» MONOPOLAR ELECTRODES, ELECTRODE ADAPTERS, HANDLES WITH ELECTRODE ADAPTER «

TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49 (7461) 1701-0 – Fax +49 (7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com

CE 0483

TEKNO-Medical Optik-Chirurgie GmbH
Sattlerstr. 11
D-78532 Tuttlingen
GERMANY
SRN: DE-MF-000005822

Phone: +49 7461 17 01 0
Fax: +49 7461 17 01 50
Mail: mail@tekno-medical.com
Web: www.tekno-medical.com

TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49 (7461) 17 01-0 – Fax +49 (7461) 17 01-50
mail@tekno-medical.com – www.tekno-medical.com

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Content

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mail@tekno-medical.com – www.tekno-medical.com

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Sattlerstrasse 11 – 78532 Tuttlingen, Germany
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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 monopolar electrodes / electrode adapters / handles with integrated electrode adapter from Tekno-Medical Optik-Chirurgie GmbH (Tekno) and their accessories are supplied non-sterile and must undergo the complete reprocessing cycle (cleaning, disinfection and sterilisation) before the first and each subsequent use.

1 SCOPE

MD

These instructions for use are valid for the monopolar electrodes, electrode adapters and handles with integrated electrode adapter with HF connection (hereinafter referred to as "**electrodes**") from Tekno-Medical Optik-Chirurgie GmbH. (See article list in the last paragraph of these instructions for use).

2 INSPECTIONS

Before each use of the electrodes, they must be checked for breaks, cracks, deformation, damage and functionality. Areas such as insulation, 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 processing them carefully, the electrodes must be subjected to professional and continuous care and reprocessing by the user.

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

4.1 Electrodes

The electrodes are reusable surgically invasive products for transient use. Depending on the model, it can be used without a handle or must be connected with a special handle. The electrodes are inserted via a trocar sleeve.

4.2 Electrode adapters

The electrode adapters are connecting pieces between the electrodes and the handles and are connected to suction / irrigation handles and only used in combination with it.

4.3 Handles with electrode adapters

Handles with integrated electrode adapter are reusable invasive products for short-term use.

4.4 Suction-irrigation handles

The suction/irrigation handle can be used to switch between the suction and rinsing functions.

5 INDICATION

The instruments are intended for use in minimally invasive surgery, in particular laparoscopy. Electrodes are inserted through trocar sleeves and used to dissect, coagulate and cut tissue.

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6 CONTRAINDICATIONS

The instrument is not intended for use on the central nervous and circulatory system.
Risks from improper use:

- Material fatigue and loss of function due to exceeding the product service life.
- Risk of electric shock due to damage to the insulation, which can occur if the operating conditions and product service life are exceeded and the reprocessing instructions are disregarded.
- Risk of injury due to use of the instrument without HF current.
- Tissue punching due to the use of a trocar sleeve with a diameter that is too large.

7 PATIENT POPULATION

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

8 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.

9 WARNINGS

Failure to observe these application and safety instructions can lead to injuries, malfunctions or other unexpected incidents!

9.1 General safety-notes

- Do not grasp the distal end.
- Do not use or repair damaged instruments.
- Do not touch sharp edges and tips.
- Do not bend the distal end.
- Tissue punching due to the use of a trocar sleeve with too large a diameter. Only use trocar sleeves with a diameter slightly larger than that of the instrument.
- All types of reusable instruments must be completely cleaned, disinfected and sterilised before they are used for the first time and before each subsequent use.
- Before each use, the instrument must be inspected for correct function and visible damage and wear, e.g. cracks or breaks.
- The transport packaging is unsuitable for the high temperatures during autoclaving and must be discarded before the first sterilisation.
- Do not overload the instruments. Overloading due to excessive force can lead to breakage, bending and malfunction of the medical device and to injury to the patient or user. Do not bend bent instruments back into their original position, risk of breakage.
- Do not use a damaged or defective product. Sort out and label damaged product immediately and exclude further use.

