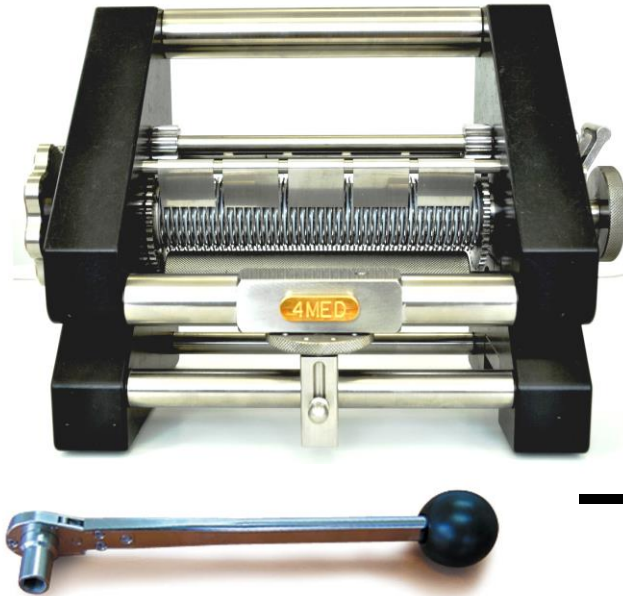


The Rosenberg Skin Graft Mesher

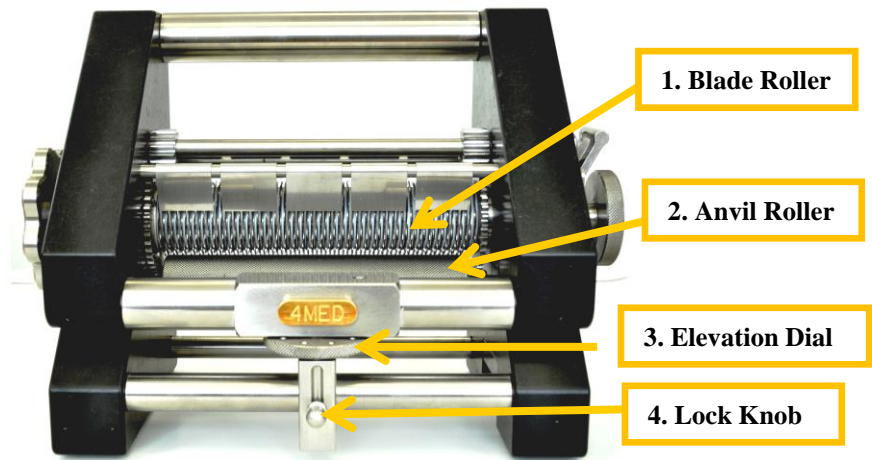


Instructions for use

CE



Rosenberg Skin Graft Mesher



Adjustment for Carrier Thickness (both Variable and Fixed Ratio Meshers):

The Rosenberg Adjustable Skin Graft Mesher may accommodate thickness level of graft carrier from 0.2mm (0.007”) to 4.0mm (0.150”) The cutting blades held in the upper blade roller (1.) perform the meshing as the skin graft is spread on the flat carrier which passes on the lower feeding anvil roller (2.).

The elevation dial (3.) regulates the distance between the upper blade roller and the lower anvil roller.

- Turning the elevation dial (3.) each “click” corresponds to movement of 0.1 mm.
- To **decrease** the distance between the upper blade roller (1.) and the lower anvil roller (2.), turn the elevation dial (3.) **clockwise**.
- To **increase** the distance between the upper blade roller (1.) and the lower anvil roller (2.), turn the elevation dial (3.) **counter clockwise**.

In order to adjust the distance between the upper blade roller (1.) and the lower anvil roller (2.) to the carrier and skin graft thickness desired, proceed the following steps.

