Instructions for Use (GA16)

Instruments and Accessories

for

Arthroscopy
Endoscopy
Laparoscopy
Resectoscopy
Urology
Hysteroscopy

made from
stainless steels as per DIN EN ISO 7153-1
and from high quality plastics approved for use in medicine

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CE 0297

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1. General

US Federal Law restricts this device to sale by or on the order of a physician only.

Our products have been especially developed and manufactured for use in medicine. The products may only be used by competent persons and only for their intended purpose.

Using them for different purposes or the non-observance of safety notes, reprocessing instructions and contraindication can cause damage to, or functional failure of, the product, or cause injuries to the patient, the operator or personnel, or even their death.

2. Product description

1. Material:
   Instruments and accessories for arthroscopy, endoscopy, resectoscopy, laparoscopy urology and hysteroscopy are made exclusively from stainless steel as per ISO 7153/1 and from high quality plastics approved for use in medicine.

2. Magnetism:
   Both instruments and accessories are magnetic!

3. Mechanical characteristics:
   HERMANN instruments are distinguished by a high degree of stability as well as by above average elasticity, ensuring excellent results in both static and dynamic loads.

- Instruments for arthroscopy:	Diameter = 3.5 mm:	Force on grip max.	100 N
	Diameter = 2.7 mm	Force on grip max.	60 N
- Instruments for laparoscopy:	Diameter > 5.0 mm	max.	150 N
	Diameter ≤ 5.0 mm	max.	50 N
Micro scissors		max.	40 N
Clip forceps:	Diameter = 10mm	Force on grip max.	150N
	Diameter = 5mm	max.	100N
- Instruments for endoscopy:	Diameter ≥ 1.8 mm:	max.	50 N

4. Design
   Because the manufacturer has designed the product to be suitable for every application, there is no risk either for the patient or the operator **if applied properly**.

3. Indication

Instruments and accessories are dedicated to the relevant defined area of arthroscopy, endoscopy, resectoscopy, laparoscopy, urology and hysteroscopy and the resulting applications for the treatment, grasping and cutting of selected tissue.

4. Contraindication

The use of instruments for arthroscopy, endoscopy, resectoscopy and laparoscopy, urology and hysteroscopy is contraindicated if the relevant procedures cannot/may not be used in the opinion of the treating physician.

Heart pacemakers can be damaged by HF current. A cardiologist is to be consulted before commencing surgery.
HF current must never be used in the immediate vicinity of flammable liquids and anaesthetics.
As instruments and accessories are magnetic, products must not be used in areas where magnetic fields are present or in which products can interfere with magnetic fields.

For further information regarding contraindication, please consult the instructions for use of the relevant HF generator manufacturer.

5. Technical notes

All instruments, accessories and equipment are to be checked for functionality before every use.
All safety procedures and notes stated by the manufacturer of the electrosurgical generator are to be observed.

! Caution: There is a possible risk of burns from non-insulated areas of the insulated products during HF surgery!
Only switch on the current if the tip of the instruments is entirely visible and touching the tissue that is to be coagulated.
The tip of the instrument must **not** touch the optics or other metal instruments during its use.

All monopolar products can be operated with a voltage of up to 5000 V DC / 3500 V AC.

Resectoscopic procedures

! Caution: The electrodes are to be checked for correct configuration before every use!
HF electrodes in connection with standard resectoscopes may be used in the standard cutting and coagulation mode only with a peak voltage of max. 2.0 kVp.

Bipolar instruments:
Bipolar instruments are to be used with the bipolar connectors of the relevant HF unit. 60 Watt in the bipolar coagulation mode of the generator may not be exceeded.

As soon as the instrument is connected to the mains power, it can be used either in the right or the left hand, and any desired hand grip position can be achieved to avoid any cramp in the hand and to prevent any signs of fatigue.
Closing the jaws: Press the grip together.
Opening the jaws: Slightly release the pressure on the grip

6. Compatibility

1) Arthroscopy
HERMANN instruments and accessories are compatible within the stated diameters for arthroscopic procedures.

2) Endoscopy
HERMANN endoscopy forceps are compatible within the stated diameters for endoscopic procedures.
The electric biopsy forceps are compatible for endoscopic procedures within the stated diameters and with a maximum device open circuit voltage of 3000 V.

