

Instruction of use



**Annastr.25/1
D-78567 Fridingen**



Reusable surgical Instruments

(Steel, Titanium, TITANIT and antimagnetic Titanium Instruments)

You get with the purchase this instrument and it is a high quality product, its proper handling and use are described below. To keep hazards for patients and users as possible, we ask you to follow the instructions carefully. The application, disinfection, cleaning and sterilization of instruments may be carried out by trained specialists.

1 Tests

The instruments must be checked before each use for proper functioning surface damage such as scratches, cracks, nicks, dents, etc., as well as bent parts, means that the instruments need to be fixed and may not be used. Do not use any damaged instruments.

2 Application

We produce our instruments as standard equipment in an operational setting for general surgery, for ophthalmology and dentistry. Responsible for the selection of instruments for specific applications, or the operational use, but the attending physician. The doctor is also responsible for proper training and sufficient information for the surgical staff and sufficient experience in handling the instruments.

3 Handling

Instruments should not twist or be overstressed by leverage as this may result in damage or breakage of instrument parts.

The Anton Hipp GmbH as a producer and seller of the products shall not be liable for any direct or consequential damages arising from improper use, handling or improper treatment, sterilization and maintenance

4 Risks

- Injury of nerves
- bleeding
- infections

5 Disposal

If the instruments are no longer to be processed or repaired, this hospital the usual disposal should be supplied.

6 Materials

Instruments made of stainless steel: DIN EN ISO 7153-1
Instruments made of pure titanium: DIN ISO 5832-2
Instruments made of titanium alloys: DIN ISO 5832-3
Instruments made of light metals: DIN EN 573-3, Aluminium

Processing: glossy or matt-polished, gold-plated, anodized

• Stainless Steel instruments

The stainless steels used for instrument manufacture specific because of their alloy passive layers as protective layer. These steels are to attack by chloride ions and aggressive water only conditionally resistant !!!

• Instruments made of pure titanium and titanium alloys

The instruments made of pure titanium and titanium alloys are treated, as the stainless steel instruments. There are no described special to note indications. In anodized titanium Instruments the color may change slightly.

• Instruments made of light metals / Aluminium

It may exclusive non-alkaline, neutral detergent and demineralized water are used, since otherwise damage can the coming of the anodized surface. alkaline cleaners approval procedures lead especially with color anodized instruments after only a few cycles of color fading and stains.

In addition to the efforts being made by the manufacturer when selecting the right materials and their careful processing, must be supplied in users of surgical instruments of a professional, ongoing maintenance and proper treatment.

7 Storage

Instruments should be stored in a clean, dry environment and individually in your packaging or in a protective container with individual compartments. Protect. Areas such as tips, cutting, etc. with appropriate tubes, caps, gauze or cloth be especially careful that there are no chemicals in the immediate vicinity of the storage area.

8 Warranty

The instruments are made of high quality steel and subjected before delivery to quality control. Should any faults occur, please contact us. But we cannot accept any liability if the instruments are suitable for the particular engagement. This should determine the user.

We cannot accept any liability for incidental or resulting damage.

When repairing the instruments by companies or individuals who have not been authorized by the Anton Hipp GmbH for repair, the guarantee is canceled.

For reasons of hygiene need instruments for repair, be completely recycled.

THE ANTON HIPPI GMBH ASSUMES NO LIABILITY WHEN SHOWN AGAINST THIS INSTRUCTION WAS VIOLATED.

9 Care

Under "care" is the application of instrument oil (physiologically acceptable white oils by DAB8, or Ph.Eur. Or USP) to understand in the joints / moving parts of the surgical instruments. Basically surgical instruments adequate care and that must undergo before functional testing.

Cleaners must guarantee that even with your constant use a "bonding" of the joint parts is excluded due to accumulated.

Other care products (paraffin / white oil-based and silicone-free) only if approved for steam sterilization and biocompatibility tested. - Damaged instruments sort out.

