INSTRUCTIONS FOR USE (Hospital Hollowware)

Reprocessing Instructions for Resterilizable Medical Devices

Manufacturer: Starkling **Method:** Re-processing instructions **Symbol:** N.A.

Product(s): Hospital Hollowware

Product Intended Use:

Starkling Hollowware are intended for use in the transportation, preparation, serving, sterilizing and storage of surgical instruments and/or medical devices/or liquid substances. Hollowware such as bedpans, urinals and sputum pots allow patients to have bowel movement, urinate, excreting sputum while in the bed.

Cautions:

- Ensure that the product is operated and used only under assistance of the person with the requisite training, knowledge or experience.
- Read, follow and keep the instructions for use.
- Use the product only in accordance with its intended use, see Intended use.
- Prior to use, visually check the product for bent, broken, cracked, worn, or missing component(s).
- Do not use the product if it is damaged or defective.

WARNINGS	• Infection hazard for patients and/or users due to reuse without sterilization. Risk of injury, illness or death due to contamination. • Hollowware must be sterilized prior to use. See sterilization instructions • Do not soak hollowware in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. • Do not exceed two hours soaking in any solution. • Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents to remove soil as these may damage the product and lead to corrosion.

	• Hollowware may only be treated by persons with the necessary specialized knowledge and training, and who can judge the potential risks with the corresponding effects. • Autoclave temperatures should not exceed 134°C / 273°F. • Do not use detergents or disinfectants containing the following substances: a. Strong Alkalines (>pH9) b. Strong Acids (<pH4) c. Phenols or iodophors d. Hydrogen peroxide (H2O2) e. Interhalogenic agents/ halogenic hydrocarbons/ iodiophors f. Strong oxidizing agents / peroxides g. Organic solvents • Water quality may influence the result of the cleaning and disinfection of the products. Therefore use only deionized water or purified water/high purified water for all the steps that require water. Corrosion of products may be caused by high contents of chloride or other minerals in tap water. If stains and corrosion occur and other reasons can be excluded, it may be necessary to test the quality of the tap water in your area. Most water quality problems can be avoided with the use of deionized water. • Never attempt to make repairs yourself. Any repairs made by the users may avoid the warranty. • The use of a product for a task other than that for which it is intended, as well as improper, ineffective and insufficient maintenance can greatly reduce the life of a product and will invalidate the product's warranty. • Consult National Infection Control / Prevention Protocols for specific guidance regarding processing of medical devices.
Limitation on re-processing:	Frequent re-treating has little effect on the product. The end of the product lifetime is usually determined by wear and damage from use. They are then to be disposed of according to hospital procedure. Do not use any damaged products.

INSTRUCTIONS

Point of use:	Remove surface contamination with a disposable cloth / paper towel. It is recommended to reprocess the products as soon as possible after they have been used. Directly after use, they can be disinfected by hand in order to reduce the risk of infection for the user. Here, the products are placed in a disinfection solution. Make sure that the products are fully immersed in the disinfection solution, and that no air bubbles are formed. Follow the instructions of the manufacturer of the disinfection solution.
Containment and transportation:	• Contain contaminated products in an approved sealed container during transport from the point of use to the decontamination area. • Reprocess products as soon as is reasonably practical following use.
Preparation for cleaning	No special requirements.
Cleaning: Automated	Use an ultrasound device such as Branson B-300 ultrasonic device or Miele G 7736 CD, or any equivalent suitable device for medical use. 1. Place products in the wire basket. 2. Rinse for 1 min. with cold water (<40°C). 3. Discharging 4. Rinse for 3 min. with cold water (<40°C). 5. Discharging 6. Ultrasonically clean for 5 min. at 55°C with a 0.5% alkaline (like Micro-90® or Neodisher® FA by Dr. Weigert) or at 45°C with an enzymatic cleaning agent such as Enzol® (Johnson & Johnson) one ounce of product per gallon of water or two ounces of product per gallon of water for cleaning devices with dried-on matter. 7. Discharging 8. Neutralize for 3 min. with warm water (>40°C) and 2 min. intermediate rinsing with warm water (>40°C). 9. Discharging **Note:** • An overdose of the cleaning/disinfection solution is to be avoided.

