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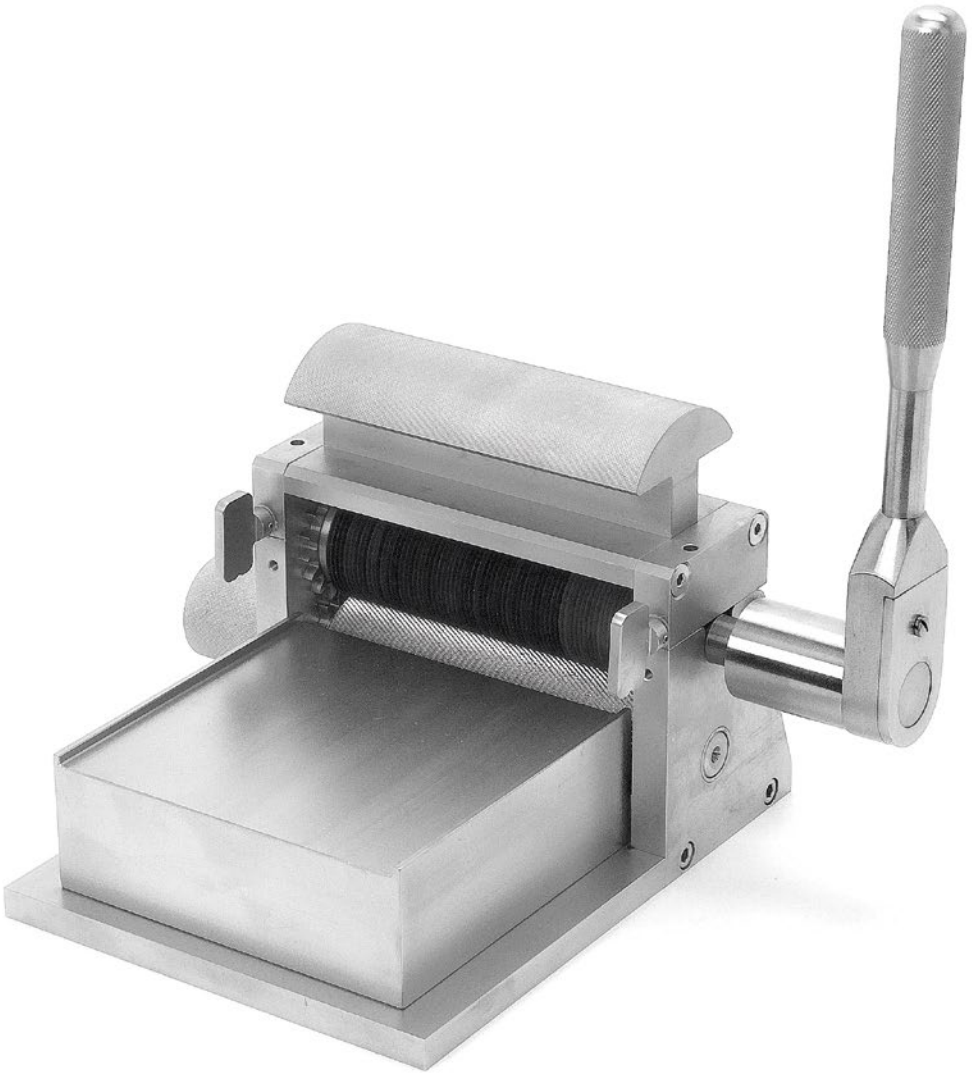
Instructions for use

Mesher

Skin expansion system

NOUVAG



Vorwort

Herzlichen Glückwunsch zum Kauf eines Produktes der Firma NOUVAG AG. Wir freuen uns, dass Sie sich für ein NOUVAG Erzeugnis entschieden haben und danken Ihnen für Ihr entgegengebrachtes Vertrauen.
Diese Bedienungsanleitung wird Sie mit dem Gerät und seinen Eigenschaften vertraut machen, damit eine möglichst lange und problemlose Funktion gewährleistet werden kann.
Im Anhang finden Sie die Konformitätserklärung und unsere autorisierten Servicestellen.

- **Bitte lesen Sie diese Anleitung vor Inbetriebnahme aufmerksam durch!**

Foreword

Congratulations on your purchase of a NOUVAG AG product. Thank you for the confidence shown in our products. Please consult the instruction manual for the use and maintenance of the device in order to ensure that it will function properly and efficiently for many years.
You will find the conformity statement and list of authorized service representatives attached.

