentally approved efficiency (for example CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration)
- if possible selection of an approved program for thermal disinfection (A_0 value ≥ 3000 or – in case of older devices - at least 5 min at 90 °C/194 °F; in case of chemical disinfection danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments
- program with a sufficient number of rinsing steps (at least three degrading steps after cleaning (respectively neutralization, if applied) or conductance based rinsing control recommended in order to prevent effectively remnants of the detergents)
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying
- regularly maintenance and check/calibration of the WD

Pay attention to following points during selection of the cleaning detergent:
- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible to the used cleaning detergent
- compatibility of the used detergents with the instruments (see chapter „material resistance„)

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.

Procedure:

1. Transfer the instruments in the WD (pay attention, that the instruments are located with the big opening downwards and that instruments have no contact).
2. Start the program.
3. Remove the instruments of the WD after end of the program.
4. Check and pack the instruments immediately after the removal (see chapters „check„, „maintenance„, and “packaging„, if necessary after additional post-drying at a clean place).

The fundamental suitability of the instruments for an effective automated cleaning and disinfection was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of an ultrasonic bath of the SONOREX series with 35 kHz (BANDELIN electronic, Berlin) for pre-cleaning, the WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh (thermal disinfection) and the pre-cleaning and cleaning detergent Neodisher mediclean forte (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.

Check

Check all instruments after cleaning or cleaning/disinfection, respectively, on corrosion, damaged surfaces, still readable marking. and impurities. Do not further use damaged instruments (for limitation of the numbers of re-use cycles see chapter „reusability„). Still dirty instruments are to be cleaned and disinfected again.

Maintenance

Instrument oils or grease must not be applied.

Packaging

Please insert the cleaned and disinfected instruments in a standard sterilization tray and pack them in sterilization containers, which fulfill the following requirements (material/process):
- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F), sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packagings to mechanical damage
- regular maintenance according to the instructions of the manufacturer (sterilization container)

A maximum weight of 8 kg per content of the sterilization tray must not be exceeded.

Sterilization

Please use for sterilization only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization
- fractionated vacuum/dynamic air removal procedure[3,4] (with sufficient product drying[5])
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- maximum sterilization temperature 138 °C (280 °F; plus tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature):

Area	fractionated vacuum/dynamic air removal	gravity displacement
USA	4 min at 132 °C (270 °F), drying time at least 20 min[5]	not recommended
Germany	5 min[6] at 134 °C (273 °F)	not recommended
other countries	at least 4 min[6] at 132 °C (270 °F) / 134 °C (273 °F)	not recommended

[3] at least three vacuum steps
[4] The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure, requires significantly longer sterilization times as well as a sterilizer, procedure, parameter, and product specific process development and validation under sole responsibility of the user.
[5] The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions, ...) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.
[6] respectively 18 min (inactivation of prions, not relevant for USA)

The fundamental suitability of the instruments for an effective steam sterilization was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the steam sterilizer HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum/dynamic air removal procedure. For this, typical conditions in clinic as well as the specified procedure were considered.

The flash/immediate use sterilization procedure must not be used.

Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

Storage

Please store the instruments after sterilization in the sterilization packagings at a dry and dust-free place.

Material resistance

Please take care that the listed substances are not ingredients of the cleaning or disinfection detergent:
- organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
- strong lyes (maximum admitted pH-value 11, neutral/enzymatic, weak alkaline, or alkaline cleaner recommended)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons

Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments.
Acid neutralizing agents or rinse aids must not be applied.

Please do not clean any instruments by use of metal brushes or steel wool.

Please do not expose any instruments to temperatures higher than 142 °C (288 °F)!

Reusability

Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on Neo Medical reusable surgical instruments.
End of life of a reusable surgical instrument is normally determined by wear and damage due to use. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used and must be absolutely replaced by a new one. The user is responsible for each further use as well as for the use of damaged and dirty instruments (no liability in case of disregard).

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ADDITIONAL INFORMATION

It remains the responsibility of the processor to ensure that the processing is actually performed, using equipment, materials and personnel in the Central Sterile Supply Department (CSSD), and achieves the desired result. This requires verification/validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.

All users shall be qualified personnel with documented expertise, competency and training. Users shall be trained on hospital policies and procedures along with current applicable guidelines and standards.

Users shall don appropriate personal protective equipment (PPE) when processing devices in accordance with the Department of Environmental and Occupational Health and Safety's (OSHA) bloodborne pathogen guidelines.

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.
Before return of products which were used in hospital environment, perform a complete processing according to these instructions. Confirmation of processing including parameters used shall be provided in the delivery note.

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	Non-sterile		Do not re-use

Manufactured by:

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