EN

Instructions for use cutting instruments

Product groups	
01.01	*Scissors*
01-02	*Micro Scissors*
01.03	*Cutting instruments*
01-04	*Cutting instrument, pen and wire*
01-05	*Chisel*
01-06	*Rongeure*
01-07	*Dermatome*
01-08	*Urethrotome*
01-09	*Punching*
01-10	*Snare instruments*

Valid from: 18.05.2022

These instructions for use replaces the previous version:	*IFU_300_V_01*

	*IMPORTANT PRODUCT INFORMATION PLEASE READ CAREFULLY BEFORE EACH CLINICAL APPLICATION!*
	*The products are non-sterile and must undergo a reprocessing process before clinical use.*
CE	*The products are medical devices, marked with CE sign*

Content

1 META INFORMATION

Dear Customer!
With the purchase of this instrument, you receive a high-quality product whose proper handling and use are described below. In order to minimise hazards for patients and users, please read the instructions for use carefully and observe them.

1.1 Manufacturer

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1.2 Applicable documents

Additional information may be required for the application of the products described here.
You can find this additional information, e.g. instructions for proper reprocessing, sterilisation, on our homepage www.anton-hipp.de.

www.anton-hipp.de

1.3 Scope

The scope of these instructions for use refers to all cutting instruments in our catalogues and brochures. A precise article-related assignment can be found in the master reprocessing instructions listed below:

For details and information on cleaning, disinfection and sterilisation as well as assignment to the item number, please refer to the document
Preparation of products/FB-134_Rev_04*
which can be found on our homepage under https://www.anton-hipp.de is available for you to download.

2 MATERIALS

The products are made of stainless steel according to DIN EN ISO 7153-1.

3 PRODUCT DESCRIPTION

Our cutting instruments are designed for surgically invasive and partly also for non-surgically invasive treatments in various specialities of medicine.

3.1 Intended Use / Indications

PG #	Product group	Intended use / Indication
01-01	Scissors	A hand instrument, not used in conjunction with an active medical device, for a surgical procedure in the field of general surgery, whose function is to cut through / cut tissue or vessels and to bluntly separate tissue structures during surgical procedures. It is also needed as an aid during operations or the treatment of patients (sutures and bandages). The surgical instrument can be reused after appropriate procedures have been performed. The medical device is used in medical practices, hospitals and clinics by surgeons, physicians and trained professionals such as dental assistants or surgical assistants.
01-02	Micro Scissors	A hand-held instrument, not used in conjunction with an active medical device, for a surgical procedure in the field of general surgery, the function of which is to sharply or bluntly separate fine tissue structures or vessels during surgical procedures. The surgical instrument may be reused after appropriate procedures have been performed. The medical device is used in medical practices, hospitals and clinics by surgeons, physicians and trained professionals such as dental assistants or surgical assistants. The products are intended for temporary use.
01-03	Cutting instruments, knives, knife holders	A hand-held instrument, not used in conjunction with an active medical device, intended for use in a surgical procedure, the function of which is to sever/cut tissue, ligaments and tendons and to bluntly separate tissue structures in surgical procedures. The surgical instrument can be reused after appropriate procedures have been performed. The medical device is used in medical practices, hospitals and clinics by surgeons and doctors.
01-04	Cutting instruments, pins and wires	A scissor-like or forceps-like stable hand instrument, not used in conjunction with an active medical device, for a surgical procedure in the field of general surgery, the function of which is to cut through metallic materials. The surgical instrument can be reused after appropriate procedures have been carried out. The medical device is used in medical practices, hospitals and clinics by surgeons, physicians and trained specialist staff such as specialist assistants in orthopaedics. The products are intended for temporary use.