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10 Sterile neutralization and cleaning

We recommend the following procedure for the reprocessing of our reusable surgical instruments:

Products:

- diagnosis
- Scissors
- SUPERCUT Scissors
- scissors with carbide tips
- SUPERCUT TITANIUM NITRIDE scissors
- Tweezers
- Forceps with tungsten carbide inserts
- hemostats
- Atraumatic clamps
- Haemostische and Dissecting
- retractors
- Needle Holder
- Needle Holders with tungsten carbide inserts
- vascular and tissue forceps
- Microsurgical instruments
- Turnstiles, thread catcher, vein stripper
- Suction and flushing pipes, needles, needles
- Self-retaining retractors
- retractors hand held
- Neurosurgery
- ENT instruments
- Otology
- Rhinology
- Mouth, jaw, and facial surgery
- Dental Surgery
- bronchoscopes, Mediastinoscopes
- tracheotomy
- Thorax, lung
- Instruments for Cardiovascular Surgery
- stomach, intestines, rectum
- liver, gall bladder, kidney
- gynecology, obstetrics
- Urology
- ophthalmology
- Bone Surgery, rongeurs
- osteosynthesis
- Hand surgery
- plaster and dressing tools
- Arthroscopic Instruments
- Station Instruments
- containers, trays

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process	machine processing
instruction	Due to the product design and the materials used, cannot defined limit shall be determined by a maximum possible number of reprocessing cycles. The lifetime of the medical devices is determined by their function and the careful handling. Defective products must have undergone the full re-making-tung process before being returned for repair. Run the surgical instruments after the end of product life professional disposal or recycling system.
Reprocessing instructions	
Preparation on site	-remove residue from the application as soon as possible - - Do not use metal brushes or steel wool to use! - Not in saline (NaCl) store! - Instruments store never opened when energized, articulated instruments, dismantle dismantled instruments, narrow lumen instruments and bodies particularly as pretreat by flushing with a gun! - Material and instrument righteous handling and storage! - Wet Disposal: Waiting time max. 1 hour to treatment! - Dry disposal: waiting time max. 3 h to treatment!
Transport	Safe storage in a closed container and transportation of instruments to the treatment site not to damage the instruments and contamination over of the environment to be avoided.
preparation for Decontamination:	If this is possible, the instruments must be disassembled for processing or opened.
Pre-cleaning:	Instrumente in kaltem Wasser für mindestens 5 Minuten einlegen. Falls möglich die Instrumente zerlegen und unter kaltem Wasser mit einer weichen Bürste reinigen bis keine Rückstände mehr sichtbar sind. Bei Hohlräumen, Bohrungen und Gewindegängen mind. 10 Sek. Mit einer Wasserpistole Druckspülen (gepulstes Verfahren) Instrumente für 15 Minuten in Ultraschallbad bei 40°C mit 0.5% alkalischen (enzymatischen) Reiniger legen und beschallen. Instrumente entnehmen und mit kaltem Wasser abspülen. Instruments insert in cold water for at least 5 minutes. If possible, the disassemble instruments and rinse under cold water with a soft brush until it is visibly clean. In cavities, holes and threads min. 10 sec. with a water pistol pressure rinse (pulsed method) Instruments for 15 minutes in an ultrasonic bath at 40 ° C with 0.5% alkaline (enzymatic-rule) Laying and sonicate cleaner. refer instruments and rinse with cold water.
Cleaning:	Instruments that can be opened, put in the open state in a basket on the insert car and start the cleaning process. MIS instruments: instruments disassembled on the inserts of the MIS module Plug. Do not plug-in tools open state in a basket on the MIS cart. 1. One minute prewash with cold water 2. evacuation 3. 3 minutes Rinsing with cold water 4. emptying 5. 5 min washing at 55 ° C +/- 5 ° C with 0.5% alkaline cleaner, enzymatic (using enzymatic cleaner only 45 ° C Cleaning temperature) Cleaner 6. emptying 7. 3 minutes neutralization with warm tap water (> 40 ° C) and neutralizer 8. drain 9. 2 minutes between rinsing with warm tap water (> 40 ° C) 10. Discharging The cleaning result must be checked by a visual inspection. The instruments must be visually clean, if necessary, the procedure must be repeated. The inspection is visual, striations critical areas such as handle structures, joints or jaw require especially careful checking
Desinfection:	Die maschinelle Thermische Desinfektion muss unter Berücksichtigung der nationalen The automatic thermal disinfection must take into account the national Requirements regarding the AO value are performed (see ISO 15883). Please note the following points: • joint instruments such as scissors, needle holders, clamps, etc. must be opened • To avoid stress corrosion cracking, instruments may with lock

