

# Instruction for use



## Reusable Instruments

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**Products:**

- Dental-Handinstrumente
- 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

### 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 devedmed 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 devedmed GmbH.

### Disposal

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

### Materials

The used materials are stainless steels according to EN ISO 7153-1

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### Treatment instructions

Process:	<ul style="list-style-type: none"><li>• <b>Cleaning</b></li><li>• <b>Disinfection</b></li><li>• <b>Sterilization with hot steam (EN 554)</b></li></ul>
<b>Warnings:</b>	<p>The instruments are delivered non-sterilized and must be cleaned before use, and disinfected and sterilized, if necessary. Remove fenders and protection-films.</p> <p>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.</p> <p>Use the right cleaning and disinfection detergents for instruments and trays for example made of chromium plated brass, anodizes aluminum or synthetics.</p> <p>Use only high acid detergents if it's absolutely necessary because such detergents determine corrosion on the surfaces and the solder joints.</p> <p>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.</p> <p>Use protective gloves or other resources (e.g. forceps) for the preparation of contaminated instruments.</p>
Limitation of re-treating:	<p>Frequent re-treating has little effect on the instruments. The end of the product lifetime is usually determined by wear and damage from use.</p> <p>They are then to be disposed of according to clinic/practice procedure. Do not use any damaged products!</p>

### Instructions

<b>Place of use:</b>	<p>Remove surface contamination, filling material and corrosive agents with a disposable cloth / paper towel.</p> <p>It is recommended to reprocess the instruments as soon as possible after they have been used.</p> <p>Instruments with adherent filling material are recommended disinfection with an ultrasound generator. Be aware the appropriateness of the instruments in respect of the ultrasonic treatment.</p> <p>Directly after use, they can be disinfected by hand in order to reduce the risk of infection for the user. Here, the instruments are placed in a disinfection solution. Make sure that the instruments are fully immersed in the disinfection solution, and that no air bubbles are formed. Follow the instructions of the manufacturer of the disinfection solution.</p>
<b>Preparation for decontamination:</b>	<p>If instruments can be taken apart, do this before treating them.</p>
<b>Cleaning: Manual</b>	<ul style="list-style-type: none"><li>• After using the instruments, immediately clean them externally with a soft cloth, sponge and a suitable, soft disinfected brush in a cleaning solution.</li><li>• The used cleaning solution must be suitable for cleaning steel products. In the use of instruments made of chromium plated brass, anodizes aluminum or synthetics, the detergents must be suitable for this instruments.</li><li>• Prepare the cleaning solution concentration and allow the instruments to soak in it exactly according to manufacturer specifications.</li><li>• The cleaning solution should not be foamy and should be suitable for manual cleaning.</li><li>• Thoroughly rinse instruments with channels and hollow spaces.</li><li>• Carry out brushing and all other cleaning steps under the surface of the liquid in order to avoid splashing contaminated liquid.</li><li>• Remove instruments from the cleaning solution.</li><li>• After rinsing with clear, running water, dry well.</li><li>• Change the cleaning solution at least once daily, or once the solution is visibly contaminated.</li></ul>

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<p><b>Ultrasound cleaning:</b></p>	<ul style="list-style-type: none"> <li>• Use an ultrasound device, which is suitable for medical use.</li> <li>• The ultrasound cleaning bath should be warmed up to a temperature, which is recommended by the manufacturers of the cleaning or disinfection solutions.</li> <li>• Usually, temperatures between 40°C and 50°C are required to have a cleaning effect.</li> <li>• Place instruments in the wire basket.</li> <li>• Place instruments in the ultrasound cleaning bath with a frequency of approx. 40 KHz for 5 minutes.</li> <li>• After the ultrasound cleaning, the instruments must be rinsed with clear, running water and dried.</li> <li>• The used cleaning / disinfection solutions must be prepared according to the manufacturer's specifications.</li> <li>• An overdose of the cleaning/disinfection solution is to be avoided.</li> <li>• The used cleaning or disinfection solutions must be suitable for cleaning steel products. In the use of instruments made of chromium plated brass, anodizes aluminum or synthetics, the detergents must be suitable for this instruments.</li> </ul> <p>The following items should also be observed:</p> <ul style="list-style-type: none"> <li>• The wire basket of the ultrasound device must be sufficiently large and deep to guarantee that the instruments are completely immersed.</li> <li>• Products must be completely covered by the cleaning solution.</li> <li>• Only use wire basins, which don't negatively affect the cleaning result.</li> <li>• Don't overload wire basins.</li> <li>• Avoid "acoustic shadows".</li> <li>• Fill all channels and hollow spaces with cleaning solutions, without air bubbles.</li> <li>• Remove instruments from the ultrasound device.</li> <li>• Blow through all channels with air to remove any remaining liquid.</li> <li>• Change the cleaning solution in the ultrasound bath at least once a day, and more often when contamination is visible.</li> </ul>
<p><b>Rinsing</b></p>	<ul style="list-style-type: none"> <li>• Place cleaned instruments in a sink with clean tap water. Use fresh tap water for every rinsing.</li> <li>• Rinse all channels completely and thoroughly with water.</li> <li>• Rinse off external surfaces of the instruments thoroughly with tap water.</li> <li>• Remove instruments from the water.</li> <li>• Blow through all channels with air to remove any remaining rinse water.</li> </ul>
<p><b>Disinfection: Manual</b></p>	<ul style="list-style-type: none"> <li>• The used disinfecting solution must be suitable for disinfecting steel products. In the use of instruments made of chromium plated brass, anodizes aluminum or synthetics, the detergents must be suitable for this instruments.</li> <li>• Place cleaned instruments in a tub with a disinfecting solution.</li> <li>• Fill all channels and hollow spaces with the disinfecting solution, free of air bubbles.</li> <li>• Cover the tub with its lid.</li> <li>• Prepare the disinfecting solution concentration and allow the instruments to soak in it according to manufacturer specifications.</li> <li>• Remove the instruments from the disinfecting solution with fresh disposable gloves.</li> </ul>
<p><b>Cleaning and disinfection: Automatic</b></p>	<p>If the possibility exists to clean the instruments with a machine, this is preferable to manual cleaning, since a standardized process can best be reached this way.</p> <ul style="list-style-type: none"> <li>• The used cleaning/disinfecting solution must be suitable for steel products. In the use of instruments made of chromium plated brass, anodizes aluminum or synthetics, the detergents must be suitable for this instruments.</li> <li>• The cleaning solution should not be foamy.</li> <li>• The basket or immersion basin of the machine must be loaded according to the manufacturer's specifications.</li> <li>• The instruments are to be placed so that channels and hollow spaces are completely and thoroughly rinsed.</li> <li>• The special features of the device model are to be taken into consideration.</li> <li>• By the mechanical cleaning and disinfection instruments with colored anodizes aluminum components can be lost the color respectively the color coding</li> </ul>

