Instructions for Use
Reusable surgical instruments with silicone handles

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1. General Information

These instructions apply to all stainless steel instruments in conjunction with silicone handles manufactured by gryphon medical solutions, LLC. After receiving products, check them for identity, completeness, integrityand function before further processing. It is absolutely necessary to fulfill or take into consideration all requirements and special information described in these instructions, otherwise the products are not suitable for clinical use. In addition, any specific instructions included with the individual products need tobe followed. In case of uncertainties, discrepancies or questions, please contact us before using, reusingor further processing the products. These instructions are not a substitute for the user's training, diligence and state-of-the-art technology. We therefore assume knowledge of the relevant legislation, standards and recommendations (e.g. RKI or AKI, see "Standards/References") and limit our focus on the product- specific instructions and information to be followed by the user with relevance to our products. Reasons for these instructions, as well as hazards incurring as a result of failure to adhere to them, are listed withinthe legislation and recommendations. Read all relevant instructions carefully before processing and using a product for the first time!

2. Warnings and Precautions

The products are supplied NON-STERILE!
These instructions apply to all reusable stainless steel instruments with silicone handles manufactured by gryphon medical solutions, LLC. After receiving products, check them for identity, completeness, integrity and function before further processing. Carefully read through these instructions before use. Keep these instructions accessible to all staff members. Before each use, the instruments need to be inspected for fractures, cracks, deformation, damages and functional reliability. Special attention should be paid to areas such ascutting edges, tips, joints, locks, ratchets and all movable parts. Instruments that show wear, corrosion, deformation, porosity or other damage must be sorted out. For repairs or replacement, please contact your representative or gryphon medical solutions, LLC. If the instrument has been used on a patient with Creutzfeldt-JakobDisease (CJD) (confirmed or suspected CJD), the instrument cannot be used again. Since even with processing and sterilization the risk of cross contamination cannot be eliminated, the instrument has to bedestroyed. Special care must be taken when handling surgical instruments to prevent damage. Use particular caution during cleaning and sterilization. For manual cleaning, be sure to use cleaning aids that do not damage the instruments. Take extra care when cleaning critical, non-accessible areas, joints, cannulations, blind holes and all movable parts. Wear protective gloves, protective glasses and protective clothing (if indicated). Instruments made of different metals must be treated separately to prevent electrolytic reactions between the metals. The operator of the medical facility has to ensure that the instruments are adequately cleaned and disinfected before steam sterilization. Insufficient cleaning/disinfection can lead to residual contamination which constitutes a hazard to the patient. Surgicalinstruments by Gryphon medical solutions, LLC are supplied non-sterile and have to be cleaned, disinfected and sterilized according to the supplied instructions before use.

3. Processing of Instruments

3.1. General Notices

All instruments have to be cleaned, disinfected and sterilized before each use; this is of special importance before the initial use of instruments which are delivered non-sterile (cleaning and disinfection after removal of protective transport packaging; sterilization after packaging). Effective cleaning and disinfection is an indispensable prerequisite for efficient sterilization. Please make sure, while using the instruments, to collect soiled pieces separately and to not place them back into the instrument tray in order to prevent additional contamination of the equipped instrument tray. Clean/disinfect the reusable soiled instruments, sort them back into the instrument tray and then sterilize the fully equipped and previously cleaned/disinfected tray. As part of your responsibility to ensure sterility of the instruments, please take care during any use to employ only sufficiently validated device and product-specific processes for cleaning/disinfection and sterilization, to regularly service and inspect all equipment (RDG, sterilizer), and to adhere to the validated parameters during each cycle. In addition, please observe all legal regulations

of your country as well as the hygiene policies issued by the medical office or hospital. This applies in particular to the various guidelines regarding effective prion inactivation.

3.2. Cleaning and Disinfection

To clean and disinfect the instruments, an automated process should be used (RDG - Washer/ Disinfector). Manual cleaning - even in combination with ultrasonic treatment - is considerably less effective and reproducible and should only be used if an automated system is not available. Pretreatment is necessary in either case.