3) Resectoscopy
HERMANN instruments and accessories are compatible within the stated diameters for resectoscopic procedures.

4) Laparoscopy
HERMANN instruments and accessories are compatible within the stated diameters for laparoscopic procedures.
The HF instruments and the cables are compatible with each other and with all instruments, cables, adapters and HF devices with a connection of 4 mm diameter and a max. device open circuit voltage of 3000 V.
HERMANN clip forceps are compatible with all items with the stated diameters and sizes. Only such types of clips that are shown on the instrument should be used.

5) Urology
HERMANN instruments and accessories are compatible within the stated diameters for urologic procedures.

6) Hysteroscopy
HERMANN instruments and accessories are compatible within the stated diameters for hysteroscopic procedures.

7. Residual risk

- Complications from breakages of the instruments during use inside the body due to overloading.
- Burns at contact areas during HF surgery due to faulty insulation of HF instruments or due to non-insulated areas of the instruments.
- Infections due to insufficiently cleaned instruments/accessories
  In this respect it is imperative to read the reprocessing instructions!
- Chemical burns / inflammations due to non-evaporated disinfectants

HERMANN does not give any guarantee that the products are suitable for the intended surgery. Only the competent user can determine this.
We do not accept any liability for any accidental or resultant damage.
HERMANN also does not accept any liability if it is proven that the instructions for use have not been followed.

8. Reprocessing instructions as per DIN EN ISO 17664

8.1 Notes and warnings

!!! All instruments/accessories are reusable. They are delivered non-sterile and have to be cleaned, disinfected and sterilised without fail by competent personnel before **each** use according to the validated infection prevention procedures!

In order to avoid any damage and deformation, components shall not be incompetently "thrown", not only during transportation but also during cleaning, sterilisation and storage, instead they shall be deposited on machine-suitable instrument carriers (e. g. sterilisation trays).

In order to avoid hole corrosion (pitting/corrosion), components are not to be deposited in physiological saline.

In order to avoid tension crack corrosion, it is principally necessary to treat instruments/accessories in their open state whenever possible. Components with ratchet lock are to be closed to their first ratchet. In order to avoid contact corrosion, never treat any chromed components having damaged surfaces, or non-stainless steel components together with stainless steel components.
Components already showing early corrosion are to be sorted out.

8.2 Limitation/Constraint of reprocessing

Frequent reprocessing has little effect on the products. The end of the product life span is usually determined by wear and tear and damage due to usage. Heavily stressed and frequently used components are to be checked and maintained or replaced frequently.

8.3 Time until cleaning/Preparation at location of use

Components are to be cleaned **immediately** after use, rough contamination is to be removed immediately at the location of use. Dirt particles must under no circumstances be allowed to become surface-dry. If cleaning is not carried out as quickly as possible, there is the risk that dirt particles or secretions can surface-dry and remain attached during cleaning and then survive the sterilisation process. To counteract any increased surface drying, components should be kept in closed disposal containers until cleaning.

8.4 Preparation for decontamination

Before cleaning

- in the case of new ex-factory products, remove the original packaging
- if present, dismount all removable parts, and dissemble any adaptors and instruments / accessories.
- Remove all seals, open up all apertures. Disassembly according to manufacturer's instructions.

Caution: All individual components to be kept and retained together. Under no circumstances may they be mislaid or mixed up with (similar) components of other manufacturers, in order to ensure any future reassembly without problems.

8.5 Cleaning

Based on international standards and national guidelines, only validated mechanical cleaning and disinfection procedures should be used.

Irrespective of whether the cleaning is mechanical or manual, it should be checked carefully as to which cleaning agent is to be used with which procedure and for which products. Thinning and application instructions are to be observed at all times.

! Do not use any chlorous or fluorine-containing cleaning agents - risk of corrosion!

8.5.1 Manual cleaning, disinfection and drying

a) Manual cleaning

The following are required for cleaning: lint-free soft cloth, various soft nylon brushes, blast pipe and nozzle, clean compressed air device

! Do not use any steel wool, metal brushes or abrasive cleaners!