9.2 HF-specific safety-notes

- Risk of burns due to HF current
- The instrument may only be used by qualified, medically and technically trained personnel.
- For patients with pacemakers, check their compatibility with HF radiation.
- Do not use explosive / flammable substances during the operation.
- Do not place the instrument on the patient.
- Avoid carbonisation of the tissue!
- Only use the instrument with a recurring peak voltage of max**. 3200 Vp** in combination with original accessories.
- The power of the HF generator must always be set as low as possible in order to achieve only the desired effect.
- Do not use the instrument for spray coagulation.
- Always position the patient leads (active electrode, neutral electrode) so that there is no contact with the patient or other leads.

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- Instruments that are temporarily not in use must always be isolated from the patient in order to avoid patient injury in the event of accidental activation of the HF current.
- Check the possible use of bipolar applications if there is a risk that the HF current could flow through relatively small cross-sectional areas of the patient's body (avoid unintentional tissue damage).
- Only activate the HF current if the contact surfaces are within the visual range and have good contact with the tissue to be treated. Do not touch any other metallic instruments, trocar sleeves, optics, cables or similar.
- Only suction may be used while the electrode is in operation.
- Remove disinfectant residues from the patient's body.
- Use a suitable neutral electrode.
- Position the neutral electrode so that the patient lies on the entire surface of the neutral electrode.
- Risk of burns due to excessive heating of the neutral electrode!
- Only use the instrument if the insulation is undamaged.
- Only touch the insulated areas with your fingers, not the contact pin.
- Adjust the voltage of the HF generator to the cutting speed to support primary haemostasis.

Always check the electrodes and handles for:

- Visibly exposed metal of the shaft of the active electrode at the connection point to the active handle,
- poor electrical connection between the active handle and the shaft of the active electrode,
- poor fit between the active handle and the shaft of the active electrode.

To connect and disconnect the cable, always hold the plug only, never pull on the cable. The use of damaged cables can lead to considerable danger. Check the cable for visible damage before each use.

Damaged HF cables must not be used!

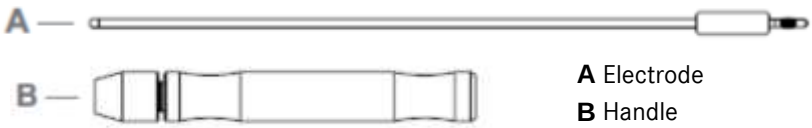
10 PRODUCT DESCRIPTION

10.1 General descriptions

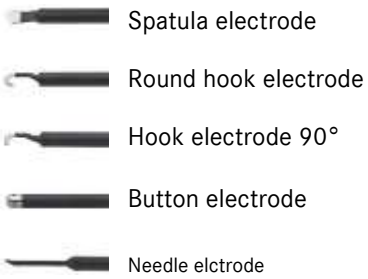
Electrodes are available with different electrode tips and are therefore also intended for different areas of application. Depending on the model, they are also equipped with a suction and irrigation opening at the distal end and must be connected to a suitable handle.
Handles are available in different designs. Depending on the model, it is possible to switch between the suction and irrigation function on the handle.

10.2 Electrodes and handles without suction-irrigation function

The following electrodes are inserted with the handle shown and do not have a suction/irrigation opening at the distal end. This means that suction and irrigation are not possible during the procedure. The electrode is inserted into the handle via the HF contact pin.



A Electrode
B Handle



Spatula electrode
Round hook electrode
Hook electrode 90°
Button electrode
Needle elctrode

Note: Electrode and handle cannot be dismantled.