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	be processed only in the first Grid Lock (never fully closed at Grid Lock) • The trays should not be overloaded, so that all instruments can be well washed
Drying:	Dry the outside of instrument through drying cycle of Cleaning / disinfecting apparatus. If necessary, manual drying using a lint-free cloth can also be achieved. Dry cavities of instruments by using sterile compressed air.
Functional testing, Maintenance:	Visual inspection for cleanliness; Assembly of instruments, maintenance and functional test according to the manual. If necessary, repeat the reprocessing process until the instrument is optically clean
Packing:	Appropriate packaging for sterilized instruments in accordance with ISO 11607 and EN 868
Sterilization:	• Sterilizing the products with fractional pre-vacuum method (DIN EN 13060 / DIN EN ISO 17665, taking into account the respective national requirements. • 3 pre-vacuum phases with at least 60 millibar pressure • Heating up to a sterilization temperature of at least 132 ° C; Max. 137 ° C • Shortest holding time: 5 minutes • Drying time: at least 10 min
Storage:	All sterilized products must be stored in a dry, clean, dust-free environment away from direct sunlight place at moderate temperatures of 5 ° C to 40 ° C. Transport and storage must not adversely affect the properties of the treated medical device.
Information to validate the treatment:	The following testing instructions, materials and equipment were used in the Validation uses: Reinigungsmittel : Neodisher Fa. Dr. Weigert, Hamburg (Alkalisch) Endozime, Fa. Ruhof (Enzymatisch) Neutralisator: Neodisher Z, Fa. Dr. Weigert, Hamburg Reinigungs-Desinfektionsgerät: Miele G 7736CD Einschubwagen: Einschubwagen E 327-06 MIC-Wagen E450
If the above-described chemicals and equipment are not available, it is up to the user to validate his process. It is to ensure the duty of the user that is the recycling process, including resources, materials and personnel suitable to achieve the required results. The prior art and often national law requiring follow validated processes.	

It is imperative to stress the steam through foreign matter, such as Rust or other contaminants to be excluded. This may be the result of corrosion or contamination (formation of fur) of the surgical instruments are avoided.

Steam for sterilization purposes must comply with DIN 58946, corresponding to part. 7 To avoid disadvantages are manuals of the manufacturer to note for steam sterilizers.

11 Additional information about instrument sterilization in sterilization containers

- There have one or two layers wrappers for wrapping the instrument baskets inside the sterilization container be used. The wrappers may absorb moisture present in sterilization containers or evaporated water at the bottom of the sterilization container.
- It is not allowed the sterilization container during sterilization, in addition to a filter paper, cloth filter or a ande-re pack packaging. This would have to mean that the passages (perforated sheets) of the sterilization container closed WAE reindeer. Of the Paper or textile filters in sterilization containers would be pressed inward. The necessary for sterilization hot steam could not in the sterilization containers into or back flow out. Also, a drying of the sterilized under the described conditions would not be possible.
- Disposable paper filter after every need and textile filters are replaced after 60 sterilization cycles.
- A drying time of the sterilized by at least 20 minutes must be strictly observed after the sterilization cycle. These before-given drying time should not be missed. After this time of sterilization containers and sterile should fully be dried. Remaining moisture or condensation in the sterilization containers can result in storage to bräunli-chen discoloration or rust on the instruments.
- **IMPORTANT!!!**
A load of 10 kg 1/1 sterilization containers practice is not allowed. Smaller sterilization containers must be provided with a corresponding lower loading

- In a suspected or actual contamination of instruments with Creutzfeldt-Jakob agent we often so proceed that the hold time is increased when the sterilization cycle for up to 30 minutes. This can cause various problems when Instrumentarium. however, it is rec-

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ommendable for the tools and the applications to choose an appropriate disinfectant prior to sterilization as e.g. the Robert Koch Institute (see literature sources) under certain conditions pretending. But if at a suspected or actual contamination of instruments not carried out safely with the Creutzfeldt-Jakob agent sterilization, the instruments must be disposed of properly.

12 When cleaning, disinfection and sterilization in particular the following sources are considered:

- AKI - Guide "instruments Proper Maintenance"
- RKI - recommendations: "Hygiene requirements in the reprocessing of medical devices"
- DIN EN 285 large steam sterilizers
- DIN EN13060 small steam sterilizers
- DIN EN ISO 15883-1-3 cleaning disinfectors
- DIN EN 868 / ANSI AAMI ISO 11607 Packaging for terminally sterilized medical devices
- DIN EN 556-1 Sterilization of medical devices - Requirements for final
- ISO 17664 Sterilization - Information of the manufacturer
- DIN EN ISO 17665-1 Sterilization method - wet heat
- EN ISO 14937 Sterilization of health care products
- DIN EN ISO 11737-1 Sterilization of medical devices - Microbiological methods part 1
- DIN EN ISO 11737-2 Sterilization of medical devices - Microbiological methods part 2
- DIN 58946-7 Sterilization, Steam sterilizers

(AKI = Working Group Instrument Preparation / RKI = Robert Koch Institute)