

The Rosenberg Skin Graft Mesher



Service & Repair Manual





Service and Repair Levels (both Variable and Fixed Ratio Meshers):

Туре	Level 1	Level 2	Level 3
Description	Select Tissue Bank Staff trained for a set of repairs	Mesher/Blade Roller to go to US Distributor	Mesher to go to 4Med US or headquarters in Israel
Example Repairs	 Lubrication of the mesher Replace a silicone foot Evaluation of the mesher Adjustment for Carrier Thickness / Test Cut Replace a bushing Replace a washer 	 All of level 1 repairs Change the blade roller Replace an anvil roller Replace the pin in the anvil roller 	 All of level 1 and 2 repairs Blade roller repaired for individual blade replacements Major damage Unknown issue

Tools to Have Available (both Variable and Fixed Ratio Meshers):

- Phillips screwdriver
- Allen Key Wrenches (various sizes)
 - o 2mm
 - o 5mm
 - Need 3rd size
 - Need 4th size
- Plastic or Wooden Dowel (need diameter)
- Carrier (to test meshing)
- Paper (to test meshing)
- Water soluble lubricant in spray bottle
- Non-shedding wipes



Product Parts List:

Part Number	Description	Details	Image	Unit
Equipment	Description	Details	Innugo	Cint
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		Ö	Each
Carriers				
9910102	Skin Graft Carrier, Standard	(W x L): 14cm x	30cm (5.5" x 12.0")	20/Box
9910102-60	Skin Graft Carrier, Long	(W x L): 14cm x 60cm (5.5" x 24.0")		20/Box
9910102-35	Skin Graft Carrier, Wide	(W x L): 16.5cm	x 35.5cm (6.6" x 14.2")	20/Box
Accessories				
9910104	Sterilizing Container with Top Filter			Each
Y800.00	Filter for Sterilization Container	filters that fit	the Sterilizing 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	cutting blades		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	h a 44 a ma ma 11 a m		Each
1510301	Anvil Roller	bottom roller	Statistics of the local division of the loca	Each
1510301-17	Anvil Roller 17cm			Each
1510306	Anvil Roller Pin for Gear	inside the ratchet mechanism		Each
1510811	Silicone Foot for Mesher	red feet on the bottom		Each
1510303	Anvil Roller Bushing Left			Each
1510302	Anvil Roller Bushing Right	bronze		Each
1510307	Anvil Roller Washer #2	black delrin, no recess	0	Each
1510308	Anvil Roller Washer #1	black delrin, with recess for bushing	0	Each
1510205	Knives Roller Bushing A			Each
1510206	Knives Roller Bushing B	bronze		Each



Service and Repair Level 1

- \checkmark Lubrication of the Mesher
- ✓ Replace a Silicone Foot
- ✓ Evaluation of the Mesher
- ✓ Adjustment for Carrier Thickness / Test Cut
- ✓ Replace a Bushing
- ✓ Replace a Washer

Lubrication of the Mesher (both Variable and Fixed Ratio Meshers):

- 1. Use a water-soluble surgical grade instrument lubricant (such as instrument milk) in spray bottle after cleaning and before sterilization to reduce friction and wear.
 - a. It is best practice to use a spray rather than soaking the mesher.
 - b. Mineral oil is not recommended as a lubricant.
- 2. Spray the lubricant between the blades, hinges, threads, knives rollers and other moving parts.
- 3. Make sure mesher rollers rotate smoothly.
- 4. Sterilize following the sterilization section in the 4Med IFU.

Replace a Silicone Foot (both Variable and Fixed Ratio Meshers):

- 1. On the bottom lower part of the mesher frame, remove any residual glue from the recessed space for the silicone foot.
- 2. Apply a pea-sized amount of glue to the tapered diameter (black arrow) of the foot.
- 3. Press the silicone foot into the recessed space on the bottom of the mesher.
- 4. Turn the mesher upright onto the lower part to allow pressure onto the foot.
- 5. Allow to completely dry.

