Instruction for use

Reusable surgical instruments

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Products:

- Scalpels, knives
- Scissors
- Forceps
- Artery clamps
- Dressing forceps and sponge forceps
- Wound and self-retaining retractors
- Probes, cotton applicators, spatulas
- Diagnostics
- Vaccination, puncture, suction
- Anesthesia
- Suture
- Bandage, cast
- Bone surgery
- Thorax, lungs
- Cardiac and vascular surgery
- Tracheotomy
- Goiter surgery, dermatology
- Intestine, stomach, rectum
- Bladder, urology – liver, gall, kidney
- Gynecology
- Obstetrics
- Otology
- Rhinology
- Oral and maxillofacial surgery
- Oral and maxillofacial surgery (palate, tonsils)
- Asepsis
- Sterilization and storage
- Sterilization (containers, ward container)
- Arthroscopy
- Ophthalmology

Symbols/Explanation:

	Manufacturer
	Indicate a potential risk for people and real values
	Advice: additional assistance or further useful information
	Not sterile
CE	CE marking according to Directive 93/42 EEC

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!

Application

We manufacture our instruments as standard instruments for operative use in general 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.

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Combination with other products / instruments

The products from FRIMED Medizintechnik 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 FRIMED Medizintechnik GmbH.

Disposal

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

Materials

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

Treatment instructions

Process:	• **Cleaning** • **Disinfection** • **Sterilization with hot steam (EN ISO 17665-1)**
Warnings:	The instruments are delivered non-sterilized and must be cleaned before use, and disinfected and sterilized, if necessary. 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.
Limitation of re-treating:	Frequent re-treating has little effect on the instruments. The end of the product lifetime is usually determined by wear and damage from use. They are then to be disposed of according to hospital procedure. Do not use any damaged products!

Instructions	
Place 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. 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.
Preparation for decontamination:	If instruments can be taken apart, do this before treating them.
Cleaning: Automated **Ultrasonic Cleaning & Disinfection**	Equipment: Ultrasonic Cleaning Unit. **Cleaning Procedure:** 1. Disassemble instruments if applicable (not required for hinged instruments) or open hinged instruments completely 2. Completely submerge instruments in the ENZOL® (Johnson & Johnson) Enzymatic Detergent Solution (one ounce per gallon of HP/HPW water) [A minimum soak of one minute is recommended, For removal of dried-on matter, extend soak time, use 2 ounces per gallon of water, and/or use warm water]. **Note:** There should be no contact between the instruments; do not overload the ultrasonic cleaning unit 3. Use the processing time recommended by the manufacturer of the ultrasonic unit. If using a cassette system, the ultrasonic cleaning time has to be at least 16 minutes, unless the manufacturer of the cleaning detergent requires a longer exposure time 4. Remove instruments from the cleaning solution and post-rinse thoroughly at least 3 times for at least one-half minute each time with high quality water, e.g., PW/HPW (see Warnings) 5. Inspect instruments for good cleaning result and repeat procedure if necessary 6. Instruments shall not touch each other during cleaning & disinfection process 7. Follow recommendations of ultrasonic cleaning & disinfection machine's manufacturer
Cleaning: Manual	1. Disassemble instruments if applicable (not required for hinged instruments) or open hinged instruments completely) 2. Add one ounce of ENZOL® (Johnson & Johnson) Enzymatic Detergent Solution per gallon of HP/HPW water 3. Soak instruments immediately after use until all organic material is removed [A minimum soak of one minute is recommended, For removal of dried-on matter, extend soak time, use 2 ounces per gallon of water, and/or use warm water] 4. Flush detergent through all channels, If necessary, mechanically clean equipment 5. Thoroughly rinse instruments, aspirating water through all channels to remove detergent