3.3. Pretreatment

Immediately after use (within a maximum of 2 hours), any visible soils need to be removed off the products.
To enable efficient cleaning and disinfection, take apart products consisting of multiple parts as far as possible according to the product specific instructions as well as to the guidelines laid out in section "Special Notices" (exchangeable parts, accessories, adaptors, interchangeable inserts etc.).
Use running water or a disinfectant; the disinfectant should be aldehyde-free (to avoid the fixation of blood impurities), be of proven efficacy (e.g. VAH/DGHM or FDA approval or CE marked), be suitable for instrument disinfection, and be compatible with the instruments (see section "Material Stability"). To manually remove impurities, use only a soft brush or clean soft cloth used exclusively for this purpose, never metal brushes or steel wool, as these could damage the surface. Check cavities and narrow lumen to ensure complete removal of all residues.

3.4. Automated Cleaning/Disinfection

When selecting a washer/disinfector (RDG), make sure

- the washer/disinfector is of proven effectiveness (e.g. DGHM- or FDA-approval or CE-marking in accordance with DIN EN ISO 15883)
- an approved program for thermal disinfection is used (minimum of 10 min at 93°C (199.4°F)) or A0- value > 3000) (chemical disinfection bears risk of leaving disinfectant residues on instruments)
- the selected program is suitable for the instruments and includes sufficient rinse cycles
- suitable water for rinsing is used (e.g. Aqua purificata/Aqua purificata valde), and furthermore, the air used for drying is filtered and therefore does not reduce the hygiene status at this point
- the washer/disinfector is regularly serviced and inspected

When selecting a cleaning agent system, make sure

- it is generally suitable for cleaning the instrument
- if no thermal disinfection is used, a disinfectant will be added with proven efficacy (e.g. VAH/DGHM- or FDA-approval or CE-marking), and this disinfectant is compatible with the used cleaning agent and the used chemicals are compatible with the instruments (see section “Material Stability”)

Strictly adhere to the manufacturer's specifications for concentrations regarding the cleaning agent and, if applicable, the disinfectant.
Process:

1. Disassemble the instruments as far as possible.
2. Place the disassembled instruments into the washer/disinfector. Take care that the instruments do not touch each other.
3. If products with narrow lumens or cavities are not connectible, these need to be placed into the washer/disinfector in a way that allows water and disinfectant to drain completely.
4. Start the program.
5. After program is complete, remove the instruments from the washer/disinfector.
6. Inspect and package the instruments as soon as possible after removal (see sections “Inspection”, “Maintenance” and “Packaging” if necessary after additional drying in a clean area).

The general suitability of the instruments to be effectively cleaned and disinfected using an automated system has been verified by an independent accredited laboratory using the washer/disinfector “RDG G 7836 CD” (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning agent “Neodisher mediclean forte” (Dr. Weigert GmbH & Co. KG, Hamburg). The procedures described above were followed.

3.5. Inspection

After cleaning, or cleaning/disinfecting respectively, check all instruments for corrosion, damaged surfaces, chips or impurities and discard damaged instruments (for quantitative limits on reusability, see section “Reusability”). Instruments with residual contamination need to be cleaned and disinfected again.

3.6. Maintenance

Reassemble disassembled instruments.
Every instrument processing needs to include lubrication. Special attention needs to be paid to the lubrication of joints, hinges and moveable parts. Make sure to use only instrument lubricants (white oil) that are approved for steam sterilization - taking into consideration the maximum applied sterilization temperature - and that feature proven biocompatibility.
Before use, check all instruments for corrosion, damaged surfaces, chips and contamination, and discard damaged instruments. Instruments that are free of damage and remain fully functional may be reprocessed and reused again (for limits of reuse, see section “Reusability”).

