EN

Instructions for use

Dermatome

NOUVAG

SYMBOLS

General warning sign	Observe instructions for use	Use-by date	Suitable for thermal disinfection
Manufacturer	Date of manufacture	Autoclavable at 134 °C	Separate collection required (WEEE)
REF Catalog number	SN Serial number	LOT Batch code	EC REP Authorized representative in the European Community
Do not use if the package is damaged	Not for reuse	CE 0197 European Conformity mark	

INTENDED PURPOSE

The dermatome including meshgraft knife roller (mesher skin expansion system) is used in skin graft / reconstructive surgery.
The dermatome is used to cut off a skin flap (unprocessed or split-skin graft) on an intact skin surface. In large-area skin grafting, the split-skin graft is mesh-shaped in a mesher to form a perforated mesh graft. The perforated skin flap is then placed on the damaged area of the skin (e.g., after burns).
The dermatome including mesher may only be operated by specialised and trained personnel. The intended use is obvious to the trained user.

CONTRA INDICATIONS

Inappropriate wound ground such as tendons, bones, exposed vessels and nerves, as well as implants.
If the location of the wound is on the flexor side of joints or mechanically stressed body parts such as the heel or neck, as well as in presence of local infections, the surgeon must decide in each case, whether a split skin transplant can be used meaningfully.
Relative or absolute contra indications may arise from general medical diagnosis or in special cases where the patient risk with motor-driven systems is significantly higher.

INTENDED USERS

Intended users are trained and qualified personnel, in professional settings (e.g. hospital, ambulatory).

AMBIENT CONDITIONS	TRANSPORT AND STORAGE	DURING USE
Relative humidity	max. 90 %	max. 80 %
Temperature	0 °C – 50 °C	10 °C – 30 °C
Atmospheric pressure	700 hPa – 1'060 hPa	800 hPa – 1'060 hPa

POSSIBLE COMBINATIONS

REF	CONTROL UNIT	INTENDED USE
3285	TCM 3000 BL	Skin grafting
3390	HighSurg 30	Skin grafting

SAFETY INFORMATION

⚠ The dermatome is supplied by us non-sterile. The dermatome must be cleaned, disinfected and sterilised before first use and immediately after each use!

Prior to using the product, before startup, and before operation, the user must always ensure that the product and accessories are in good working order and are clean, sterile and operational.

Improper use or repair of the product, or failure to observe these instructions, relieves NOUVAG from any obligation arising from warranty provisions or other claims.

⚠ The use of the product other than that for which it was designed is not permitted. The responsibility is solely carried by the operator.

Manipulate the instrument only when the motor is at a standstill.

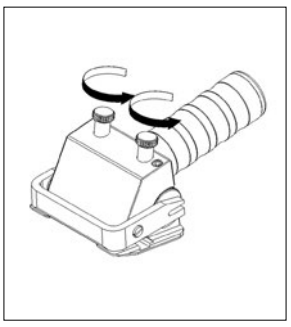
The dermatome shall only be operated by qualified and trained personnel.

Do not clean the dermatome with compressed air!

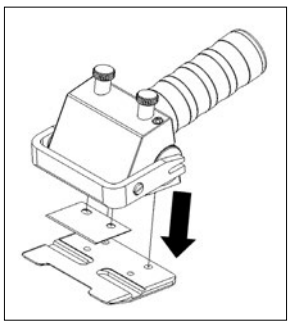
The dermatome may be operated up to a maximum of 14'000 rpm.

USE

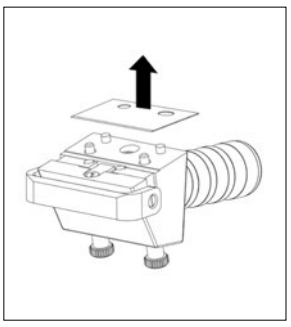
REPLACING THE BLADE



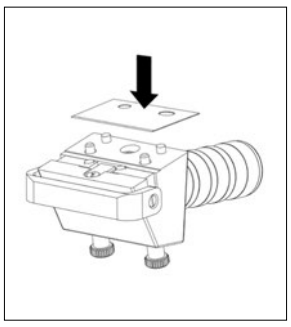
Unscrew both knurled screws at the top of the dermatome head until the base plate is released.



