Note: If possible, the instruments are to be transported from the place of use to the reprocessing facilities in dry condition in order to avoid the protein that can deposit due to the cleaning agent that is used.

Infection Risk by Improper Cleaning Agents

Using improper cleaning agents can provoke an infection control risk. Only use cleaners that are approved in accordance with national hygiene-related regulations and local guidelines.

Risk of Infection and Damage Due to Residues of Cleaning Agents

After cleaning thoroughly rinse each component with deionized water during the last rinse cycle in order to remove all residues. Do not use tap water for the last rinse cycle.

Risk of Damage Due to Incompatible Cleaning Agents

Incompatible cleaning agents can cause considerable damage to the STAND. Therefore, only use cleaners recommended by Bimini Health Tech for use with the STAND.

Information on Validation of Reprocessing

If the above described chemicals and machines are not available it is the user's responsibility to ensure validation of the reprocessing method used.

It is the reprocessor's responsibility to ensure that the reprocessing actually performed with equipment, materials and personnel in the reprocessing facility achieves the desired result. This requires validation and routine monitoring of the process.

Likewise, any deviation from the instructions provided must be properly evaluated by the reprocessor for effectiveness and potential adverse consequences.

DISCLAIMER

These Pre-Cleaning, Cleaning & Sterilization Guidelines are provided as guidelines only, and should not be used in place of the guidelines or standards otherwise followed by a given Operating Room Supervisor, Surgeon, Facility, Hospital, or Institution. Bimini Health Tech relies on the Surgeon or Facility to decide on the best cleaning techniques and/or sterilization methods available for cleaning and sterilization of Dermapose Refresh Syringe Stand. See Product Warranty for more information.

REFERENCES

Bimini Health Tech recommends adherence to local guidelines, including but not limited to:

- ISO 17664-1:2021, 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
- ISO 17665:2024, Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices
- FDA's "Guidance for Industry and Food and Drug Administration Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Issued March 2015"
- Robert Koch Institute's "Hygiene requirements for the reprocessing of medical devices", October 2012

TERMS AND FITNESS OF USE

- The lifecycle of reusable instruments is undefined because the lifecycle depends on frequency of use and other factors, such as force(s) applied during use and/or autoclaving. The decommissioning, repair or proper disposal of medical devices may be necessary at any time and Bimini Health Tech relies on the user to routinely inspect the devices prior to use to ensure device reliability and fitness for use.
- Instruments are vulnerable to forces applied during surgery and/or repeated autoclaving (heat exposure to metals) that may cause these devices to separate at their bases, become bent and/or collapse during use. Before, during and after use, always inspect the stands and syringes to ensure properly mated surfaces and fitness of use.

By accepting the enclosed items, Dermapose Product Distributors agree to the following terms and conditions:

- Product Distributors agree to maintain product traceability records to include the name of the person, clinic, hospital and or organization to which each product was sold or supplied, and any corresponding product lot numbers, serial numbers and device identifiers.

PRODUCT COMPLAINTS

- Distributors are required to notify Bimini Health Tech regarding any product complaint, immediately, upon each and every occurrence.
- **European Reporting Requirements:** Any serious incident that has occurred in relation to the device should be reported to Bimini Health Tech and the competent authority of the Member State in which you, as the user and/or patient, are established.

REF Reference number	Consult instructions for use or consult electronic instructions for use
LOT Lot number	Keep package dry
Manufacturer	Do not use if package is damaged
Provided non-sterile. Must clean and sterilize prior to use.	CE Mark
EU REP European Authorized Representative	

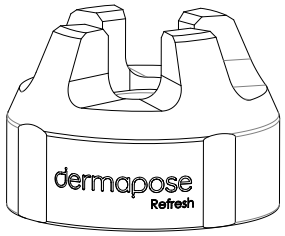
℞ ONLY **CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician**

biminihealthtech.com/resources/instructions-for-use

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dermapose

INSTRUCTIONS FOR USE

Dermapose Refresh Syringe Stand

600-034-01 Rev G **Effective Date: 10/28/2026**

INTENDED USE

To support the Dermapose Refresh Syringe in an upright position while in the sterile field.