- A. Press on lock knob (4.) all the way down.
- B. Rotate the elevation dial (3.) clockwise until it stops, this is considered fully closed. Consider this the starting point.
- C. To **increase** the distance between the upper blade roller (1.) and the lower anvil roller (2.), turn the elevation dial (3.) **counter clockwise**, the desired number of “clicks”. Typically turning the elevation dial (3.) increments of 5 “clicks” at a time is best.
- D. Test the height the distance between the upper blade roller (1.) and the lower anvil roller (2.), use a 4Med carrier.
- E. Insert the carrier between upper blade roller (1.) and the lower anvil roller (2.) and check the cutting with paper. Note: if performed on the sterile field, the inner paper liner from a sterile glove package can be used.
- F. Adjust the final distance between upper blade roller (1.) and the lower anvil roller (2.) according to the desired cutting results.

Adjustment of the Ratios (both Variable Ratio Mesher Only):

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. 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 to the desired meshed ratio, proceed the following steps.

- A. Place the adjustable skin graft mesher on flat surface.
- B. Position the mesher with the front of the mesher facing the user (**Figure A.**).
- C. With your right hand, turn the locking wheel (**6.**) **counter clockwise**
- D. Push the right gear (**5.**) to the right with fingertip until it is flush with the black frame.
- E. As the locking wheel (**6.**) is turned **counter clockwise**, the blades are released and the roller lock (**7.**) will be engaged automatically.

