Instructions for use
reusable Instruments

Symbol	Erläuterung
	„Caution“
	„Consult instruction for use“
	„Non-sterile“

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Products:

- Dental hand instruments
- Tooth forceps
- Bone surgery
- Scalpels, knives
- Scissors
- Forceps
- Artery clamps
- Wound retractors
- Probes, spatulas
- Suture
- Syringes
- Chiropody

With the purchase of this instrument, you have acquired a high-quality product. The proper handling and use is described below.
In order to minimize hazards to patients and users, we ask that you carefully observe the instructions for use. Only trained professionals may use, disinfect, clean and sterilize the instruments.

Tests

The instruments must be checked to make sure they work properly before every use.
Damage to the surface, such as scratches, cracks, nicks, dents, etc., as well as bent parts are indications that they may not be used. The products are then to be repaired or are to be disposed of according to hospital procedure. Do not use any damaged products!

Area of use

We manufacture our instruments as standard instruments for the surgery. The treating physician, however, is responsible for the selection of instruments for certain applications or for operative use. The physician is also responsible for the appropriate training and sufficient information for the OP personnel, and for having sufficient experience using the instruments.

Handling

The instruments may not be overstressed by twisting or levering, since this can lead to instrument parts becoming damaged or broken.

Risks

- Injury to nerves, vessels, and tissue
- Bleeding
- Infections
- Thromboses

Complications

In general, complications seldom occur. The frequency and severity of the complication depends on the type of examination.

Combination with other products / instruments

The products from devemed GmbH may not be combined with products, components and instruments from other manufacturers under any circumstances. Combinations with products from other manufacturers may negatively affect the result of the operation and are not allowed, since the used components might not be compatible with one another.
It is recommended to only use instruments and accessories from devemed GmbH.

Disposal

If the instruments should no longer be reparable and treatable, these are to be disposed of according to clinic/practice procedure.

Materials

The used materials are stainless steels according to DIN EN ISO 7153-1 and aluminum alloys according to DIN EN 573-3.

Treatment instructions

Process:	• **Cleaning** • **Disinfection** • **Sterilization with moist heat (DIN EN ISO 17665-1)**
⚠ **Warnings:**	The instruments are delivered non-sterilized and must be cleaned before use, and disinfected and sterilized, if necessary. Remove fenders and protection-films. For the preparation sensitive instruments must brought in special racks or holding devices. Broach with colored anodizes aluminum handle will be damaged and losing the color coding by alkaline detergent. Use the right cleaning and disinfection detergents for instruments and trays for example made of chromium plated brass, anodizes aluminum or synthetics. Use only high acid detergents if it's absolutely necessary because such detergents determine corrosion on the surfaces and the solder joints. The instruments may only be treated by persons with the necessary specialized knowledge and training, and who can judge the potential risks with the corresponding effects. Use protective gloves or other resources (e.g. forceps) for the preparation of contaminated instruments.
Limitation of retreating:	Due to the design of the product, it is not possible to determine a defined limitation of the maximum practicable treatment cycles. The life time of the products is conditioned through their function and preserve handling. Defective products have to pass through the complete re-treating before returning for repair. If the instruments should no longer be reparable and treatable, these are disposed of according to clinic procedure.
Procedure:	**Automated Cleaning Process**
Preparation at the point of use:	Remove surface contamination with a disposable cloth/paper towel It is recommended to reprocess the instruments as soon as possible after they have been used. Remove gross soling immediately after the use. Don't use a fixating detergent or hot water (>40° C), as this can cause the fixation of residua which may influence the result of the reprocessing process.
Transportation:	Safe storage and transportation in a closed container to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for decontamination:	The devices must be reprocessed in an opened or disassembled state.
Pre-cleaning:	Immerse the instrument into cold tap water for at least 5 minutes. Dismantle the instruments If possible and brush under cold tap water until all visible residues are removed. Inner lumens, threads and holes are flushed each with a water jet pistol for minimum 10 seconds in the pulsed mode Immerse the instrument into an ultrasonic bath with alkaline or enzymatic detergent (0,5%) and treat with ultrasonic for 15 minutes at 40°C. The instrument is taken out of the bath and rinsed with cold tab water again.
Cleaning:	Put the instruments opened and or, if possible, in a disassembled state on an instrument tray. 01 1 min. pre-cleaning with cold water 02 Draining 03 3 min. pre-cleaning with cold water 04 Draining 05 5 min cleaning at 55°C, 45°C with 0,5 % alkaline, enzymatic detergent (if enzymatic detergent is used, the cleaning temperature is 45°C). 06 Draining 07 3 min neutralization with warm water (>40°C) and neutralizer 08 Draining 09 2 min rinse with warm water (>40°C) 10 draining
Desinfection:	Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0-Value (see ISO 15883)
Drying:	Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.
Functional testing, maintenance:	Visual inspection for cleanliness, assembling and functional testing according to instructions of use. If necessary perform reprocessing process again until the instruments are visibly clean.
Packaging:	Appropriate packaging for sterilization according ISO 11607 and EN 868