INSTRUCTIONS FOR USE

Clean and sterilize all devices prior to use. Inspect the Dermapose Refresh Syringe Stand to ensure that there is no damage or wear.

CONTRAINDICATIONS

- Do not use Dermapose Refresh Syringe Stand if it does not meet the requirement(s) for use in the intended surgical procedure(s).
- Follow hospital policy and procedure(s) whenever and wherever they take precedence over this protocol. After use in surgery, always clean the stand prior to sterilization. Failure to use approved cleaning & sterilization procedures may void the Product Warranty.

WARNINGS

- Reusable stands are supplied non-sterile and require cleaning and sterilization prior to use. For cleaning and sterilization instructions, refer to this document.
- Do not use alkaline-based cleaning agents to clean Dermapose Refresh Syringe Stand. Alkaline-based (pH>7) detergents and solutions corrode metals. The center hole requires particular attention during cleaning.
- This document pertains to reusable devices only and these instructions are not intended for devices labeled "For Single-Use Only." Dermapose single-use devices must not be reused or reprocessed, as they are not designed to perform as intended after the first usage. Please refer to the device label and the package insert to identify them as "For Single-Use Only" or "Reusable."
- Since the reusable Dermapose Refresh Syringe Stand is supplied non-sterile and requires cleaning and sterilization before use, the appropriate sections of these instructions may be applied unless other specific instructions are provided in the package insert. The healthcare facility should ensure that the combination of cleaning and sterilization used actually results in devices that are safe for use in surgery.
- Alternative methods of processing may be equally suitable. In the event that National cleaning and sterilization requirements conflict with these instructions, the National cleaning and sterilization requirement should be followed as applicable.

CAUTION

Before using any Dermapose Refresh Syringe Stand, visually inspect it to ensure it is appropriate for the desired surgical application. Reusable stands are vulnerable to repeated autoclaving (heat exposure to metals) that may cause them to wear out over time. Before, during and after use, always inspect the devices and syringes to ensure properly mated surfaces and fitness of use.

LIMITATIONS AND RESTRICTIONS ON REPROCESSING

Repeated heat exposure and reprocessing affects these stands. Decommissioning of the devices is normally determined by wear and damage due to use.

INSTRUCTIONS

Point of Use

1. Remove excess blood and debris with disposable cloth and/or non-shedding wipe.
2. Dermapose Refresh Syringe Stand should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
3. Remove all syringes from stand prior to cleaning.
4. Transport the STAND from the place of use to the reprocessing facility. The parts can be transported either dry or immersed in fluid. Contaminated parts are to be transported in containers in order to prevent the environment and personnel from potential contamination. When transporting dry, please ensure that no soiling can dry on the instruments. Do not use fixating agents or hot water (>40 °C / 104 °F) since these promote protein coagulation and can impair the cleaning result.

Pre-Cleaning

5. Use a low-foaming enzymatic detergent of a neutral pH value (6-8) for cleaning. Cidezyme GI is recommended. The concentration of cleaning solution is to be selected according to the cleaning agent producer's specifications.
6. Immerse the STAND in cleaning solution mixed with room temperature water (deionized if possible) for at least ten (10) minutes or longer in case of stubborn or dried on soilings. At start, flush the hollow center of the STAND with 5mL of cleaning solution using a syringe. Brush the outside of the STAND under cold running water using a soft bristled nylon brush until all visible residues are removed. Brush the hollow center of the STAND at least three times using a suitable bottle brush. After cleaning, rinse all parts with potable cold water.

Cleaning

7. Clean Dermapose Refresh Syringe Stand using either the MANUAL or AUTOMATED method detailed below.

Cleaning: MANUAL

7.1 Use a low-foaming enzymatic detergent of a neutral pH value (6-8) for cleaning. Cidezyme GI is recommended. It is advised not to use strong acid or alkaline cleaning agents. The concentration and temperature of the cleaning solution is to be selected according to the cleaning agent producer's specifications. Do not mix with other cleaners.

