

- Steam Sterilizer
- Sterilization plastic bags
- Sterilization wrap

Preparation for Sterilizing

Once cleaned, and inspected, the Dermapose Refresh STAND should be double wrapped according to AAMI/CSR technique. The packaging for terminally sterilized instruments should fulfill the following requirements: EN ISO 11607. Steam sterilization (moist heat) is recommended. Healthcare facilities should validate the process that they use, employing the actual equipment and operators that routinely process the devices. After each Pre-Cleaning and Cleaning Procedure, follow the appropriate Sterilization Process listed next:

Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended. Autoclaves should comply with the requirements of, and be validated, maintained, and checked in accordance with EN 285/EN 13060, EN ISO 17665, and ANSI AAMI ST79.

Once purchased, all Dermapose Refresh STAND arrive in non-sterile pouches, labeled to identify each device. Upon initial use, remove all devices from nonsterile pouches and follow the Cleaning Instructions, then place in a wrapped autoclave tray, as described above.

Sterilization

STERILIZER CYCLE TYPE	GRAVITY	PRE-VACUUM
Minimum Temperature	132 °C	132 °C
Cycle Time	15 minutes	4 minutes
Minimum Dry Time	20 minutes	20 minutes
Sample Configuration	Double Wrapped	Double Wrapped

Process the product with steam sterilization using a gravity process at 132°C (269.6°F) for at least fifteen (15) minutes or process the product with steam sterilization using a pre-vacuum process at 132°C (269.6°F) for at least four (4) minutes. No adverse effects on the Dermapose Refresh STAND are expected after sterilization at 134°C (273°F) for a maximum of thirty (30) 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.

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.

NOTE Where there is a concern about TSE/vCJD contamination, the World Health Organization recommends processing through a pre-vacuum steam sterilization cycle for 18 minutes @ 134° C. (WHO/CDS/CSR/APH/2000.3, WHO Infection Control Guidelines for TSE, March 1999.)

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. Puregraft 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 STAND. See Product Warranty for more information.

REFERENCES

FDA Draft Guidance for Industry and FDA Staff – Processing and Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, 2011.

AAMI ANSI TIR 30 and TIR 12.

EN ISO 11607 (ANSI AAMI ISO11607): Packaging For Terminally Sterilized Instruments (replaced EN 868-1 and ISO 11607)

EN ISO 17665 (ANSI AAMI ISO17665): Sterilization Of Health Care Products, Moist Heat (Replaced EN 554 and ISO 11134)

ANSI/AAMI ST79: Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities

EN ISO 17664: Sterilization of Medical Devices – Information To Be Provided By The Manufacturer For The Processing Of Resterilizable Medical Devices.

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 Puregraft 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:

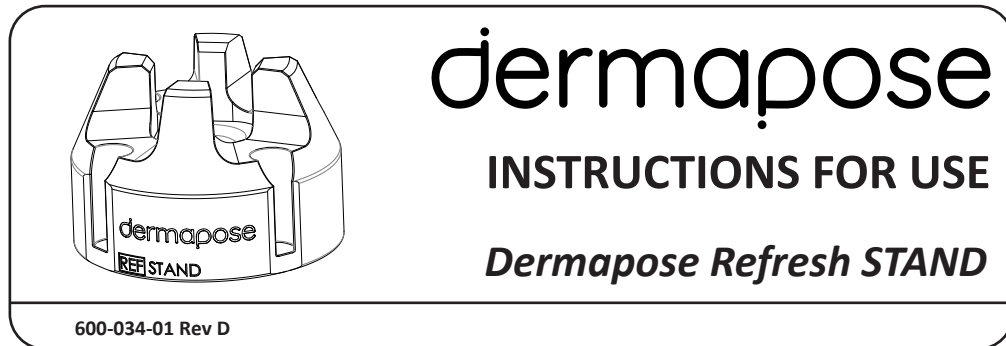
- Product Distributors agree to maintain product traceability records to include the name of the person, clinic, hospital and or organization to which each product was sold or supplied, and any corresponding product lot numbers, serial numbers and device identifiers.

PRODUCT COMPLAINTS

- Distributors are required to notify Dermapose 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	 I	See Instructions For Use		Keep package dry
 LOT	Lot number		Do not use if package is damaged		Provided non-sterile. Must clean and sterilize prior to use.
	Manufacturer		CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician		

 Bimini Health Tech
420 Stevens Ave, Suite 220
Solana Beach, CA 92075 USA
Tel: +1 858 348 8050
Fax: +1 858 217 5134



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 STAND to ensure that there is no damage or wear.

