EN

Operating Instructions

Dermatome

Ref. 31895 EN, V18/19

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 on the flexor sides of joints or mechanically stressed body parts such as the heel or neck, as well as 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

135°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

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Safety instructions

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

⚠	Das Instrument wird von uns unsteril ausgeliefert. Vor dem erstmaligen Einsatz und sofort nach jedem Gebrauch muss das Dermatom gereinigt, desinfiziert und sterilisiert werden.	⚠	Unsachgemäßer Gebrauch des Instruments, sowie Nichteinhaltung unserer Anweisungen, entbindet uns von jeder Garantieleistung und anderen Ansprüchen.
⚠	Instrument nicht mit Druckluft reinigen.	⚠	Das Instrument darf nur mit 14'000 U/min. betrieben werden.
⚠	Manipulationen am Instrument nie mit laufendem Motor durchführen, wegen Verletzungsgefahr.	⚠	Das Instrument darf ausschließlich von fachkundigem und geschultem Personal verwendet werden.
⚠	Das Instrument darf ausschließlich bei stillstehendem Motor aufgesetzt werden.	⚠	

Explanation of symbols

	Pay attention to the accompanying documents	CE 0197	CE mark with Notified Body		Do not use when packaging is damaged
⚠	Warning	SN	Serial number		Do not reuse
135°C	Autoclavable at 135°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	Expansions-Faktor	VE*	REF
1.5 : 1 Trägerplatte	1.5 : 1	20 Ex.	1981
3.0 : 1 Trägerplatte	3.0 : 1	20 Ex.	1982
6.0 : 1 Trägerplatte	6.0 : 1	20 Ex.	2105

**VE: Verpackungseinheit*

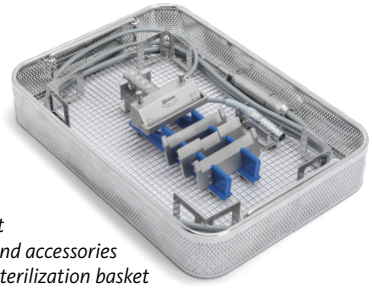
REF 19872
Dermatome 100 reduction base plate to 75 mm

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

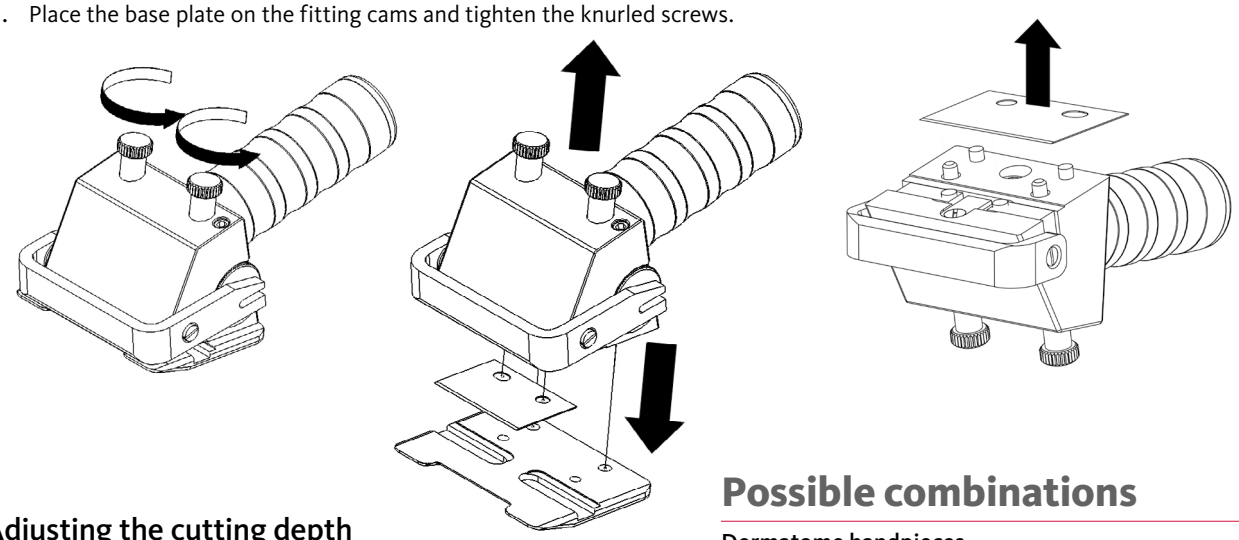


***REF 4131**,*
Sterilization basket for Dermatomes and accessories
***REF 4133**, Lid for sterilization basket*

Operation

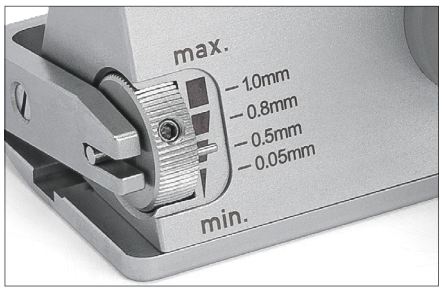
Replacing the blade

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 expertly.
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:	Max. 90 %	Max. 80 %
Temperature:	0°C – 60°C	10°C – 30°C
Athmospheric pressure:	700 hPa – 1060 hPa	800 hPa – 1060 hPa

