

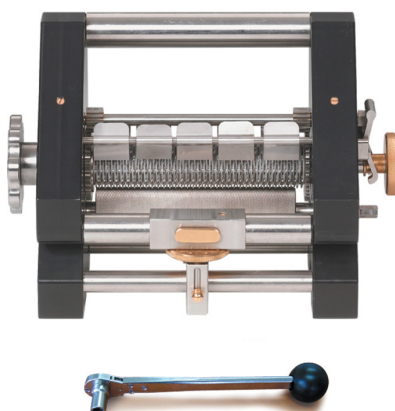


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# The Rosenberg Adjustable Skin Graft Mesher



## Instructions for use





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## **Rosenberg Adjustable Skin Graft Mesher** **Instructions for use**

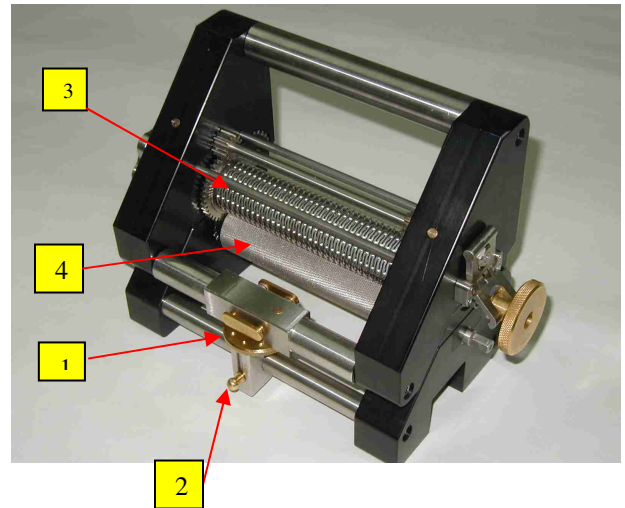
### **Adjustment for carrier thickness.**

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.

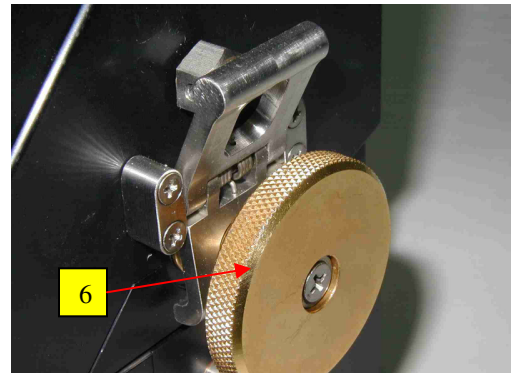
In order to adjust the Mesher to the carrier thickness, please proceed the following steps.

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





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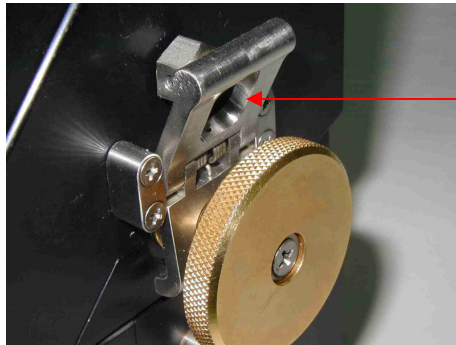
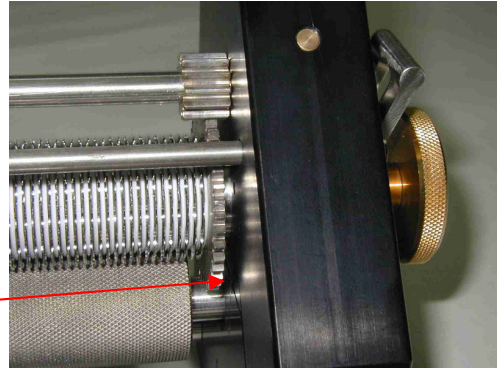
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### To adjust the ratio:

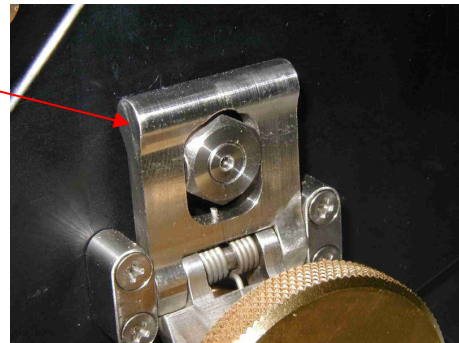
Place the adjustable skin graft Mesher on flat surface. Position the Mesher so that the elevation dial is facing you. With your right hand, turn the locking wheel (6) anticlockwise and push the right gear (7) to the right. The blades are released and the roller's locking mechanism (8) will be engaged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

