Surgical implants and instruments

Please read the complete reprocessing instructions carefully before you start using the medical devices, as they contain important information.
The instructions listed below have been validated by SIGNUS as being suitable for the reprocessing of medical devices. The manufacturer's information was prepared in accordance with the current standard specifications of DIN EN ISO 17664. Mechanical reprocessing is preferable.
Medical devices that have not been properly reprocessed pose a high risk of infection to patients, users and, if applicable, third parties, as well as the risk of malfunction. Implants and instruments intended for single use must not be reprocessed after use. Implants may only be reprocessed if their reprocessing is not prohibited on the product label.
It is the responsibility of the reprocessor to ensure that the actual reprocessing performed with the equipment, materials and personnel used at the reprocessing facility achieves the desired result. This requires appropriate measures to validate and routinely monitor the procedures and the equipment employed.

Brief overview:
- Maximum permissible temperature during reprocessing: 137° C
- Reprocessing authorised by manufacturer
- All non-sterile products must be reprocessed in the SIGNUS trays
- Preparation before cleaning, ultrasonic bath if necessary
- Recommended cleaning: mechanical, washer-disinfector, validated according to EN ISO 15883, mild alkaline detergent; detergent used for validation: neodisher Mediclean forte
- Recommended disinfection: thermal, > 90° C, > 5 min. or A0 value ≥ 3000
- Drying: up to 120° C, 20 min.
- Packaging: according to EN ISO 11607 and EN 868.
- Recommended sterilisation: moist heat, 132° C - 137 °C, 4 min. holding time, EN ISO 17665
- Items to be sterilised must be dry

Restrictions on use
- The products may only be used by persons who have been specifically trained or instructed in their use.
- The treating, medically trained personnel is responsible for selecting the correct surgical medical device.
- Defective products must no longer be used and must be excluded from further use. They must be clearly marked as being "defective" and sorted out.

Warnings for reprocessing
- Before each use, the surgical instruments and non-sterile implants must undergo a full reprocessing cycle according to the instructions given below.
- For implants, the reprocessing cycle begins with mechanical cleaning, as implants must be disposed of professionally after use (i.e. patient contact) in accordance with the instructions for use.
- The repeated cleaning of medical devices improves the passive layer, which subsequently protects the device from potential corrosion. A slight discolouration of the medical devices is quite common here, and is not a cause for complaint.
- When reprocessing the products, it is imperative to ensure compliance with all legal and occupational health and safety requirements regarding personal work and workplace hygiene, as well as own personal protection. Country-specific laws and regulations must be observed.
- Exercise caution when handling products with pointed parts or sharp edges.
- The manufacturer's instructions in this reprocessing guideline have been validated across the entire process, from cleaning and disinfection to sterilisation, and ensure that safe reprocessing and reuse are possible in accordance with the intended purpose, provided that the instructions are followed precisely.
- In the event of product contamination with prions (including suspected contamination), special reprocessing procedures must be performed in accordance with the relevant national guidelines and in-house procedures, as set out in the WHO and RKI guidelines. If this is not assured, the products must be disposed of appropriately after use.
- As a matter of principle, the operator is responsible for ensuring that the products are reprocessed professionally, particularly if own methods are used that deviate from the manufacturer's instructions in this guideline.
- We would like to expressly point out that only chemicals approved for the reprocessing of medical devices may be used, and that the provisions of the respective manufacturers must be observed.
- Manual cleaning and disinfection procedures, if used as the primary method, are not approved within the scope of these reprocessing instructions by the manufacturer. In the case of a manual procedure, the reprocessor must specify this in a standard working instruction and evaluate same appropriately.

Limitations on the period of use
- Due to the product design, the basic materials used and the manner they are processed, it is not possible to specify a general limit on the number of reprocessing cycles.
- The lifespan of the products depends instead on their function, careful reprocessing in accordance with these instructions, and caring handling of the products.
- The user can determine when the product has reached the end of its service life by referring to the potential faults and limiting properties listed under "Maintenance-Inspection-Testing".