! With the chemical products to be used for cleaning (recommended ph value: between 7.0 and 8.5), the manufacturer's data regarding concentration, temperature and application time are to be strictly adhered to. Also check the chloride concentration in the water in order to avoid pitting corrosion. The instructions for use of the instrument manufacturers must be followed without fail.

Solutions for use shall be prepared fresh daily, in the case of heavy contamination more frequently, to prevent corrosion.

All individual components shall be placed into a cleaning and disinfection bath holding non-fixing disinfectants, suitable for the relevant instruments. Application time according to data of the disinfectant manufacturer. Then rinse thoroughly with cold water (≤ 20 °C). Movable parts are to be moved during the disinfection and during the rinsing.
Fixed contaminations are to be treated with a mild rinsing agent. In the case of endoscopic parts, use a low surfactant medical endoscope cleaning agent with a neutral pH value (e.g. Enzol™).
Endoscopic components can be placed into a hand-warm solution for a maximum of 60 minutes to remove stubborn contaminations.

Hollows and internal components, in particular areas with difficult access, should be cleaned with cleaning brushes and perhaps cleaning pistol or jets, until all visible contaminations are completely removed. Components with a flushing connection that cannot be removed are to be flushed thoroughly with a cleaning solution.
Endoscopic instruments are highly sensitive and easily damaged. Components with cavities and channels/pipes are therefore to be treated with particular care.

Thereafter, cleaning in the ultrasonic bath is carried out.

! Not suitable for optics and cables!

Components must be completely covered by the cleaning solution. Instruments with joints must be treated in their open state. Ensure suitable trays (= wire-mesh trays). Do not overload the trays. Ensure that products with large surfaces do not throw any acoustic shadows. The ultrasonic bath is to be renewed daily, and more frequently if soiled heavily.

Dip parts for 3-5 minutes, flexible endoscopy instruments for max. 2 min., in an ultrasonic cleaning bath with a frequency of at least 35 kHz.

After the ultrasonic bath, rinse all components, in order to completely remove any residual cleaning material. If disinfection is not possible immediately afterwards, the components must be completely dried, this is preferably done using compressed air.

Check instruments/accessories for visible contamination. Repeat the cleaning process if contamination is visible, and check again.

b) Disinfection

! Do not use any chlorous or fluorine-containing disinfectants - risk of corrosion!

! Chemical disinfection is not suitable for aluminium components!

Chemical disinfection at max. 60 °C / 140 °F (appli cation time min. 60 minutes) if thermal disinfection in rinsing appliance is not possible - for thermo-labile instruments as for instance endoscopes, or

large, angular optics. Instruments or tools – dismantled, if appropriate – are to be placed into the sieve insert of the disinfectant bath. Dip the sieve insert into the disinfectant bath which is filled with a disinfectant solution. Hollows must be wetted entirely with the disinfectant solution. Use gripping forceps with rubber jaws for treating the instruments / accessories during the disinfection process. If different aids are used, components could be damaged. Use only such disinfectant solutions that are expressly approved by their manufacturers for use with the relevant products. Disinfectant solutions must always be applied diluted. Do not use any foaming solutions.
(List of disinfectants: DGHM – disinfectant for hospitals and practice, RKI – disinfectant for officially instructed disinfection measures).

Renew disinfectant solutions daily.

! Strictly follow manufacturer's dosage instructions and application times for disinfectants!

After the disinfection bath, components must be rinsed with demineralised water. Outer surfaces of components, all channels and hollows must be rinsed thoroughly with water in order to completely remove any disinfectant residues. The components must be dried immediately afterwards.

c) Drying

Every component must be completely dry inside and out after cleaning / disinfection, in order to prevent corrosion or malfunction. Excess liquid is to be dried off additionally using sterile cloth / swabs; hollow components or hinges, internal channels and areas that are difficult to access can be dried using the compressed air device. Thereafter the components are wrapped in sterile cloths and stored in closed containers.

8.5.2 Mechanical cleaning, disinfection and drying (combined)

Mechanical cleaning is the preferred method, in particular for all pointed and delicate components as well as for light conducting cable. When using mechanical cleaning in the washer, the washer program includes thermal disinfection and subsequent drying.

! With the chemical products to be used for cleaning, the manufacturer's data regarding concentration, temperature and application time are to be strictly adhered to. Also check the chloride concentration in the water in order to avoid pitting corrosion. The instructions for use of the instrument manufacturers must be followed without fail.