CONTRAINDICATIONS

- Do not use Dermapose Refresh STAND if they do not meet the requirement(s) for use in the intended surgical procedure(s).
- Whenever and wherever hospital policy and procedure(s) 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 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 reusable Dermapose Refresh STAND is supplied non-sterile and require 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 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 it 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 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. Prepare to presoak the stand in a basin large enough to accommodate the stand using an enzymatic cleaner according to the cleaning agent instructions.

Preparation for Decontamination

5. Place devices in a solution as per enzyme solution manufacturer instructions using lukewarm (22-43°C) tap water.
6. Completely submerge stand in the enzyme solution and soak for at least 20 minutes.

Cleaning

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

Cleaning: MANUAL

- 7.1 Remove the devices from the enzyme solution and rinse in lukewarm (22-43°C) tap water.
- 7.2 Clean all stand surfaces with a soft-bristle brush and lukewarm (22-43°C), tap water mixed with the enzymatic cleaning agent as described by the manufacturer of the cleaning agent
- 7.3 Clean the inside lumens of the stand using a soft-bristled, nylon brush until all visible debris has been removed. Using a syringe with a volume of 60ml, thoroughly and aggressively flush stand lumens, holes and other difficult to reach areas.
- 7.4 Repeat at least 3 times with lukewarm (22-43°C) tap water-enzyme solution at a concentration recommended by the manufacturer.
- 7.5 Finish by flushing the stand at least 3 times with a syringe (60ml) filled with ultrafiltered, RO, DI, distilled and/or demineralized water.
- 7.6 Place prepared enzymatic cleaning agent in an ultrasonic cleaner.
- 7.7 Completely submerge stands in the cleaning solution and sonicate for 10 minutes at 40-45 kHz.
- 7.8 Rinse instrument in ultra-filtered, RO, DI, distilled and/or demineralized water for at least 3 minutes or until there is no sign of blood or soil on the device in the rinse stream. Repeat the sonication and rinse steps above.
- 7.9 Thoroughly dry moisture from the instrument with a clean, absorbent and non-shedding wipe.

Cleaning: AUTOMATED

- 7.1 Remove the devices from the enzyme solution and rinse in lukewarm (22-43°C) tap water.
- 7.2 Transfer the stand(s) into the automatic washer/disinfector for processing.
- 7.3 Orient the stand to facilitate drainage in a way to allow flushing.
- 7.4 Select the cycle and ensure the following set of cycle parameters are properly programmed.
- 7.5 Remove the stand from the automatic washer/ disinfector and dry using a clean soft non-shredding cloth and filtered pressurized air at < 40 psi.
- 7.6 Visually inspect the stand for cleanliness and repeat the cleaning procedure if necessary.

Drying

8. Wipe dry with a non-shedding wipe.
9. Ensure stand is properly cleaned and dry prior to autoclaving by visually inspecting each instrument.

Maintenance, Inspection and Testing

10. Inspect each instrument to ensure it is clean and has been sterilized before use.
11. Visually inspect each instrument for damage and signs of distortion.
12. If any sign of damage or distortion, call Puregraft immediately for repair or replacement.

PACKAGING

Once cleaned and inspected, the dry Dermapose Refresh STAND should be double wrapped according to AAMI/CSR technique. The packaging for terminally sterilized instruments should fulfill requirements EN ISO 11607.

STERILIZATION

- Steam sterilization (moist heat) is recommended.

PRE-VACUUM

- Wrapped Goods Cycle 4 minutes @ 132° C / 270° F. Dry Time: 20 to 30 minutes, according to load size.

STORAGE

- Identify and store sterilized stands in accordance with EN ISO 11607.

ADDITIONAL INFORMATION

- For Instructions for Use see the Package Insert, supplied with the stands.

▲ SUPPLIED NON-STERILE Reusable stands are supplied non-sterile and require cleaning and sterilization prior to use. For cleaning and sterilization instructions, refer to this document.

CLEANING INTRODUCTION

This document is intended to give general guidance for cleaning and sterilization of supplied non-sterile, reusable Dermapose Refresh STAND. Equipment, operators, cleaning agents and procedures all have a contribution to the efficacy of device processing, and the health care facility should ensure that the combination actually in use results in devices which are safe for use. Alternative methods of processing may be equally suitable. In the event of conflicting National cleaning and sterilization requirements, these should prevail over Puregraft recommendations. Dermapose Refresh STAND should be cleaned with ASP Cidezyme® / Enzol® Enzymatic Detergent Solution. For more information regarding these products, visit ASP's website for Cidex® Products on-line: <https://www.emea.aspij.com/products/manual-solutions>

Once Dermapose Refresh STAND have been used in surgery, they must be cleaned using a neutral pH (7) enzymatic cleaning solution. For cleaning of reusable devices, follow the instructions below.