7.2 Immerse the STAND in an ultrasound bath with cleaning agent mixed with 20°C water (deionized if possible). The STAND must stay in the ultrasound bath for at least five (5) minutes.

7.3 Afterwards, flush each end of the STAND, and the O-ring on the bottom of the STAND with a water jet pistol for 15 seconds.

7.4 After cleaning, rinse all parts with cold deionized water for 30 seconds.

7.5 Cleaning check- check all surfaces and hollow spaces for visible contamination. Return contaminated parts to the cleaning process.

Cleaning: AUTOMATED (Recommended)

7.1 The recommended washer is the G 7836 CD (Miele Professional, with rack and mobile injector unit E429 for lumina) programmed for neutral processing with the cleaning agent Thermosept RKN- zym (Schulke, Norderstedt).

7.2 The water inflow into the washing machines must start at lower temperatures (approx. 20 °C/ 68.0 °F) to prevent thermal coagulation of proteins.

7.3 Program the washer to run the following cycle:

- 2-minute pre-cleaning with cold tap water
- Drain
- 5-minute cleaning with 40 °C tap water and 0.3% cleaning solution
- 3-minute rinse with cold deionized water
- Drain
- 2-minute rinse with cold deionized water
- Drain

Drying

8. Perform drying at 70 °C (158 °F) for at least fifteen (15) minutes. Ensure stand is properly cleaned and dry prior to autoclaving by visually inspecting each instrument.

Cooling

9. The product should be cooled down to 30 °C (86 °F).

Check and Inspection

10. Visually check the parts for damage and wear. Reject any damaged part. Note: If damaged parts shall be returned to Bimini Health Tech or to an authorized supplier they must be cleaned and sterilized before and be accompanied with the relevant documented evidence.

STERILIZATION

Packaging

In accordance with ISO 11607, the dried STAND must be double-wrapped using Steriking flat rolls (Tyvek and laminate material). The packaging must be large enough so that the sterile barrier is not subject to stress.

Sterilization Cycle

Sterilization must be performed in a steam sterilizer validated according to ISO 17665. Bimini Health Tech has validated both a pre-vacuum and a gravity displacement steam sterilization cycle for the Dermapose Refresh STAND.

STERILIZER CYCLE TYPE	GRAVITY	PRE-VACUUM
Minimum Temperature	132 °C	132 °C
Cycle Time	15 minutes	3 minutes
Minimum Dry Time	3 minutes	3 minutes
Sample Configuration	Double Wrapped	Double Wrapped

Recommended: Pre-Vacuum Cycle

Process the product with steam sterilization using a pre-vacuum process at 132° C (269.6°F) for at least three (3) minutes. The sterilization cycle should consist of three pre-vacuum phases. No adverse effects on the STAND are expected after sterilization at 134 °C (273 °F) for a maximum of thirty (30) minutes.

Gravity Displacement Cycle

This device has also been validated with a gravity displacement cycle. Process the product with steam sterilization using a gravity displacement process at 132°C (269.6 °F) for 15 minutes.

Drying Time

The minimum drying time for both the pre-vacuum and gravity displacement cycles is 3 minutes.

Prior to each sterilization procedure, always check the batch process record for the respective sterilizer to ensure that the cycle complies with the required parameters.

The STAND should not be subjected to sterilization temperatures of greater than 138 °C (280.4 °F) or sterilization times of longer than thirty (30) minutes.

Storage

The individual sterile plastic bags have to be stored in a closed cupboard, protected from light, dust, humidity and extreme fluctuations in temperature. The shelf life is determined by the product specifications of the sterile packaging used.

Maintenance

The STAND is not intended for maintenance.

GENERAL INFORMATION

The Dermapose Refresh STAND is intended to be reprocessed after use. In order to prevent patient infections, all components must be reprocessed each time before use.

New, non-sterile STAND parts are to be treated like used products. They must be fully cleaned, and sterilized prior to use.

The design and the materials of the device only allow specific methods for reprocessing.