- **Please read instructions carefully before operating!**

Table of contents

EN

1 Product description

1.1 Intended use and operation

The Mesher (Skin expansion system) is applied for obtaining split skin grafts in plastic surgery for the treatment of larger wound areas and burns.
The Skin grafts are placed on a mesh board which is provided with fine, recessed line markings and is guided through the Meshers slot by a blade roll. This causes a consistent perforation of the skin graft, similar to a chain-link fence, allowing the transplant to be drawn in width. The resulting split skin graft can thus cover a bigger wound area.

1.2 Contraindications

Inappropriate wound base as tendons, bones, exposed vessels and nerves, as well as implants. When the wound is situated at the flexures of joints or at high mechanical strain areas of the body, such as heel or neck, as well as by local infections, the surgeon must decide in each case whether a split skin graft can be used wisely.

1.3 Technical data, Mesher

Dimensions including ratchet (W x D x H) ---------- 210 x 195 x 110 mm
Length of the ratchet ---------- 175 mm
Weight including ratchet ---------- 4.9 kg
Blades diameter ---------- 30 mm
Blades interstices ---------- 1.5 mm
Slot between blades roll and backing roll ---------- 0.5/1.0 and 1.5 mm
Maximum slot width for mesh boards ---------- 95 mm
Material ---------- Medical stainless steel

1.4 Ambient conditions

	Transport and storage:	**Operation:**
Relative humidity:	Max. 90 %	Max. 80 %
Temperature:	0°C – 60°C	10°C – 40°C
Atmospheric pressure:	700 hPa – 1060 hPa	800 hPa – 1060 hPa

1.5 Warranty coverage

Purchasing the Mesher (Skin expansion system) entitles you to a 1-year warranty. If you return the warranty card for registration within four weeks of the date of purchase, warranty coverage will be extended for a further **6 month**.
Consumable parts are not covered by the warranty. Improper use or repair, or failure to observe these instructions, relieve us from any obligations arising from warranty provisions or other claims.

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2 Explanation of symbols

	Important information		Observe instructions for use
	Do not use if packaging is damaged		Biohazard
	Warning		CE symbol
	Manufacturer		Date of manufacture
	Not for reuse		Symbol indicating order number
	Date of expiry		Symbol indicating lot number

3 Safety information

Your safety, the safety of your team, and of course that of your patients is very important to us. It's therefore essential to bear the following information in mind.

3.1 Modifications and misuse

If modifications are made by the user/operator or a third party to the Mesher and the accessory equipment provided, or if these items are used by these individuals for a purpose other than that for which the items were designed (according to chapter 1.1 Intended use and operation), the manufacturer assumes no responsibility and the guarantee is void.

3.2 Essential requirements

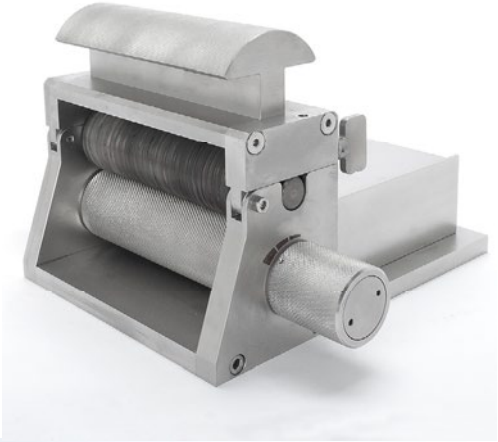
	The Mesher may only be operated by qualified and trained personnel!		Improper use or repair of the device and failure to observe these instructions relieve us from any obligations arising from warranty provisions or other claims.
	The use of third-party products is the responsibility of the operator. Functionality and patient safety cannot be guaranteed with third-party accessories.		Prior to using the device, before startup, and before operation, the user must always ensure that the device and accessories are in good working order and are clean, sterile and operational.
	Repairs may only be performed by authorized NOUVAG service technicians!		

3.3 During use

	The device is not sterile on delivery. All sterilizable parts must be sterilized before use (see chapter 8, Cleaning, disinfection and sterilization).		The employment of the Mesher other than that for which it was designed (see chapter 1.1) is not permitted. The responsibility is solely carried by the operator.

