

Safety measures



- The handpiece is delivered in non sterile condition. Clean, disinfect, and sterilize the handpiece before the first application and immediately after each use!
- The handpiece is able to a maximum speed of 10.000 rpm.
- Attache the handpiece to the motor only when it's standing still.
- Perform manipulations on the instrument 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.

Intended use / indication

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.

Contraindication / Limitations

- 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.

Symbols

	LOT number		Autoclave at 134°C		Suitable for thermal disinfection		Date of manufacturing		Order number
	Warning		Manufacturer		CE symbol with notified body		Serial number		Observe instructions for use
	Important information		Do not reuse		Information on disposal		European Authorized Representative		Surfaces may heat up

Technical data, Handle with Conform Cannula Handpiece

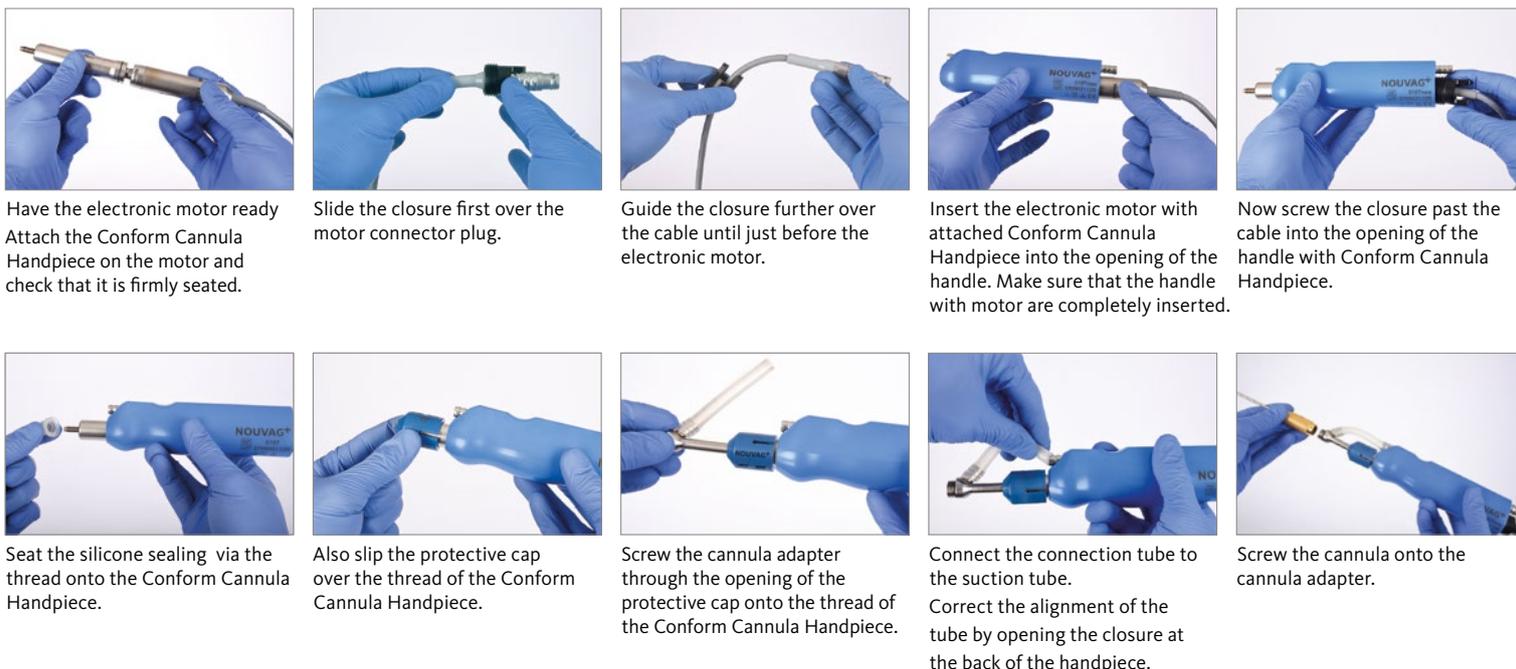
Handle		5107
Conform Cannula Handpiece		5077nou
Transmission ratio		2.8 : 1
Maximum speed		10.000 rpm
Cannula stroke		2.0 mm
Coupling		acc. to ISO 3964
Weight without electronic motor		300 g