WARNINGS AND PRECAUTIONS

▲ WARNING Do not use alkaline-based detergents or cleaning agents to clean Dermapose Refresh STAND.

▲ WARNING Staff should use suitable protective clothing and equipment at all times. In particular, take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the cleaning agent(s).

MANUAL CLEANING

Equipment required

- Personal protective equipment as recommended by the cleaning agent supplier (minimum overalls, gloves, face/eye shield.) or as prescribed by the doctor, clinic or hospital setting, when required. Staff should use suitable protective gear and/or clothing and equipment at all times.
- Non-shedding wipes.
- Ultrasonic bath large enough to allow complete immersion of the device. Frequency according to manufacturer's instructions, and at a temperature setting according to the manufacturer's instructions.
- A neutral, pH (7), enzymatic cleaning agent, intended for manual cleaning and suitable for ultrasonic treatment.
- Suitable soft bristle nylon, soft bristle brushes, appropriately sized for stand diameter internal and length. Do not use metal or steel wool.
- Syringes with a volume of 60ml.
- Tap water and basin(s) large enough to accommodate rinsing the devices.
- Basin(s) large enough to accommodate each device.
- Ultra-filtered, RO, DI, distilled and/or demineralized water.
- Recommended: ASP Cidezyme® / Enzol® Enzymatic Detergent Solution. For more information regarding ASP Cidezyme, visit ASP's website online: <https://www.emea.aspij.com/products/manual-solutions>

Pre-Cleaning Procedure

- Stands should be cleaned within 30 minutes of use to minimize the potential for drying of contaminants prior to cleaning. Immediately after each use, perform initial cleaning by wiping each Dermapose Refresh STAND free of blood and debris using a clean towel or non-shedding disposable wipe.
- It is important never to hold stands in a dry container, which allows blood and debris to dry onto device surfaces and makes cleaning more difficult. If rinsing and decontamination processes are not immediately available, pretreat devices or hold them in a neutral pH (7) holding/presoak enzymatic instrument cleaning solution, using a basin large enough to totally submerge the device.

Soak

1. The Dermapose Refresh STAND will be soaked in a cleaning solution of ultra-filtered, RO, DI, distilled and/or demineralized water and neutral pH (7) enzymatic detergent such as 0.5% ASP Cidezyme® / Enzol® Enzymatic Detergent Solution at room temperature (20°C ± 2°C) for 5 minutes. At the beginning of the soak time, lumen(s) will be flushed with 5 mL of the cleaning solution using a syringe.
2. Soak in a basin large enough to accommodate Dermapose Refresh STAND. Completely submerge all devices in the enzyme solution.

Initial Rinse

3. The outside of the Dermapose Refresh STAND will be brushed under cold tap water (14°C – 18°C) with a soft bristled nylon brush until all visible residues are removed.
4. Lumen(s) of the Dermapose Refresh STAND will be brushed with a suitable bottle brush for at least 3 times from end to end. Ensure that any debris inside the stands lumen(s) is cleared, making sure there are no blockages and rinsing freely flows through the stands lumen(s).
5. Inspect each device. Generally, un-magnified visual inspection under good light conditions is sufficient. All parts of the stand(s) should be checked for visible contaminants and/or distortion or damage. Particular attention should be paid to recessed features (such as openings in the stand). For Dermapose Refresh STAND that may have been impacted, check that each is not damaged.

Manual Cleaning Procedure

▲ WARNING: Never use metal bristle brushes or steel wool, as these may score or damage the interior of the stand(s).

▲ CAUTION: Federal law (USA) restricts this stand to sale by or on the order of a physician.

6. Place Dermapose Refresh STAND in an ultrasonic bath of ultra-filtered, RO, DI, distilled and/or demineralized water and neutral pH (7) enzymatic detergent such as 0.5% Cidezyme (ASP) for 5 min at room temperature (20°C ± 2°C) according to manufacturer's instructions. The sample will afterwards be thoroughly rinsed under cold running deionized water (14°C – 18°C) for 30 seconds.

