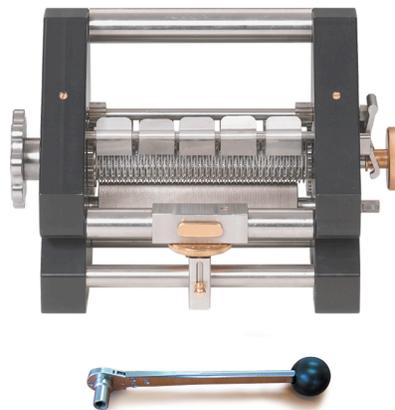




The Rosenberg Adjustable Skin Graft Mesher



Instructions for use





Rosenberg Adjustable Skin Graft Mesher Instructions for use

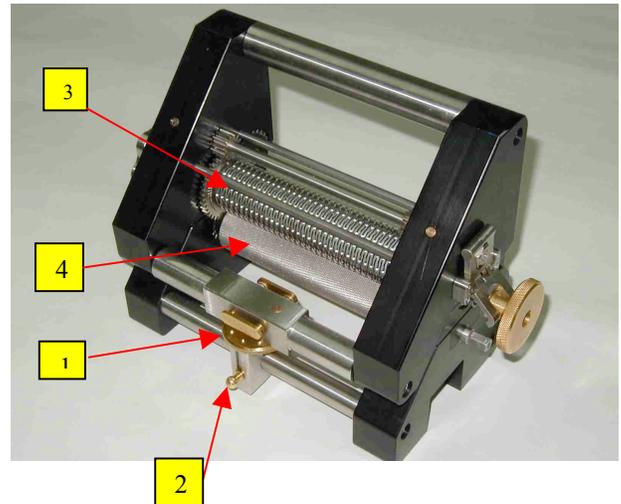
Adjustment for carrier thickness.

The adjustable Skin Graft Mesher may accommodate thickness level of graft carrier from 0.1mm to more than 5 mm. The cutting blades that are held in the upper cutting roller (3) do the meshing and press into the skin graft that is spread on the flat carrier plate that passes on the lower feeding roller (anvil) (4).

The elevation dial (1) regulates the distance between the upper cutting roller and the lower anvil roller. Turning the elevation dial (1) each “click” corresponds to movement of 0.1 mm. In order to move the elevation dial, you must push down on the lock knob (2). To decrease the distance between the two rollers, turn the elevation dial (1) clockwise. To increase the distance, turn the dial counterclockwise.

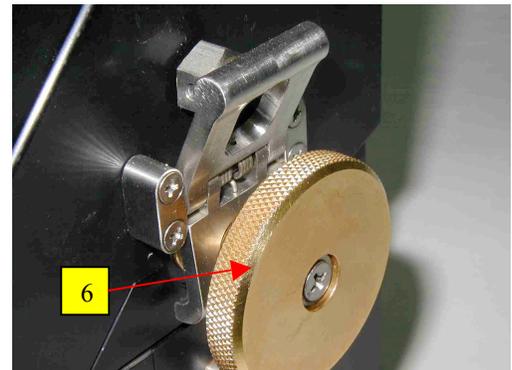
In order to adjust the Mesher to the carrier thickness, please proceed the following steps.

1. Press on lock knob (2) all the way down.
2. Rotate the elevation dial (1) clockwise all the way.
3. If you are using **4Med** carrier turn counterclockwise the elevation dial 5 “clicks”
4. Insert the carrier between the anvil roller and the blades roller, and check the cutting with paper.
5. Adjust the final distance according to the cutting results.