4 Scope of delivery

Ref.	Description	Quantity
	Mesher set, Ref. 1986 with Stericase and silicone mat	
1986a	Mesher, skin expansion system	1 unit
30444	Ratchet with case	1 unit
4128	Sterilization Container “Stericase”, 465 x 280 x 150 mm	1 unit
4126	Non slip silicone mat, 450 x 270 mm	1 unit
31584	Operation manual, Mesher, on CD-ROM	1 unit



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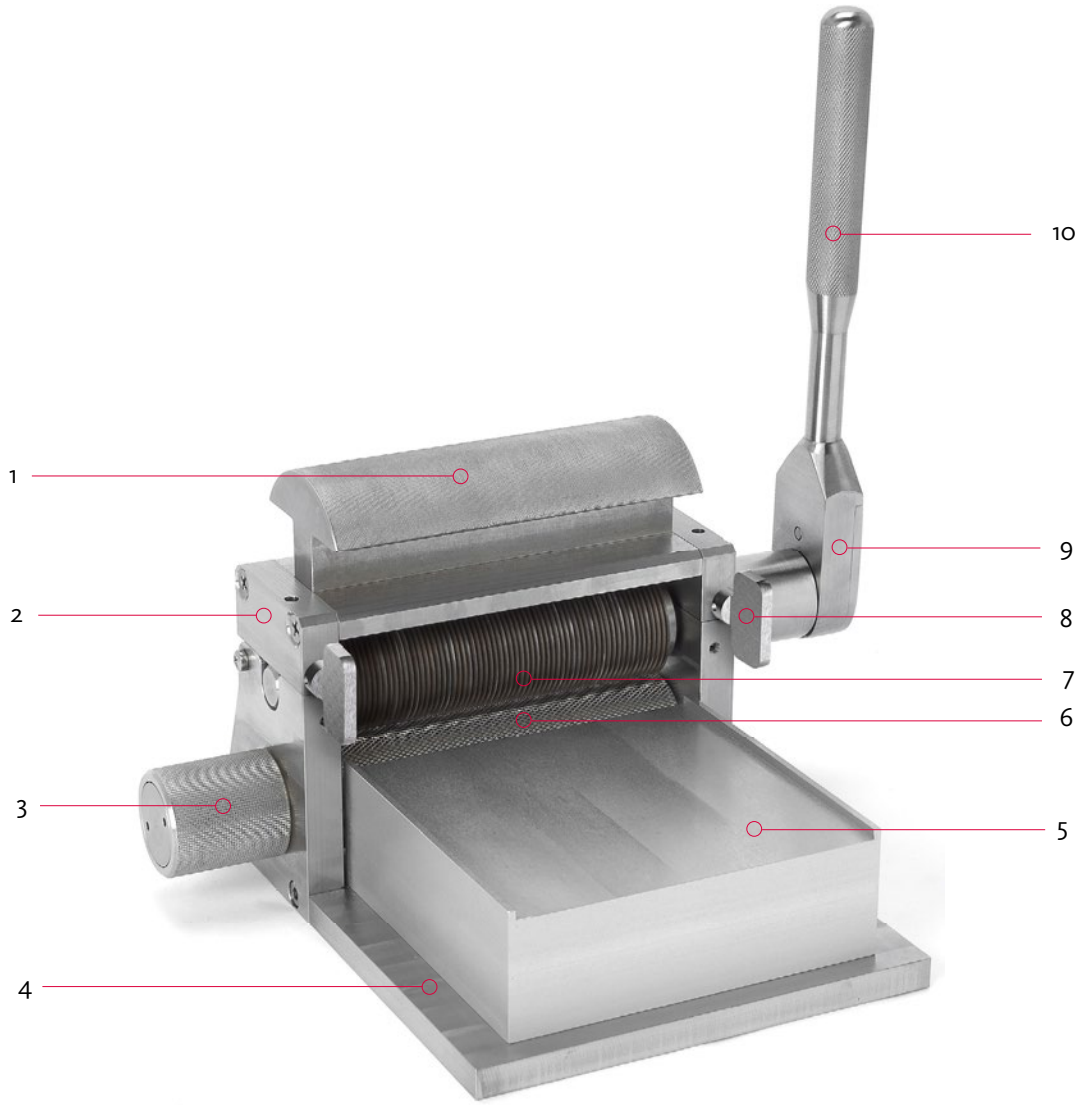
5 Device overview