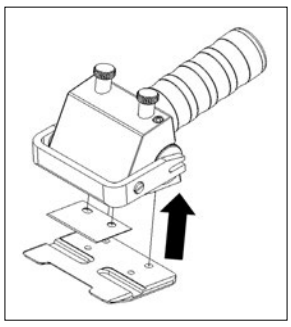
Carefully loosen the base plate from the positioning cams and remove.



Remove the blade and dispose of it properly.

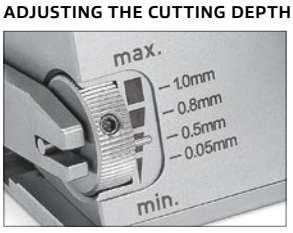


Place a new, sterile blade in the positioning cams.



Place the base plate in the positioning cams and retighten both knurled screws.

ADJUSTING THE CUTTING DEPTH



By turning the knurled wheel at the back of the dermatome the cutting depth can be adjusted between 0.05 mm and 1.00 mm.

REPROCESSING INSTRUCTIONS

⚠ In relation to patients with Creutzfeldt Jakob disease or its variant (vCJK) no responsibility can be assumed for the reuse of the dermatome. The Robert-Koch Institute recommends removing used products from circulation after use in order to avoid infecting other patients, users and third parties.

⚠ Never clean the dermatome in an ultrasonic bath! This impairs the functionality of the dermatome.

Reprocessing restrictions	Frequent reprocessing has only a limited impact on the dermatome. The end of the products service life is normally determined by wear and damage through use. The instrument is designed for 250 sterilization cycles.
General handling	**1.** The dermatome must be thoroughly cleaned, disinfected and sterilised before initial operation (products straight from the factory) and also immediately following each use. Only a cleaned and disinfected dermatome enables correct sterilisation! **2.** The dermatome should always be treated with utmost care when being transported, cleaned, serviced, sterilised and stored. **3.** We recommend the use of mildly alkaline and enzymatic cleaners with as low a silicate content as possible to avoid staining (silicatization) on the dermatome. **4.** Only commercial grade DGHM-/VAH-listed agents may be used for cleaning and disinfection. See these agent manufacturers' specifications for the method of use, action time and suitability of disinfection and cleaning substances. **5.** Operating instructions for the equipment and chemicals etc. used during reprocessing must be strictly followed. **6.** Dosage of chemicals, exposure times and exposure temperatures for cleaning and disinfection must be strictly followed. **7.** The end of product life may be reached before the 250 sterilization cycles in case of excessive wear and damage from use. **8.** Do not overload the washer. Avoid rinsing blind spots. Ensure secure storage in the machine. **9.** Observe the regulations valid in your country for the reprocessing of medical devices. **10.** NOUVAG recommends the use of a screen basket with rinsing bar from 3mach (NOUVAG REF 51401), a reusable container for convenient preparation and storage (including transport) of the products. The screen basket can be used for safe storage of the products during the rinsing process as well as during and after sterilization until the products are used. The screen basket is suitable for use with sterilization paper or a rigid sterilization container. It does not have a barrier effect on its own to protect sterility.
Preparation at the point of use	After surgery immediately remove blood, secretion, tissue and bone residue with a disposable cloth/paper towel, do not allow to dry! Dried residues cause corrosion.
Safe-keeping and transport	Contaminated products must be stored and transported to the preparation site in a closed container to avoid damaging the products and the contamination of the environment.
Cleaning and disinfection, pre-cleaning	**Unscrew the base plate and dispose of the blade properly.** **1.** Wipe the dermatome with a damp disposable cloth / paper towel, removing all visible dirt. **2.** Brush the dermatome under running tap water using a soft brush (e.g. Insitumend GmbH, REF MED100.33). **3.** Rinse the outer surface of the dermatome for 10 seconds with a water pressure gun at a pressure of at least 2.0 bar (e.g. HEGA Medical, REF 6010 or REF 7060). Local tap water is sufficient for this purpose, since the last step is always a machine cleaning with deionized water, so possibly hard water with lime traces from the pre-cleaning cannot remain on the dermatome.

