EN

Instructions for use

Handle with Conform cannula handpiece

NOUVAG

SYMBOLS

General warning sign	Warning! Hot surface	Observe instructions for use	Note
Manufacturer	Date of manufacture	Autoclavable at 134°C	Separate collection required (WEEE)
LOT Batch code	REF Catalog number	SN Serial number	EC REP Authorized representative in the European Community
Suitable for thermal disinfection	Not for reuse	CE 0197 European Conformity mark	

INTENDED PURPOSE

MEDICAL INDICATIONS

The handle with Conform cannula handpiece, in conjunction with the integrated suction device, ensures the vibration movement of the attached liposuction cannula, loosening and splitting the fatty tissue, while simultaneous suction of the detached fat cells.

CONTRA INDICATIONS

// Infectious wounds – Liposuction may only be performed after the treatment of the infection and necrotic tissue.
// In principle, generally poor health of the patient.
// Liposuction shortly after a strict diet of the patient.
// Morbid obesity – Large suction volumes increase the risk of death due to fluid shifts.
// Intravascular infusion of liquids.

Relative or absolute contraindication may result from the general patient status or the risks of anesthesia related to the treatment. Relevant cases in the literature must be taken into consideration.

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

SAFETY INFORMATION

⚠ Handle, handpiece, cannula adapter and closure are delivered in a non-sterile condition. These parts must be cleaned, disinfected and sterilized before initial use and immediately after each use!

The handpiece is able to a maximum speed of 12.000 rpm.

Attache the handpiece to the motor only when it's standing still.

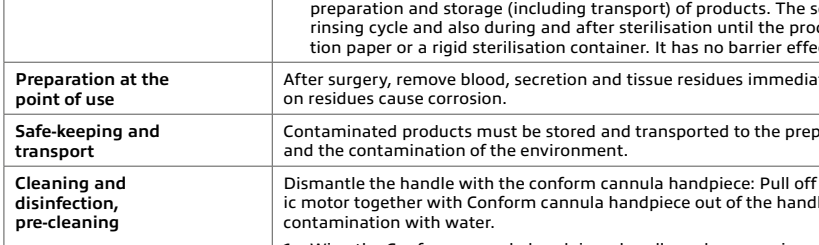
Perform manipulations on the product only when the motor is at a standstill.

⚠ Any guarantees on our part or other claims against us become void in the case of inappropriate use of the handpiece or failure to comply with our instructions!

In extreme cases the handpiece may heat up excessively.

The handpiece may only be used by competent and trained personnel.

OVERVIEW

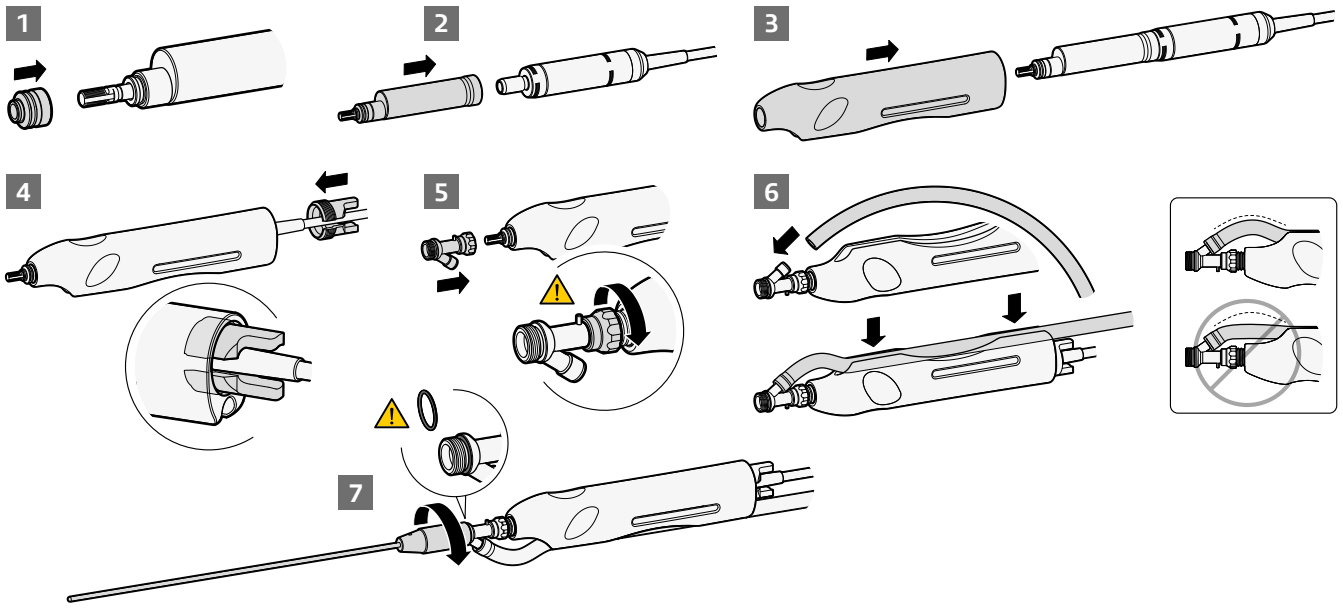


POSSIBLE COMBINATIONS

REF	CONTROL UNIT	INTENDED USE
4179-115	Vacuson 60 LP (115 V)	Liposuction
4179-230	Vacuson 60 LP (230 V)	Liposuction
3392	LipoSurg	Liposuction