1. Carrying and press-handle
2. Hinged bridge
3. Pull and twist knob for setting the backing roll pressure
4. Baseplate
5. Insertion platform for mesh boards
6. Backing roll with adjustment
7. Blade roll
8. Clamping wing grip for hinged bridge
9. Transport ratchet
10. Ratchet grip

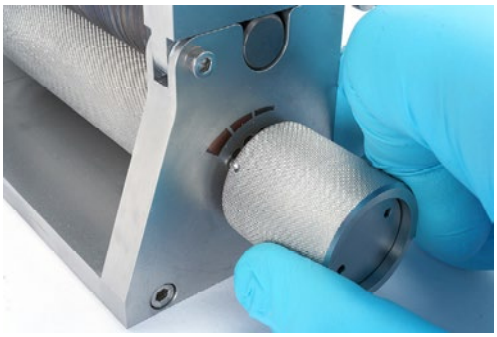
6 Startup

6.1 Setting up the device

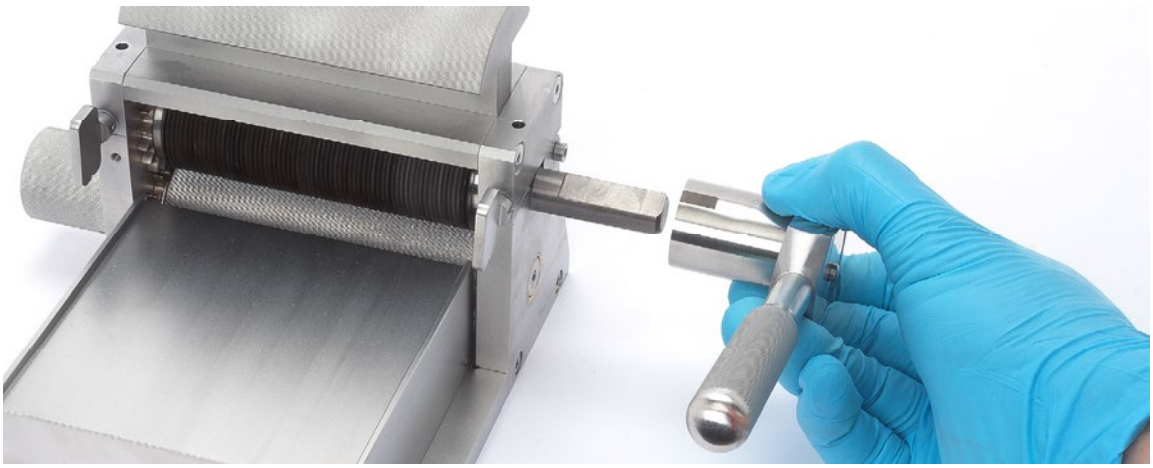
- The working height for accessing the Mesher is ideal if a standing position is assumed with arms slightly bent. Often the Mesher needs to be pressed down, while with the other hand the ratchet is accessed. To route the occurring forces to the direction of gravity the ratchet is preferably pulled from a less than vertical position down to the table.
- Place the sterilized Mesher, with all required parts on an even, non slip surface and make sure to have good access to all controls.
- Do not allow the operating range of the device to be compromised by limiting factors.
- The insertion slot and the exit side of the Mesher must be fully visible at all times.

6.2 Device preparation

1. Set the pull and twist knob to one of the positions, which is most suitable for the intended to use mesh board. The blades on the blade roll must completely penetrate the skin section on the mesh board to ensure a uniform extension of the skin section. The pressure of the blade roll on the mesh board with the skin section must be relatively high to achieve clean perforations of the skin section.