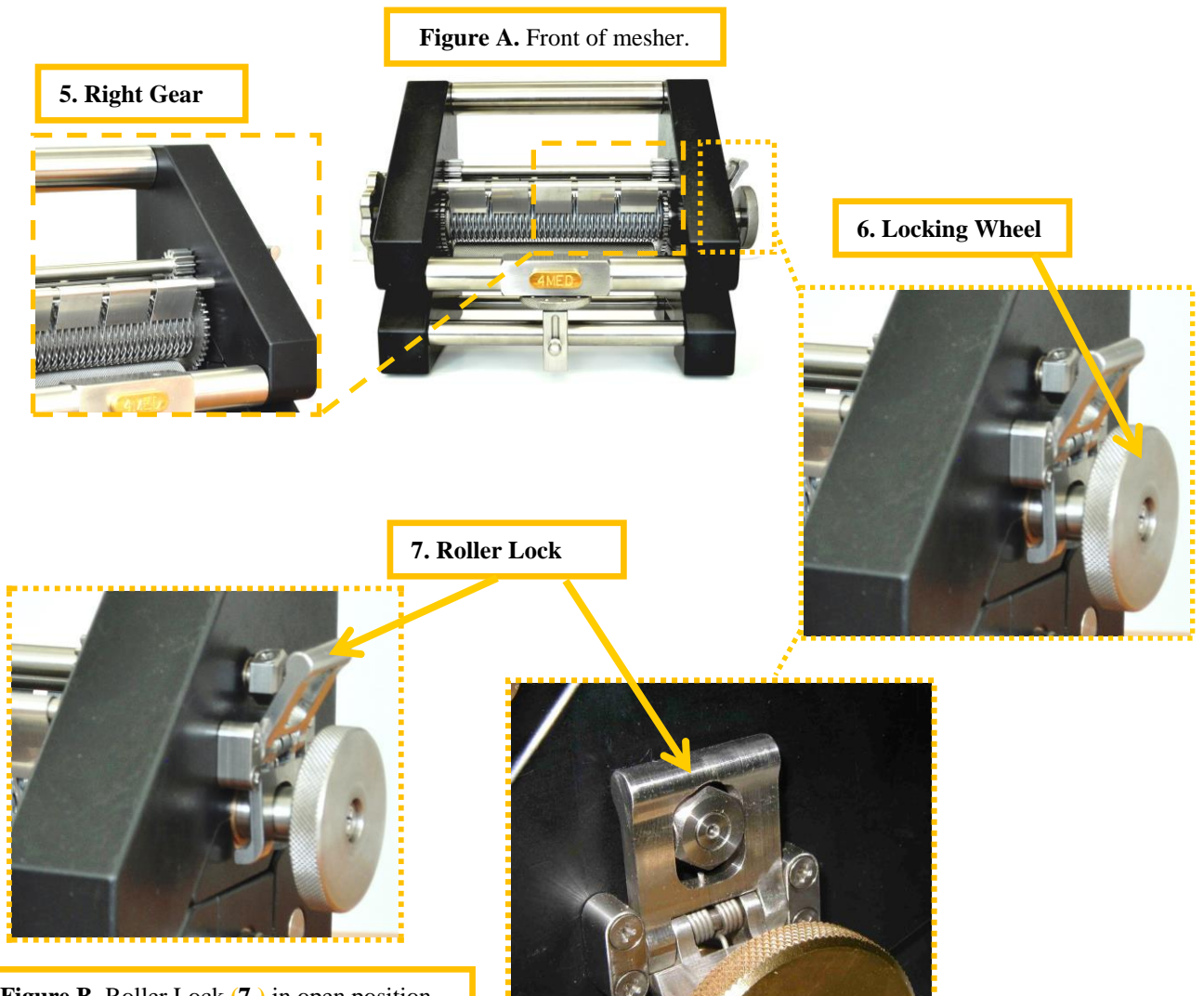


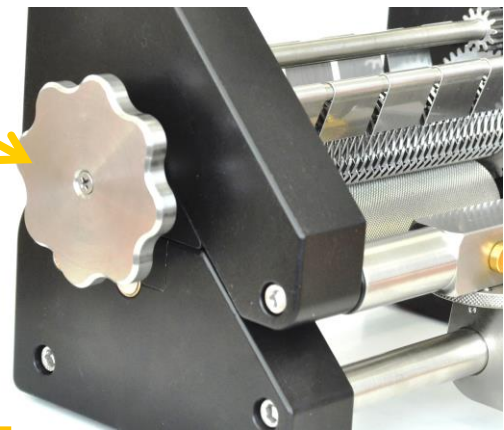
Figure B. Roller Lock (7.) in open position.

Figure C. Roller Lock (7.) in locked position.

Adjustment of the Ratios (Variable Ratio Mesher Only) (continued):

- F. With your left hand, adjust the ratio by turning the adjustment wheel (8.) clockwise or anticlockwise. The paired blades are moved.
- G. The meshing ratio is shown by a pointer wheel (Figure D.) on the left gear (9.) which is situated inner left side of the mesher.
- H. The marks on the pointer are 5:1, 4:1, 3:1, 2:1, 1.5:1, 1:1 (Figure E.).
- I. Once the desire ratio has been achieved, the locking wheel (6.) should be turned clockwise until it is tight.
- J. This will reengage the system and will lock the blades in their position. The roller lock (7.) will return the open position (Figure B.).

8. Adjustment Wheel



9. Left Gear w/ Ratios



Figure D. Ratio pointer. Shown at 5:1 position.

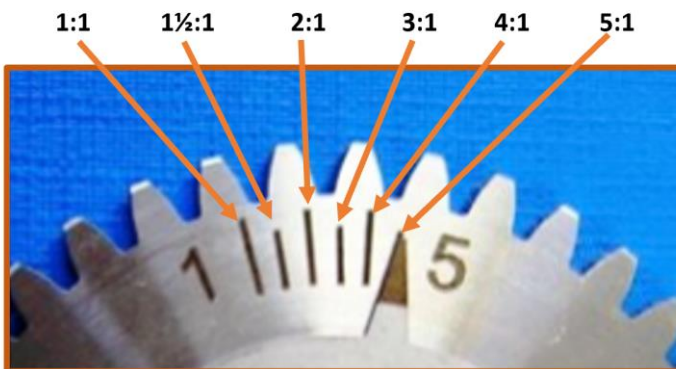
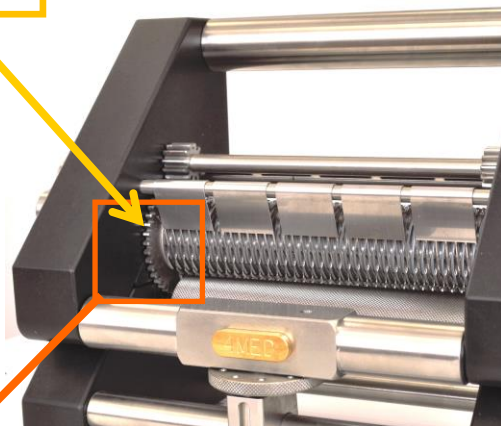


