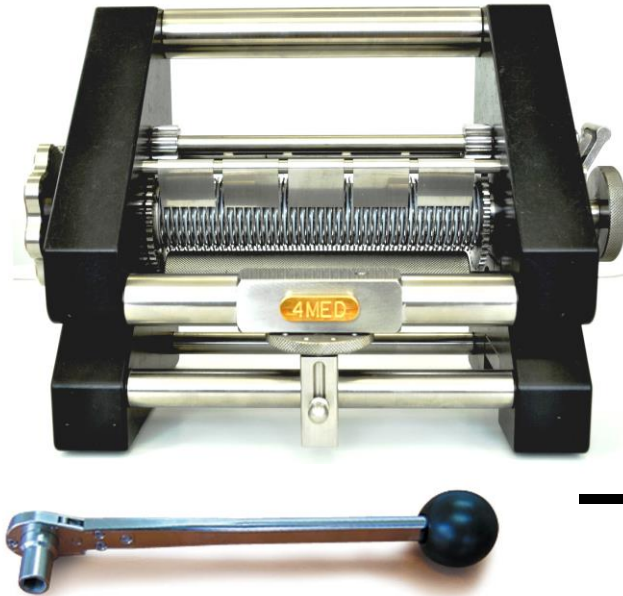


The Rosenberg Skin Graft Mesher



Disinfection & Sterilization

CE



Instructions for Cleaning (both Variable and Fixed Ratio Meshers):

The skin graft mesher is made of two hinged parts, upper (14.) and lower (15.), that may be opened for cleaning and maintenance (Figure I.). The elevation dial (3.) holds the two parts together. The gold color push-pull mechanism (13.) locks the two parts to the elevation dial (3.).

- Pushing the push-pull mechanism (13.) in toward the mesher locks the two parts.
- Pulling the push-pull mechanism (13.) away from the mesher unlocks the two parts.

If the mesher is difficult to open, make sure the elevation dial (3.) is not turned all the way down. If it is turned all the way down, move it counter clockwise one click.

Shown here is the gold color push-pull mechanism (13.) from the top view. The front gold plate should be flush against the bar when the mesher is closed correctly



Figure G. Correctly closed push-pull mechanism.



Figure H. Incorrectly closed push-pull mechanism.

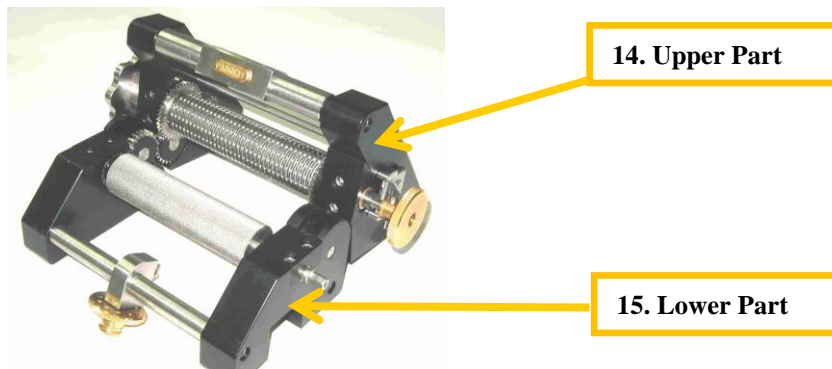
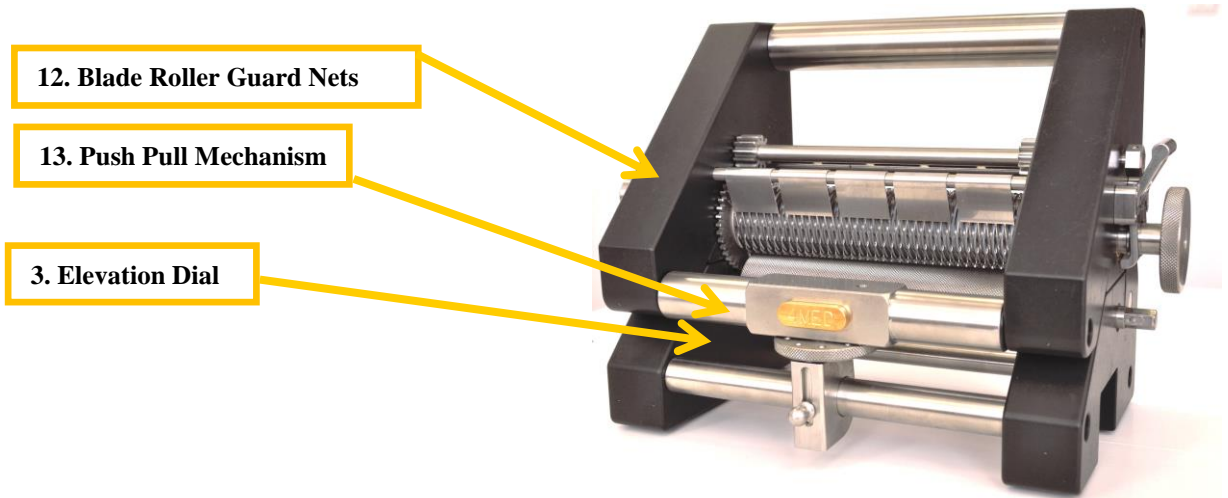


