» SUCTION-IRRIGATION CANNULAS WITH TRUMPET-VALVES «

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CE 0483

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Content

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In order to keep risks to patients, users or third parties as low as possible, the instructions for use must be carefully followed. The use, reprocessing and testing of the instruments may only be carried out by trained specialists. Before using the instrument, the entire instructions for use must be read. This also applies to the instructions for use of the accessories used. The specifications, safety instructions and warnings in the respective instructions for use must be strictly adhered to and followed.

The reusable **suction-irrigation cannulas with trumpet valve** from Tekno-Medical Optik-Chirurgie GmbH and their accessories are delivered non-sterile and must go through the complete reprocessing cycle (cleaning, disinfection and sterilization) before the first and every subsequent use.

1 SCOPE

MD

This instruction manual is valid for the suction-irrigation cannulas with trumpet valve (hereinafter referred to as **"cannulas**") from Tekno-Medical Optik-Chirurgie GmbH. (See article list in the last paragraph of this instruction manual.)

2 INSPECTIONS

Before each use of the cannulas, they must be inspected for breaks, cracks, deformations, damage and functionality. Areas such as connections and working ends must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged instruments must be discarded.
In addition to the efforts made by the manufacturer in selecting the right materials and carefully processing them, the user must provide the suction tubes with professional and continuous care and professional reprocessing.!

3 HANDLING

All surgical instruments should always be handled with the utmost care when transporting, cleaning, maintaining, sterilizing and storing. This applies in particular to fine suction cannulas with small diameters.
New instruments should undergo three machine cleaning cycles before initial sterilization. This leads to the formation of a passive layer on the surface that protects the instrument from discoloration and corrosion.
New instruments should be stored without protective packaging, in a closed cupboard / drawer, in ambient air. It is important to ensure that the applicable hygiene regulations are adhered to.
For new instruments that are to be stored for a longer period of time, we recommend removing them from the sealed plastic bag and treating them with a medical oil approved for sterilization.

4 PURPOSES

The instruments are intended for use in minimally invasive surgery. The instruments are used to rinse the surgical area and/or suction the fluids and tissue fragments that accumulate during the procedure.
The laser guide is used to hold glass fibres for the use of medical laser technology.
The cannulas are **not** intended for use in direct contact with the central nervous system or to correct defects in the heart or central circulatory system!

5 CONTRAINDICATIONS

Patients in whom, in the opinion of the treating physician, there is a general risk of surgery or the suction instrument cannot be used without endangering the patient.
The instrument is used exclusively by medical staff specially trained in surgical techniques. The attending physician is also responsible for ensuring that the operating room staff and their employees have sufficient knowledge of how to use and handle the instruments. The experienced user is responsible for selecting the appropriate suction instrument.
There are no other specific contraindications known.

6 PATIENT POPULATION

Apart from the contraindicated uses listed in these instructions for use, there are no restrictions on the patient population.

7 DISPOSAL

If the instruments can no longer be repaired and reconditioned, the instruments must be disposed of in accordance with the applicable country-specific regulations and laws.

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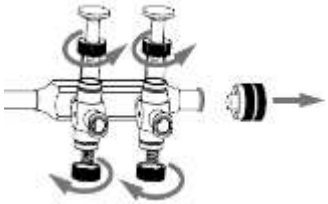
8 WARNINGS

Failure to follow these usage and safety instructions could result in injury, malfunction, or other unexpected events.
All types of reusable suction instruments must be completely cleaned, disinfected and sterilized before first use and before each subsequent use.
Before each use, the suction instrument must be inspected for correct function and for visible damage and wear, such as cracks or breaks. The continuity of the suction instruments must be ensured before each use.
The packaging is unsuitable for the high temperatures during autoclaving and must be discarded before the first sterilization.
Do not overload the instruments. Overloading due to excessive force can lead to breakages, bending and malfunctions of the medical device and injuries to the patient or user. Do not bend bent instruments back to their original position, risk of breakage.
Do not use a damaged or defective product. Immediately sort out and label damaged products and exclude further use.
⚠ When connecting the rinsing cannulas to the suction rinsing device, ensure that the flexible connecting hose is securely and tightly connected at all times during use.
Select a vacuum power (negative pressure) on the suction pump that is appropriate for the surgical procedure and the amount of liquid to be suctioned. If the vacuum power is too high, it can damage sensitive tissue structures; if the suction power is too low, the resulting amount of liquid may not be removed efficiently.
Follow the suction pump manufacturer's operating instructions.
You can switch between the suction and rinsing functions using a double trumpet valve on the handle.
Notice:
During suction, tissue fragments can become lodged in the suction/rinsing holes. Therefore, rinse the suction-rinsing tube several times during the procedure outside the operating site.