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<b>Disinfection: Automatic</b>	<ul style="list-style-type: none"> <li>• Close the machine, select the program and start.</li> <li>• After the end of the program, check whether all program stages were carried out and all control parameters are fulfilled.</li> <li>• Open the cleaning / disinfection device and remove the instruments with disinfected hands or with fresh disposable gloves.</li> <li>• Dry channels and hollow spaces with compressed air. If necessary, dry the instruments with a lint-free cloth.</li> </ul>										
<b>Neutralization / clear rinsing</b>	<ul style="list-style-type: none"> <li>• Place disinfected instruments in a sink/tub with microbiologically pure/sterile water. Use fresh water for each instrument.</li> <li>• Rinse external surfaces of the instruments, all channels and hollow spaces thoroughly with water in order to remove any remaining disinfectant.</li> <li>• Remove instruments from the water.</li> </ul>										
<b>Drying and function test:</b>	<ul style="list-style-type: none"> <li>• Dry external surfaces with a lint-free cloth and with compressed air.</li> <li>• Dry all channels and hollow spaces completely with compressed air.</li> <li>• Before the functions test the instruments with joints must be treated with physiologically inert instrument oil. The oil or spray must be permeable for hot steam/applicable for the sterilization and resistant to temperature</li> <li>• Check instruments to see whether they function correctly.</li> </ul>										
<b>Maintenance, checks</b>	Sort out damaged instruments and submit them for repairs. Before sending them to the repair service, it is imperative that the instruments be sterilized.										
<b>Packaging:</b>	The instruments should be packaged in a suitable container or a suitable sterilization package before sterilization (EN 868, Parts 1- 10). The sterilization packaging depends on the sterilization method, transport and storage. The packaging has a considerable influence on the sterilization result. The packaging is to be selected so that the instruments fit in it. Use a sterilization indicator for the packaging and write down the sterilization and expiration date on the packaging.										
<b>Sterilization:</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;"><i>Recommended sterilization method:</i></td> <td>Steam sterilization with saturated steam with a fractionizing vacuum (EN 554)</td> </tr> <tr> <td><i>Recommended temperature:</i></td> <td>134 °C</td> </tr> <tr> <td><i>Recommended pressure:</i></td> <td>3 bar</td> </tr> <tr> <td><i>Duration:</i></td> <td>≥ 5 min</td> </tr> <tr> <td><i>Drying time:</i></td> <td>≥ 15 min</td> </tr> </table> <p>After sterilization, check the packaging of the sterilized instruments for damage. Check the sterilization indicators.</p>	<i>Recommended sterilization method:</i>	Steam sterilization with saturated steam with a fractionizing vacuum (EN 554)	<i>Recommended temperature:</i>	134 °C	<i>Recommended pressure:</i>	3 bar	<i>Duration:</i>	≥ 5 min	<i>Drying time:</i>	≥ 15 min
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<b>Storage:</b>	Store the sterilized, packaged instruments in a closed cabinet, protected from dust, moisture and temperature fluctuations. Store instruments not together with chemicals. <b>Attention: Not packaged instruments are non sterile</b>										
<b>Additional information:</b>	<p>Further information for the treatment of medical products:</p> <ul style="list-style-type: none"> <li>• Internet: <a href="http://www.rki.de">http://www.rki.de</a></li> <li>• Internet: <a href="http://www.a-k-i.org">http://www.a-k-i.org</a></li> <li>• 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."</li> <li>• Empfehlung der Kommission für Krankenhaushygiene am Robert-Koch-Institut (RKI) – Infektionsprävention in der Zahnheilkunde – Anforderungen an die Hygiene</li> <li>• 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 (ISO 17664:2004)</li> </ul>										
<b>Manufacturer contact info:</b>	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.

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### **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.

### **Manufacturer and Service Address**

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