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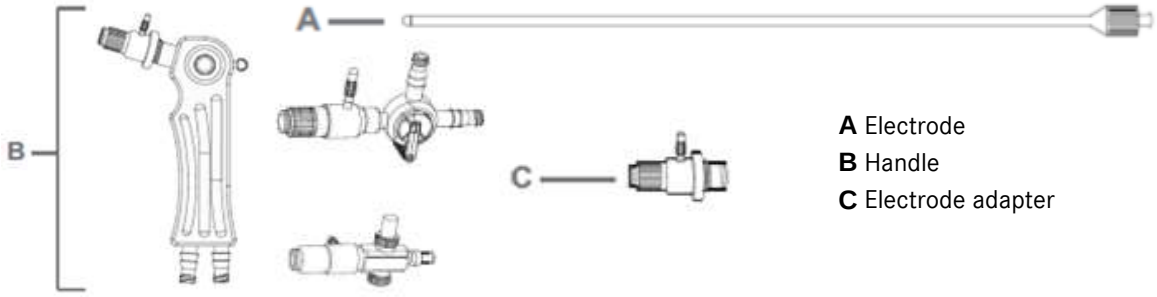
10.3 Electrodes and handles with suction-irrigation function

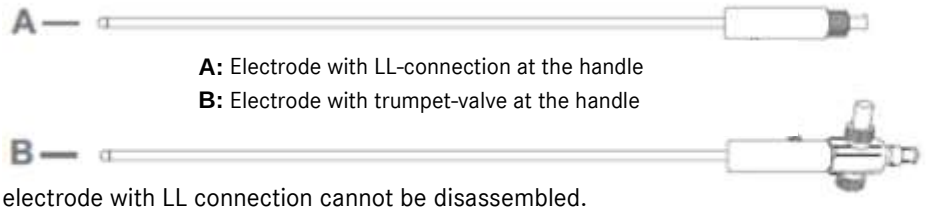
The following electrodes are either connected to a suction / irrigation handle via an electrode adapter or inserted directly into a handle with an integrated electrode adapter. The handle and electrode adapter are fitted with an HF contact pin. An opening at the distal end enables suction and irrigation.
Depending on the model, a regulator or trumpet valve on the handle is used to switch between the suction and rinsing functions. Markings on the handle facilitate assignment.



A Electrode
B Handle
C Electrode adapter

10.4 Electrodes with suction-irrigation function and integrated handle

The following electrodes do not require the use of an additional handle. Suction and irrigation are performed via the trumpet valve or the LL connection at the proximal end of the electrode.



A: Electrode with LL-connection at the handle
B: Electrode with trumpet-valve at the handle

Note: The electrode with LL connection cannot be disassembled.

10.5 Areas of application for electrodes

The following overview shows areas of application for the different electrodes

10.5.1 Button electrodes

Use	+ compatible / incompatible
Coagulation	+
Cut	-
Vaporisation	+

10.5.2 Spatula electrodes, hook electrodes 90°, round hook electrodes, needle electrodes

Use	+ compatible / incompatible
Coagulation	+
Cut	+
Vaporisation	+

11 TECHNICAL DATA

11.1 Operating Conditions

Parameter	Value
Peak voltage	**3200** Vp
Duty cycle	≤ 30 s; not suitable for continuos use

11.2 Product life elctrodes

Parameter	Value
Reprocessing	≤ 50 Cycles
Time	≤ 2 Years

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11.3 Product life handles and adaptors

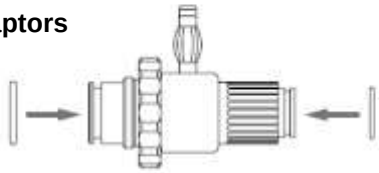
Parameter	Value
Reprocessing	≤ 400 Cycles
Time	≤ 5 Years

12 ASSEMBLY AND DISASSEMBLY

12.1 Assembly

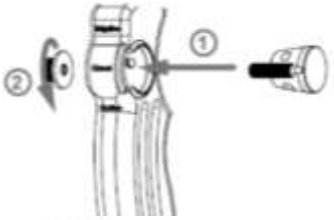
⚠ **Reprocess instruments prior to assembly!**

12.1.1 Electrode adaptors



Insert O-rings.