Adjust the ratios

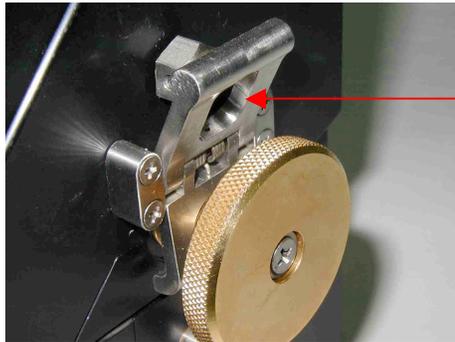
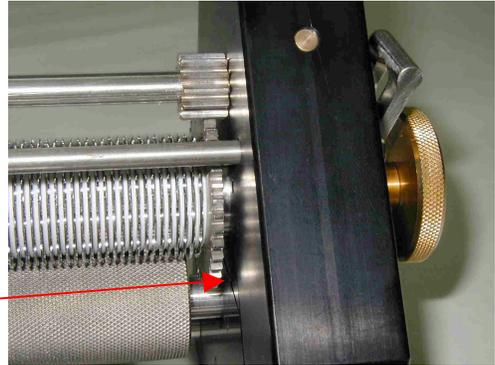
Each cutting blade is made of two paired halves, each contributing to the length of the incision. By changing the angular position of the two paired blades, the meshing ratio can be adjusted. When the two paired blades are completely parallel, the result is a minimal incision with a meshing ratio of 1:1. This expansion will just perforate and offer good drainage and adherence of the graft to its bed. Increasing the angle between the paired blades increases the length of the actual incision and the meshing ratio up to 5:1



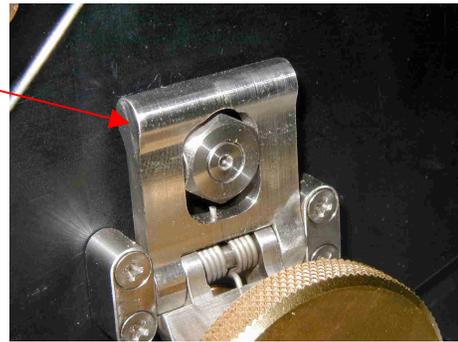
To adjust the ratio:

Place the adjustable skin graft Mesher on flat surface. Position the Mesher so that the elevation dial is facing you. With your right hand, turn the locking wheel (6) anticlockwise and push the right gear (7) to the right. The blades are released and the roller's locking mechanism (8) will be engaged automatically.

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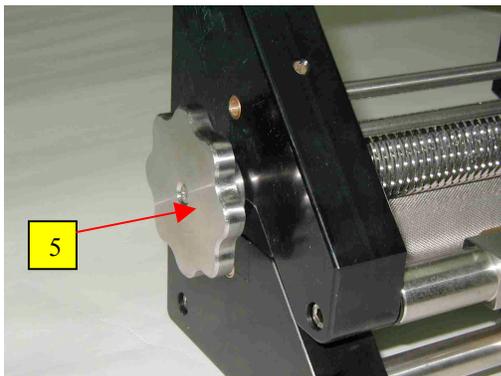


Roller locking (8) open position

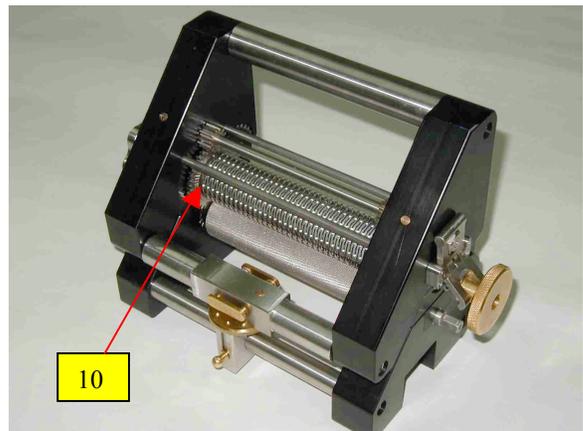
Roller locking (8) locked position

With your left hand, adjust the ratio by turning the adjustment wheel (5) clockwise or anticlockwise. The paired blades are moved. The meshing ratio is shown by a pointer (11) which is situated on a wheel on the inner left side of the Mesher (10). The marks in the pointer are 5:1, 4:1, 3:1, 2:1, 1.5:1, 1:1

Once the desired ratio has been achieved, the locking wheel (6) should be turned clockwise until it is tight. This will unlock the system, and will lock the blades in their position.