All individual components shall be placed into a cleaning and disinfection bath holding non-fixing disinfectants, suitable for the relevant instruments. Application time according to data of the disinfectant manufacturer. Then rinse thoroughly with cold water (≤ 20 °C). Movable parts are to be moved during the disinfection and during the rinsing.

Thereafter, cleaning in the ultrasonic bath is carried out.

! Not suitable for optics and cables!

Components must be completely covered by the cleaning solution. Instruments with joints must be treated in their open state. Ensure suitable trays (= wire-mesh trays). Do not overload the trays. Ensure that products with large surfaces do not throw any acoustic shadows. The ultrasonic bath is to be renewed daily, and more frequently if soiled heavily.

Dip parts for 3-5 minutes, flexible endoscopy instruments for max. 2 min., in an ultrasonic cleaning bath with a frequency of at least 35 kHz.

After the ultrasonic bath, all components are to be rinsed.

Check instruments/accessories for visible contamination. Repeat the cleaning process if contamination is visible, and check again.

Thereafter place the components in the washer.

Ensure correct loading of the sieves or inserts, appropriate to the rinsing.
Multi-component products with threads, springs, ratchets or hinges, as well as components with joints, should be cleaned in their open state. Do not overload the wire sieves, place heavy components on the bottom of the sieve. Ensure that products with large surfaces do not throw any rinsing shadows.

In the washer, carry out the automatic washing:

! Caution: Only autoclavable optics may be placed into the washer with the following program. Otherwise, a program with a lower temperature should be selected.

The manufacturer recommends the following procedure:

- 2x pre-rinses with cold water without any additives
- Cleaning at 55 °C ± 2 °C for at least 5 minutes with an alkaline cleane r (for the mechanical cleaning of thermo-stable and thermo-labile instruments,
  e.g. neodisher ® MediClean)
- 1st intermediate rinsing with cold water, neutralisation e.g. with neodisher ® Z
- 2nd intermediate rinse with cold water
- Thermal disinfection at 92 °C ± 2 °C for at least 5 minutes
- Drying at 50 °C for at least 30 minutes
  (In the event of any remaining dampness – place the instruments into a drying cabinet for after-drying at 60 °C)
  The drying time depends on the loading and on the type of items being rinsed.

Check instruments / accessories for visible contamination. Repeat the cleaning process if contamination is visible, and check again.

8.6 Checking/Maintenance/Testing/Care

Instruments must be free from visible residues. Critical areas (grips, joints, jaw grooving, teeth, hollow components) require particularly careful checking.

Before every usage it should be checked as to whether the instrument/accessory is fully usable and functioning properly:

For that purpose, all disassembled components are to be re-assembled, and any worn parts and defective individual components are to be replaced. Insulation in particular is to be checked for damage.

If any visible damage like cracks, abnormal bending, breakages or malfunctions appear, the part must not be used any more. Particular attention should be paid to gaps, ratchets, points, pipes (and their continuity) and other components difficult to access.
Also the cutting ability of cutting edges should be checked.

Resectoscopy: The resectoscope should be assembled at the operating table. The electrodes are to be checked for correct configuration before every use.

Check the surfaces of cables, connectors and electrode grips for irregularities. No cables with brittle or damaged insulation may be used. If in doubt, use professional testing devices to check any functionality.

If the inspection result is unsatisfactory, take the component out of circulation and replace it with a different one, and the defective component (after complete processing) is to be returned to the manufacturer for assessment or reworking. Defective HF cables or electrode grips cannot be repaired. They should always be renewed
Caution: **Do not** carry out any repairs yourself! These may only be carried out by trained competent personnel.

Products with mobile components must be lubricated or oiled on the joint parts or on all moveable parts after cleaning, but before sterilisation. Use only biological oils without any acids, they should be able to be steam-sterilised and vapour-permeable; pure neatsfoot oil is recommended. When using special instrument oil solutions, the products can be placed into the solution for a certain time. In certain instrument washing machines, the lubrication process is already integrated. Re-rinsing is not required. The components can be packed after drying. Please remove excess oil before packing. Plastic surfaces must not be treated with instrument care products.