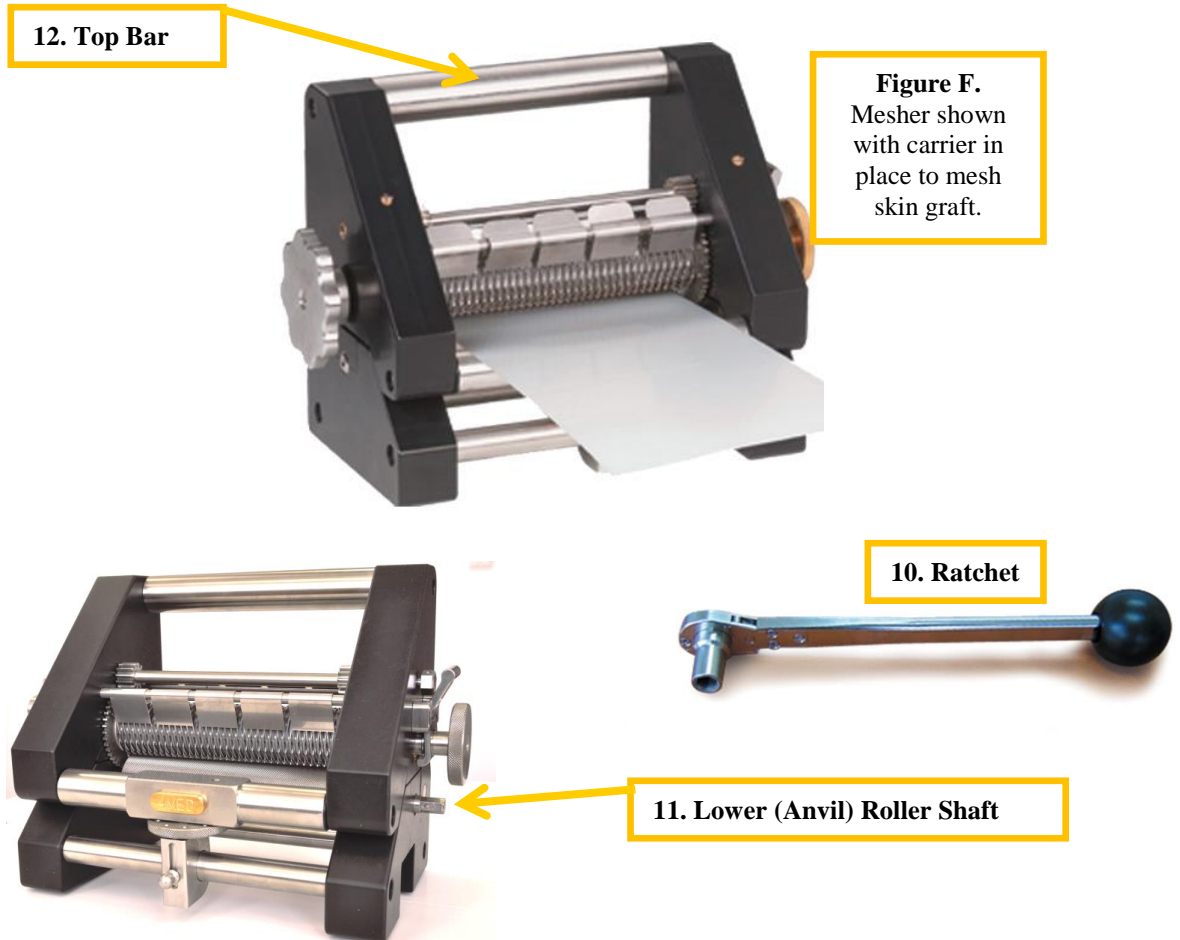
Figure E. All ratio positions.



Important: Do not attempt to use the Mesher unless the blades are tightened, and the roller lock is released (Figure B.).