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Ratio 1:1



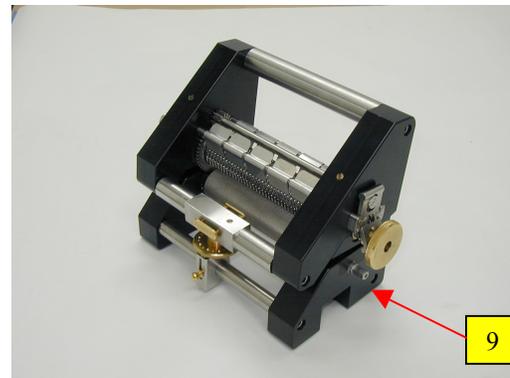
Ratio 2:1



Ratio 5:1

Important: Do not attempt to use the Mesher unless the blades are tightened and the roller lock is released.

First apply the skin graft to the carrier. Then place the carrier on the flat surface in front of the roller. The rotation of the two rollers is effectuated by a set of transmission gears that may be activated by a cranking ratchet or by a special power unit. The cranking ratchet may be attached to the lower roller shaft (9) that is situated on the right side, under the locking wheel. Make sure that the ratchet is set for forward movement, then crank the carrier through the rollers.



**** WARNING: Do not use metal instruments near the blades for pushing the skin through or pulling it out.**

If the power unit is available, the Mesher has to be mounted on the sterilization container that is fitted with the optional transmission. The power unit must be inside the container. It is not necessary to line up the Mesher to the power unit transmission exactly. Once the power unit is turned on, the Mesher will go into place automatically. The system may be activated with the on/off switches on the container's lid, and that are situated on the right side in front and back of the Mesher. The cranking ratchet can not be used when the Mesher is hooked up to the power unit transmission. Using the power option, a single operator can activate the entire system. The right hand feeds the carrier plate into the Mesher and the left hand activates the switch. The right hand follows the extruded carrier from behind the Mesher. The unit may be stopped by pushing on one of the switches.



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.

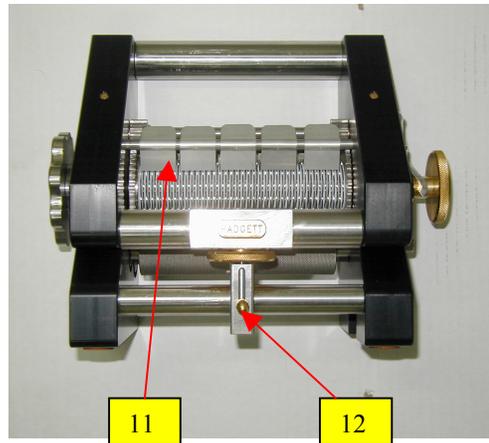
Clean after each procedure by rinsing in distilled water.

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

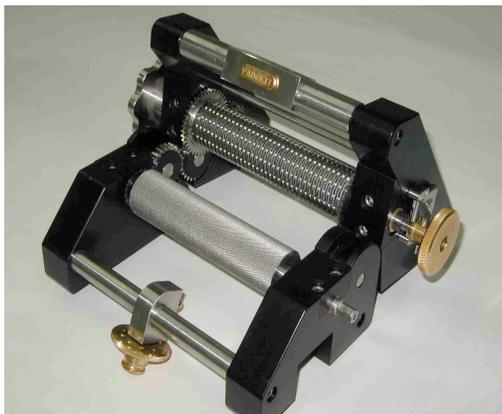
Washing and Decontamination

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 be observed.
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.



4MED "Rosenberg" Skin Graft Mesher

PRODUCT WARRANTY

This Limited Warranty covers the Rosenberg Skin Graft Mesher (the "Product").

1. LIMITED TWO YEARS WARRANTY: Subject to the limitations set forth below, 4Med Ltd. ("4med") warrants to its customer ("Buyer") that the Product will be free from defects in material and workmanship for a period of one (1) year from the date of shipment. The total warranty period for any Product shall not exceed one (1) year from the date of shipment.
2. EXCEPTIONS TO WARRANTY:
 - 2.1 The Limited Warranty set forth in Section 1 does not cover defects, damage to the Product or Product failure caused by:
 - (a) a defect or failure in any product not manufactured by 4MED, including, but not limited to, a product installed but not manufactured by 4MED;
 - (b) shipping, or improper handling by others;
 - (c) improper storage, installation, maintenance or repair by others;
 - (d) abuse, abnormal use or accident.
 - (e) use for a purpose or in a manner for which the Product was not intended;
or
 - (f) improper cleaning and washing;
 - (g) improper site design by others.