SIGNUS Medizintechnik GmbH
Industriestr. 2 I 63755 Alzenau/Germany
t. +49 (0) 6023 9166 0 I f. +49 (0) 6023 9166 161
info@signus.com I www.signus.com

CE	Medical devices Class I
CE 0483	Medical devices Classes Ir, IIa, IIb, III

SIGNUS The Spine Sign®

REPROCESSING STEPS

Initial treatment at the point of use
Coarse contamination is removed immediately after using the surgical instruments. Care must be taken here to ensure that potential organic matter does not dry on and that encrustations are avoided. Procedures need to be established which do not adversely affect subsequent cleaning and disinfection, whereby disposal times should be allowed for.
There must be no more than 2 hours between the last use of the instruments and their initial treatment prior to dry disposal.
- Lint-free cleaning of the instruments
- Rinse under running water (soft tap water) or distilled water, or soak in water at a temperature of < 25° C > 1 min.
- Canals, lumina and cavities are flushed out using a syringe to prevent blockages.
- Do not allow saline solution, blood, bodily fluids, tissue, bone fragments or other organic particles to dry on the instruments before cleaning.
- The instruments are then transported in puncture-resistant, sealed containers suitable for transporting instruments to the Central Sterilisation Department (CSD).

Materials and work environment:
- Clean, lint-free disposable wipes
- Protective clothing and disposable gloves
- Running, cold tap water (< 25° C)
- Syringe for rinsing canals.
- Puncture-proof transport container with lid

Preparation before cleaning
- It is essential to disassemble the instruments as far as possible (see product-specific documentation) and to rinse all individual parts under running, cold tap water at a temperature of < 25° C and clean them with a soft brush.
- It is particularly important to clean the hinges, grooves and teeth thoroughly with the instruments open until no visible debris can be seen.
- Optional ultrasonic cleaning: products with cavities, as well as joints, threads, hinges and springs, require additional cleaning in an ultrasonic bath.
  - Place the instruments in an ultrasonic bath containing a mild alkaline cleaning solution at 40° C for 10 min. Follow the manufacturer's instructions for the ultrasonic bath.
  - After removing the instruments from the ultrasonic bath, rinse them thoroughly under running tap water, and use a high-pressure water jet to rinse cavities and hard-to-access areas with cold tap water at a pressure of approx. 3 bar for at least 20 seconds to remove all cleaning agents.
  - Wipe off excess moisture with a clean, absorbent, lint-free disposable wipe.
- Place the pre-cleaned instruments opened into a rinsing basket without overlapping and preventing the formation of rinsing shadows.
- Attach instruments with canals and lumina to the corresponding fittings on the loading tray of the washer-disinfector.

Materials and work environment:
- Well-lit workplace
- Protective clothing and disposable gloves
- -Running, cold tap water (< 25° C), water jet gun
- Brush with soft plastic bristles for superficial cleaning
- 50 ml syringe for flushing out canals, lumina and cavities, or water jet gun with a water pressure of up to 3 bar
- Rinsing basket for storing the instruments
- Clean, lint-free disposable wipes
- Tub containing enzymatic solution (according to own specifications)
- Soft nylon brushes for surfaces
- Narrow nylon brushes for lumina and cavities
- Soft tap water (< 25° C), and water jet gun, approx. 3 bar.
- Ultrasonic bath (40° C, 10 min.)
- Mild alkaline detergent (e.g. 0.5 % Neodisher Mediclean Forte)

Machine cleaning
- Machine cleaning and thermal disinfection in a washer-disinfector is strongly recommended.
- Any chemical residues remaining from disposal and manual pre-cleaning must be removed through thoroughly rinsing before machine cleaning.
- The requirements for the washer-disinfector are set out in EN ISO 15883 and are mandatory.
- The trays and the machine must be loaded suitable for rinsing; hollow bodies and lumina must be connected to the rinsing nozzles of the washer-disinfector and rinsed completely. Rinsing shadows must be avoided.
- Instruments must be placed according to their mechanical sensitivity, without stacking too many instruments on top of one another.
- Implants must be cleaned and disinfected in the designated SIGNUS tray.
- The validated parameters for machine cleaning after starting are as follows:
  - Pre-rinse: > 2 min. with cold tap water (< 25° C)
  - Emptying
  - Cleaning: min. 5 min. at 55° C (e.g. 0.5 % alkaline detergent Neodisher Mediclean Forte)
  - Emptying
  - Neutralisation with demineralised water: min. 3 min. (no rinse aid), <25°C
  - Emptying
  - Intermediate rinsing with demineralised water: min. 2 min., >25°C
  - Emptying
  - Final rinsing with thermal disinfection (see below)

The instructions of the washer-disinfector manufacturer must be strictly adhered to.