Final Rinse

7. Following ultrasonic process, rinse twice with ultra-filtered, RO, DI, distilled and/or demineralized water in a clean basin at room temperature (18 °C to 26 °C) and dry remaining wetness with non-shedding wipes.
8. Visually inspect each Dermapose Refresh STAND for remaining contaminants and dryness. Prior to autoclaving, all internal and external compartments of the stand should be dry and completely clean. If contaminants remain, repeat the cleaning process, including the pre-cleaning stage. Remaining wetness may be removed with medical grade compressed air (20-40 psi), and/or clean and lint-free, single-use wipes. Visually inspect each instrument to ensure that it is completely dry.
9. Re-inspect the dry stand(s). If encrusted contaminants remain on the device after completion of the cleaning step in the ultrasonic bath, repeat the cleaning steps as described above until all devices are free from contaminants.
10. Once cleaned and inspected, the dry Dermapose Refresh STAND should be double wrapped.

AUTOMATED CLEANING

Equipment required

- Personal protective equipment as recommended by the cleaning agent supplier (minimum overalls gloves, face/eye shield.), the automated cleaning equipment manufacturer or as prescribed by the doctor, clinic or hospital setting, when required. Staff should use suitable protective gear and/or clothing and equipment at all times.
- Syringes with a volume of 60ml.
- Tap water and basin(s) large enough to accommodate rinsing the devices.
- Clean soft non-shedding cloth.
- Filtered pressurized air at < 40 psi.
- ASP Cidezyme® / Enzol® Enzymatic Detergent Solution or equivalent.
- Miele Professional G 7836 CD automated cleaner large enough to hold the stand.

Pre-Cleaning Procedure

- Stands should be cleaned within 30 minutes of use to minimize the potential for drying of contaminants prior to cleaning. Immediately after each use, perform initial cleaning by wiping each Dermapose Refresh STAND free of blood and debris using a clean towel or non-shedding disposable wipe.
- It is important never to hold stands in a dry container, which allows blood and debris to dry onto device surfaces and makes cleaning more difficult. If rinsing and decontamination processes are not immediately available, pretreat devices or hold them in a neutral pH (7) holding/presoak enzymatic instrument cleaning solution, using a basin large enough to totally submerge the device.

Soak

1. The Dermapose Refresh STAND will be soaked in a cleaning solution of ultra-filtered, RO, DI, distilled and/or demineralized water and neutral pH (7) enzymatic detergent such as 0.5% ASP Cidezyme® / Enzol® Enzymatic Detergent Solution at room temperature (20°C ± 2°C) for 5 minutes. At the beginning of the soak time, the lumen will be flushed with 5 mL of the cleaning solution using a syringe. Soak in a basin large enough to accommodate each Dermapose Refresh STAND. Completely submerge all devices in the enzyme solution.

Rinsing

2. The outside of the Dermapose Refresh STAND will be brushed under cold tap water (14°C – 18°C) with a soft bristled nylon brush until all visible residues are removed.
3. The lumen of the Dermapose Refresh STAND will be brushed with a suitable bottle brush for at least 3 times from end to end. Ensure that any debris inside the stand lumen is cleared, making sure there are no blockages and rinsing freely flows through device lumen(s).
4. Visually inspect each Dermapose Refresh STAND. Make sure all the devices are clean, non-greasy and unclogged.

Automated Cleaning

5. The Dermapose Refresh STAND samples will be connected to the hose of the rack of the automatic washer/disinfector for processing. Orient the stand(s) to facilitate drainage in a way to allow flushing. The following cycle should be followed:
 - 2 min pre-cleaning with cold tap water
 - Draining
 - 5 min cleaning with 40°C tap water and 0.3% cleaning solution such as Thermosept RKN-zym (Schülke, Norderstedt)
 - Draining
 - 3 min rinsing with ultra-filtered, RO, DI, distilled and/or demineralized water
 - Draining
 - 2 min rinsing with ultra-filtered, RO, DI, distilled and/or demineralized water
6. Remove the stand(s) from the automatic washer/disinfector and dry using a clean soft non-shedding cloth and filtered pressurized air at < 40 psi. Visually inspect the stand(s) for cleanliness and repeat the cleaning procedure if necessary.

STERILIZATION

Equipment required

- Personal protective equipment as recommended by the cleaning agent supplier (minimum overalls, gloves, face/eye shield.), the automated cleaning equipment manufacturer or as prescribed by the doctor, clinic or hospital setting, when required. Staff should use suitable protective gear and/or clothing and equipment at all times.