EN

Operating Instructions

Dermatome

Ref. 31895 EN, V23/21

Intended use and operation

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 knowledgeable and trained personnel. The intended use is obvious to the trained user.

Contra indications/Limitations

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.

Technical data

134 °C				
Reference number:	1992nou	1991nou	1990nou	1983nou
Designation:	Dermatome 25	Dermatome 50	Dermatome 75	Dermatome 100
Coupling motor side, norm:	ISO 3964	ISO 3964	ISO 3964	ISO 3964
Speed (set):	14,000 rpm	14,000 rpm	14,000 rpm	14,000 rpm
Cutting width:	25 mm	50 mm	75 mm	100 mm
Cutting depth (tolerance 0/+0,1 mm):	0,05 – 1,00 mm	0,05 – 1,00 mm	0,05 – 1,00 mm	0,05 – 1,00 mm
Maximum torque:	6 Ncm	6 Ncm	6 Ncm	6 Ncm
Weight:	330 g	420 g	560 g	700 g

Manufacturer and service providers

Switzerland

Nouvag AG · St.Gallerstrasse 25 · CH-9403 Goldach
Tel. +41 (0) 71 846 66 00
info@nouvag.com · www.nouvag.com

CE 0197

Germany EC REP
Nouvag GmbH · Schulthaißstrasse 15 · D-78462 Konstanz
Tel. +49 (0) 7531 1290-0 · Fax +1 (0) 7531 1290-12
info-de@nouvag.com · www.nouvag.com

USA
Nouvag USA · 5986 Highway 144 · Walnut Springs, Texas 7690, USA
Phone +1 817 887-9814 · Fax +1 817 887-9817 · Toll free (800) 673 7427
info@nouvagusa.com · www.nouvagusa.com

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Instructions on disposal

Local, national regulations must be observed when disposing of instruments. Do not dispose of instruments with household waste. Observe the national regulations for the disposal of infectious waste.

Safety instructions

Your safety, that of your team and your patients' is our prime concern. It is therefore vital to observe the following instructions.

⚠	The instrument is not delivered in sterile condition! The Dermatome has to be cleaned, disinfected and sterilized prior first use and immediately after each use.	⚠	Improper use and repair of the device as well as not complying with the instructions relieve us from any obligations regarding guarantee or other claims.
⚠	Don't clean instrument with compressed air.	⚠	The Dermatome may only be operated with speeds up to 14'000 rpm.
⚠	Never manipulate instrument with a running motor due to the risk of injuries.	⚠	The instrument may be operated by trained and experienced personnel only.
⚠	Attach instrument to the motor only when the motor is standing still.		

Explanation of symbols

	Pay attention to the accompanying documents	EC REP	European autorized representative		Do not use when packaging is damaged
⚠	Warning	SN	Serial number		Do not reuse
134°C	Autoclavable at 134°C	REF	Reference number (Order number)		Date of expiry
	Suitable for thermal disinfection	LOT	LOT number		Manufacturer

Spare parts and accessories

***REF 1919**, PU 10 pieces*
Spare blade for Dermatome 100

***REF 1995**, PU 10 pieces*
Spare blade for Dermatome 75

***REF 1996**, PU 10 pieces*
Spare blade for Dermatome 50

***REF 1997**, PU 10 pieces*
Spare blade for Dermatome 25

***REF 3285**, TCM 3000 BL*
Set of control unit with electronic motor and pedal.

***REF 1986nou**, Mesher,*
Skin expansion system

Skin transplant mesh boards	Expansion relation	VE*	REF
1.5 : 1 carrier plates	1.5 : 1	20 Ex.	1981
3.0 : 1 carrier plates	3.0 : 1	20 Ex.	1982
6.0 : 1 carrier plates	6.0 : 1	20 Ex.	2105