Evaluation of the Mesher (both Variable and Fixed Ratio Meshers):

- 1. Check all screws are hand tight.
- 2. Check for free movements of hinges.
- 3. Check if the tolerances are too large between hinges and bushings.
 - a. They should be snug but move freely.
- 4. Check proper locking of push-pull locking mechanism.
 - a. The skin graft mesher is made of two hinged parts, upper (3.) and lower (4.), that may be opened for cleaning and maintenance (Figure C.).
 - b. The elevation dial (2.) holds the two parts together.
 - c. The gold color push-pull mechanism (1.) locks the two parts to the elevation dial (2.).
 - Pushing the push-pull mechanism (1.) in toward the mesher locks the two parts.
 - Pulling the push-pull mechanism (1.) away from the mesher unlocks the two parts.
 - d. If the mesher is difficult to open, make sure the elevation dial (2.) 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 (1.) from the top view. The front gold plate should be flush against the bar when the mesher is closed correctly.



Figure A. Correctly closed push-pull mechanism.



Figure B. Incorrectly closed push-pull mechanism.





Evaluation of the Mesher (both Variable and Fixed Ratio Meshers) (continued):



5. Ensure that the lower lock mechanism does not move to the left or the right on the shaft.



- a. If the lower locking mechanism moves laterally on the shaft:
 - i. Remove knob (indicated as #7 below).
 - ii. Make sure to position the screw (indicated as #3 below) in the groove of the shaft.
 - iii. Hand tighten screw (indicated as #3 below) until the mechanism do not moves left and right but allows it to rotate over the shaft.
 - iv. Use 2mm Allen key to lock the Allen screw (indicated as #2 below).





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

1. Check quality of cutting by using test material (such as paper or silicone) on a skin graft carrier.



- 2. The Rosenberg Adjustable Skin Graft Mesher may accommodate thickness level of graft carrier from 0.2mm (0.007") to 4.0mm (0.150").
- 3. The cutting blades held in the upper blade roller (5.) perform the meshing as the skin graft is spread on the flat carrier which passes on the lower feeding anvil roller (6.).
- 4. The elevation dial (7.) regulates the distance between the upper blade roller and the lower anvil roller.
 - Turning the elevation dial (7.) each "click" corresponds to movement of 0.1 mm.
 - To **decrease** the distance between the upper blade roller (5.) and the lower anvil roller (6.), turn the elevation dial (7.) **clockwise**.
 - To **increase** the distance between the upper blade roller (5.) and the lower anvil roller (6.), turn the elevation dial (7.) **counter clockwise**.
- 5. To adjust the distance between the upper blade roller (5.) and the lower anvil roller (6.) to the carrier and skin graft thickness desired, proceed the following steps.
 - A. Press on lock knob (8.) all the way down.
 - B. Rotate the elevation dial (7.) clockwise until it stops, this is considered fully closed. Consider this the starting point.
 - C. To **increase** the distance between the upper blade roller (**5**.) and the lower anvil roller (**6**.), turn the elevation dial (**7**.) **counter clockwise**, the desired number of "clicks". Typically turning the elevation dial (**7**.) increments of 5 "clicks" at a time is best.
 - D. Test the height the distance between the upper blade roller (5.) and the lower anvil roller (6.), use a 4Med carrier.
 - E. Insert the carrier between upper blade roller (5.) and the lower anvil roller (6.) 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 (5.) and the lower anvil roller (6.) according to the desired cutting results.



Replace a Bushing or Washer on the Blade (Top) Roller (both Variable and Fixed Ratio Meshers):



- 1. Open the mesher into two parts, the upper part (3.) and lower part (4.) (Figure C.).
- 2. On the back side of the mesher on both sides of the upper part (3.) there are two Allen screws. Use 2mm Allen key to remove these screws (11.) and (12.).



- 3. With the mesher back facing the user, the Allen screw on the side with the locking wheel (9.) is longer (15mm) (10.). Use 2mm Allen key.
- 4. Open the mesher and remove the 2 (two) main hinges (12.).





<u>Replace a Bushing or Washer on the Blade (Top) Roller (both Variable and Fixed Ratio Meshers)</u> (continued):

- 1. With the mesher back facing the user, on the left side of the mesher the main hinge comes out with the gear (14.), 2 (two) washers (15.), and 2 (two) bushings (13.) attached as pictured below.
- 2. Replace the worn bushings or washers.