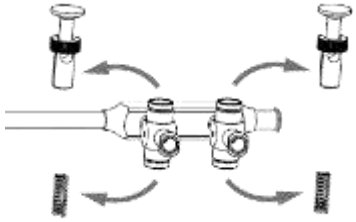
9 ASSEMBLY AND DISASSEMBLY

Notice: The laser-guide cannot be disassembled.

9.1 Disassembly

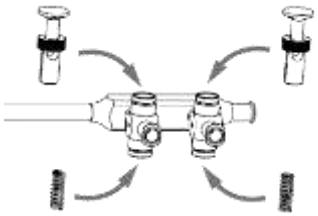


Unscrew the knurled rings and Luer cap.

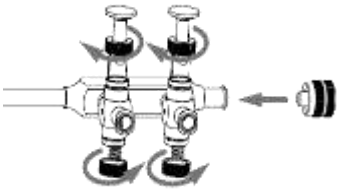


Remove pistons and springs.

9.2 Assembly



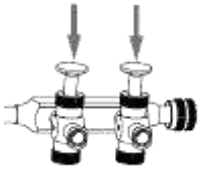
Insert pistons and springs.



Screw on the knurled rings and Luer cap

9.3 Functional testing

Squeeze the trumpet valve and release it again.
Trumpet valve is pushed back up again by the spring



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10 REPROCESSING

In general, surgical instruments may only be reprocessed by persons who have the necessary expertise for the intended activities.
Detailed information on the reprocessing of surgical instruments can be found in the "**Red Brochure**" of the AKI.
Under www.a-k-i.org you will also find links to laws, standards and publications of processing expert committees.
Due to the product design and the materials used, no defined limit of maximum feasible applications can be set. The service life of medical devices is determined by their function and gentle handling. Frequent reprocessing has little effect on the product. The end of product life is usually determined by wear and damage caused by use. The legibility of the marking has been verified over 200 preparations.

10.1 On-site preparation

Immediately after use, remove coarse dirt from the instruments. Do not use any fixing agents or hot water (>40°C), as this will cause residues to freeze and may affect the success of cleaning.

10.2 Transport

Safe storage in a closed container and transport of the instruments to the reprocessing site to avoid damage to the instruments and contamination to the environment.

10.3 Preparation for decontamination

If possible, the instruments must be disassembled or opened for reprocessing. The instruments must be stored on machine-compatible instrument carriers in a dishwasher-safe manner. The condition of the instrument panels must not impair the subsequent cleaning and disinfection by means of sound or rinsing shadows.

10.4 Manual pre-cleaning

For manual cleaning / pre-cleaning, never use metal brushes, metal sponges or abrasive cleaning agents.
Place the instruments in cold water for at least 5 minutes. If possible, disassemble the instruments and clean them under cold water with a soft brush until no residue is visible. Pressure flush cavities, holes and threads with a water gun for at least 10 seconds (pulsed method, minimum pressure 2 bar).
Place instruments in an ultrasonic bath at 40°C for 15 minutes with 0.5% alkaline or enzymatic cleaner and sonicate.
Remove instruments and rinse with cold water.
The cleaning solution should be changed at least once a day, more often if necessary. Too much contamination impairs the cleaning effect and increases the risk of corrosion.
National laws and guidelines must be observed.

10.5 Automated cleaning

Place the opened instruments in a sieve tray on the slide-in carriage and start the cleaning process. Disassemble instruments as much as possible.

Step	Parameter	
Pre-rinsing 1	Rinsing-temperature + water quality	Cold tap water
	Exposure time	60 s
Pre-rinsing 2	Rinsing-temperature + water quality	Cold tap water
	Exposure time	180 s
Cleaning	Cleaning-temperature	45°C
	Water quality	Tap water
	Exposure time	300 s (worst case condition) / RKI Recommendation: 600 s
	Detergent	Neodisher Medizym
	Concentration	0,50 %
Neutralization	Rinsing-temperature	40°C
	Water quality	Tap water
	Exposure time	180 s
	Neutralizing detergent	Neodisher Z
	Concentration	0,10 %
Post-rinsing	Rinsing-temperature	40 °C
	Water quality	Deionized water
	Exposure time	120 s

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10.6 Automated (thermal) disinfection

Step	Parameter	
Thermal Disinfection	Disinfection-temperature	90°C (A_0 3000)
	Water quality	Deionized water
	Exposure time	300 s
Drying	Drying of the outside of the instruments by the drying cycle of the washer-disinfector. If necessary, manual drying can also be achieved with the help of a lint-free cloth. Dry cavities and channels of the instruments with sterile compressed air. Allow products need to cool down to room temperature.	