01-05	*Chisels & Osteotomes*	*Chisel and osteotome; nasal osteotome; flat chisel; rhachiotome: A surgical, chisel-like hand instrument for cutting and/or shaping bone by poking during an orthopaedic procedure. It is held by the surgeon, who applies a manual force to the proximal end of the instrument via a surgical hammer. The distal end (the cutting or sharp edge) is sharp, often flat, sometimes curved (concave), and usually bevelled on both sides. It is made of stainless steel and is a reusable instrument.*
01-06	*Rongeure (Gouge/bone splinter pliers)*	*A stable hand-held instrument, not used in conjunction with an active medical device, intended for a surgical intervention in the field of bone surgery, plastic surgery, the function of which is assigned to the The surgical instrument is used for* cutting through bones and bone parts and for *smoothing bones by nibbling them off during surgical procedures. The surgical instrument can be reused after appropriate procedures have been performed. The medical device is used in dental practices, hospitals and clinics by surgeons and physicians. The products are intended for temporary use.*
01-07	*Dermatome*	*A hand instrument, not used in conjunction with an active medical device, intended for a surgical procedure in the field of plastic surgery. Used to obtain uniformly thick and thin skin flaps for free grafting. The medical product is used in hospitals and clinics by surgeons, doctors and trained specialist personnel such as plastic surgery assistants. The products are intended for temporary use.*
01-08	*Urethrotome*	*A hand-held instrument, not used in conjunction with an active medical device, intended for a surgical intervention in the field of urology, whose function is to Used to cut strictures in the urethra. The instrument is designed with a laterally movable small knife at the distal end. The surgical instrument can be reused after appropriate procedures have been performed. The medical device is used in medical practices, hospitals and clinics by specialised personnel e.g. surgeons, specialists in urology. The products are intended for temporary use.*
01-09	*Punching*	*A hand-held instrument, not used in conjunction with an active medical device, intended for a surgical procedure in the field of general surgery, the function of which is to remove tissue or bone samples. The instrument may be equipped with a ring handle or pistol grip. The ring handles or pistol grips have elongated shafts with punch-like or mechanical*

		locking mechanisms at the distal end. The surgical instrument may be reused after appropriate procedures have been performed. The medical device is used in medical practices, hospitals and clinics by qualified personnel e.g. surgeons, specialists in e.g. general surgery, orthopaedics, neurosurgery, plastic surgery. The products are intended for temporary use.
01-10	*Snare instruments*	*A hand-held instrument, not used in conjunction with an active medical device, intended for a surgical or invasive procedure, the function of which is to grasp and separate (ligate) tissue, tonsils or fistulas in the ENT. Due to the loop-like design at the distal end, the loop can be tied by means of a lifting movement in order to fix or separate the tissue, tonsils or fistulas. The surgical instrument can be reused after appropriate procedures have been performed. The medical device is used in medical practices, hospitals and clinics by specialist staff e.g. ENT specialists. The products are intended for temporary use.*

3.2 Range of application

The use of our instruments takes place in almost all areas, among others in:

- ✓ *Ophthalmology*
- ✓ *ENT medicine*
- ✓ *Orthopaedics*
- ✓ *Abdominal surgery*
- ✓ *Urology*

3.3 Contraindications

The products are contraindicated for all other uses except the techniques mentioned in the intended purpose / indication(s).

4 WARNINGS

- ✓ *Excessive application of force or axial forces can lead to excessive stress as a result of which the instruments may break.*
- ✓ *To avoid any contact corrosion, instruments with damaged surfaces must be discarded immediately!*
- ✓ *The products are supplied non-sterile and must be cleaned, disinfected and sterilised before first use.*
- ✓ *Defective products must not be used and must have undergone the entire reprocessing process before being returned.*
- ✓ *Please note additional instructions enclosed with the product*
- ✓ *Remove all protective covers and protective films before first use or preparation.*
- ✓ *The safe combination of the products with each other or of the products with implants must be verified by the user before clinical use.*
- ✓ *Avoid improper throwing or dropping of instruments.*
- ✓ *In case of use of the products in patients with Creutzfeldt-Jakob disease or HIV infection, we decline any responsibility for reuse.*

5 COMPLICATIONS / SIDE EFFECTS

After contact with the instrument, hypersensitivity reactions can be triggered in a patient with material intolerance to stainless steel. In the event of such a reaction, the procedure must be stopped immediately and the necessary steps taken.

In the course of market monitoring, further potential complications / side effects could be identified:

1. *Breakage of the instrument and injury to the patient or user*
2. *Perforation (intestinal perforation) in shearing.*
3. *Cuts*
4. *Lack of compatibility*

6 QUALIFICATION OF THE USER

These products are only intended for qualified doctors or specialist personnel with sufficient experience in the respective areas of application, e.g.

- ✓ *Ophthalmology*
- ✓ *Otorhinolaryngology*
- ✓ *Orthopaedics*
- ✓ *Abdominal surgery*
- ✓ *Urology*

designed. Explanations of detailed surgical procedures are therefore omitted.