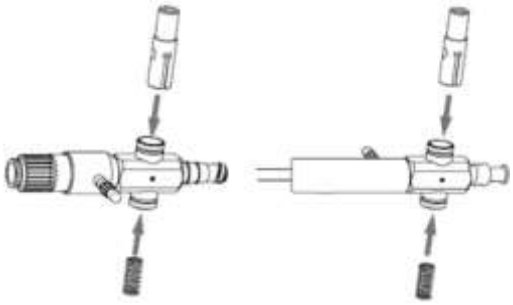
12.1.2 Suction-irrigation handles with regulator



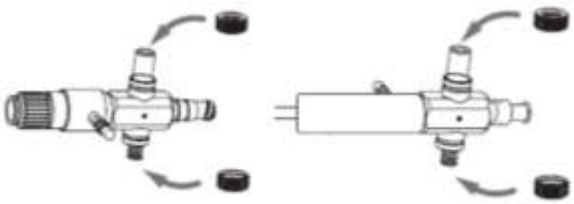
1 Insert cock.
2 Screw tight with spring cap.

Insert O-ring

12.1.3 Electrodes and handles with trumpet-valve



Insert pistons and springs



Screw on knurled rings.

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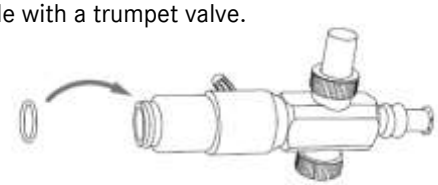
Note: Carry out the following step only for the handle with a trumpet valve.

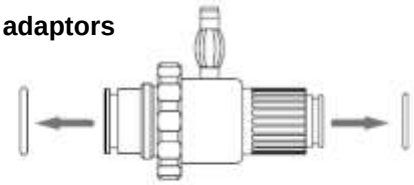
Insert O-ring



12.2 Disassembly

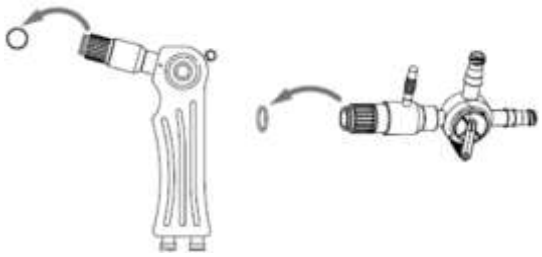
Only the handles with suction-rinsing function and the electrode with trumpet valve can be dismantled.

12.2.1 Electrode adaptors

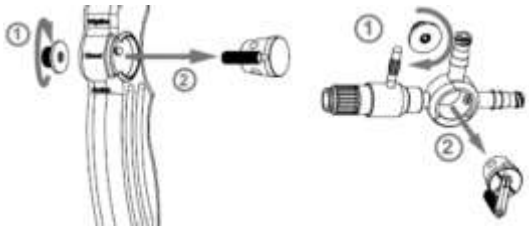


Remove O-rings

12.2.2 Suction-irrigation handles with regulator

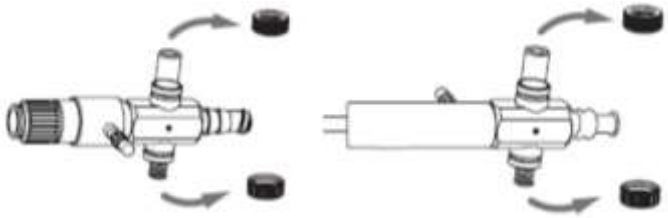


Remove O-rings

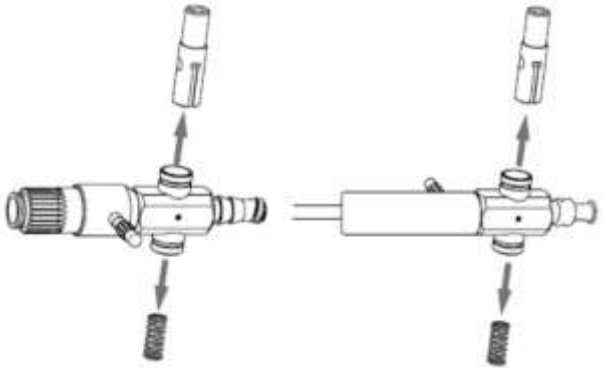


1 Unscrew spring cap.
2 Remove cock.

12.2.3 Electrodes and handles with trumpet valve



Unscrew knurled rings.