Compatibility

Bimini Health Tech distinguishes between two types of compatibility:

1. Micro-biological compatibility

2. Material compatibility

Any deviations from the reprocessing guidelines laid out in these Instructions for Use must be validated by the processor to achieve both micro-biological and material compatibility.

Selection of Processing Method

The appropriate processing procedure should be selected according to the national hygiene provisions and local guidelines of hospital hygiene.

Per the Spaulding Classification, the STAND is considered a non-critical device. However, due to its use in the sterile field, and contact with other sterile devices, Bimini Health Tech recommends sterilization for this device.

The STAND must be cleaned (either by automated or manual methods) and sterilized prior to first use, and before being reused. Disinfection is an optional intermediate step which may be performed between cleaning and sterilization.

Both manual and automated cleaning of the device leads to acceptable results. However, manual cleaning methods bear a certain risk of infection for the cleaning personnel. Automated cleaning methods minimize this risk and moreover, have the advantage of being validated by a standardized procedure for greater consistency.

Automated Cleaning

When selecting the washer, please check to ensure:

- It is certified and accredited (e.g. by FDA or CE marked according to DIN EN ISO 15883);
- The program includes a sufficient number of rinse cycles;
- Only sterile or low-germ (max. 10 germs/mL) and low-endotoxin (max. 0.25 endotoxin units/mL) water is used;
- The drying air is filtered;
- The machine is maintained and inspected regularly.

When selecting the cleaning agent, please check to ensure:

- It is suitable for cleaning medical products;
- The chemicals are compatible with the product;
- The concentrations indicated by the producer of the cleaning agent are strictly followed.

Manual Cleaning

When selecting the cleaning agent, please check to ensure:

- It is suitable for cleaning medical products;
- The chemicals are compatible with the product;
- The concentrations and reaction times indicated by the producer of the cleaning agents are strictly followed;
- Only sterile or low-germ (max. 10 germs/mL) and low-endotoxin (max. 0.25 endotoxin units/mL) water is used;
- The drying air is filtered.

Control and Checking

All reprocessing procedures must be reviewed regularly. The concentration of the cleaning agent must be tested daily to prevent the solution from being diluted and losing its effectiveness. All sterilization procedures are to be regularly checked using biological indicators.

Cleaning and sterilization must only be carried out by trained staff in rooms specifically designated for this purpose.

Workplace Safety and Health

Prevention of Infections and Chemical Burns

Bodily particles of the patients and decontamination chemicals present a hazard. Protective equipment is required for protection against dangerous chemicals and potentially infectious materials. During cleaning, disinfection, and sterilization processes, wear protective equipment comprising of eye protection, face shield, moisture-resistant clothes, tight-fitting chemical- resistant gloves that are sufficiently long so that no skin areas remain uncovered. Always remove contaminated protective equipment before leaving the processing facilities.

Toxic Chemical Fumes

As protection against toxic chemical fumes, the reprocessing room must be sufficiently ventilated.

Preparation of Reprocessing at the Place of Use

The reusable parts of the STAND are to be prepared for the subsequent reprocessing immediately after they have been used, still in the operating room.

When reprocessing medical products, take care to work carefully according to the local safety regulations.

Preparation and Transport

Remove the rough surface soiling using a disposable cloth or a paper towel. Transport the product components from the place of use to the reprocessing facilities. The parts can be transported either dry or immersed in fluid. Contaminated parts are to be transported in containers in order to prevent the environment and personnel from potential contamination. When transporting dry, please ensure that no soiling can dry on the instruments. Do not use fixating agents or hot water (>40 °C / 104 °F) since these promote protein coagulation and can impair the cleaning result.

- The subsequent cleaning must begin within three (3) hours after use. If this time limit is exceeded, special measures are to be taken to achieve a proper cleaning effect. It is recommended to start with the reprocessing of the STAND immediately after use.
- When transporting the instruments immersed in fluid, the cleaning must begin within one (1) hour after use. Saline is not suited for immersion.
- The above indicated time limits for transport must not be exceeded. Never leave a used instrument overnight before reprocessing. If an instrument is left in dry condition for a longer period, heavy soilings may dry on, leading to encrustations that may be difficult to remove.