**VE: Verpackungseinheit*

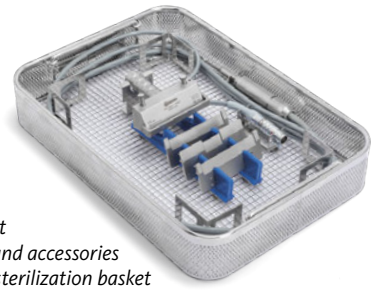
REF 19872
Dermatome 100 reduction base plate to 75 mm

REF 19871
Dermatome 100 reduction base plate to 50 mm

REF 19869
Dermatome 100 reduction base plate to 25 mm

REF 19887
Dermatome 75 reduction base plate to 50 mm

REF 19886
Dermatome 75 reduction base plate to 25 mm

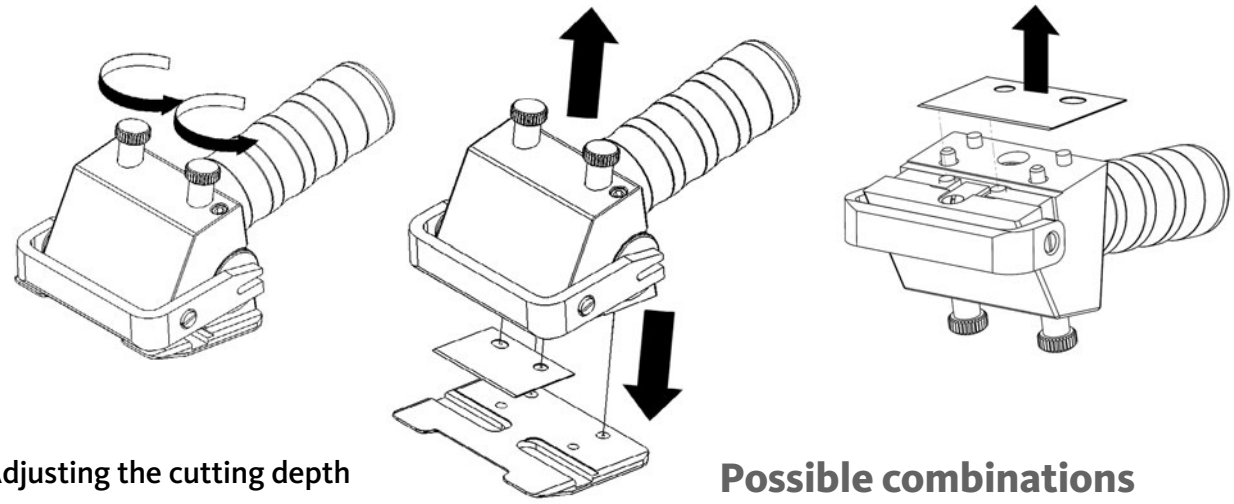


***REF 4131**,*
Sterilization basket for Dermatomes and accessories
***REF 4133**, Lid for sterilization basket*

Operation

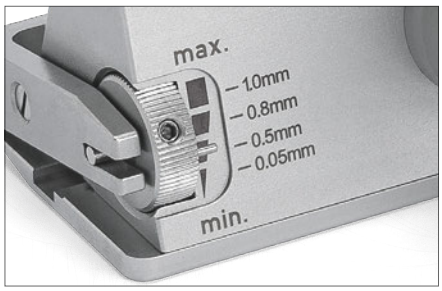
Replacing the blade

1. Unscrew both knurled screws at the head of the Dermatome.
2. Take off the base plate.
3. Remove the old blade and dispose of properly.
4. Place the new, sterile blade on the fitting cams.
5. Place the base plate on the fitting cams and tighten the 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 and 1.00 mm.



Possible combinations

Dermatome handpieces
25 REF 1992nou; 50 REF 1991nou; 75 REF 1990nou; 100 REF 1983nou
are exclusively used:

- in combination with the surgery motor system TCM 3000 BL (REF 3285), which controls the Dermatome handpiece via the upstream electronic motor and enables the setting of the speed, according to the use.
- in combination with the surgery motor system HighSurg 30 (REF 3390), which controls the Dermatome handpiece via the upstream electronic motor and enables the setting of speed according to the use.