Figure I. Mesher shown open for disinfection.



Disinfection Precautions (both Variable and Fixed Ratio Meshers):

(In accordance with ISO 17664-Sterilization of medical devices)

The disinfection process is dependent on effective cleaning and washing. Severe soiling should be removed under running water in a sink draining continually, using a soft plastic bristle brush to clean the blade roller and guard nets. It may be necessary to remove the blade roller guard nets (12.). Simply snap the off from the back when the mesher is open. To put the guards back on, place the guards over the blades, leaving a space between each pair of guards.

Recommendations (both Variable and Fixed Ratio Meshers):

- Water soluble lubricant in spray bottle use after cleaning and before sterilization.
- Neutral pH enzymatics and disinfectants.
- Inspect every time for debris by rotating the blades.
- Use plastic bristle brush for blade cleaning.
- Check to make sure mesher rotates smoothly

Warnings(both Variable and Fixed Ratio Meshers):

- Do not use abrasive cleaners such as low or high pH or corrosive enzymatic and disinfectants.
- Do not use saline on the mesher at any time.
 - Saline solution has a corrosive effect on stainless steel and should not be used for cleaning or rinsing.
- Do not use any metal/wire bristle brushes anywhere on the mesher.
- Do not use mineral oil as a lubricant.
- Ultrasonic cleaning should not be used at any time.
 - Ultrasonic cleaning will completely remove the lubricant from the bushings and may render the instrument inoperative.
 - Ultrasonic cleaning may affect calibration and damage the blades.
- Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.

Reprocessing Limitations:

- Repeated processing, according to the instructions below, has minimal effect on the 4Med reusable Mesher.
- End of life of the mesher is normally determined by wear and damage due to improper use.

Point of Use:

- Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a damp cloth.
- Body fluids and tissue should not be allowed to dry on the Mesher prior to cleaning.

Containment/ Transportation:

- Universal precautions for handling contaminated/biohazardous materials should be observed.
- The mesher should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.



Manual Disinfection Instructions (both Variable and Fixed Ratio Meshers):

- Failure to properly clean the device may lead to inadequate sterilization.
- Note: The mesher should always be moved in the closed position.
- Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments. *Refer to the sterilization section that follows.*
- The enzyme solutions should be changed when it becomes grossly contaminated (bloody and/or debris).

Recommended Manual Disinfection Procedure (both Variable and Fixed Ratio Meshers):

Decontamination				
Step	Description	Instructions	Accessories	Duration
1	Contamination Removal	<ol style="list-style-type: none"> 1. Prepare neutral pH enzyme cleaning agent (soaking solution) at the use-dilution and temperature recommended by the manufacturer. 2. Completely submerge the mesher in enzyme solution and allow it to soak for 20 minutes. 3. Open the mesher, use a soft plastic bristle brush to gently clean the device (attention should be given to crevices, lumens, mated surfaces and other hard-to-clean areas) until all visible soil has been removed. 4. The close the mesher. 5. Remove the device from the enzyme solution and rinse in purified water for a minimum of 3 minutes. 6. Thoroughly flush lumens, holes and other difficult to reach areas. 	<ul style="list-style-type: none"> • Decontamination Sink • Neutral pH enzyme cleaning agent • Soft plastic bristle brush • Purified water • Do not utilize metal cleaning brushes or abrasive pads • Do not use abrasive cleaners • Do not use saline • Do not ultrasonic cleaning 	Until all visible soil is removed with no sign of blood or soil in the rinse stream
2	Drying	<ol style="list-style-type: none"> 7. Dry the mesher with a clean, disposable, absorbent, non-shedding wipe. 8. Medical quality filtered compressed air may be utilized if available. 	<ul style="list-style-type: none"> • Absorbent, non-shedding wipes • Medical quality filtered air 	Until product is visually dry
Disinfection				
3	Disinfection Application	<ol style="list-style-type: none"> 9. Apply neutral pH disinfectant to the device's surface area per manufacturer's recommendations. 	<ul style="list-style-type: none"> • Neutral pH disinfectant • Spray bottle or other manual applicator 	Contact time will vary per product usage, minimum of 1 (one) minute is recommended
4	Manual Disinfection	<ol style="list-style-type: none"> 10. While neutral pH disinfectant is on the device surface clean all contact surfaces, joints, mated areas utilizing a clean soft plastic bristle brush. 	<ul style="list-style-type: none"> • Neutral pH disinfectant • Soft plastic bristle brush 	Complete when the mesher surface, joints have been fully cleaned
5	Final Rinse	<ol style="list-style-type: none"> 11. Rinse mesher in purified water. 	<ul style="list-style-type: none"> • Purified water 	Minimum of 1 (one) minute is recommended
6	Final Drying	<ol style="list-style-type: none"> 12. Dry the mesher with a clean, disposable, absorbent, non-shedding wipe. 13. Medical quality filtered compressed air may be utilized if available. 	<ul style="list-style-type: none"> • Absorbent, non-shedding wipes • Medical quality filtered air 	Until product is visually dry