2. Align the marking on the transport ratchet with the flattened part of the axis of the blade roll and join it.



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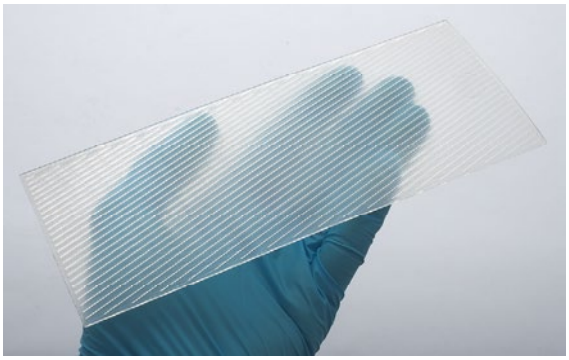
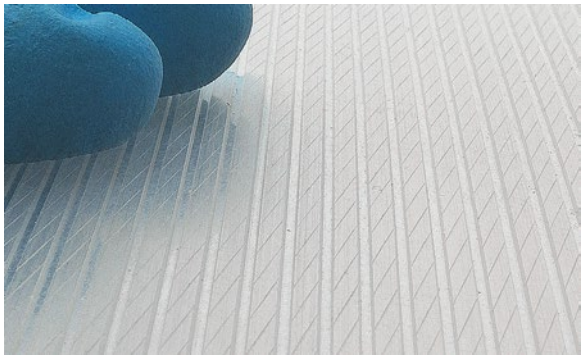
3. Preposition the selected sterile mesh board next to the Mesher with the fluted side up.





Check the expiry date of the mesh boards and ensure that the packaging is not damaged.
Using non-sterile mesh boards can result in serious infection.

- Prior to use check Mesher and its accessories for damage.
- Use the Mesher and its accessories only when they are in perfect working condition.
- Make sure the Mesher stands on a stable surface, because high forces may occur during the meshing procedure.

Mesh boards are intended for single use only. The re-sterilization of the mesh boards change the material in a manner that can result in failure of the system. This may result in serious infections.

If further skin sections of the same patient have to be processed, the same mesh board may be used during the operation, as long as the mesh board is still in good working condition.

Use only mesh boards distributed by Nouvag AG, otherwise the proper function of the system cannot be guaranteed.

7 Operation

7.1 Preliminary works

The skin sections, which will be processed for expansion, have to be gathered from the patient with a Dermatome. The skin section is laid out and carefully smoothened on the mesh board with the epidermal side facing down.

7.2 Use of the Mesher

Lay the mesh board with the skin section centered on the insertion platform of the Mesher, so that the mesh board can be processed thru the roller pair.

Slide and push the mesh board with the skin sample against the roller pair, so the plate lines up in a right angle with the roller pair.

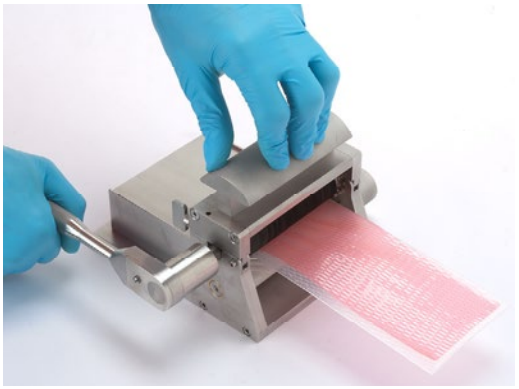
Carefully use the ratchet in slow motion while pushing the mesh board with the skin section thru the roller pair by slightly pressing from the back.