7 COMBINATION PRODUCTS & ACCESSORIES

The products are not applied with other products and are offered without accessories.
Medical white oil can be used for instrument care.
Theraband can be used for the function check, see also chapter Function check.

No.	*Item number*	*Description*	*Application*
1.	*63.919.00*	*Technical white oil w. container, 250 ml*	*For all articulated instruments*
2.	*THERABAND RED MEDIUM*	*Thera-Band red medium strong, 15cm x 45m*	*For all surgical scissors (function control)*
3.	*ZB1.000.01*	*Fabric quality RO 18*	*For all bandage scissors*

7.1 Scalpels with interchangeable blades

Scalpels can be combined with blades according to DIN EN 27740. The scalpels are designed to be compatible with figures 3, 4 according to DIN 58849-2.

8 APPLICATION & SAFETY INSTRUCTIONS

The products must be checked for defects, cracks, nicks or other damage before use. Damaged products must be sorted out.
The products are delivered in a non-sterile condition and must be completely cleaned, disinfected and sterilised by the user before first use.

9 STORAGE INSTRUCTIONS

Before use, the products must be stored in an environment that maintains their packaging and purity. Dry atmosphere, no extreme temperatures, no exposure to sunlight, ionised radiation and contaminated particles. To avoid corrosion, pay special attention to the absence of chemicals in the immediate vicinity.

10 CLEANING & DISINFECTION

10.1 Basics

If possible, a mechanical process (washer-disinfector) should be used for cleaning and disinfection. A manual process - also using an ultrasonic bath - should only be used if a mechanical process is not available or according to country-specific requirements (e.g. in Germany a mechanical process is mandatory for critical B products) due to the significantly lower effectiveness and reproducibility.

Pre-treatment must be carried out in both cases.

10.2 Pretreatment

Immediately after application (within a maximum of 2 h), coarse contamination must be removed from the products. If this time cannot be observed due to the duration of the application or as a result of organisational aspects, the user must determine and validate measures on his own responsibility in order to prevent the soiling from drying through:

1. *Dismantle the products as much as possible*
2. *Rinse the products for at least 1 min under running water (temperature < 35 °C/95 °F). Rinse all lumina of the products at least three times (auxiliaries and minimum volume depend on the cavity to be rinsed).*
3. *Place the disassembled products in a sufficiently large pre-cleaning bath (in an ultrasonic bath that has not yet been activated) for the specified exposure time so that the products are completely covered. Make sure that the products do not touch each other. Support the pre-cleaning by completely brushing all inner and outer surfaces (at the beginning of the soaking time). The brushes for the channels must be slightly larger than the respective channel inner diameter; the shaft length of the brush must be at least as long as the channel.*
4. *Activate the ultrasound for a renewed minimum exposure time (but not less than 5 min).*
5. *Then remove the products from the pre-cleaning bath and rinse them thoroughly with water at least three times (at least 1 min). Rinse all lumina of the products at least three times (auxiliaries and minimum volume depend on the cavity to be rinsed).*

When selecting the cleaning agent system to be used, pay attention to this,

- *that this is basically suitable for cleaning invasive medical devices made of metals and plastics,*
- *that the cleaning agent is suitable for ultrasonic cleaning (no foam development),*

- *that the detergent is compatible with the products*

The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent or detergent and disinfectant, as well as specifications for post-rinsing, must be strictly adhered to. Use only freshly prepared solutions, only sterile or low-germ (max. 10 germs/ml) as well as low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) or, for drying, only a soft, clean and lint-free cloth (caution: be careful with products with rough surfaces, threads, sharp edges or similar, on which particles from the cloth can stick!) and/or filtered air.