Overview



Operation

Preparing the Handle with Conform Cannula Handpiece



Possible combinations

Handle with Conform Cannula Handpiece, REF 5077nou is exclusively used:

- In conjunction with the liposuction devices, Vacuson 6o LP (REF 4178) and Vacuson 6o LP (REF 4179), which control the Conform cannula handpiece via the upstream electronic motor 21 and enable settings for the number of strokes, according to the cannula used and the area of application.
- In conjunction with the liposuction device LipoSurg (REF 3392), which controls the Conform cannula handpiece via the upstream electronic motor 21 and enable settings for the number of strokes, according to the cannula used and the area of application.



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.

Ambient conditions

	Transport and storage:	Operation:
Relative humidity:	Max. 90 %	Max. 80 %
Temperature:	0 – 60°C; (32 – 140°F.)	10 – 30°C; (50 – 86°F.)
Atmospheric pressure:	700 – 1060 hPa	800 – 1060 hPa

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.
Motor is not running.	Cable brake	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.

Spare parts and accessories

Description	REF
Lubrifiuid for lubrication of straight and contra-angle handpieces and electronic motors	2128
Complete handle for Conform Cannula Handpiece, 1 unit.....	5107
Protective cap for the Conform Cannula Handpiece.....	40376
Silicone sealing/PU with 5 units.....	40377
Clip set for suction tube fixation at motor cable, 5 units.....	29061
Suction tube, from vacuum pump to Conform Cannula Handpiece, 9 x 6.5 x 4000 mm, 1 unit.	6026
Connection tube (5 x 2 x 79 mm) between handle and tube adapter, non sterile, 1 unit.	29063
Cannula adapter for Conform Cannula Handpiece, incl. connection tube, (5 x 2 x 79 mm) sterilizable, 1 unit.....	75705
Luer Lock adapter for luer lock liposuction cannulas, 1 unit.....	28557
Suction cannulas for Liposuction (sterilizable).....	REF
Cannula handlebar with opening for false air ventilation	4391
Cannula handlebar without opening	4390
Curved cannula for femoral liposuction, Ø 3 mm, length 200 mm, 22 openings 1,5 mm.....	4362
Curved cannula for femoral liposuction, Ø 3 mm, length 300 mm, 30 openings 1,5 mm.....	4365
Curved cannula for femoral liposuction, Ø 4 mm, length 200 mm, 22 openings 1,5 mm.....	4368
Curved cannula for femoral liposuction, Ø 4 mm, length 300 mm, 30 openings 1,5 mm	4372
Angled cannula, 30°, for liposuction, Ø 3 mm, length 200 mm, 22 openings 1,5 mm	4381
Straight cannula, Ø 1,5 mm, length 150 mm, 1 oval opening	4361
Straight cannula, Ø 2 mm, length 150 mm, 1 oval opening.....	4364
Straight cannula, Ø 2 mm, length 150 mm, 18 openings 1,0 mm.....	4373
Straight cannula, Ø 3 mm, length 150 mm, 18 openings 1,5 mm.....	4374
Straight cannula, Ø 3 mm, length 200 mm, 22 openings 1,5 mm	4378
Straight cannula, Ø 3 mm, length 300 mm, 30 openings 1,5 mm	4387
Straight cannula, Ø 4 mm, length 200 mm, 22 openings 2,0 mm.....	4379
Straight cannula, Ø 4 mm, length 300 mm, 30 openings 1,5 mm	4388

Manufacturer and Service points

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The complete list of all Nouvag-authorized service points worldwide are to be found on our Website, under: www.nouvag.com/en/service/service_provider

