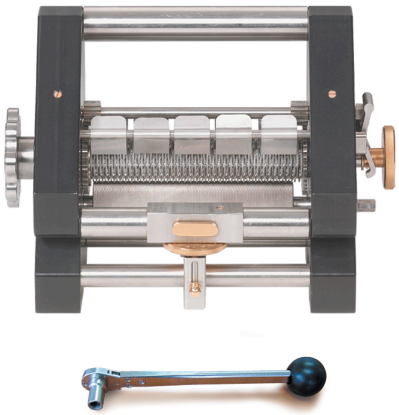
The Rosenberg Adjustable Skin Graft Mesher



Cleaning and Sterilization

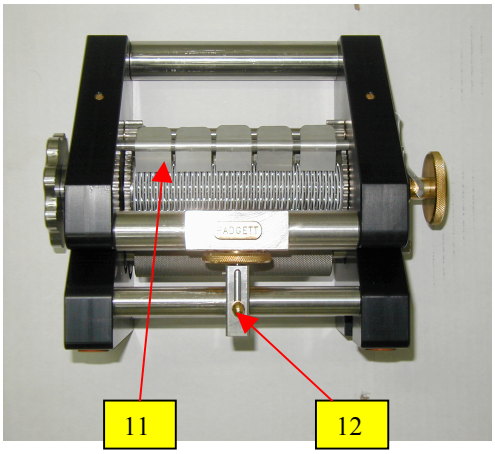
Instructions for Cleaning.

The adjustable skin graft Mesher is made of two hinged parts, upper and lower, that may be opened for cleaning and maintenance. A micrometric elevation dial holds the two parts together. A push-pull lock locks (12) the two parts to the elevation dial. Pushing it toward the Mesher locks the two parts and pulling it out or pushing it from the inside of the Mesher to the outside, unlocks it. If the Mesher is difficult to open, make sure the elevation dial is not turned all the way down. If it is turned all the way down, move it counterclockwise one click.
Clean after each procedure by rinsing in distilled water.

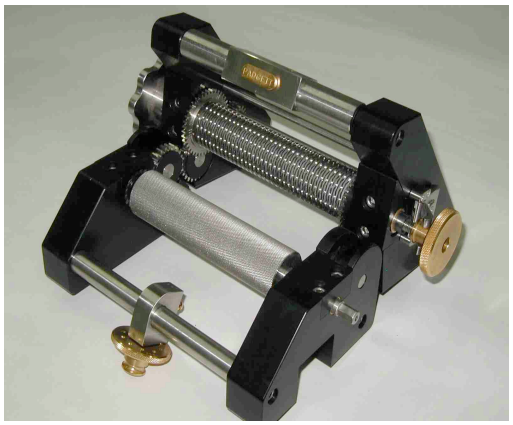
*** Do not use saline on the Mesher at any time.**

Washing and Decontamination

The decontamination process is dependent on effective cleaning and washing of instruments. Severe soiling should be removed under running water in a sink draining continually, using brushes -+ brush. It may be necessary to remove the upper cutting roller guard nets (11).
Simply snap the off from the back, when Mesher is open. To put the guards back on, place the guards over the blades, leaving a space between each pair of guards. Carefully wipe the entire unit dry after cleaning.



The Mesher is opened for cleaning



Instrument Care, Cleaning and Sterilization Instruction

In accordance with ISO 17664

Warnings

1. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.
2. Ultrasonic cleaning **should not** be used at any time.
3. Open the Mesher prior to cleaning
4. Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Enzymatic and cleaning agents with neutral pH are recommended.
5. Failure to properly clean the device may lead to inadequate sterilization

Reprocessing Limitations

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

INSTRUCTIONS

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 instruments prior to cleaning.

Containment/ Transportation:

1. Universal precautions for handling contaminated/biohazardous materials should beobserved.
2. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

Preparation of Cleaning Agents:

Prepare neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer.

Manual Cleaning Procedure:

1. Use the neutral pH enzyme soaking solution that has been prepared.
2. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. Use a soft-bristled brush to gently clean the device (particular attention shall be given to crevices, lumens, mated surfaces and other hard-to-clean areas) until all visible soil has been removed.

Note: The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid).

3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
4. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.
5. Repeat Steps 4 with freshly prepared cleaning solution.
6. Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.

Automated Cleaning Procedure:

Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.

Disinfection:

Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments. See sterilization section below.

Inspection/Function Testing:

1. Carefully inspect each device 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 hinges and box-locks) to ensure smooth operation throughout the intended range of motion.
4. Check instruments with long slender features (particularly rotating instruments) for distortion.
5. Check that the devices assemble readily with mating components.

Note: If damage or wear is noted that may compromise the function of the instrument, contact your 4Med representative for a replacement.

Maintenance:

Lubricate hinges, threads and other moving parts with a commercial water-based surgical grade instrument lubricant (such as instrument milk) to reduce friction and wear. Spray the lubricant between the blades.

Packaging

1. It is recommended using 4Med's sterilizing container with top filter. Load the device into the container and lock the cover.
2. The device may be loaded into dedicated instrument trays or general purpose sterilization trays for sterilization. If applicable, use standard medical grade steam sterilization wrap following the AAMI double wrap method (ANSI/AAMI ST79-2006)

Sterilization:

Steam sterilize using either validated method:
a) Gravity cycle for 30 minutes at a minimum temperature of 134°C (273°F).
b) Pre-vacuum cycle for 4 minutes at a minimum temperature of 132°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.
Note: Where there is a concern about TSE/vCJD contamination, the World Health Organization recommends processing through a prevacuum steam sterilization cycle for 18 minutes at 134°C (273°F). (WHO/CDS/CSR/APH/ 2000.3, "WHO Infection Control Guidelines for TSE," March 1999).

Additional Information

1. Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.
2. Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.