Materials and work environment:
- Washer-disinfector according to EN ISO 15883 (e.g. Miele G7735 CD)
- Mild alkaline detergent: optional: Neodisher Mediclean Forte, Dr. Weigert
- Demineralised water in accordance with EN 285; low bacterial count, but at minimum potable water quality (reference value < 15µS) for the last intermediate and final rinse

Thermal disinfection
- Machine thermal disinfection: 90° C, for > 5 min.
- Compliance with the corresponding requirements for the A0-value (typical A0=3000 n. DIN EN ISO 15883)

Materials and work environment:
- Washer-disinfector according to EN ISO 15883 (e.g. Miele G7735 CD)

Drying
- Machine drying with hot air at <120° C for 20 min.

SIGNUS Medizintechnik GmbH
Industriestr. 2 I 63755 Alzenau / Germany
t. +49 (0) 6023 9166 0 I f. +49 (0) 6023 9166 161
info@signus.com I www.signus.com

CE	Medical devices Class I
CE 0483	Medical devices Classes Ir, IIa, IIb, III

SIGNUS The Spine Sign®

Maintenance-Inspection-Testing
Cooling of the products to room temperature!

The inspection, maintenance and packaging of the instruments / implants may only be performed by qualified personnel. Implants only require visual inspection.

1. Visual inspection (prior to assembly):
Inspection of the instrument surfaces or the individual components prior to assembly, if necessary, using an illuminated magnifier or a microscope. Particular attention is to be paid to the inspection of joints (closing section), profiles, grooves, and other difficult to access structures:
- **Are residual contamination or residues still present?**
  If yes, perform manual post-cleaning and repeated complete machine cleaning and disinfection until no further residual contamination can be detected.
- **Are traces of corrosion (rust, pitting) visible?**
  If yes, the relevant instrument must be marked, sorted out immediately, and replaced.
- **Is the surface damaged by cracks (also hairline cracks) or other signs of wear?**
  If yes, the relevant instrument must be marked, sorted out immediately, and replaced.
- **Is the labelling of the medical device still fully legible?**
  If the product can no longer be clearly identified, it must be replaced or relabelled by SIGNUS.

2. Assembly and maintenance
- Reassemble the disassembled instruments in their correct order.
- Manually treat moving parts such as joints, threads and sliding surfaces with a suitable, medically approved instrument oil (steam-sterilisable care product based on paraffin- / white oil, biocompatible acc. to EU standard).
- Spread the oil in the joint by repeatedly opening and closing, and remove the excess care product with a clean, lint-free cloth.
- Observe product-specific assembly / disassembly instructions!

Caution:
- Do not use mineral oil or silicone lubricants!
- Do not immerse instruments fully in the care product!

3. Function test
Pay particular attention to the following aspects and possible malfunctions during the function test:
- Damage, such as broken tips, bent or loose parts (screws), broken carbide inserts
- Perfect closing of jaw parts
- Proper and safe function of locks and blocks
- Easy and smooth movement of handles, as little play as possible of the instruments
- Correct repeat and spring pressure (punches, hollow-point forceps etc.)
- Integrity of lumina, if present
- No other signs of wear i.e. on seals, insulation or coatings

If defects are identified during functional testing, the instruments must be labelled and definitely excluded from further use.

Materials and work environment:
- Well-lit and clean environment
- Disposable gloves
- Illuminated magnifier, microscope
- Appropriate instrument oil based on paraffin / white oil
- Lint-free, clean cloth
- Hospital in-house inspection devices

Packaging
All non-sterile implants and instruments must be reprocessed in the SIGNUS trays. SIGNUS has validated sterilisation in the tray. The use of other sterile barrier systems for the steam sterilisation of individually packaged instruments lies in the responsibility of the user.
To prepare for subsequent steam sterilisation, packaging of the trays is performed in suitable sterile barrier systems according to the standards:
- EN ISO 11607-1, -2
- EN 868-2 to -10

The manufacturers' specifications for the respective packaging systems must be observed.
Adequate protection of the instruments and the packaging system against mechanical damage and impairment of the sterile barrier must be ensured.
Pay attention to an adequate size of the packaging system.