Disposal

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

Reprocessing instructions

Reprocessing restrictions	Frequent reprocessing has only a limited impact on the handpiece. 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	<ol style="list-style-type: none"> The instrument 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 instrument permits proper sterilisation! The instrument should always be treated with utmost care when being transported, cleaned, serviced, sterilised and stored. We recommend the use of mild alkaline and enzymatic cleaners with as low a content of silicate as possible in order to avoid staining (silicatising) the instruments. 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. Follow precisely the operating instructions of the devices and chemicals etcetera, used during preparation. Adhere exactly to the chemical dosages, action times and exposure temperatures during cleaning and disinfection. The end of the products service life is determined by wear and damage through use. For the handpiece it can be reached even before the 250 sterilization cycles, that they're designed for, due to wear and tear. Do not overload washer. Avoid blind spots while rinsing. Pay attention to secure storage in the machine. Follow the applicable regulations in your country for reprocessing medical devices. Only the cannula adapter and the locking clamp may be cleaned in an ultrasonic bath. The other parts must never be subjected to ultrasonic cleaning! This will impair the functionality. Nouvag recommends using a screen basket with a rinse strip e.g. From 3mach, 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. 					
Attention! 	In relation to patients with Creutzfeldt Jakob disease or its variant (vCJK) no responsibility can be assumed for re-use of the handpiece. The Robert-Koch Institute recommends removing used products from circulation after use in order to avoid infecting other patients, users and third parties.					
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	<p>Disassemble the Conform Cannula Handpiece (remove the suction tubes, unscrew the liposuction cannula, remove the closure, pull the electronic motor together with the Conform Cannula Handpiece out of the handle and detach it from the motor. Discard the silicone seal and replace it with a new one at reassembly. Remove the tube holding clips from the motor cable) Wash off visible contamination with water.</p> <ol style="list-style-type: none"> Wipe visible impurities with a moist expandable cloth/tissue paper from the Conform Cannula Handpiece and accessories. Brush the Conform Cannula Handpiece and accessories under running tap water using a soft brush (e.g. manufacturer Insitumed GmbH). Rinse the outer surface of the Conform Cannula Handpiece for 10 seconds with a water pistol (at a pressure of at least 2.0 bar; manufacturer e.g. HEGA Medical. 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 handpiece. Rinse parts with lumen with a cleaning gun with a jet nozzle attachment (e.g. manufacturer HEGA Medical) for at least 30 seconds. 					
Cleaning	Mechanical cleaning <ol style="list-style-type: none"> After pre-cleaning place the Conform Cannula Handpiece and its accessories in the strainer basket. Mechanical cleaning is only successful if the pre-cleaning, described above, is adhered to! 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). After completing the cleaning programme (inc. Thermal disinfection) check the Conform Cannula Handpiece, the locking clamp and the cannula adapter for visible contamination in grooves and gaps. Repeat the cleaning cycle, if necessary. 	Automatic cleaning process (Vario TD programme) <ol style="list-style-type: none"> Pre-clean with cold water for 4 minutes. Empty Clean for 5 minutes at 55°C with 0.5 % alkaline or at 40°C with 0.5 % enzymatic cleaner. Empty Neutralise with cold water for 3 minutes. Empty Inter-rinse for 2 minutes with cold water. 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 Ao value (see DIN EN ISO 15883-1). We recommend an Ao value of 3,000 for the instrument. 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 Dry the Conform Cannula Handpiece using the cleaning/disinfection unit's (CDU) drying cycle. If required, manual drying can also be achieved by using a lint-free cloth. When drying manually, take particular care with the grooves and gaps of the instrument. Then spray the instrument again with the care spray "Lubrifiuid" for 3 seconds. 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 Conform Cannula Handpiece in an upright position without any attachments. Dry the instrument for at least 30 minutes. Then spray it with the care spray "Lubrifiuid".				