7



**Roller locking (8) open position**

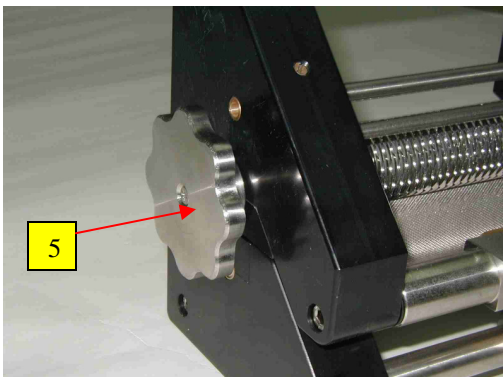
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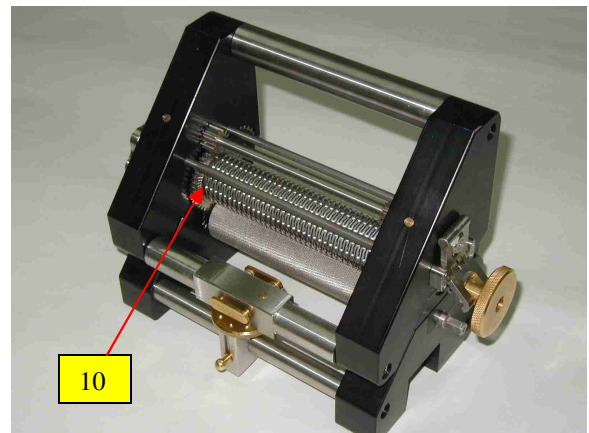
**Roller locking (8) locked position**

With your left hand, adjust the ratio by turning the adjustment wheel (5) clockwise or anticlockwise. The paired blade 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 desire ratio has been achieved, the locking wheel (6) should be turn clockwise until it is tight. This will unlock the system, and will lock the blades in their position.



5



10



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**Ratio 1:1**



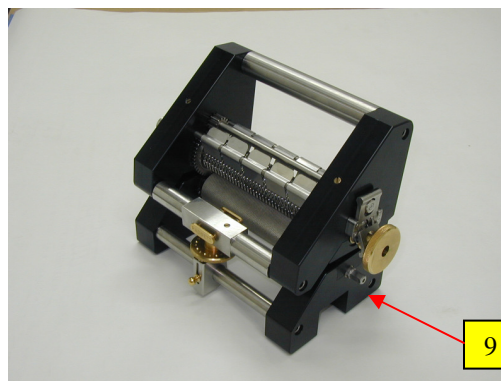
**Ratio 2:1**



**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.





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## **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.

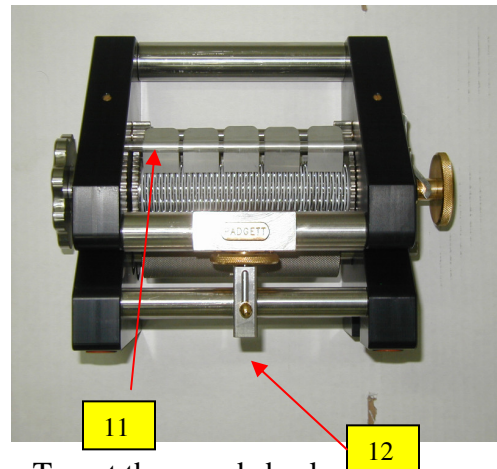
**\* Do not use saline on the Mesher at any time.**

### **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.

For automated washing machines a typical cycle should include the following: cool/warm wash detergent (neutral pH) below coagulation temperature (<60 degrees C), rinse to remove detergent, hot wash (eg 90 degree C) and assisted drying cycle.



### **Sterilization.**

The adjustable skin graft Mesher should be sterilized prior to each meshing procedure.

Lubrication should not be used on this instrument.

Each institute should establish the efficacy of its sterilizing procedure by appropriate method, such as the use of commercially available chemical or biological monitors. This instrument may be autoclaved or flash autoclaved.

**The Mesher is opened for cleaning**





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## **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.



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- 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



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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 North Carolina, 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.

EC Authorized representative: Ozat EU Amsterdamer Weg 41, 4269 Dortmund Germany