Cleaning	**Mechanical cleaning** **1.** After pre-cleaning, place the dermatome on a suitable attachment. Place the small parts in the strainer basket. **2.** Mechanical cleaning is only successful if the pre-cleaning, described above, is adhered to! **3.** Cleaning is done using the Vario TD programme in the cleaning and disinfection unit (CDU). For the cleaning process it is advisable to use DI water (fully desalinated water). **4.** After completing the cleaning program (incl. thermal disinfection) check the dermatome for visible contamination in the grooves and gaps. Repeat cleaning if necessary.	**Automatic cleaning process (Vario TD programme)** **1.** Pre-clean with cold water for 4 minutes. **2.** Empty **3.** Clean for 5 minutes at 55 °C with 0.5% alkaline or at 40 °C with 0.5% enzymatic cleaner. **4.** Empty **5.** Neutralise with cold water for 3 minutes. **6.** Empty **7.** Inter-rinse for 2 minutes with cold water. **8.** Empty
Disinfection	**Mechanical disinfection** The cleaning/disinfection unit has a thermal disinfection programme which follows after the cleaning. When performing mechanical thermal disinfection, give due consideration to the national requirements relating to the A0 value (see DIN EN ISO 15883-1). We recommend an A0 value of 3.000 for the dermatome. Disinfection must be carried out with DI water.	**Warning** When inadequately rinsed or exposed to the disinfectant or detergent for too long, the dermatome can corrode. Please see the corresponding detergent and disinfectant's package insert for dwell times.
Drying	**Mechanical drying** Drying of the dermatome through the drying cycle of the cleaning/disinfection unit's (CDU). If required, manual drying can also be achieved by using a lint-free cloth. Pay particular attention to the grooves and spaces between the dermatome. Then spray the dermatome again with Lubrifluid. Every CDU must provide a corresponding drying procedure through the manufacturer (see ISO 15883-1). Please follow the corresponding CDU-manufacturer's directions and operating instructions.	**Manual drying** Set up the dermatome vertically so that water can run out more easily. Allow the dermatome to dry for at least 30 minutes. Then spray the dermatome again with Lubrifluid.
Inspection and care	**1.** Carry out a visual inspection for damage, corrosion and wear. **2.** After cleaning and disinfecting, spray the dermatome with lubricant spray and wipe with a lint-free cloth moistened with DI water (see instructions on spray can).	
Sterilisation	Sterilisation of the products is performed with a fractionated pre-vacuum steam sterilisation process (in accordance with DIN EN 13060 / DIN EN 285) giving due consideration to the respective national requirements. **Minimum requirements:** **1.** Pre-vacuum phases: 3 **2.** Sterilisation temperature: minimum 132 °C – maximum 137 °C (within the sterile band) **3.** Holding time: At least 5 minutes (full cycle) **4.** Drying time: At least 10 minutes When sterilising several products during one sterilisation cycle, do not exceed the maximum steriliser load (see manufacturer's details). A drying cycle must be added in the case of autoclaves without a vacuum function. After sterilisation an immaculate sterilisation result must be detected by examining the appropriate indications. According to the Robert-Koch Institute preparation ends with the documented release for use of the medical device. If the sterilised dermatome is not used immediately after sterilisation, it must be labelled with the sterilisation date on the packaging.	
Storage	**Storing the sterile packaging** The sterilised product must be stored away from dust, humidity and contamination. During storage, direct sunlight should be safely avoided. After the expiry date has passed, do not use the product any longer.	**Handling the sterile packaging** Before taking out the product, check for the packaging to be intact. When taking out the product, follow the respective aseptic procedures.
Information for validating the preparation	The above preparation process has been verified by a validated procedure. **The following materials and machines were used:** **1.** Alkaline cleaner: Neodisher® Mediclean; Chemische Fabrik Dr. Weigert GmbH & Co. KG **2.** Enzymatic cleaner: Neodisher® MediZyme; Chemische Fabrik Dr. Weigert GmbH & Co. KG **3.** Cleaning and disinfection unit: Miele G 7836 CD **4.** Rack trolley: Miele E429 **5.** Strainer basket/flush socket bar: 3mach (NOUVAG REF 51401) **6.** Autoclave: Selectomat 666-HP (MMM) **7.** Sterile packaging: Sterisheet 100; Broemeda Amcor Flexibles GmbH Chemicals and machines other than those mentioned can also be used. In such a case consult the manufacturers or suppliers to find out whether their products confer the same performance as the products that the procedure was validated with. If you should opt for a different procedure for reprocessing to the one given above, you are required to correspondingly establish the suitability.	