Sterilization:	*Recommended method of sterilization:* Sterilization of instruments by applying a fractionated pre-vacuum process (according. ISO 13060 / ISO17665) under consideration of the respective country requirements. *Recommended temperature:* 132°C, maximum temperature 137°C *Recommended pressure:* 3 prevacuum phases with at least 60 millibar *Holding time:* ≥ 3 min *Drying time:* ≥ 10 min After sterilization, check the packaging of the sterilized instruments for damage. Check the sterilization indicators.
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C.
⚠	**Attention: Not packaged instruments are non sterile!**
Reprocessing validation study information	The following testing test devices, materials & machines have been used in this validation study: Detergent: Neodisher FA; Dr. Weigert; Hamburg (Alkalisch) Endozime, Fa. Ruhof (Enzymatisch) Neutralizer: Neodisher Z; Dr. Weigert, Hamburg Washer / Disinfector: Miele G 7735 CD Instrument Rack: E 327-06 Details: see report: Cleaning: SMP-Report: 017007011901-2 |-3 |-8 Sterilization: SMP-Report: 07910021004
Additional instructions:	If the described chemistry and machines are not available, it is the duty of the user to validate his process
It is the duty of the user to ensure that the reprocessing processes, including resources, materials and personnel, are capable to reach the required results. State of the art and often national law requiring these processes and included resources are to be validated and maintained properly.	
Additional information:	Further information for the treatment of medical products: • Internet: http://www.rki.de • Internet: http://www.a-k-i.org • Hygienic requirements for treating medical products, recommendation of the commission for hospital hygiene and infection prevention at the Robert Koch Institute (RKI) and the Federal Institute for Medicine and Medical Products (BfArM) with regard to the “Hygienic requirements for treating medical products.” • Empfehlung der Kommission für Krankenhaushygiene am Robert-Koch-Institut (RKI) – Infektionsprävention in der Zahnheilkunde – Anforderungen an die Hygiene • For information, since the product can’t be re-sterilized: EN ISO 17664 Sterilization of medical products. Information to be provided by the manufacturer for the treatment of re-sterilizable medical products • Information for sterilization: DIN EN ISO 17665-1 Sterilization of health care products – moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
Manufacturer contact info:	See manufacturer and service address.

The above-listed instructions were validated as SUITABLE by the medical product manufacturer for the treatment of a medical product so that it can be used again. The one who performs the treatment is responsible for making sure that the actual treatment carried out with the used equipment, material and personnel in the treatment facility achieves the desired results. For this, usually validation and routine monitoring of the method is required.

Guarantee
The products are made of high-quality materials and undergo a quality control before delivery. If errors should still occur, please refer to our service department.
We cannot make any guarantees as to whether the products are suitable for the operation in question. That must be determined by the user himself.
We can accept no liability for random or resulting damage. devemed GmbH accepts no liability if it can be proven that these instructions for use were violated.

Attention:
In case the instruments are used on patients who have Creutzfeldt-Jakob disease or an HIV infection, we refuse to take any responsibility if they are reused.

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