Sterilisation
Avoid product damage. Observe the maximum load limit of the machine. See the manufacturer's instructions for use.
Sterilisation with humid heat / steam pursuant to EN ISO 17665 and EN 285 is preferable to other sterilisation procedures, whereby the following process parameters have been validated as being effective and which allow achieving an SAL value (Sterility Assurance Level) of 10^{-6} reliably.
- Fractionated vacuum method (3 pre-vacuum phases)
- Validated temperature/holding time:
  132° C / 3 min. (DIANA tray SH01AY 10min)
- Recommended temperature / holding time: 134° C / 4 min.
- Drying time: 30 min.

The condensate present must be evaporated and removed from the goods, the packaging and the chamber to ensure subsequent storability.
The effectiveness of the above mentioned process is given according to the definition in Standard EN 556-1.

Materials and work environment:
- Steam steriliser with fractionated vacuum (e.g. Varioclav 400 E, Fisher Scientific)
- Storage, transport
- Storage of the sterilised products in a dry, clean, dust-proof environment, separate from non-sterile products.
- Protect against direct light and extreme fluctuations in temperature.
- It is essential to observe the stipulations of the sterile barrier system's packaging manufacturer.
- The stipulations of the Hygiene Officer and the manufacturer apply with regard to the maximum storage period.
- The national stipulations on the storage and handling of sterile goods are to be observed.
- Transport must not have a negative effect on the properties of the sterile goods

Disposal
Products must be disposed of in accordance with the relevant national regulations and laws after they have been fully reprocessed by the user.

SIGNUS Medizintechnik GmbH
Industriestr. 2 I 63755 Alzenau/Germany
t. +49 (0) 6023 9166 0 I f. +49 (0) 6023 9166 161
info@signus.com I www.signus.com

CE	Medical devices Class I
CE 0483	Medical devices Classes Ir, IIa, IIb, III

SIGNUS The Spine Sign®

Disclaimer
Among other things, the manufacturer's liability is excluded in the case of:
- Use of the products outside their intended use
- Inappropriate handling
- Failure to observe the notes in these instructions for use
- The use of unsuitable or unapproved reprocessing chemicals and devices
- Product modifications and repairs by unauthorised parties

Returns
Before being returned, the used tray/instrument must be subjected to a validated reprocessing procedure. This must be documented on the delivery note provided, which must be enclosed with the return shipment.

Reporting obligations
Please report any product defects that, when our products are used according to the instructions for use, have caused or could have caused harm to patients, users or third parties (so-called reportable incidents) to the manufacturer immediately and, where applicable, to your competent authority.
Incidents must be reported immediately after they occur so that important reporting deadlines can be met and further incidents prevented.
The affected products must be sorted out, reprocessed and have to be returned to the manufacturer for examination. Your local specialist dealer will be pleased to assist you in this matter.
After receipt of your report. we will inform you of the necessary next actions within a reasonable timeframe.

Symbols used
Symbolism according to DIN EN ISO 15223-1

	Manufacturer and date of manufacture
	Medical device
	Batch code
	Serial number
	Product identification number
	CE marking
	Article number
	Consult the electronic instructions for use
	Caution!
	Non-sterile
	Do not re-use
	Do not resterilise
	Temperature limit
	Do not use if packaging is damaged
	Sterilised using irradiation
	Single sterile barrier system
	Double sterile barrier system
	Use by

SIGNUS Medizintechnik GmbH
Industriestr. 2 I 63755 Alzenau/Germany
t. +49 (0) 6023 9166 0 I f. +49 (0) 6023 9166 161
info@signus.com I www.signus.com

CE	Medical devices Class I
CE 0483	Medical devices Classes Ir, IIa, IIb, III

SIGNUS The Spine Sign®