Manual cleaning and disinfection	<ol style="list-style-type: none"> After pre-cleaning immerse the Conform Cannula Handpiece for 15 minutes in a bath with enzymatic cleaner (e.g. 0.5 % MediClean or 0.5 % MediZym). Clean accessories such as e.g. the cannula adapter for 15 minutes in an ultrasonic bath (0.5 % MediClean or 0.5% MediZym). Follow the instructions of the manufacturer of the detergent. Perform a complete post-clean of the product under running drinking water, using a soft brush. Intensely rinse, if there is any cavities and lumen existing, with a water pressure gun (or similar) for at least 30 seconds. To remove the detergent, rinse the products under running city water (drinking quality) for at least 30 seconds. 	Warning  Do not clean the Conform Cannula Handpiece in an ultrasonic bath!				
Manual disinfection	After cleaning, immerse the products for 5 minutes in a bath with a suitable disinfectant (e.g. Neodisher 0.5 % Medi Clean or 0.5 % MediZym). It must be ensured that all surfaces are completely wetted with the disinfectant. Follow the manufacturers instructions of the disinfectant. After disinfection thoroughly rinse all products with deionized water to remove the disinfectant (> 1 min.).					
Manual drying	Set up the Conform Cannula Handpiece vertically, separated from all attachments, to make sure the outflow of water is favored. Dry products with a lint-free paper towel. Then dry with suitable compressed air in accordance with the RKI recommendation. Pay particular attention to the drying of hard to reach areas.					
Inspection and care	<ol style="list-style-type: none"> First remove all the attachments from the Conform Cannula Handpiece, if not done already. Perform a visual inspection for damage, corrosion and wear. At the next step, spray the Conform Cannula Handpiece with "Lubrifiuid" spray. Place the spray attachment onto the spray can and spray the handpiece from the coupling side with Lubrifiuid spray for about 3 seconds. Then wipe it with a damp cloth (observe the instructions for use of the product). After spraying the handpiece, re-install the attachments on the Conform Cannula Handpiece. 					
Sterilization	Sterilization of the handpiece is performed with a fractionated pre-vacuum steam sterilization technique (in accordance with DIN EN 556-1/DIN EN ISO 17665-1) giving due consideration to the respective national requirements. <p>Minimum requirements:</p> <table border="0"> <tr> <td>1. Pre-vacuum phases: 3</td> <td>3. Holding Time: At least 3 minutes (Full cycle).</td> </tr> <tr> <td>2. Sterilisation temperature: At least 132°C – Max. 134°C</td> <td>4. Drying Time: At least 20 minutes (Max. 30 minutes).</td> </tr> </table> <p>When sterilizing several products during one sterilisation cycle, do not exceed the maximum sterilizer load. (See manufacturer's details). A drying cycle must be added in case of autoclaves without a post-vacuum function. After sterilization an immaculate sterilization 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.</p>		1. Pre-vacuum phases: 3	3. Holding Time: At least 3 minutes (Full cycle).	2. Sterilisation temperature: At least 132°C – Max. 134°C	4. Drying Time: At least 20 minutes (Max. 30 minutes).
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Storage	Storing the sterile packaging The sterilised product must be stored away from dust, humidity and contamination. During storage, direct sunlight must 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: <ol style="list-style-type: none"> Alkaline cleaner: Neodisher® Mediclean; Chemische Fabrik Dr. Weigert GmbH & Co. KG Enzymatic cleaner: Neodisher® MediZyme; Chemische Fabrik Dr. Weigert GmbH & Co. KG Cleaning and disinfection unit: Miele G 7836 CD Rack trolley: Miele E429 Strainer basket/flush socket bar: 3mach (NOUVAG REF 51401) Autoclave: Selectomat 666-HP (MMM) Sterile packaging: Sterisheet 100; Broemeda Amcor Flexibles GmbH <p>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.</p>					
Note 	There is no experience available from conducting other sterilization procedures such as plasma sterilization, low temperature sterilization procedure, etc. Users bear full responsibility if they use a procedure which differs from the validated sterilization procedure described!					
Attention! 	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.					