Meshing Skin Grafts (both Variable and Fixed Ratio Meshers):

1. Apply the skin graft to the 4Med carrier.
2. Place the carrier on the flat surface in front of the roller. **(Figure F.)**
3. The cranking ratchet **(10.)** should be attached to the lower roller shaft **(11.)** that is situated on the right side, under the locking wheel.
 - a. The rotation of the two rollers occurs by a cranking ratchet activating a set of gears within the black mesher frame.
4. Make sure that the ratchet is set for forward movement, then crank the carrier all the way through the upper blade roller and the lower anvil roller.
 - a. If the user needs to reverse the carrier, flip the lever on the ratchet to the reverse position, then the carrier can be backed out.
5. The user should place their left hand on the top bar **(11.)** to prevent the mesher from rocking back while cranking the ratchet.
6. The carrier can be reused to mesh skin grafts during the procedure.
 - a. The sterile, single-use carriers are recommended to be used one per patient.
 - b. If after passing through the mesher the carrier begins to bow, turn the carrier over and mesh on the other side of the carrier.
7. It is recommended to use a sterile plastic tissue pick-up or forceps to need to retract the skin from the cutting roller blades.
 - a. **WARNING: Do not use metal instruments near the blades to push the skin through or to pull it out of the blades. This can cause damage to the edge of the blade.**



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

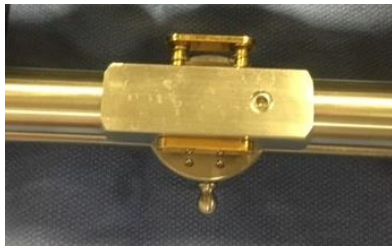


Figure G. Correctly closed push-pull mechanism.



Figure H. Incorrectly closed push-pull mechanism.

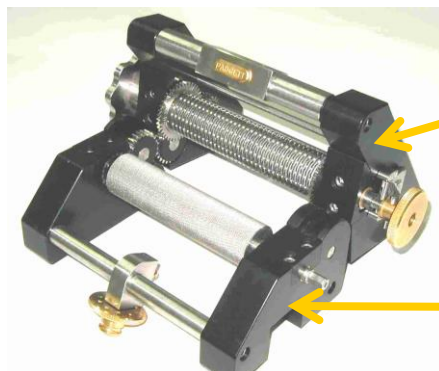
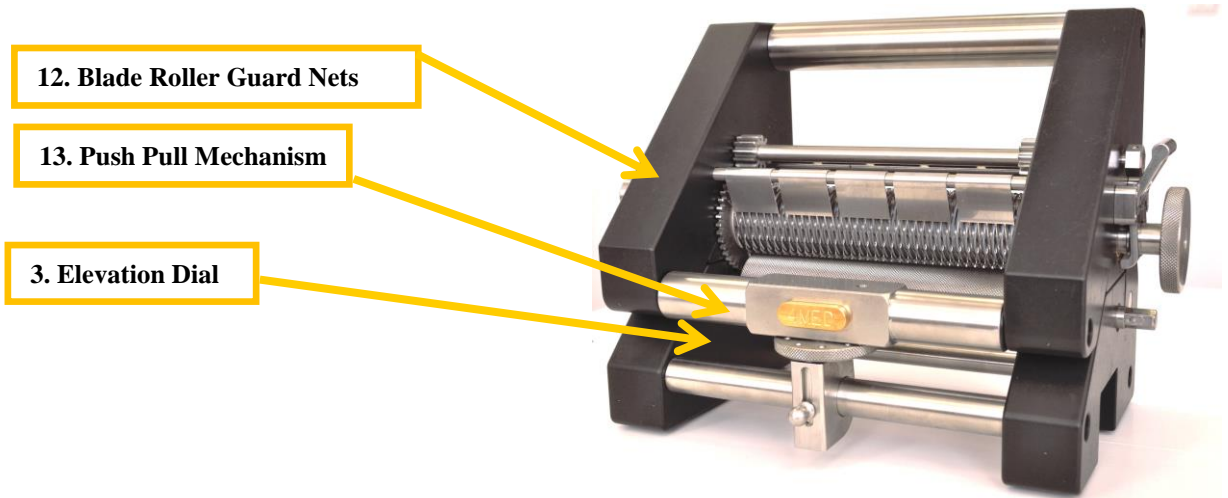


Figure I. Mesher shown open for disinfection.



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.). Refer to the guard nets section that follows.