	• Special instructions of the manufacturer of the automated cleaning machine have to be followed. • Inspect products for good cleaning result and repeat procedure if necessary. The best effects are achieved by cleaning and rinsing the products immediately after each application. **The following items should also be observed:** • The wire basket of the ultrasound device must be sufficiently large and deep to guarantee that the products are completely immersed. • Products must be completely covered by the cleaning solution. • Only use wire basins, which don't negatively affect the cleaning result. • Don't overload wire basins. • Avoid "acoustic shadows". • Fill all channels and hollow spaces with cleaning solutions, without air bubbles. • Remove products from the ultrasound device. • Blow through all channels with air to remove any remaining liquid. • Change the cleaning solution in the ultrasound bath at least once a day, and more often when contamination is visible.
Cleaning: Manual	Prepare the cleaning bath with detergent like Enzol Enzym (Johnson & Johnson) using one ounce of product per gallon of water or two ounces of product per gallon of water for cleaning devices with dried-on matter or prepare according to the manufacturer's instructions. • Rinse the products with cold tap water (<40°C) until all visible soil has been removed. If needed a soft bristle brush should be used to remove stuck dirt/soil. • Placed products in the prepared cleaning bath so that they are completely submersed. Observe residence time 2-3 minutes or according to the manufacturer's instructions. • Clean the product in the bath manually using a soft brush. Brush all surfaces/channels and insides of products several times. • Rinse the product under running tap water to remove the detergent.

	• Inspect the products for good cleaning result and repeat procedure if necessary. • Products are now ready for high-level disinfection or sterilization.
Disinfection:	Prepare disinfectant solution with solution like Cidex® OPA (Johnson & Johnson) using one ounce of product per gallon of water or two ounces of product per gallon of water with dried-on matter or prepare according to the manufacturer's instructions. • Completely submerge products in the disinfectant solution. • Soak for a minimum of 12 minutes at 20°C or higher to destroy all pathogenic microorganism. • There should be no contact between the products. • Remove the products from the disinfecting solution with fresh disposable gloves. • Thoroughly rinse the products by immersing it completely in water. Use deionized water. • Keep the product totally immersed for a minimum of one minute in duration. • Manually flush all lumens with large volumes of rinse water. • Remove product and discard the rinse water. Always use fresh volumes of water for each rinse. • Repeat the rinse procedure two additional time with a large volumes of fresh water to remove the Cidex® OPA solution residues. Residues may cause serious side effects. Three separate, large volume water immersion rinses are required. **IMPORTANT NOTE:** Before using a Cidex® Solution for high level disinfection, a Cidex® test strip should be used to ensure that the solution concentration is minimally effective. Consult with the Cidex® user instructions, as well as the original equipment manufacturer's instructions for the Cidex® test strips, for guidance prior to use.
Drying:	Products must be thoroughly dried and all residual moisture must be removed before they are stored. Use a soft, absorbent towel/cloth to dry external surfaces. Compressed air may be used to aid the drying process.

Maintenance:	Product can be cleaned following the guidelines in the 'Cleaning' and 'Disinfection' above. Periodically check the condition of the Product, making sure there is no sign of corrosion. Discard the damaged products.

Inspection and Function Testing:	• Prior to use, visually check the product for bent, broken, cracked, worn, or missing component(s). • Edges and surface should be free of nicks. • Do not use the product if it is damaged, blocked or defective. • If products are still dirty, repeat cleaning and disinfection procedures.
Packaging:	A standard packaging material should be used. Ensure that the pack is large enough to contain the product without stressing on it. When used as intended, these products do not need an outer wrap or additional protection. Always use protective caps for packaging / storage of clean products, where needed.
Sterilization:	Hollowware must be processed in the completely open position to allow sterilant contact of all surfaces. Recommended sterilization method: Steam sterilization with saturated steam with a fractionizing vacuum (EN ISO 17665) Recommended temperature: 134 °C Recommended pressure: 3 bar Duration: ≥ 5 min Drying time: ≥ 15 min After sterilization, check the packaging of the sterilized products for damage. Check the sterilization indicators. **Note:** Sterilization can only be maintained if the products remain packaged or wrapped, impermeable to microorganisms, following a validated sterilization.
Storage:	Hollowware have to be stored under bellow listed conditions • Stored in dry area. • Between -20°C - 49°C and 10% - 95% relative humidity. • Protected from direct sunlight, moisture and excessive airflow.
Additional Information:	When sterilizing multiple products in one autoclave cycle ensure that the sterilizer's maximum load is not exceeded.

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This instructions provided above have been validated by the medical device manufacturer as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

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