10.3 Mechanical cleaning/disinfection (WD)

When selecting the WD, pay attention to the following,

- *that the WD basically has a tested effectiveness (e.g. DGHM or FDA approval/clearance/registration or CE marking according to DIN EN ISO 15883),*
- *that, if possible, a tested programme for thermal disinfection (A0 value > 3000 or - for older units - at least 5 min at 90 °C/194 °F) is used (in the case of chemical disinfection, there is a risk of disinfectant residues on the products),*
- *that the programme used is suitable for the products and contains sufficient rinse cycles (at least three depleting steps after cleaning (or neutralisation, if applied) or conductivity control recommended to effectively prevent detergent residues)),*
- *that only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used for rinsing,*
- *that the air used for drying is filtered (oil-free, low in germs and particles) and*
- *that the WD is regularly maintained, checked and calibrated.*

When selecting the cleaning agent system to be used, pay attention to this,

- *that this is basically suitable for cleaning invasive medical devices made of metals and plastics,*
- *that - if thermal disinfection is not used - a suitable disinfectant with tested efficacy (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is also used and that this is compatible with the cleaning agent used, and*
- *that the chemicals used are compatible with the products (see chapter "Material resistance").*

The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent and, if applicable, disinfectant, as well as the instructions for rinsing must be strictly observed.

Procedure:

1. *Place the products in the washer-disinfector. Make sure that the products do not touch each other.*
2. *Start the programme.*
3. *Remove the products from the washer-disinfector at the end of the programme.*
4. *Check and pack the products as soon as possible after removal.*

Proof of the basic suitability of the products for effective manual cleaning and disinfection was provided by an independent, officially accredited and recognised (§ 15 (5) MPG) test laboratory using the pre-cleaning and cleaning agent Cidezyme/Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt). The procedure described above was taken into account.

11 FUNCTIONAL TESTING AND PACKAGING

The products must be checked for cleanliness and functionality after reprocessing and before sterilisation. If necessary, the reprocessing process must be repeated until the product is visually clean.

Please pack the products or the sterilisation trays in sterilisation containers or very large products in single-use sterilisation packaging (single or double packaging) that meet the following requirements (material/process):

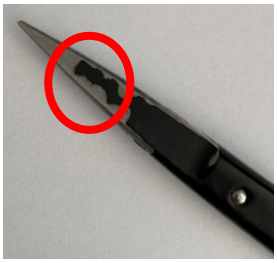
- *DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)*
- *suitable for steam sterilisation (temperature resistance up to at least 138 °C (280 °F) sufficient steam permeability)*
- *Sufficient protection of the products or sterilisation packaging against mechanical damage.*
- *Regular maintenance according to the manufacturer's specifications (sterilisation container)*
- *A maximum weight of 10 kg per package/content of the sterilisation container must not be exceeded*

Check the scissors for flawless surfaces and functionality. Do not use severely damaged instruments, instruments with unrecognisable marks (markings), signs of corrosion or blunt cutting edges. Do not resharpen blunt scissors yourself.

Without crack and break

Crack with fracture

Homogeneous surface



Damaged surface

12 STERILISATION

Only the sterilisation methods listed below may be used for sterilisation; other sterilisation methods are not permitted.

12.1 Steam sterilisation:

- *fractionated vacuum process (with sufficient product drying)*
- *Steam steriliser according to DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)*
- *Validated according to DIN EN ISO 17665 (valid IQ/OQ (picking) and product-specific performance assessment (PQ))*
- *Maximum sterilisation temperature 134 °C (273 °F; plus tolerance according to DIN EN ISO 17665)*
- *Sterilisation time (exposure time at the sterilisation temperature):*

Country	*fractionated vacuum process*
Germany	*min. 5 min at 134 °C (273 °F)*
USA	*min. 4 min at 132 °C (270 °F), drying time min. 20 min*
France	*min. 5 min at 134 °C (273 °F)* *if required for prion inactivation Sterilisation time 18 min*
other countries	*min. 5 min at 132 °C (270 °F) / 134 °C (273 °F)*

Proof of the basic suitability of the products for effective steam sterilisation was provided by an independent, officially accredited and recognised (§ 15 (5) MPG) test laboratory using the HST 6x6x6 steam steriliser (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum process. Typical conditions in clinics and medical practices as well as the procedure described above were taken into account.

⚠ ***Hint:***
For further details and information on cleaning, disinfection and sterilisation, please refer to the document
Preparation of products/FB-134_Rev_04*
which can be found on our homepage under https://www.anton-hipp.de is available for download.

12.2 Storage

Store sterilised instruments in sterile packaging in a closed cabinet, protected from dust, moisture and temperature fluctuations.

13 DISPOSAL

If the instruments can no longer be reprocessed, they should be disposed of in accordance with hospital practice.