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.**

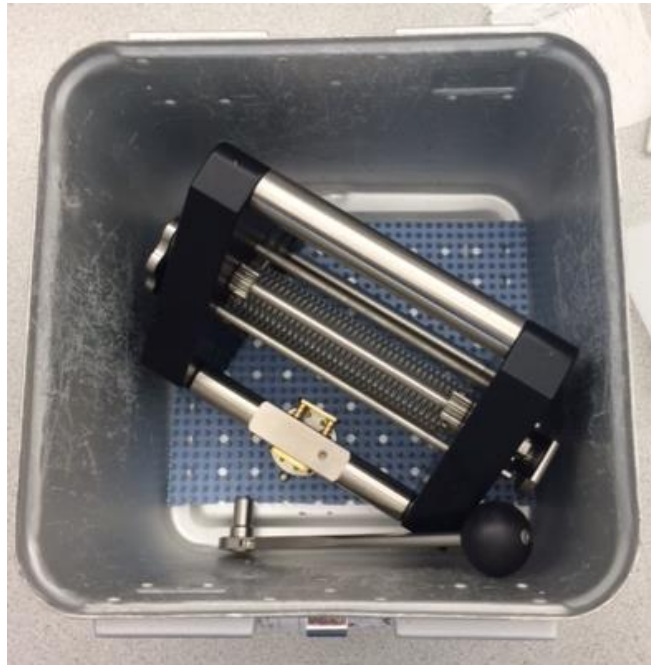
Maintenance (both Variable and Fixed Ratio Meshers):

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.

Sterile, Single-Use Carriers Information:

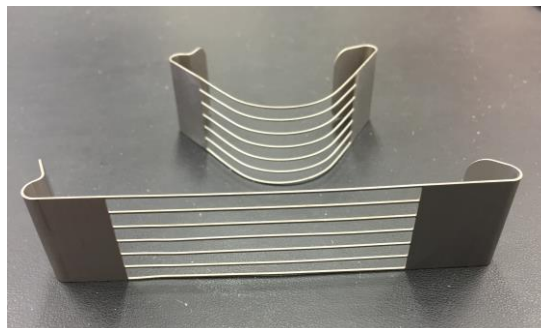
- Sterile, single-use packaged carriers should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.
- Sterile packaged carriers should be examined closely prior to opening to ensure that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

Carriers Sizes Available:

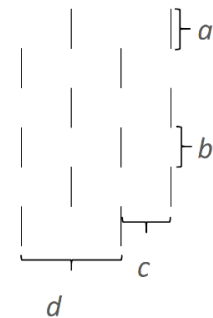
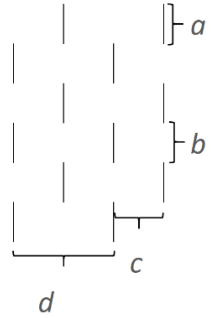
Type	Standard	Long	Wide
Part Number	9910102	9910102-60	9910102-35
Units	20/Box	20/Box	20/Box
Material	High Density Polyethylene	High Density Polyethylene	High Density Polyethylene
Dimensions (W x L)	14cm x 30cm (5.5" x 12.0")	14cm x 60cm (5.5" x 24.0")	16.5cm x 35.5cm (6.6" x 14.2")

Blade Roller Guard Nets:

- The guard nets that are included with the variable and select fixed meshers are designed to help prevent the skin graft from rolling around the blade while being meshed.
- They can remain in place for disinfection and sterilization.
- To remove the guard net, open the mesher (**Figure I.**) and snap them off from the back of the bar above the blade roller.
- To put the guards back on, close the mesher and place the guards over the blades, leaving a space between each pair of guards. Snap them onto the bars in front and behind the blade roller.