3.7. Packaging

Sort the cleaned and disinfected instruments into the sterilization trays and place those into single use sterilization packages or sterilization containers that meet the following requirements: in accordance with DIN EN ISO/ANSI AAMI ISO 11607 and EN 868-2 to -10

- suitable for steam sterilization (temperature resistant up to at least 137°C (279°F), sufficient steam permeability)
- sufficient protection of instruments and sterilization packaging against mechanical damage
- regularly serviced according to manufacturer guidelines (sterilization container)

3.8. Sterilization

For sterilization, only the following sterilization methods may be used; other methods of sterilization are not permissible.
Steam sterilization

- fractionated vacuum process/pre-vacuum process or gravity displacement process (with sufficient product drying)
- steam sterilizer in accordance with DIN EN 13060 or DIN EN 285 respectively
- validated in compliance with ANSI/AAMI/ISO 17665-1:2006 (valid commissioning and product specific performance qualification)
- maximum sterilization temperature of 134°C (273°F); plus tolerance in compliance with ANSI/AAMI/ISO 17665-1:2006.
- sterilization time (exposure time at sterilization temperature) at least 5 min at 134 °C (273 °F)

The general suitability of the instruments for effective steam sterilization has been verified by an independent accredited laboratory using the steam sterilizer "MMM Münchener Medizin Mechanik GmbH, Planegg, Deutschland" applying the fractionated vacuum process and the gravity displacement process. The procedures described above were followed. After completion of steam sterilization, allow the products to cool to room temperature (approx. 20°C (68°F)) before opening the sterilization packaging. The flash sterilization process is principally not permissible. In addition, do NOT use dry-heat sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization or plasma sterilization.

3.9. Storage
After sterilization, the instruments have to be stored in the sterilization packaging in a dry and dust-free place.

3.10. Material Stability
When choosing a cleaning agent and disinfectant, make sure that they do not contain the following:
- organic, mineral and oxidizing acids
- stronger alkaline solutions (pH > 11 not permissible, mildly alkaline detergents recommended)
- organic solvents (alcohol, acetone,...), benzine
- halogenated hydrocarbons, chlorine, iodine
- ammonia

3.11. Reusability
With due care, and as long as the instruments are undamaged and fully functional, they can be reprocessed and reused again. Product life is limited due to damage and normal wear and tear; such products are to be discarded after reprocessing. Product life is dependent on a variety of factors including nature and duration of use, as well as handling, storage and transport of instruments. Diligent inspections and function tests before subsequent use is the best way to recognize and discard a no-longer-functioning instrument.

4. Returns
Any product returns may only be sent to us after completed and clearly evident disinfection/sterilization (appropriate packaging with sterility indicators, decontamination certificate etc.). The relevant hygiene and facility regulations must be observed. If no proof of cleaning/sterilization is included, the cost of proper cleaning will be charged to you.

5. Warranty
Safety notice: It is the responsibility of the operator/ product user to ensure proper cleaning, disinfection and sterilization of the products. It is imperative to comply with national legislation, including any restrictions.

Gryphon Medical Solutions, LLC, as the manufacturer of the products, excludes any warranty claims and assumes no liabilityfor direct loss or consequential loss as a result of:
- use of products for purpose other than originally intended
- improper use, application or handling
- improper processing and sterilization
- improper maintenance and repairs
- failure to follow the operating instructions

6. Information and Symbols on Labels

Product is delivered non-sterile.

REF Reference number of item

LOT Identification number assigned to a particular quantity or lot of material from the manufacturer.


Read the instructions for use.

7. Standards - References
AKI1 - Guidelines “Instrumenten-Aufbereitung richtig gemacht”
RKI2 - Recommendation: “Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten”
DIN EN 285 Large Steam Sterilizers

DIN EN 13060 Small Steam Sterilizers
DIN EN ISO 15883-1-3 Washer-Disinfectors
DIN EN ISO/ANSI AAMI ISO 11607 and EN 868-2 to -10 Packaging Materials DIN EN ISO 17664 / ANSI AAMI ST81 Sterilization – Manufacturer‘s Information DIN EN ISO 17665-1-2 Sterilization Process – Moist Heat
1 AKI: Working Group Instrument Preparation
2 RKI: Robert-Koch Institute

8. Validation
The above guidelines for reprocessing have been validated as "suitable" for preparing a medical product for reuse. Responsibility lies with the user (reprocessor) to ensure that the actual reprocessing using equipment, materials and staff within the operator's facility will achieve the desired results. Usually this requires process validation and routine monitoring measures. Additionally, any deviation from the provided instructions by the user (processor) should be properly evaluated for effectiveness and potential adverse consequences.

Gryphon Medical Solutions, LLC does not accept any liability if these instructions for use have not been observed orfollowed.

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