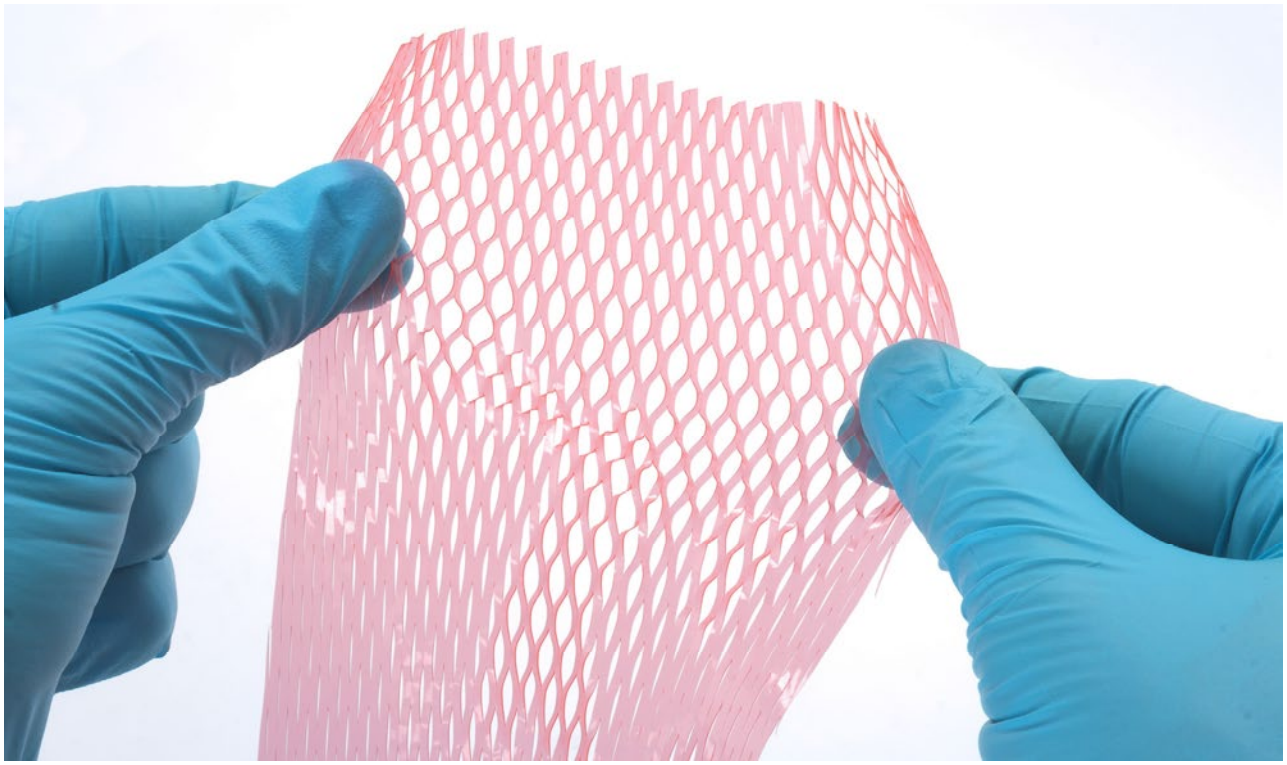
As a small part of the mesh board with the skin section is already fixed between the roller pair you can work the ratchet with higher force while your other hand stabilizes the Mesher by pressing down on the carrying and press handle.

It may happen that the skin section is lifted up by the blade roll while working the mesh board thru the roller pair. Therefore it's essential to follow the meshing procedure with an eye on the outlet side of the Mesher and if necessary peel away the grafted skin section from the blade roll manually and lay it back on the mesh board.

That works best, if the skin picked up by the blade roll, is still only a small section.

After the mesh board with the on set skin section was worked thru the Mesher, the so called split skin section can be slightly stretched out on the mesh board to easily examine the quality of the graft. The adhesion force prevents the edges of curling up.





The resulting split skin transplant complies with the requirements, when any perforations can be separated and the stretching of the transplant is done effortlessly.
If there are parts at which the perforation has not completely cut through the skin, it is because the counter-pressure on the blade roll was set too low.

8 Cleaning, disinfection and sterilization

The following points are important with regard to caring for the material:

- Perform cleaning, disinfection and sterilization after every treatment!

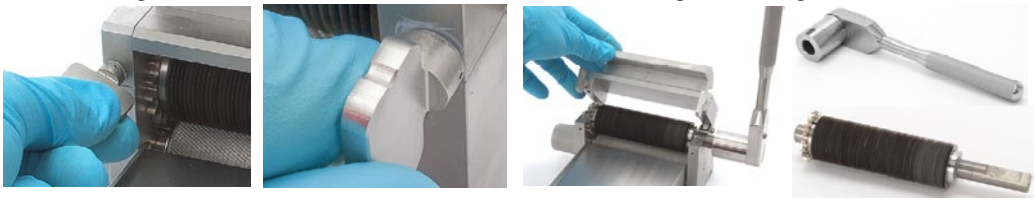
8.1 Mesh boards

- Single use mesh boards may not be reused!
- Mesh boards must be disposed off properly after use!
- Don't use mesh boards when the package was open or damaged.
- Don't use mesh boards when expiry date is timed out.
- Use only mesh boards from Nouvag AG.

8.2 Reprocessing instructions, Mesher

Reprocessing restrictions	Frequent reprocessing of the Mesher has only a limited impact. The end of the product service life is normally determined by wear and damage through use.