Inspection/Function Testing (both Variable and Fixed Ratio Meshers):

1. Carefully inspect the mesher to ensure that all visible blood and soil has been removed.
2. Visually inspect for damage and/or wear.
3. Check the action of moving parts (such as blade rollers) to ensure smooth operation throughout the intended range of motion.
4. Check that the guard nets are positioned correctly.
5. Check that the mesher closes and locks correctly.
6. **Note: If damage or wear is noted that may compromise the function of the instrument, contact your 4Med representative for evaluation, service or a replacement.**

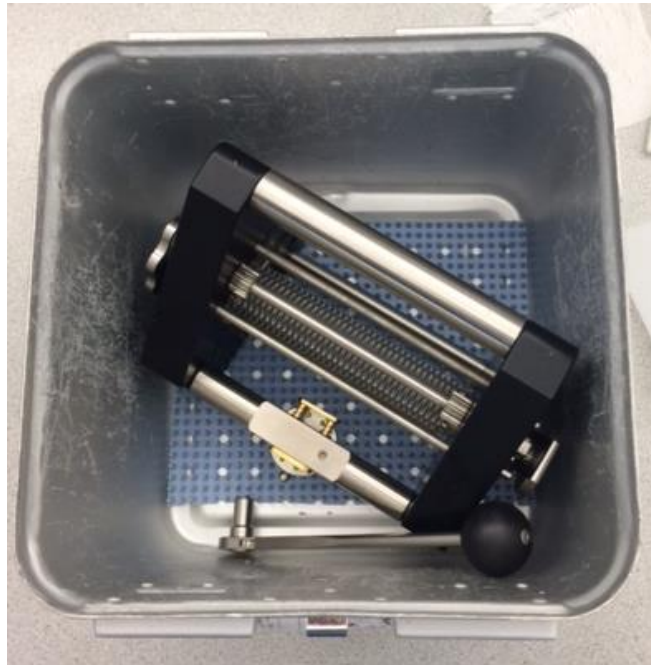
Maintenance (both Variable and Fixed Ratio Meshers):

1. Lubricate hinges, threads, knives rollers and other moving parts with a commercial water based surgical grade instrument lubricant (such as instrument milk) to reduce friction and wear.
2. Spray the lubricant between the blades.
3. **Mineral oil is not recommended as a lubricant.**

Packaging for Sterilization (both Variable and Fixed Ratio Meshers):

1. It is recommended using 4Med's sterilizing container with top filter.
2. Load the mesher into the container at a 45° angle (**Figure J.**) and lock the cover.
3. The mesher may be loaded into dedicated instrument trays or general-purpose sterilization trays for sterilization.
 - a. Validation of the use of dedicated instrument trays or general-purpose sterilization trays would be performed by the customer.
4. If applicable, use standard medical grade steam sterilization wrap.

Figure J. Mesher shown (top view) in the sterilizing container.





Sterilization of Mesher (both Variable and Fixed Ratio Meshers):

Steam sterilize using validated method:

- Pre-vacuum cycle for 4 minutes at a minimum temperature of 134°C (270°F).
 - When sterilizing multiple instruments in one steam sterilization cycle, ensure that the sterilizer manufacturer's maximum load is not exceeded.
 - Drying times will vary according to load size and should be increased for larger loads.
- Flash (unwrapped) sterilization by exposure at 132°C/270°F should only be used as an emergency procedure.

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