- ✓ *Ensure that instruments are disposed of adequately protected so that sharp edges, cutting edges do not pose physical hazards.*
- ✓ *That the respective country-specific laws and regulations are complied with.*

14 RESTRICTION OF RECYCLING

The products are basically reprocessable. Due to the product design, the materials used and the intended use, no numerically defined end of life of the medical devices can be predicted. The products may no longer be reused,

- ✓ *in case of damage to the surface (e.g. rust formation, cracks, sharp edges or similar).*
- ✓ *if the labelling is no longer legible and traceability is therefore no longer guaranteed*
- ✓ *If the coatings are damaged (see also chapter Functional test)*
- ✓ *After treatment of a patient infected with Creutzfeldt-Jakob disease.*
- ✓ *when the products no longer fulfil their function (cuts).*

In the above cases, the products must be disposed of.

15 Serious incidents

Any serious incident occurring in relation to the medical device shall be reported to the manufacturer and the competent authority in the Member State where the user and/or the patient is located.

16 WARRANTY

The products are made of high-quality materials and are subjected to quality control before delivery. Should faults nevertheless occur, please contact our service department. However, we cannot guarantee that the products are suitable for the respective operation. This must be determined by the user himself. We cannot accept any liability for accidental or resulting damage.

Any product liability expires,

- ✓ *in case of damage due to improper storage, handling, cleaning and / or sterilisation.*
- ✓ *in case of faulty cleaning and sterilisation*
- ✓ *in case of non-observance of these instructions for use*

17 Maintenance and repair

Maintenance and repairs may only be carried out by Anton Hipp GmbH itself or by persons authorised to do so by Anton Hipp GmbH. This is the only way to preserve guarantees and warranty claims. Defective instruments can be sent to Anton Hipp GmbH for repair. Anton Hipp GmbH will assess whether the instrument can be repaired or not. When returning the faulty instrument, a delivery note with the following information must be enclosed:

- ✓ *Clinic address, contact person and telephone number*
- ✓ *Article number of the returned faulty instrument*
- ✓ *Description of the problem*
- ✓ *Evidence of decontamination*

18 ADDITIONAL INFORMATION

If the chemicals and machines described here are not available, and if the reprocessing process is not to be carried out as described, it is the user's responsibility to validate his process accordingly.

Further instructions for the reprocessing of medical devices:

- ✓ *Internet: http://www.rki.de*
- ✓ *Internet: http://www.a-k-i.org*
- ✓ *Requirements for hygiene in the reprocessing of medical devices Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Requirements for hygiene in the reprocessing of medical devices".*

18.1 APPLICABLE STANDARDS - REFERENCES

When cleaning, disinfecting and sterilising, pay particular attention to the following sources:

1. *AKI - Guide "Instrument reprocessing done right*
2. *RKI - Recommendation: "Hygiene requirements for the reprocessing of medical devices DIN EN 285 Large steam sterilisers*
3. *DIN EN 13060 Small steam sterilisers*
4. *DIN EN ISO 15883-1-3 Washer-disinfectors*
5. *DIN EN 868 / DIN EN ISO 11607-1 Packaging for medical devices to be sterilised in their final packaging*
6. *DIN EN 556-1 Sterilisation of medical devices - Requirements for final packaging*
7. *DIN EN ISO 17664 Sterilisation - Information from the manufacturer*
8. *DIN EN ISO 17665-1 Sterilisation process - moist heat*
9. *DIN EN ISO 14937 Sterilisation of health care products*
10. *DIN EN ISO 11737-1 Sterilization of medical devices - Microbiological process Part 1*
11. *DIN EN ISO 11737-2 Sterilisation of medical devices - Microbiological process Part 2*
12. *DIN 58946-7 Sterilisation, steam sterilisers*
13. *(AKI=Arbeitskreis Instrumenten-Aufbereitung / RKI = Robert Koch Institute)*

19 SYMBOL EXPLANATIONS

The conformity assessment procedure for the products was carried out under sole responsibility. These instruments are marked with CE without the number of the Notified Body.

	*Manufacturer*		*Store dry*
	*Non-sterile*		*Protect from sunlight*
	*Do not reuse*		
	*Attention*		
	*Follow the instructions for use*		
	*CE marking*		
	*Batch designation*		
	*Order number*		
	*Conditionally MR-safe*		
	*Medical device*		