ARTIQO GmbH
Hans-Böckler-Straße 57
59348 Lüdinghausen
Germany

T +49 (0)2591 89315-00
F +49 (0)2591 89315-10
www.artiqo.de/en

NA30-04-05 – Reprocessing instructions for the instrument set for implant systems

Instructions regarding the reprocessing (cleaning, disinfection, sterilisation and storage) of reusable surgical instruments in accordance with ISO 17664.

Applicability: All reusable medical devices from ARTIQO GmbH with fixed designs (no moving parts) and simple joint mechanisms.

General information:

- All instruments are supplied unprocessed and non-sterile.
- Remove the devices from the packaging and reprocess them completely before using them for the first time! The use of the protective transport packaging during reprocessing is NOT permitted.
- This information is intended to provide hospital staff with support in the safe handling and reprocessing of reusable devices.
- Reprocessing should be performed as soon as possible after use. Do not allow contamination to dry on the instruments.
- Difficult-to-reach areas such as hollow spaces, narrow cavities and joints require special attention.
- Instruments that can be dismantled should always be dismantled prior to their reprocessing.
- Joints and locking mechanisms should always be in an open state.
- Do not immerse instruments made of stainless steel in physiological saline solution (risk of corrosion).
- Do not allow the instruments to come into contact with aggressive substances (acids, alkalis, oxidising or reducing substances, harsh cleaning agents, etc.)
- Preferably use pH-neutral agents.
- Where applicable, alkaline cleaning agents used must be completely neutralised and rinsed off.
- Do not clean the instruments in their trays.
- Do not use hard water, use ultrapure water in the final step to remove any mineral residues.
- Do not use wire brushes or wire wool.
- Do not place heavy objects on top of delicate ones.
- Use only silicone-free care lubricants suitable for the subsequent sterilisation process.
- Instruments with scales for comparative checks and measurements must be handled with care and any functional check instructions in the respective instructions for use observed!
- Improper reprocessing can cause anodised titanium surfaces to discolour (e.g., as a result of cleaning agent residues), which can render labelling unreadable.
- Storage in metal containers (with the exception of stainless steel and aluminium containers) is not permitted.
- Implement measures to protect against damage during transport, cleaning and storage.
- For already reprocessed devices: handle the packaging and sterilisation containers carefully and protect them against damage and dangerous environmental influences. Especially after extended periods of storage, it is always important to check carefully that packaging, such as sterilisation paper or containers, is undamaged before using reusable, already reprocessed devices again.

Reprocessing limitations:

Frequent, properly conducted reprocessing has little effect on the metal instruments. Their service life is generally dictated by wear and/or damage caused by use. Plastic components (e.g., ball head impactors made of POM C and trial heads) have limited reprocessability and must be replaced if they show signs of degradation such as cracks, detachments, etc.

⚠ Some instruments feature colour marks made of ceramic, which degrade over time with repeated reprocessing. If the colour marks develop visible or tangible changes (such as cracks, detachments, protrusions), please notify the manufacturer so that suitable repair measures can be implemented.

Initial treatment directly after use:

Removal of surface contamination:

Coarse contamination should be removed directly after use. Avoid tissue and blood drying on the devices, for example by wiping down the surfaces. Cannulas, cavities and blind holes must be rinsed out with water. Complex instruments such as rasp adapters feature additional holes through which the mechanisms inside can be rinsed. Blood and tissue remnants can lead to corrosion.

Preclean the grooves on the rasps with a brush if necessary. Do not use wire brushes or wire wool.

Instrument storage and transport: Store parts in a place where they are protected against impacts and damage and not in the intended trays. If necessary, collect small parts in suitable containers to ensure they are not lost.

Manual cleaning & disinfection:

This instrument set contains instruments in the “Critical A” risk class in accordance with the Robert Koch Institute’s “Hygiene Requirements for the Reprocessing of Medical Devices” (2012). Manual reprocessing is not recommended, as it generally does not satisfy the requirements on reproducibility and process reliability of a validated,

ARTIQO GmbH
Hans-Böckler-Straße 57
59348 Lüdinghausen
Germany

T +49 (0)2591 89315-00
F +49 (0)2591 89315-10
www.artiqo.de/en

automated process. We therefore recommend the use of an automated washer-disinfector in accordance with ISO 15883-1 & -2.

Precleaning:

Time and again, residues from the washer-disinfector are "vaporised" onto the instruments and become visible as "flash rust". To avoid such deposits, ARTIQO recommends ultrasonic precleaning.

Recommended parameters:

- Clean instruments under running water (<40°C) using a soft brush and rinse through with a cleaning gun until no contamination is visible;
- Place in an ultrasound bath with 0.5% neodisher® MediClean forte for 15 min. at <40°C;
- Rinse with water for 10 sec. to remove cleaning agent residues.

Automated cleaning & disinfection:

The instruments must always be reprocessed using a validated process. The efficacy of the washer-disinfector must be demonstrated (e.g., FDA approval or CE mark in accordance with EN ISO 15883).

ARTIQO recommends the following parameters for automated cleaning and disinfection, which have been validated by an accredited laboratory:

Washer-disinfector: Miele PG 8535 (or similar) in combination with an (alkaline) cleaning agent: neodisher® MediClean forte; ratio: 5 ml/L (0.5%) (Chemische Fabrik Dr. Weigert GmbH & Co. KG, Hamburg, Germany).