Wrong combination of products
Damage to the product and injury to the patient, user or third parties are possible.

- Only use the different products together if the purpose and the relevant technical data, such as working lengths, diameters, and so on match.
- Always follow the instructions for use of the products used in combination.

Troubleshooting

Error	Cause	Solution
Motor is running but the blade doesn't move	Dermatome is not correctly coupled	Press Dermatome firmly against the motor. Check for proper seating.
Instrument runs irregularely	Blade is not clamped correctly	Adjust the blade correctly.
Instrument is noisy	Dirty or badly lubricated	Spray 3 seconds with Nou-Clean spray

Ambient conditions

	Transport and storage:	Operation:
Relative humidity:	10 % – 90 %	Max. 80 %
Temperature:	0°C – 60°C	10°C – 30°C
Atmospheric pressure:	700 hPa – 1060 hPa	800 hPa – 1060 hPa

Reprocessing instructions

Reprocessing restrictions

Frequent reprocessing has only a minor impact on the Dermatome. The end of the product's service life is normally determined by wear and damage through use. The Dermatome is designed for 500 sterilization cycles.

General handling

1. The Dermatomes must be thoroughly cleaned, disinfected and sterilized before initial operation (products straight from the factory) and also immediately following each use. Only a cleaned and disinfected instrument permits proper sterilization!
2. The Dermatomes must always be treated with utmost care when being transported, cleaned, serviced, sterilized and stored.
3. We recommend the use of mild alkaline and enzymatic cleaners with as low a content of silicate as possible in order to avoid staining (silicatisation) of the instruments.
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. Follow precisely the operating instructions of the devices and chemicals, used during preparation.
6. Adhere exactly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection.
7. Due to excessive wear and damage through use the end of the Dermatomes service life can be reached before the 500 sterilization cycles.
8. Do not overload washer. Avoid rinsing obstacles. Pay attention to secure storage in the machine.
9. Follow the applicable regulations in your country for reprocessing medical devices.
10. Don't clean the Dermatomes in an ultrasonic bath. It would lead to the impairment of its functionality.
11. Nouvag AG recommends using a screen basket for small parts, a re-usable container for comfortable preparation and storage (including transport) of the products. The screen basket can be used to keep products safe both during the rinsing cycle and also during and after sterilisation until the products are used. The screen basket is suitable for use with sterilization paper or a rigid sterilization container. It has no barrier effect itself in order to maintain sterility.

Attention!

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

Storage and transport

The Dermatomes must be wet treated immediately after use. This means that the Dermatomes are to be transported moist in a closed container so that no residues can dry on the Dermatomes. Safe storage and transport for reprocessing the Dermatomes must be ensured in order to avoid damage. The preparation must take place promptly (< 4 hours).

Disassembly and preparation for decontamination

Unscrew the base plate and dispose of the blade properly. If possible, the products must be dismantled before the subsequent reprocessing steps or, when opened, sent to the further reprocessing steps. Avoid rinsing obstacles. The Dermatomes are prepared in suitable screen baskets in an automatic cleaning process. To do this, fix the Dermatomes in the cleaning basket with a safe distance. Overlapping with each other is to be avoided in order to exclude damage to the products by the cleaning process.

Cleaning

Mechanical cleaning

1. Place attachments such as base plates and cnurled screws in an ultrasonic bath containing alkaline cleaner with a sonication time of 10 minutes and a frequency of 35 kHz. The instructions of the cleaning agent manufacturer must be followed.
2. Place the main body of the Dermatomes for 15 minutes in an immersion bath with enzymatic cleaner.
3. Then rinse under running water with a soft brush . Thoroughly rinse out cavities and lumens, if present, with a water pressure gun (or similar) (> 30 Sek.).
4. To remove cleaning agent, rinse the products under running tap water (> 15 Sek.).