INSTRUCTIONS

At location of use	Remove soiling with a disposable cloth/paper towel.
Storage and transport	No special requirements. Due to the risk of drying and corrosion, reprocessing must be performed without undue delay.
Preparation for cleaning	Remove the ratchet. Turn the clamping wing-grips to open the hinged bridge. Remove the blade roll. Remove soiling from Mesher, blade roll and the ratchet under running water using a suitable brush.  Don't put the Mesher in an ultrasonic bath.
Automatic cleaning and disinfection	Equipment: Neutral or alkaline cleaning agent in b recommended concentration. 1. Place Mesher, ratchet and blade roll in a fine meshed basket. 2. Set a cleaning cycle that offers sufficient cleaning and rinsing. Perform the last rinse with deionized water. 3. Perform a 10-minutes rinse cycle at 93°C to facilitate thermal disinfection. 4. When removing the Mescher, the ratchet and the blade roll check to verify whether soiling is still visible in gaps and grooves. If necessary, repeat the cycle or clean manually.
Manual cleaning	Equipment: Neutral or alkaline cleaning agent in the recommended concentration, suitable brush and running water. *Procedure:* 1. Rinse off and brush away surface contaminants from the Mesher, ratchet and the blade roll. 2. Use the brush to apply cleaning agent to all surfaces and gaps. 3. Rinse Mesher, ratchet and blade roll thoroughly under running water.

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Manual disinfection	For manual disinfection place the Mesher, ratchet and blade roll in an RKI*-tested disinfectant. (Action time according to the disinfectant manufacturer's specifications). * RKI disinfectant list (Robert Koch Institute).
Drying	If a drying program is not provided by the washer-disinfector, the Mesher, ratchet and the blade roll have to be dried manually or in a drying cabinet.
Inspection, assembly and maintenance	Perform a visual inspection for damage, corrosion and wear. Treat bearings and bushings with a drop of biocompatible oil. Install blade roll in the Mesher and close the bridge.
Packaging	Individually: Enclose Mesher and ratchet in the Stericase with new paper filter.  
Sterilization	Autoclave in a vacuum autoclave at max. 135°C for at least 5 minutes. When sterilizing several instruments in one sterilization cycle, do not exceed the sterilizer's maximum load. A drying cycle must be added in case of autoclaves without a post-vacuum function. Dry Mesher in the Stericase for at least 1 hour at room temperature. * The temperature hold times are based on the country-specific guidelines and standards.
Storage	No special requirements. If the sterilized Mesher is not used immediately following sterilization, the Stericase must be marked with the sterilization date. It is advisable to add a sterilization indicator. 

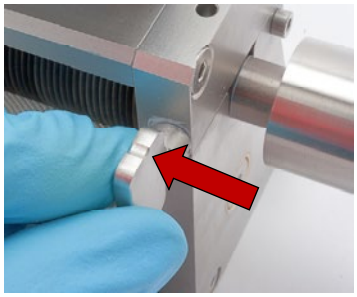
The above-mentioned instructions were validated as suitable from NOUVAG AG. The person accomplishing the treatment is responsible that the treatment that actually took place leads to the desired results in the treatment facility with the available equipment, materials, and personnel. To ensure this it is normally necessary to validate and supervise the process. Each deviation from the instructions provided should be evaluated carefully with regard to effects and negative consequences.

9 Maintenance

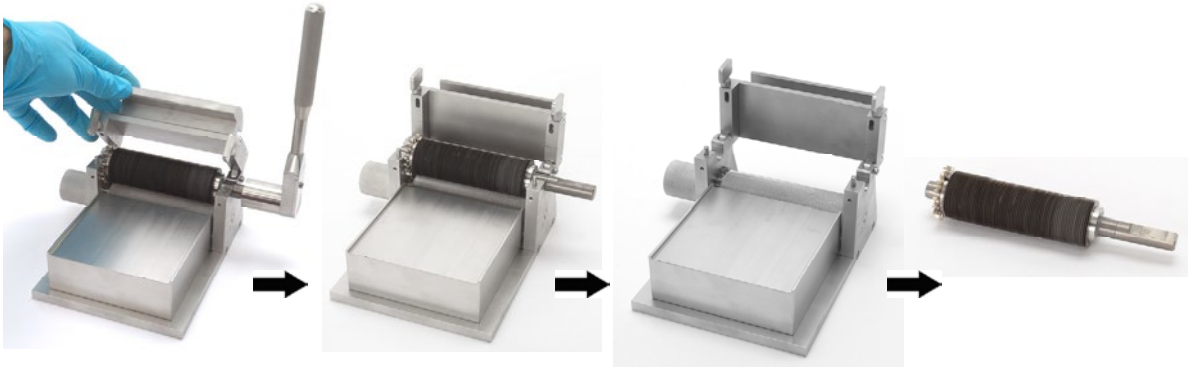
9.1 Blade roll

Depending on the load, the blades of the blade roll are subject to wear. The blades have to be exchanged when the cutting quality slowly declines. If only a few blades are defect, due to accidently have the blade roll fallen down, the blades can all be changed separately.