The following cleaning programme for automated cleaning has been validated by an external laboratory and is recommended for the cleaning:

Automated cleaning (e.g., with MIELE PG 8535):
- Prerinsing with cold water at ≤ 40°C for ≥ 2 min.;
- Cleaning for ≥ 10 min. (0.5% neodisher® MediClean forte at 55°C, not above 60°C);
- Neutralisation for ≥ 3 min. (with 0.1% neodisher® Z);
- Rinsing with lukewarm water for ≥ 2 min. (< 40°C);
- Thermal disinfection at 93°C for ≥ 5 min. (or A0 > 3,000 in modern machines)
- Drying at 100°C for ≥ 18 min.

Experience has shown that difficult-to-reach areas can be best cleaned with a cleaning gun.

Reprocessing with other validated processes is also possible. In this case, the reprocessor is responsible for the validation of their reprocessing process (RKI Guidelines 2012).

When selecting alternative cleaning agents, please note:

- The cleaning agent should always be suitable for the reprocessing of metal and plastic instruments.
- When non-pH-neutral cleaning agents are used, the cleaning cycle must include a neutralising step.
- Only use disinfectants with verified efficacy and compatibility with the cleaning agent used.
- The pH, cleaning duration and temperature must be selected in accordance with the recommendations for use of the cleaning agent.

Cleaning control: The instruments must be removed from the machine as soon as the cleaning programme is complete, as residual moisture if they remain there for an extended period of time can create favourable conditions for corrosion. The instruments and critical areas in particular must be inspected thoroughly for visible contamination and residual moisture. If required, the procedure should be repeated immediately or manual post-cleaning performed with subsequent thorough rinsing with demineralised, low-germ water, followed by post-drying with medical-grade compressed air.

Inspection, repairs and testing:

Prior to sterilisation, the instruments should be inspected for damage, deformations, wear and corrosion. If proper functioning is no longer guaranteed, wear is evident on the instrument or a change to the colour mark is identified (cracked, loose, slightly protruding colour mark), the items in question must be repaired or replaced.
Take special care not to contaminate the instruments again during inspection and assembly!

Exclusion of liability: ARTIQO GmbH rejects all liability for the use of damaged and/or contaminated medical devices.

Care products: Small quantities of suitable, high-quality, silicone-free, physiologically harmless care products should be used for moving parts. The care product must be suitable for sterilisation processes, e.g., medipoint® – special oil spray, manufacturer: Dispomedica GmbH, Hamburg, Germany

Test for proper functioning:

Moving and jointed instruments must be checked for ease of movement. The performance of functional checks is recommended.

ARTIQO GmbH
Hans-Böckler-Straße 57
59348 Lüdinghausen
Germany

T +49 (0)2591 89315-00
F +49 (0)2591 89315-10
www.artiqo.de/en

NA30-04-05 – Reprocessing instructions for the instrument set for implant systems

Packaging:

Trays: The use of standardised packaging materials (with an appropriate packaging method) or approved sterile containers is mandatory to preserve the sterility. Steam penetration and coating of the surfaces must be ensured. The packaging and its contents must be protected against mechanical damage.

Sterilisation:

Saturated steam sterilisation with the fractionated prevacuum process is recommended. Recommended parameters: min. 134°C with a holding time of at least 5 min. or min. 121°C with a holding time of at least 20 min., with a subsequent drying time of 25 minutes. When alternative processes are used, the reprocessor is responsible for validating the process in advance. In principle, the instruments are also suitable for ethylene oxide sterilisation. For the use of alternative methods, please contact ARTIQO GmbH directly.

Caution: Older ball head impactors may still be made of a POM copolymer. Sterilisation at 134°C results in a shorter service life for these instruments than observed with sterilisation at 121°C.

POM-C was replaced with the more degradation-resistant PPSU in 2023.

Storage:

The reprocessed instruments should be stored in a dry, clean place protected from dust, vermin and unauthorised access. The preservation of the sterility depends on the packaging, any damage to the packaging, the environmental conditions and the period of storage. The instruments should not be stored sterile for excessive periods of time.

Transport:

Please use our transport packaging for returns and include the completed cleaning and sterilisation form.

The information provided here does not release the reprocessor from their obligation to validate the corresponding cleaning and sterilisation process in accordance with the RKI/KRINKO recommendations.

References:

DIN EN ISO 17665: Sterilization of health care products – Moist heat: Requirements for the development, validation and routine control of a sterilization process for medical devices

DIN EN ISO 17664-1: Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices. Part 1: Critical and semi-critical medical devices

DIN EN ISO 15883-1 ff, Washer-disinfectors – Part 1: General requirements, terms and definitions and tests; Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

RKI/KRINKO/BfArM recommendation regarding "Hygiene Requirements for the Reprocessing of Medical Devices"; Bundesgesundheitsblatt (Federal Health Bulletin) 2012 55:1244–1310
(https://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Kommission/Downloads/Hygiene_Requirements_Medical_Devices_2012.pdf?__blob=publicationFile)

Recommendation of the KRINKO at the Robert Koch Institute and the BfArM: Supplement to the recommendation "Hygiene Requirements for the Reprocessing of Medical Devices" Epid Bull 2018;6:67 – 68 | DOI 10.17886/EpiBull-2018-006.
(https://edoc.rki.de/handle/176904/2976)

http://www.a-k-i.org/aktuelle-themen/metall-korrosion/fremd-u-flugrost/

Düsseldorf District Council Requirements on the Hygienic Reprocessing of Medical Devices in North Rhine-Westphalia
https://www.brd.nrw.de/system/files/media/document/2023-12/20231213_2_24_Pharmazie_Medizin_Anforderungen_hygienische_Aufbereitung_Medizinprodukte.pdf

Version: 24/01/2024