- 3. On the back side of the mesher on both sides of the upper part there are 2 (two) Allen screws. Use 2mm Allen key to replace these screws.
- 4. Re-assemble the upper and lower parts of the mesher.
 - a. With the mesher back facing the user, put the top part of the mesher on the lower part and align the holes of the main hinges.
 - b. Insert the stainless-steel gear hinge (with the new bushings and washers inside) on the left side (given back side of mesher is facing the user). Note Hole in gear must be aligned with the hole of the small Allen screw.



Note: Hole in gear must be aligned with the hole of the small Allen screw.



- 5. On the back side of the mesher on both sides of the upper part (3.) there are two Allen screws. Use 2mm Allen key to replace these screws (11.) and (12.).
- 6. With the mesher back facing the user, the Allen screw on the side with the locking wheel (9.) is longer (15mm) (10.). Use 2mm Allen key.





11. Short Allen screw (5mm)



<u>Replace a Bushing or Washer on the Anvil (Bottom) Roller (both Variable and Fixed Ratio</u> <u>Meshers):</u>

1. With the front of the mesher facing the user, use 5mm Allen key to remove the 4 (four) screws holding the 2 (two) covers of the anvil roller.



2. It is best practice to keep the removed anvil roller covers and screws on their corresponding left and right sides of the mesher.



- 3. Lift the anvil roller from the mesher.
- 4. Check the bushings on both side of the anvil roller (Figure G.). They should rotate smoothly.
- 5. Look for visible damage. Damaged bushings will result in uneven perforation of the skin graft or test material.
- 6. Pull the anvil roller bushing right (19.) from the anvil roller. Check for damage. Replace, if necessary.
- Follow steps 1 through 6 in the "*Replacing the Pin in the Anvil (Bottom) Roller*" section to check and/or replace the anvil roller bushing left (18.); anvil roller washer #1 (recessed) (23.); anvil roller washer #2 (flat no recess) (24.); and gear (25.).



<u>Replace a Bushing or Washer on the Anvil (Bottom) Roller (both Variable and Fixed Ratio</u> <u>Meshers) (continued):</u>

8. Re-assemble the anvil roller with the covers (16.), and secure with the Allen screws.





Service and Repair Level 2

- ✓ Change the Blade Roller
- ✓ Replace an Anvil Roller
- ✓ Replace the Pin in the Anvil Roller

Changing the Blade (Top) Roller (both Variable and Fixed Ratio Meshers):

- 1. With the front of the mesher facing the user, use 5mm Allen key to remove the 4 (four) screws holding the 2 (two) covers of the blade roller.
- 2. It is best practice to keep the removed blade roller covers (20.), and screws on their corresponding left and right sides of the mesher.
- 3. Lift the blade roller from the mesher.

Figure H. Left side of Blade Roller with cover and screws removed.



Figure I. Right side of Blade Roller with cover and screws removed.



20. Blade Roller Covers

(removed from mesher frame).

Figure J. Left side of Blade Roller

21. Blade Roller Bushing A **Figure K.** Right side of Blade Roller (removed from mesher frame).



22. Blade Roller Bushing B



Changing the Blade (Top) Roller (both Variable and Fixed Ratio Meshers) (continued):

- 4. Check the blade roller bushings (21.) and (22.) on both sides of the blade roller (Figure J) and (Figure K.). They should rotate smoothly.
- 5. Pull the blade roller bushing A (21.) from the blade roller. Check for wear or damage. Replace, if necessary.
- 6. Pull the blade roller bushing B (22.) from the blade roller. Check for wear or damage. Replace, if necessary.
- 7. Look for visible damage. Damaged bushings will result in uneven perforation of the skin graft or test material.
- 8. Re-assemble the washers and the bushings.
- 9. Re-assemble the blade roller with the covers (20.) into the frame and secure with the Allen screws.

<u>Replacing the Anvil Roller and/or the Pin in the Anvil (Bottom) Roller (both Variable and Fixed</u> <u>Ratio Meshers):</u>

- 1. If the blade roller does not rotate when turning the anvil roller. This is the result of a broken pin in the anvil roller gear caused by excessive torque.
- 2. It is best practice to keep the removed anvil roller bushings and washers on their corresponding order as they are removed.