For UK: The washer disinfection cycle should run at a minimum of 90°C for a minimum of 1 minute.

10.7 Functional testing

After each cleaning, the products must be macroscopically clean, i.e., free of visible contamination. Stained products must be sorted out immediately and given special treatment. All moving parts must be checked with particular attention. If errors or damage occur, the products must be sorted out immediately.
Functional testing and maintenance of the instruments must be carried out extremely thoroughly. A suitable maintenance procedure increases the service life of the instruments.

10.8 Packaging

Select standard-compliant packaging of the instruments for sterilization according to DIN EN ISO 11607-1, DIN EN 868-2 and DIN EN 868-8.

10.9 Sterilization

Sterilization of the products using a fractionated vacuum process (according to DIN EN ISO 17665), taking into account the respective national requirements.

Pre-vacuum	3 times
Sterilization temperature	134 °C
Sterilization time	5 min
Drying time	20 min.

The use of other sterilization methods is beyond our responsibility.

Sterilization parameters UK:

Sterilization of the instruments by applying a fractionated pre-vacuum process (according to Health Technical Memorandum 01-01 Part C):

- Heat up to a minimum sterilization temperature of 134° - 137°C (maximum temperature 137°C).
- Minimum holding time: at least 3 min.

10.10 Storage

The sterilized instruments must be stored in suitable packaging in a dry, clean and dust-free environment and at a constant level of humidity. The distance between the floor and the shelf should be at least 30cm.
The storage period is to be determined by the user himself.
Protect from sunlight!

10.11 Information on the validation of the reprocessing

The following materials and machines were used in the processing process:

Detergent	Neodisher Medizym 0,5 % (v/h)
Neutralisator	Neodisher Z 0.1% (v/v)
Washer-disinfector (RDG)	Miele PG 8535
Steam-autoclave	Lautenschläger ZentraCert
For details see test reports: 23277 / 23278 / 23279 (CleanControlling Medical GmbH & Co. KG, 08-2021)	

11 ADDITIONAL INSTRUCTIONS

If the chemicals and machines described above are not available, it is up to the user to validate his process accordingly. It is the responsibility of the user to ensure that reprocessing, including resources, materials and personnel, is suitable to achieve the required results. The state of the art and national laws require the following of validated processes. During reprocessing, the temperature acting on the instrument should **not** exceed **140°C**.
In principle, mechanical cleaning and disinfection are always preferable to manual cleaning. With mechanical cleaning and disinfection, there is greater safety in the process. Never use metal brushes, metal sponges or abrasive cleaning agents for manual cleaning / pre-cleaning. The instruments must not be sterilized in hot air sterilizers.
Do not use caustic cleaning agents. Do not use strong oxidizing cleaning agents. Agents with a neutral pH value (7.0) are best suited.

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12 REPORTING PRODUCT ISSUES

In accordance with the requirements of Regulation (EU) 2017/745 on medical devices and our quality management system, all product problems must be reported to the manufacturer.
During business hours, you can reach us by phone at +49 (0) 7461 / 1701-0.
Outside of regular business hours, please send an email to safety@tekno-medical.com.
Serious incidents must also be reported to the competent authority in their locality.

13 WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. If errors still occur, please contact our service. Tekno-Medical cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself. Tekno-Medical assumes no liability for incidental or resulting damages.
Tekno-Medical accepts no liability if it is proven that these instructions for use have been violated.

Attention: In the case of the use of the instruments in patients with Creutzfeldt-Jakob disease, Tekno-Medical declines any responsibility for reuse.

14 SERVICE AND REPAIR

Do not carry out any repairs or modifications to the product on your own. Only authorized personnel of the manufacturer are responsible and provided for this. Defective products must have gone through the entire remanufacturing process before being returned for repair.
For returns, use our RMA application form and the decontamination certificate.
You can find the forms on our homepage: https://www.tekno-medical.com/de/service/reparaturservice/.

15 SYMBOLS

The symbols used in this instruction and on the label have the following meaning according to DIN EN ISO 15223-1:

	Attention!		Manufacturer
MD	Medical device		Date of manufacturing
NON STERILE	Non-sterile		Read the instructions for use
REF	Catalogue number		Protect from sunlight
LOT	Lot-number		Store in a dry place
UDI	Unique device identification		
CE 0483	CE mark with the number of the notified body: **mdc – medical device certification GmbH** Kriegerstrasse 6, 70191 Stuttgart		

REF

16 PRODUCT LISTING

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704-580	704-582	704-583*

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