Replacing the blade roll:



Turn clamping wing pair oppositely, until the notches are visible from the top. The bridge locking is now open.



- Remove the ratchet and hinge the bridge up to the stop.
- Remove blade roll and dispose of properly. Insert new blade roll and close bridge.
- Lock the bridge by turning the clamping wing pair towards each other. The notches point down and are not visible anymore.

- Don’t lay the blade roll on hard surfaces, the blades may be damaged!
- Do not resharpen the blades. The cutting precision will be lost and the backpressure may be lost due to reduced diameter of the blades.

9.2 Information on disposal

When disposing of devices, device parts and accessories, the regulations prescribed by law must be observed.
Do not dispose of devices with household waste. To ensure environmental protection, old devices can be returned to the dealer or manufacturer.

Contaminated single use mesh boards are subject to specific disposal requirements.
Please observe currently valid national disposal regulations for infectious waste.

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10 Malfunction and troubleshooting

Malfunction	Cause	Solution	Reference in the operation manual
Mesh board is not feeding	Roller pair did not catch the mesh board.	Press mesh board with a slight pressure against the roller pair.	7.2 Use of the Mesher
	Backing roll builds up too little backpressure	Adjust pull-twist-knob to a smaller roller distance.	6.2 Device preparation
Split skin transplant can not, or not all the way, be stretched all the way.	Backing roll builds up too little backpressure	Adjust pull-twist-knob to a smaller roller distance.	6.2 Device preparation
Mesh board is worked thru the Mesher but the split skin transplant is not on it.	Split skin transplant got stuck on the blade roll.	After the first pressing of the ratchet check whether the split skin is stuck on the blade roll. Lay the split skin back on the mesh board	7.2 Use of the Mesher

If a fault cannot be rectified, please contact your supplier or an authorized service center. The addresses are provided on the last page of this operation manual.

11 Consumables and spare parts

Parts	Ref.
Skin transplant mesh board with a mesh factor of 1.5 in PU of 20 pieces	1981
Skin transplant mesh board with a mesh factor of 3.0 in PU of 20 pieces	1982
Skin transplant mesh board with a mesh factor of 6.0 in PU of 20 pieces	2105
Skin transplant mesh board with a mesh factor of 9.0 in PU of 20 pieces	2106
Spare blade roll	75591
Non slip silicone mat, 450 x 270 mm	4126
Spare paper filter for Stericase in PU of 100 pieces	4127
Spare ratchet with case	30444
Mesher operation instructions on CD-ROM	31584*

**At Nouvag AG the operation instructions are delivered as a PDF-File on a CD-ROM, together with the according device. If you prefer a printed version of it, we will send you one, free of charge, by postal delivery. If you cannot find the manual anymore, we'll send you a spare one in PDF-Format by E-Mail.*

To order additional parts, please contact our customer service department.

Anhang DE
Appendix EN
Appendice FR
Appendice IT
Apéndice ES

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NOUVAG

Service center

Switzerland

Nouvag AG ▪ St. Gallerstrasse 25 ▪ CH-9403 Goldach
Phone +41 71 846 66 00
info@nouvag.com ▪ www.nouvag.com

CE 0197

Germany

Nouvag GmbH ▪ Schulthaissstrasse 15 ▪ DE-78462 Konstanz
Phone +49 7531 1290-0
info-de@nouvag.com ▪ www.nouvag.com

EC REP

A complete list of Nouvag certified service centers are found on the Nouvag website at:
www.nouvag.com/service

Post market surveillance

In the event of problems with the product or in the event of a serious incident, please immediately download, compile and send the following form

https://nouvag.com/media/attachments/2022/05/19/for_8-308.pdf

as a PDF to this address: **complaint@nouvag.com**

Nouvag AG ▪ St. Gallerstrasse 25 ▪ CH-9403 Goldach
Tel. +41 71 846 66 00
info@nouvag.com ▪ www.nouvag.com

Nouvag GmbH ▪ Schulthaissstrasse 15 ▪ DE-78462 Konstanz
Tel. +49 7531 1290-0
info-de@nouvag.com ▪ www.nouvag.com

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