8.7 Packing

All products that can be sterilised, and which are subject to intermediate storage, transportation and possible further storage until being used, are to be sterilised in suitable packaging.

Choose packaging depending on the sterilisation procedure!
For steam sterilisation:

Place components in their assembled state into sterile transparent packaging and seal, or use a suitable container for sterilised goods, if appropriate. (If appropriate, read separate instructions for use!) Do not exceed recommended load weights in order to avoid the formation of too much condensate during sterilisation. If heavy sets are unavoidable, spread the components across several packaging units.

8.8 Sterilisation

! Do not use hot air sterilisation on any instruments/accessories containing rubber/plastic or on any components with coatings/insulation! Due to the high temperatures associated with this method, the microstructure of the steel in these instruments could change and/or the rubber/plastic/coating and/or insulation components could be damaged or the entire product could be destroyed.

The manufacturer recommends steam sterilisation as per DIN EN ISO 17665-1:

Recommended temperature: 132℃/270℉, holding time ≥ 4 minutes - or 134℃/273℉, holding time ≥ 5 minutes.
Drying time 10 min. If the drying process proves to be insufficient, then further drying can be undertaken.

Sterilisation devices have different construction and performance characteristics, therefore any cycle parameters should always be harmonised with the manufacturer's instructions for the relevant sterilisation device and the applied load configuration.

Operating instructions and recommendations of the steriliser manufacturer are to be followed precisely!

The relevant sterilisation procedure should be tested and validated regularly!

8.9 Storage

Please store the instruments/accessories in their packaging, dry and clean. Please take particular care that there are no chemicals within close vicinity. Transportation in packed state only. To ensure safe use of the products it is imperative to observe that the sterile packaging remains undamaged.
Direct sunlight onto cables and plastic components over longer periods should be avoided. Please use a sterilisation indicator for the packaging and note down the sterilisation and expiry dates on the packaging.

8.10 Additional information

Causes of corrosion on stainless steels:

- damaged surfaces
- reaction to surgical exudates like blood, pus or bodily secretions over longer contact periods with the instruments
- excessive exposure to certain solutions: salt solutions, iodine solutions, chloride and strong acids, alkaline solutions as well as improper use of disinfectants!
- poor water quality during cleaning, steam sterilisation or rinsing of instruments - caused, for example, by rusty water pipes, immersion of rust metal particles into steam sterilisers etc.
- insufficient maintenance of instruments; in the case of corrosion, rust can be transferred to other components (avoid contact without fail, as it is very dangerous during sterilisation)

Measures for prevention of corrosion, and recommendations

- carefully prepare correctly packed and sterilised instruments before the operation; selection of instruments depends on the kind of surgery. Always check that the external packaging is intact and the expiry date of the components.
- ensure **that** the contents have been sterilised, by checking the sterilisation indicator inside the sieve.
- arrange the instruments in subsequent order of use during the operation; leave any unused components in the sieve; do not prepare instruments until just before the operation.
- remove blood and other exudates from the instruments – if possible even during the operation; put components back in their allocated place after use.
- flush cannulated components, in order to avoid drying of blood and bone.
- use Ringer-Lakat or salt solution to clean the instruments, but do not place them in the solution.
- start the cleaning process immediately after the operation; all components used during the operation are regarded as contaminated.
- clean the components at a specially designated location within the operating theatre. If the instruments are moved directly to the central sterilisation area, please cover them beforehand, to avoid risk of contamination of personnel or the environment. Please wear protective clothing during removal and cleaning of contaminated components.

8.11 Residual risk for reprocessing

The manufacturer has validated that the above instructions for the preparation of an instrument are suitable for the re-use of such instrument. It is incumbent upon the reprocessor to ensure that the actual reprocessing carried out with the equipment, materials and personnel within the reprocessing unit, achieves the desired results. This normally requires the validation and routine monitoring of the process. Equally, any deviation from the instructions provided shall be carefully evaluated by the reprocessor for their effectiveness and possible detrimental consequences.

9 Symbols

CE 0297	**CE marking with code of the notified body DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main**
	**Manufacturer**
	**Batch Code**
	**Article number**
	**Attention!**
	**Unsterile**
	**Follow the instructions for use**