Preparation instructions

Reprocessing restrictions	Frequent repeated preparation only has 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	Remove surface contaminants with a disposable cloth/paper towel immediately after each use. After submerge in cold water (< 40°C). Don't use warm water (> 40°C) or fixating disinfectants.	
Storage and transport	Wet the products immediately after use. This means that the products are to be transported moist in a closed container, so that no residues on the products can dry up. Safe storage and safe transport to prepare the dermatome must be ensured to avoid damage. The preparation should be carried out promptly (< 4 hours).	
Disassembly and preparation for decontamination	If possible, the products are to be dismantled before the subsequent preparation steps or, when open, sent to the further preparation steps. Rinse shadows are to be avoided. The Dermatome must be prepared in suitable baskets or rinse dishes. The dermatomes should be fixed in the cleaning basket with a minimum distance to each other. Overlap is to be avoided in order to prevent damage to the products during the cleaning process. Unscrew the base plate and dispose of blade properly.	
Cleaning	**Manual cleaning process** 1. Submerge Dermatoms in an ultrasonic bath with an alkaline cleaner (0.5 % Neodisher® MediClean forte) with a sonication time of 10 minutes and a frequency of 35 kHz. Follow the instructions of the detergent manufacturer. 2. Completely clean the dermatomes with a soft brush. Thoroughly flush (> 30 seconds), if present, cavities and lumens, with a water pressure gun (or equivalent). 3. Rinse the products under running tap water to remove the detergent (> 15 seconds).	**Automatic cleaning process (Miele G7835 CD)** 1. Pre-clean for 1 minute with cold tap water < 40°C, drain water. 2. Pre-clean for 3 minutes with cold tap water < 40°C, drain water. 3. Five minutes of cleaning at 55°C (± 5°C) with 0.5 % alkaline detergent (0.5 % Neodisher® Mediclean forte), drain water. 4. Neutralize for 3 minutes (Neodisher® Z) with cold tap water < 40°C, drain water. 5. Rinse 2 minutes with cold deionized water. 6. The special instructions of the manufacturer of the cleaning machine are to be observed!
Disinfection	**Manual disinfection** Equipment: neutral or alkaline cleaning agent, soft brush, running water: 1. Rinse and brush away surface contaminants from the Dermatome. 2. Use a brush to apply cleaning agent to all surfaces and gaps. 3. Rinse the Dermatome thoroughly under running water.	**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 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	If a drying programme is not provided by the washer-disinfector, the Cranial Perforator Handpiece must be dried manually or in a drying cabinet.	
Maintenance, inspection and testing Ref. 1958 	Perform a functional test and check for contamination. If necessarry repeat the cleaning and disinfection cycles. Perform a visual inspection for damage, corrosion and wear. Maintain the dermatome by spraying it with NouClean spray with attached spray adapter (REF 1958) for approx. 3 seconds. Wipe off excess liquid with moistened cloth. 	
Packaging	Individually: Pack Dermatome handpiece in individual packaging for sterile items. The bag must be large enough to ensure that the seal is not under tension. Sets: Sort Dermatome handpieces onto trays intended for the purpose or place on all-purpose sterilization trays.	
Sterilization	Autoclave in the vacuum autoclave at 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 the case of autoclaves without a post-vacuum function. Dry the Dermatome handpiece in the bag with the paper side facing upwards at room temperature for at least one hour. * The temperature hold times are based on the country-specific guidelines and standards.	
Storage	No special requirements. If a sterilised Dermatome handpiece is not used immediately following sterilization, the packaging needs to be marked with the sterilization date. It is advisable to add a sterilization indicator.	

The above-indicated instructions were validated by NOUVAG AG as being suitable for preparing a medical device to be reused.
The preparer is responsible for ensuring that the actually performed preparation involving the equipment, materials and personnel used in the preparation facility achieves the desired results. This normally requires validation and routine monitoring of the procedure. Likewise, each deviation from the provided instructions should be carefully analyzed for its effect and potential detrimental consequences.

Instructions for disposal

Bei der Entsorgung von Instrumenten müssen lokale, landesübliche Vorschriften beachtet werden. Instrumente nicht mit dem Hausmüll entsorgen. Beachten Sie die landesüblichen Vorschriften zur Entsorgung von infektiösem Müll.