OPERATION

PREPARING THE HANDLE WITH CONFORM CANNULA HANDPIECE



REPROCESSING INSTRUCTIONS

⚠ Avoid long waiting times before reprocessing because of the risk of drying and corrosion. Keep the products moist after use so that contamination cannot dry on. The time interval between use and preparation of the products should not exceed 2 hours..

Reprocessing restrictions	Frequent reprocessing has only a limited impact on the product. 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 product must be thoroughly cleaned, disinfected and sterilised before first use (new products from the factory) and immediately after each use. Only a cleaned and disinfected product enables correct sterilisation! **2.** The product should always be handled with the utmost care during transport, cleaning, care, sterilization and storage. **3.** We recommend the use of mildly alkaline and enzymatic cleaners with the lowest possible silicate content to avoid staining (silicatisation) on the product. **4.** Only commercially available, DGHM/VAH-listed agents may be used for cleaning and disinfection. The method of use, duration of action and suitability of disinfectants and cleaning agents are to be taken from the information provided by the manufacturers of these agents. **5.** Operating instructions for the equipment and chemicals etc. used during reprocessing must be strictly adhered to. **6.** Dosage of chemicals, exposure times and exposure temperatures for cleaning and disinfection must be strictly observed. **7.** In the event of excessive wear and damage from use, the end of the product life may be reached even before the 250 sterilisation cycles. **8.** Do not overload washer. Avoid rinsing blind spots. Pay attention to secure storage in the machine. **9.** Follow the applicable regulations in your country for reprocessing medical devices. **10.** Handle and accessories may be cleaned in an ultrasonic bath. However, the Conform cannula handpiece must not be cleaned with ultrasound! This will impair the functionality. **11.** NOUVAG recommends using a screen basket with a rinse strip from 3mach (REF 08-21-1), a re-usable container for comfortable preparation and storage (including transport) of 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 sterilisation paper or a rigid sterilisation container. It has no barrier effect itself in order to maintain sterility.
Preparation at the point of use	After surgery, remove blood, secretion and tissue residues immediately with a disposable cloth/paper towel, do not allow to dry! Dried-on 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	Dismantle the handle with the conform cannula handpiece: Pull off suction tube, unscrew liposuction cannula and closure, pull electronic motor together with Conform cannula handpiece out of the handle and remove tube holding clips from motor cable. Wash off visible contamination with water. **1.** Wipe the Conform cannula handpiece, handle and accessories with a damp disposable cloth/paper towel, removing all visible dirt. **2.** Brush the Conform cannula handpiece, handle and accessories with a sufficiently large, soft round brush under water in cleaning solution. **3.** Rinse the Conform cannula handpiece, handle and accessories for 10 seconds from the outside with a water pressure gun (with a min. pressure of 2.0 bar). Local tap water is sufficient for this, as the last step is always mechanical cleaning with deionised water and any hard water with traces of limescale from pre-cleaning cannot remain on the handpiece.