Remove pistons and springs.

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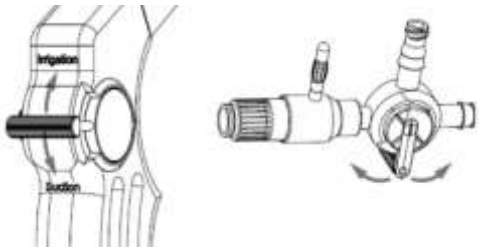
12.3 Functional testing

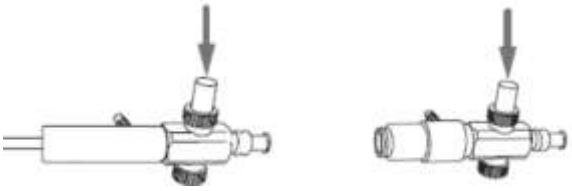
The functional test shows whether the instrument and its components function properly. Carry out the functional test immediately after assembly.

12.3.1 Suction-irrigation handles with regulator



The regulator can be moved perfectly.

12.3.2 Suction-irrigation handles with trumpet valve



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

13 ACCESSORIES

Warning: Risk of injury from using incompatible instruments. Only use original accessories!

13.1 Trocar sleeve

Electrode	Compatible trocar sleeve
Ø 5 mm	Ø 5 mm Ø 5,5 mm

Note: When using trocar sleeves with larger diameters, reducers must be used.

13.2 HF-generators

Use HF generators that meet the technical requirements in the “Technical data” chapter. The electrodes were equipped with the HF generator W.O.M. Electrosurgical Unit Model HF400 tested.

14 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.

14.1 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.

14.2 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.

14.3 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.

TEKNO - MEDICAL Optik Chirurgie GmbH
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mail@tekno-medical.com – www.tekno-medical.com

14.4 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.

14.5 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

14.6 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.

14.7 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.

14.8 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.

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14.9 Sterilization

Sterilization of the products using a fractionated vacuum process (according to DIN EN ISO 17665-1), 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.

14.10 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.

14.11 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)	

15 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 the remanufacturing process, 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. Strongly alkaline cleaning agents damage plastics and anodized coatings.
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.

16 REPORTABLE EVENTS

In accordance with the requirements of the Regulation (EU) on Medical Devices 2017/745 (MDR) and our quality management system, even the smallest problems with this product should always be reported to TEKNO

If you cannot reach us directly for reportable events, please send an email to:

safety@tekno-medical.com

Serious incidents must also be reported to the local authority responsible.

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Phone +49 (7461) 1701-0 – Fax +49 (7461) 1701-50
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17 WARRANTY

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

Attention: In case of use of the instruments in patients with Creutzfeldt-Jakob disease or its variants (vCJD, BSE, TSE), Tekno declines any responsibility for reuse.

18 SERVICE AND REPAIR

Do not carry out repairs or modifications to the product on your own. Only authorized personnel of the manufacturer are responsible and intended for this.

Defective products must have gone through the entire remanufacturing process before being returned for repair. For returns, use our RMA request form and decontamination certificate.

Forms at: https://www.tekno-medical.com/de/service/repair service

19 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, D – 70191 Stuttgart		

REF

20 PRODUCT LISTING

Printed on 20.11.2023

704-760	706-152	706-158-45	706-182-45	762-101	762-104-25
704-761	706-152-45	706-159	706-184	762-101-25	762-105
704-762	706-154	706-159-45	706-184-45	762-102	762-105-25
704-763	706-154-45	706-180	706-186	762-102-25	795-4910
704-764	706-156	706-180-45	706-186-45	762-103	
704-765	706-156-45	706-182	706-187	762-103-25	
706-150	706-158	706-182-45	706-187-45	762-104	

TEKNO GERMANY
TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49 (7461) 1701-0 – Fax +49 (7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com

CE 0483