- 1. Pull anvil roller bushing left (18.) from the anvil roller. Check for wear or damage. Replace, if necessary.
- 2. Pull the anvil roller washer #1 (recessed) (23.) from the anvil roller. Check for wear or damage. Replace, if necessary.
- 3. Pull the gear (25.) from the anvil roller. Check for damage. Replace, if necessary.
- 4. Remove the pin (26.) from the hole in the anvil roller. Check for damage. Replace, if necessary.
- 5. Pull the anvil roller washer #2 (flat no recess) (24.) from the anvil roller. Check for damage. Replace, if necessary.
- 6. Re-assemble the gear, the washers and the bushings.
 - a. The recessed side anvil roller washer #1 (recessed) (23.) should face the bronze bushing
 - b. The anvil roller washer #2 (flat no recess) (24.) is positioned on the inside part of the gear.
- 7. Re-assemble the anvil roller with the covers (16.) into the frame and secure with the Allen screws.



Final Inspections (both Variable and Fixed Ratio Meshers):

1. Ensure the mesher is closed correctly and locked by the front locking mechanism. Shown here is the gold color push-pull mechanism from the top view. The front gold plate should be flush against the bar when the mesher is closed correctly.





Figure A. Correctly closed push-pull mechanism.

Figure B. Incorrectly closed push-pull mechanism.

2. Adjustment the mesher for desired thickness setting.



The Rosenberg Adjustable Skin Graft Mesher may accommodate thickness level of graft carrier from 0.2 mm (0.007") to 4.0 mm (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**.

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 elevation 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 (five) "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 or silicone.
- F. Adjust the final distance between upper blade roller (1.) and the lower anvil roller (2.) according to the desired cutting results.



Final Inspections (both Variable and Fixed Ratio Meshers) (continued):

- 3. Ensure that the meshing is uniform. Mesh paper and ensure the slit length is the same. Check several places on the paper or silicone sheet. Measuring the slit length at the following points:
 - a. Front top left and right sides
 - b. Front middle left and right sides
 - c. Front bottom left and right sides
 - d. Back top left and right sides
 - e. Back middle left and right sides
 - f. Back bottom left and right sides

Mesher Slit Lengths Reference Chart:

Туре	'Rosenberg' Variable Ratio	1:1 Fixed Ratio	2:1 Fixed Ratio	
Part Number	9910100	9916100	9914100	
Number of Blades/Disc	8	16	14	
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 (slit length can slightly vary based on the thickness and elasticity of the skin graft or type of material being cut)	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	$a = 3.0 \text{mm}$ $b = 3.0 \text{mm}$ $c = 1.5 \text{mm}$ $d = 3.0 \text{mm}$ $ \qquad] - a$ $ \qquad \qquad] - b$ $ \qquad \qquad - c$ d	a = 5.0mm $b = 2.5mm$ $c = 1.1mm$ $d = 2.2mm$ $ - a$ $ - b$ $ - c$ d	



Service and Repair Level 3

- ✓ Blade roller repaired for individual blade replacements
- ✓ Major damage
- ✓ Unknown issue

When needed any service or repair event (in Level 1 or 2) can be returned for servicing. The above listed in Level 3 require the mesher to go to 4Med US or headquarters in Israel. Please follow the return instructions to ship the mesher for service.

Return Instructions:

- 1. Disinfect and sterilize the mesher (see 4Med Mesher Instructions For Disinfection-Sterilizing).
- 2. Please return the mesher and the container in separate boxes. (*This is important the mesher should not be shipped in the sterilization container because it needs to be padded.*)
 - a. Wrap the ratchet in bubble wrap and place it in front of the mesher either flat on the bottom or at an angle inside the box. It will not come into contact with the blades when placed in front of the mesher.
 - b. If you have the original packing material, the white foam ends and the white box, <u>this</u> is the best way to pad the mesher (see picture below).



- c. If you do not have the white foam ends, please use either bubble wrap or similar, or even scrunched up newspaper to cushion the mesher. Try to use a FedEx 11 x 11 x 11" box.
- d. Put it wrapped in a box about the size of the mesher and <u>then that box in a 2nd box</u> a bit larger, also with bubble wrap or paper as a cushion.
- e. Seal securely with packing tape.
- 3. <u>Confirmation of disinfection, sterilization and drying must be returned with the shipment</u> showing the device is safe to touch when received. (Your account representative can send to a form to use).
- 4. Ship via your preferred method to the location designated by your account representative.
- 5. Please send your account representative the tracking number, if possible.

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