There is no experience available from conducting other sterilisation procedures such as plasma sterilisation, low temperature sterilisation procedure, etc. Users bear full responsibility if they use a procedure which differs from the validated sterilisation procedure described!

Please also comply with the applicable legislation in your country and the medical practice or hospital's hygiene rules. This especially applies to the varying requirements for an effective inactivation of prions.

MALFUNCTIONS AND TROUBLESHOOTING

PROBLEM	CAUSE	SOLUTION
Motor runs, but blade does not move.	Dermatome is not optimally coupled to motor.	Press the dermatome onto the motor until it snaps into place. Check the seat with a counter movement.
Dermatome does not run smoothly.	Blade is not optimally clamped.	Align the blade correctly.
Dermatome is loud.	Dermatome is poorly lubricated or dirty.	Spray the dermatome with lubricant spray.

ACCESSORIES AND SPARE PARTS

REF	DESCRIPTION
1919	Spare blade for Dermatome 100, PU 10 pcs.
1995	Spare blade for Dermatome 75, PU 10 pcs.
19869	Rreduction base plate to 25 mm, for Dermatome 100
19871	Rreduction base plate to 50 mm, for Dermatome 100
19872	Rreduction base plate to 75 mm, for Dermatome 100
19886	Rreduction base plate to 25 mm, for Dermatome 75
19887	Rreduction base plate to 50 mm, for Dermatome 75
1986nou	Mesher skin expansion system
1981	Skin transplant mesh board, 1.5:1, PU 20 pcs.
1982	Skin transplant mesh board, 3.0:1, PU 20 pcs.
2105	Skin transplant mesh board, 6.0:1, PU 20 pcs.
4131	Sterilisation basket for dermatome and accessories
4133	Lid for sterilisation basket

INFORMATION ON DISPOSAL

When disposing of the device, device components and accessories, the regulations issued by the legislator must be followed.
Used electrical and electronic equipment is hazardous waste and must not be disposed of with household waste.

TECHNICAL DATA

REF	1990nou	1983nou
		
Description	Dermatome 75	Dermatome 100
Cutting width	75 mm	100 mm
Cutting depth (+0.1 mm/0 mm)	0.05 mm – 1.00 mm	0.05 mm – 1.00 mm
Torque max.	6 Ncm	6 Ncm
Speed (set)	14'000 rpm	14'000 rpm
Coupling	ISO 3964	ISO 3964
Weight	560 g	700 g

POST MARKET SURVEILLANCE

In the event of incidents related to the use of the medical device, please contact immediately the manufacturer by email complaint@nouvag.com or by phone.

To provide adequate information, please compile the incident questionnaire at the web address
Nouvag.com > Contact us > Incident questionnaire.

MANUFACTURER AND SERVICE POINTS

Switzerland
NOUVAG AG
St. Gallerstrasse 25
9403 Goldach

Phone +41 71 846 66 00
info@nouvag.com
nouvag.com

Germany
NOUVAG GmbH
Schulthaissstrasse 15
78462 Konstanz

Phone +49 7531 1290-0
info-de@nouvag.com
nouvag.com

A complete list of NOUVAG certified service points are found on the NOUVAG website:
Nouvag.com > Service