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	6. Rough-dry equipment, including all channels 7. Inspect the instruments for good cleaning result and repeat procedure if necessary
Cleaning: Automated	**Automated Cleaning & Disinfection Equipment:** Thermal Disinfector Unit (Washer-Disinfector) Consider the following when using a thermal disinfector unit (washer-disinfector): • Efficiency of the thermal disinfector unit (washer-disinfector) (e.g. EN ISO 15883-1, HTM-01 if required by local regulations and guidelines) • Thermal disinfection program that is approved (e.g. per EN/ISO 15883-1 recommended temperatures/times: 70°C / 158°F for 100 minutes or 80°C / 176°F for 10 minutes, or 90°C / 194°F for 1 minute; alternatively a thermal disinfection process delivering an A0 value > 3000 may be used as required in some European countries) and suitability for instruments as well as sufficient rinsing steps. • Thoroughly post-rinse, preferably with high quality water, e.g., PW/HPW (see Warnings) **Washer-Disinfector Procedure:** 1. Disassemble instruments if applicable (not required for hinged instruments) or open hinged instruments completely 2. Place the instruments in the thermal disinfector unit (washer-disinfector), assuring no contact between the instruments 3. Initiate the cycle 4. Remove the instruments from the thermal disinfector unit (washer-disinfector) after the end of cycle
Disinfection:	**Disinfection Procedure:** 1. Completely submerge instruments in the CIDEX® OPA (Johnson & Johnson) disinfectant solution and soak for a minimum of 12 minutes at 20°C or higher to destroy all pathogenic microorganism 2. There should be no contact between the instruments. **Rinsing Procedure:** 1. Following removal from CIDEX® OPA (Johnson & Johnson) Disinfectant Solution, thoroughly rinse the instruments by immersing it completely in a large volume (e.g., two gallons) of water. Use HP/HPE water 2. Keep the device totally immersed for a minimum of one minute in duration 3. Manually flush all lumens with large volumes (not less than 100 mL) of rinse water 4. Remove instrument and discard the rinse water. Always use fresh volumes of water for each rinse 5. Do not reuse the water for rinsing or any other purpose 6. Repeat the procedure two (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh HP/HPW water to remove CIDEX® OPA Solution residues. Residues may cause serious side effects. Three (3) separate, large volume water immersion rinses are required
Drying:	• Allow post-drying step in a clean place, or use filtered air for drying to prevent recontamination • If drying is achieved as part of a washer-disinfector cycle, do not exceed 110°C / 230°F • Completely dry instruments before packaging.

Inspection, Maintenance & Function Testing:	• These devices should be inspected before each use. Visually examine the devices for obvious physical damage including:
	  ○ Cracked, broken or otherwise distorted parts
	  ○ Damage including cuts, punctures, nicks, abrasion, unusual lumps, significant discoloration
	  ○ Tips for damage, corrosion or misalignment condition
	  ○ Impurities, damage and wear
	  ○ Instrument cutting edges free of nicks
	• If instruments are still dirty, repeat cleaning and disinfection procedures
	• Reassemble disassembled instruments. Check for smooth movement of hinge without excessive “play”. Locking (ratchet) mechanisms should be checked for action
	• Apply a small quantity of surgical grade lubrication oil (suitable for steam sterilization with manufacturer's certification that the lubricant will not affect the sterilization efficiency of the oiled instruments, and that the biocompatibility of the lubricant will be maintained during the sterilization cycle) to instrument hinges.

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	• Check instrument for cuts, voids, cracks, breaks, tears, abrasions, etc.) of all instruments, accessories and equipment
Packaging:	• Always use protective caps for packaging / storage of clean instruments Consider the following in the selection of suitable sterilization containers: • Conformity with ANSI AAMI (EN) ISO 11607 (EN 868-8) • Suitable for steam sterilization (temperature resistance up to 141°C / 286°F • Sufficient protection of the instruments and the sterilization packaging against mechanical damage • Sterilization container - regular maintenance according to the manufacturer's instructions Alternatively, standard sterilization packaging (e.g., paper/foil, single or double packaging) can be used. Consider the following during the selection of suitable sterilization packaging: • Conformity with ANSI AAMI (EN) ISO 11607 (EN 868-2…) • Suitable for steam sterilization (temperature resistance up to 141°C / 286°F • Sufficient protection of the instruments and the sterilization packaging against mechanical damage.
Sterilization:	Thoroughly clean instruments of all foreign matter prior to sterilization. Follow the sterilizer manufacturer's instructions for operation and loading. **STANDARD STERILIZATION METHODS:** **METHOD-1:** Unwrapped instruments should be placed in steam autoclave sterilizer Sterilization Cyrcle | Temperature | Pressure | Exposure Time Autoclave | 132°C/270°F | 30 psi | 3 minutes Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature. There must be direct steam exposure to all surfaces of the instruments being sterilized including the internal surface and tubes channels. Allow instrument to air cool to room temperature before use. **NOTE:** Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times. **CAUTION:** Autoclave temperatures should not exceed 137°C / 279°F; casing, cable insulation or other non-metallic parts may be damaged. **Do not sterilize with hot air.**
Storage:	Store instruments after sterilization in a dry and dust-free place. Sterilization can only be maintained if the instruments remain packaged or wrapped, impermeable to microorganisms, following a validated sterilization. The status of the sterilization has to be clearly indicated on the wrapped packages or the containers. For safety reasons, keep sterile and non-sterile instruments separated.
Packaging:	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.

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." • 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)
Manufacturer contact info:	See manufacturer and service address.

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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.
FRIMED Medizintechnik 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 recommend to discarding the surgical instruments. No reuse recommended.