Mesh Products:

Type	'Rosenberg' Variable Ratio	1:1 Fixed Ratio	2:1 Fixed Ratio
Part Number	9910100	9916100	9914100
Unit	Each	Each	Each
Sterilization Box Available	Yes	Yes	Yes
Guard Nets Available	Yes	Yes	No
Number of Blades/Disc	8	16	14
Carriers Used	Standard or Long	Standard or Long	Standard or Long
Blade Material	Stainless Steel	Stainless Steel	Stainless Steel
Spacer Material	Teflon	Teflon	Stainless Steel
Width	14cm (5.5")	14cm (5.5")	14cm (5.5")
Thickness Range	0.2mm to 4.0mm (0.007") to (0.150")	0.2mm to 4.0mm (0.007") to (0.150")	0.2mm to 4.0mm (0.007") to (0.150")
Nature of the Cut	Each cutting blade is made of two paired halves, each contributing to the length of the incision.	Each cutting blade is designed to the length required for the incision into the skin.	Each cutting blade is designed to the length required for the incision into the skin.
Measurements of the Cuts <i>(slit length can slightly vary based on the thickness and elasticity of the skin graft or type of material being cut)</i>	1:1 slit length = 6.5mm 1½:1 slit length = 8.0mm 2:1 slit length = 9.0mm 3:1 slit length = 10.0mm 4:1 slit length = 12.0mm 5:1 slit length = 13.0mm	a = 3.0mm b = 3.0mm c = 1.5mm d = 3.0mm 	a = 5.0mm b = 2.5mm c = 1.1mm d = 2.2mm 



Product Parts List:

Part Number	Description	Unit
Equipment		
9914100	Skin Graft Mesher with Ratchet, Fixed Ratio 2:1, 14 blade	Each
9916100	Skin Graft Mesher with Ratchet, Fixed Ratio 1:1, 16 blade	Each
9914100-17	Skin Graft Mesher with Ratchet, Fixed Ratio 2:1 (Wide, 17cm) 14 blade	Each
9916100-17	Skin Graft Mesher with Ratchet, Fixed Ratio 1:1 (Wide, 17cm) 16 blade	Each
Carriers		
9910102	Skin Graft Carrier, Standard	20/Box
9910102-60	Skin Graft Carrier, Long	20/Box
9910102-35	Skin Graft Carrier, Wide	20/Box
Accessories		
9910104	Sterilizing Container with Top Filter	Each
Y800.00	Filter for Sterilization Container	100/Pack
1710009	Guard for Mesher	5/Pack
9911010	Ratchet for Mesher	Each
Parts		
3310200	Knife Roller Assembly, Variable Ratio Mesher	Each
3314200	Knife Roller Assembly, Fixed Ratio 2:1, 14 blade	Each
3316200	Knife Roller Assembly, Fixed Ratio 1:1, 16 blade	Each
3314200-17	Knife Roller Assembly, Fixed Ratio 2:1 (Wide, 17cm) 14 blade	Each
3316200-17	Knife Roller Assembly Fixed Ratio 1:1 (Wide, 17cm) 16 blade	Each
3310300	Anvil Roller Assembly	Each
3310300-17	Anvil Roller Assembly 17cm	Each
1510301	Anvil Roller	Each
1510301-17	Anvil Roller 17cm	Each
1510306	Anvil Roller Pin for Gear	Each
1510811	Silicone Foot for Mesher	Each
1510303	Anvil Roller Bushing Left	Each
1510302	Anvil Roller Bushing Right	Each
1510307	Anvil Roller Washers #2	Each
1510308	Anvil Roller Washers #1	Each
1510205	Knives Roller Bushing A	Each
1510206	Knives Roller Bushing B	Each



4MED "Rosenberg" Skin Graft Mesher

PRODUCT WARRANTY

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

LIMITED ONE YEAR 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.

1. **EXCEPTIONS TO WARRANTY:**

1.1 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.

1.2 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.

2. **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.**

3. **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 one (1) 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. 7, Shikma St. Sapirim Industrial Park, P.O. Box 1028 Sderot 8700101, 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 the 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:	US Sales Office:
4Med Ltd 7, Shikma St. Sapirim Industrial Park P.O. Box 1028 Sderot 8700101 Israel Tel: +972 (0)8 680-5223, Fax: +972 (0)8 680-5221 Email: info@4med.co.il Webpage: www.4med.co.il , www.4med-surgical.com	4Med USA 40 Bedford Rd, 2nd floor Armonk, NY 10504 USA Tel: +1 914-861-0480; Fax: +1-888-475-5089 Email: sales@4med-surgical.com