Cleaning	**Mechanical cleaning** 1. Conform cannula handpiece, handle and accessories are inserted into the strainer basket after pre-cleaning. 2. Mechanical cleaning is only successful after following the pre-cleaning described above! 3. Cleaning is done using the Vario-TD programme in the washer-disinfector (WD). The use of deionised water (fully demineralised water) is recommended for the cleaning process. 4. After completion of the cleaning programme (incl. thermal disinfection), check the Conform cannula handpiece, handle and accessories for visible contamination in grooves and gaps. Repeat cleaning if necessary.	**Automatic cleaning process (Vario-TD program)** 1. Pre-clean for 4 minutes with cold water (<40°C). 2. Empty 3. Clean for 5 minutes at 55°C with 0.5% alkaline cleaner or at 40°C with 0.5% enzymatic cleaner. 4. Empty 5. Neutralise for 3 minutes with cold water (<40°C). 6. Empty 7. Inter-rinse for 2 minutes with cold water (<40°C). 8. Empty
Disinfection	**Mechanical disinfection** The washer/disinfector has a thermal disinfection programme which follows after the cleaning. The mechanical thermal disinfection must be carried out taking into account the national requirements regarding the A0 value (see DIN EN ISO 15883-1). We recommend an A0 value of 3.000 for the Conform cannula handpiece. Disinfection must be carried out with DI water.	**⚠ Warning** When inadequately rinsed or exposed to the disinfectant or detergent for too long, the instrument can corrode. Please see the corresponding detergent and disinfectant's package insert for dwell times.
Drying	**Mechanical drying** The products are dried by the drying cycle of the WD. If necessary, additional manual drying can be achieved with the help of a lint-free cloth. Pay particular attention to the grooves and spaces between the instruments. Each WD must provide an appropriate drying procedure on the part of the manufacturer (cf. DIN EN ISO 15883-1). Please follow the corresponding instructions and instructions for use of the manufacturer of the WD.	**Manual drying** Place the products vertically, separated from the attachments, to encourage liquid to flow out. Allow the products to dry for at least 30 minutes.
Manual cleaning	1. After pre-cleaning, place the Conform cannula handpiece in an immersion bath with enzymatic cleaner for 15 minutes. Clean the handle and accessories in an ultrasonic bath for 15 minutes. Follow the instructions of the cleaning agent manufacturer. 2. Clean products completely with a soft brush under running drinking water. Rinse cavities and lumens, if any, intensively (>30 sec.) with a water pressure gun (or similar). 3. To remove the cleaning agent, rinse products under running tap water (drinking quality) (>30 sec.).	**⚠ Warning** Do not clean the Conform cannula handpiece in an ultrasonic bath!
Manual disinfection	After cleaning, immerse the products in a bath of suitable disinfectant for 5 minutes. Make sure that all surfaces are covered with the disinfectant. Follow the instructions of the disinfectant manufacturer. After disinfection, rinse all products thoroughly with deionised water (>1 min.) to remove the disinfectant.	
Inspection and care	1. Visually check for damage, corrosion and wear. 2. Spray the Conform cannula handpiece with a lubricating spray for maintenance. To do this, attach the spray adapter to the spray can and spray the handpiece from the coupling side for about 3 seconds. 3. Then wipe off with a damp cloth (follow the product's instructions for use).	
Sterilisation	The sterilisation of the products is carried out with a fractionated pre-vacuum steam sterilisation process (steam steriliser according to DIN EN 13060 or DIN EN 285), taking into account 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, the maximum load of the steriliser must not be exceeded (see manufacturer's instructions). For autoclaves without vacuum, a drying phase must be performed. After sterilisation, the perfect sterilisation result must be checked using appropriate indications. According to the Robert-Koch Institute, reprocessing ends with the documented release for use of the medical device. If the sterilised Conform cannula handpiece 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, moisture and contamination. During storage, direct sunlight must be safely avoided. After the expiry date, the product must be reprocessed.	**Handling the sterile packaging** Before taking out the product, check the integrity of the sterile packaging. When taking out the product, the relevant aseptic regulations must be observed.
Information for validating the preparation	The above reprocessing process has been proven by a validated procedure. **The following materials and machines were used:** 1. Alkaline cleaner: Neodisher® MediClean forte; Chemische Fabrik Dr. Weigert GmbH & Co. KG 2. Lubricant spray: LUBRIFLUID®; BienAir 3. Cleaning and disinfection unit: Steelco, PWD 8626 4. MIS loading carrier 5. Autoclave: Webeco, A65-1 6. Sterile packaging: steriCLIN® #3FVLI330114 Chemicals and machines other than those mentioned can also be used. In such a case consult the manufacturers or suppliers to determine whether their products confer the same performance as the products that the procedure was validated with. If you decide to use a reprocessing method other than the one mentioned above, it is your responsibility to demonstrate suitability accordingly.	

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 is not running.	Motor connector is not plugged in at the control unit.	Plug in the motor connector to the control unit.
	Cable breakage	Exchange motor cable with a new one.
Motor is running but cannula does not move	Conform cannula handpiece is not correctly connected with the motor.	Press motor firmly onto the Conform cannula handpiece, until it clicks into place. Check seating.

TECHNICAL DATA

HANDLE	REF 5107
CONFORM CANNULA HANDPIECE	REF 5077nou
Speed max.	12'000 rpm
Cannula stroke	2.0 mm
Number of strokes	max. 4'200 strokes/min.
Transmission ratio	2.8 : 1
Coupling	ISO 3964
Weight (with electronic motor, without cable)	370 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.

ACCESSORIES AND SPARE PARTS

REF	DESCRIPTION
2128	Lubricant spray LUBRIFLUID
5107	Handle complete
40378	Bellows seal, PU 5 pcs.
29061	Clip set, for tube set attachment to motor cable, PU 5 pcs.
6026	Disposable suction tube 9x6.5x4000 mm, sterile
75732	Cannula adapter for Conform cannula handpiece
28557	Luer-Lock adapter for Luer-Lock liposuccion cannulas
4391	Cannula handle with opening for false air ventilation, Luer-Lock connection, sterilizable
4390	Cannula handle without opening, Luer-Lock connection, sterilizable
14991	O-ring FPM 9.0x1.0 mm

INFORMATION ON DISPOSAL

When disposing of the device, device components and accessories, the regulations issued by the legislator must be followed.
When discarding the device components and accessories, please comply with the issued statutory regulations.

MANUFACTURER AND SERVICE POINTS

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