Automatic cleaning process (Miele G7835 CD)

1. Pre-clean for 1 minute with cold tap water at < 40°C, drain the water.
2. Pre-clean for 3 minutes with cold tap water at < 40°C, drain the water.
3. Five minute cleaning at **55°C (± 5°C) with 0.5 % alkaline detergent** or **0.5 % Neodisher® Mediclean forte**, drain the water.
4. Neutralize for 3 minutes (Neodisher® Z) with cold tap water at < 40°C, drain the water.
5. Intermediately rinse for 2 minutes with cold deionized water.

The specific instructions of the manufacturer of the cleaning machine must be observed!

Disinfection

Manual disinfection

1. Immerse the dermatome in an RKI (Robert Koch Institute) or VAH (Verbund für angewandte Hygiene)-listed disinfectant. It must be ensured that the disinfectant really reaches all areas of the product. Moving parts are to be operated. The process is validated with the following disinfectant: 3 % DESOMEDAN ID. Contact time: 15 minutes. The instructions of the disinfectant manufacturer must be followed.
2. Rinsing of the products (complete rinsing inside, outside and cavities) in deionized water (> 15 sec.)

Automatic disinfection (Miele G7835 CD)

Automatic, thermal disinfection in washer-disinfector, taking into account the national requirements of the A0-3000 value, > 5 minutes at 92°C (± 2°C), demineralised water, drainage.

Drying

Manual drying with a lint-free cloth. In order to largely avoid water residues in cavities, it is recommended to blow them out with sterile compressed air.

Automatic drying according to automatic drying process of the washer-disinfector for 30 minutes at 60°C (± 5°C). Never expose the product to heat above 140°C! Possibly let follow manual drying with a lint-free cloth and blow out lumen using sterile, oil-free compressed air.

Maintenance, inspection and testing

Perform a functional test and check for contamination. If necessary, repeat the cleaning and disinfection steps. Perform a visual inspection for damage, corrosion and wear. Maintain the Dermatome with a 3 second burst of NouvaOil spray. Wipe off excess care product with a damp cloth.

Packaging

Pack the Dermatome handpiece in an individual sterile packaging. The bag must be large enough so that the seal is not under tension. It is advisable to enclose a sterility indicator. Sets: Sort dermatome handpieces into trays provided for this purpose or place on all-purpose sterilization trays.

Sterilization

Sterilize the Dermatome using a fractioned pre-vacuum process (according to DIN EN ISO 17665-1), taking into account the respective national requirements. We recommend a fractioned pre-vacuum process with the following parameters: 134°C / 273.2°F, ≥ 5 minutes holding time, 3 pre-vacuum cycles, drying time: at least 10 minutes. Flash sterilization is unsuitable for products with lumen !

Storage

Store sterile products in suitable packaging and in a dry, clean and dust-free environment, protected from damage. If the sterilized Dermatome handpiece is not used immediately after sterilization, the sterile packaging must be labeled with the sterilization date.

Information on the reprocessing validation

The above mentioned reprocessing instructions were proven by a validation. The following materials and machines were used:

1. Alkaline cleaner: Neodisher® Mediclean; Chemical factory Dr. Weigert GmbH & Co. KG
2. Enzymatic cleaner: Neodisher® MediZyme; Chemical factory Dr. Weigert GmbH & Co. KG
3. Washer-disinfector: Miele G 7836 CD
4. Insert trolley: Miele E429
5. Steam sterilizer: Selectomat 666-HP (MMM)
6. Sterile packaging: Sterisheet 100; Broemeda Amcor Flexibles GmbH

Chemicals and machines other than those mentioned can also be used. In this case you agree with the manufacturers or suppliers whether their products provide the same performance as the products with which the process was validated. If you decide to use a different reprocessing method than the one mentioned above, it is your duty to prove suitability accordingly.

Note

There are no empirical values with regard to the implementation of other sterilization processes, such as plasma sterilization, low-temperature sterilization processes, etc. The user bears full responsibility when using a method other than the validated sterilization method described!

Attention!

Please also observe the legal provisions applicable in your country and the hygiene regulations of the doctor's practice or hospital. This applies in particular to the different requirements for effective prion inactivation.