2.2 The Limited Warranty is void if:

- (a) Any materials or other Product not provided by, or authorized by 4MED, are used with the Product; or
- (b) 4MED does not receive timely notice of the alleged defects in accordance with the terms of Section 6 below.

3. **EXCLUSIVE REMEDY:** Subject to compliance with the terms in Section 6 below, 4MED will, at its option and in its sole discretion, repair or replace any defective Product. THE EXCLUSIVE REMEDY UNDER THIS LIMITED WARRANTY, UNDER ANY OTHER EXPRESS WARRANTY NOT NEGATED HEREBY AND UNDER ANY IMPLIED WARRANTIES NOT NEGATED HEREBY (INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR PURPOSE), IS REPAIR OR REPLACEMENT OF DEFECTIVE PRODUCT. IN NO EVENT WILL WARRANTY COMPENSATION, OR OTHER DAMAGES AVAILABLE FROM 4MED, EXCEED THE SALE PRICE RECEIVED BY 4MED FOR THE PRODUCT.
4. **EXCLUSION OF CONSEQUENTIAL AND INCIDENTAL DAMAGES:** THIS LIMITED WARRANTY, ANY OTHER EXPRESS WARRANTY NOT NEGATED HEREBY AND ANY IMPLIED WARRANTY NOT NEGATED HEREBY (INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE), DO NOT COVER, AND 4MED WILL IN NO EVENT BE LIABLE FOR, INCIDENTAL OR CONSEQUENTIAL DAMAGES, including, but not limited to, lost profits, the cost of removal, disassembly and shipment of the defective Product, injury to other property, loss of use, or other commercial losses or installation of any replacement Product. Where, due to operation of law, consequential and incidental damages under this Limited Warranty, under any other express warranty not negated hereby or under any implied warranty not negated hereby (INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR PURPOSE) cannot be excluded, such damages are expressly limited in amount to the sales price received by 4MED for the Product. This exclusion of consequential and incidental damages, and the provision of this Limited Warranty limiting remedies hereunder to repair or replacement, are independent provisions, and any determination that the limitation of remedies fails of its essential purpose or any other determination that either of the above provisions is unenforceable, shall not be construed to make the other provision unenforceable.
5. **EXCLUSION OF OTHER WARRANTIES:** This Limited Warranty is in lieu of all other warranties, express or implied. ALL OTHER WARRANTIES, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSLY DISCLAIMED.
6. **NOTICE TO 4Med:** 4MED will not pay for the cost of repair or replacement performed other than in accordance with this Limited Warranty. Subject to the terms of this Limited



Warranty, 4MED will, at its option and in its sole discretion, repair or replace the defective Product provided;

- A. the defect is reported to 4MED in writing within the applicable two (2) year warranty period;
- B. 4MED authorizes return of the defective part for replacement or repair; and
- C. the defective part is returned to 4MED freight and transportation costs prepaid, with a suitable letter and a copy of the purchase invoice. The letter should include a detailed written description of the defect and how and when the Product containing the defective part was used. All shipping and transportation costs associated with the return of the defective part are the responsibility of Buyer.

Written notice of a Product or a component part believed to be defective as covered by this Limited Warranty should be sent to: 4Med Ltd. Nahal-Oz 85145 Israel and should include Buyer's name and address, proof of purchase, and a brief description of the defects. 4MED will ship (freight collect) to Buyer Product repaired or replaced under this Limited Warranty.

- 7. **PRODUCT REPAIR:** 4MED's obligations under the Limited Warranty to repair any defective Product are subject to the following terms:
 - A. all repair work shall be provided by 4MED;
 - B. Buyer shall provide 4MED with a suitable work environment; and
 - C. 4Med guarantee the supply of replacing part for 10 years from the date of the purchase of the Product.
- 8. **CHOICE OF LAW:** This contract shall be governed by, and construed in accordance with, the internal laws and judicial decisions of the State of Israel, without regard for any choice or conflict of laws considerations.
- 9. **SEVERABILITY:** In the event any portion of this Limited Warranty shall be determined to be invalid under any applicable law, such provision shall be deemed null and void and the remainder of this Limited Warranty shall continue in full force and effect.

Manufacturer and distributor:

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