

EN

Instructions for use of the Product group PG04 arthroscopy

Valid from: 21.10.2026

Language version for professional users

Belgium	Denmark	Germany	Estonia	Finland
BE	DA	DE	ET	FI
Ireland	Croatia	Latvia	Luxembourg	Malta
GA	HR	LV	LU	MT
Netherlands	Austria	Poland	Romania	Slovenia
NL	AT	PL	RO	SL
Cyprus				
EL				

These instructions for use
Replaces the previous version:

IFU_400_V_01_EN



IMPORTANT PRODUCT INFORMATION PLEASE READ CAREFULLY BEFORE EVERY CLINICAL APPLICATION!



The products are non-sterile and must undergo a reprocessing process before clinical application.



CE marking with notified body number

contents

1	META INFORMATION	4
1.1	manufacturer.....	4
1.2	SRN number.....	4
1.3	Applicable documents.....	4
1.4	scope	4
1.4.1	BASIS UDI DI.....	4
1.5	Obligation to report serious incidents	5
1.6	Symbol declarations	5
2	PRODUCT DESCRIPTION	5
2.1	Arthroscopes	5
2.2	Information on quantitative and qualitative data on the material.....	6
2.2.1	Material information	6
3	PURPOSE DETERMINATION	6
3.1	Indication / application restrictions	6
3.1.1	indications.....	6
3.1.2	Application restrictions.....	6
3.2	contraindication	6
3.3	Patient population.....	7
3.4	users	7
3.5	Application environment.....	7
3.6	Warnings, application instructions.....	7
4	Lifetime, residence time	7
5	SAFETY INSTRUCTIONS	8
5.1	Undesirable side effects / complications / risks.....	8
5.1.1	Unwanted side effects / complications / risks	8
5.2	Unsterile product	8
5.3	Exclusion of reusability.....	8
6	PREPARATION - CLEANING, DESINFECTION, CARE AND STERILISATION - OF PRODUCTS.....	9
6.1	GENERAL COMMENTS.....	9
6.2	WARNINGS	9
6.3	CLEANING AND DISINFECTION	9
6.4	PRE-TREATMENT AT THE PLACE OF USE	9
6.5	DEPOSIT (transport for processing (e.g. ZSVA))	10
6.5.1	Dry disposal	10
6.5.2	Wet disposal	10
6.6	MANUAL PRE-CERTIFICATION	10

IFU _400

Instructions for use



6.7	MACHINE CLEANING/DESINFECTION	10
6.8	CONTROL / LIVING PERIOD OF PRODUCTS	12
6.9	MAINTENANCE	12
6.10	PACKAGING	12
6.11	STERILISATION.....	13
6.11.1	Steam sterilization.....	13
6.12	STORAGE	13
6.13	MATERIAL RESISTANCE	13
6.14	REUSABILITY & LIMITATION	14
7	COMBINATION WITH OTHER PRODUCTS	14
7.1	instruments	14
8	EXCLUSIONS OF LIABILITY & GUARANTEE	14

1 META INFORMATION

Dear customer!

With the purchase, you will receive a high-quality product, the proper use of which is described below. In order to keep hazards to patients and users as low as possible, we ask you to read and observe the instructions for use carefully.

APPLICATION TRAINING:

Anton Hipp GmbH also offers user training on its systems and products. Please contact your direct dealer or contact us.

caution



Please read the information in this manual carefully. Improper handling and care, as well as misused use, can lead to risks for patients and users. Please also note the prints on the packaging.

1.1 manufacturer



Anton Hipp
Annastraße 25/1
78567 Fridingen an der Donau
Tel. +49 7463 / 993030
E-Mail info@anton-hipp.de
Internet www.anton-hipp.com

1.2 SRN number

- DE-MF-000005493

1.3 Applicable documents

Additional information may be required for the application of the products described here. This additional information, e.g. information on proper treatment, sterilization or surgical techniques, can be found on our homepage www.anton-hipp.com.

1.4 scope

The scope of these instructions for use covers the following products or systems:

1.4.1 BASIS UDI DI

Product family	BASIS UDI DI
arthroscopy	40665910000000042XV

1.5 Obligation to report serious incidents

Serious incidents related to the device shall be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established. This notification must be made immediately after the occurrence, so that important notification deadlines can be met. The products concerned must be segregated, processed and sent to the manufacturer for examination. Your specialist dealer will be happy to help you with this. Upon receipt of your notification, we will inform you of the further necessary measures within a reasonable timeframe.

1.6 Symbol declarations

The CE marking with the notified body number shall apply only to arthrosopes. These instruments shall be marked with CE marking without a notified body number.

	manufacturer		Store dry
	Information on the production period		Protect from sunlight
	Unambiguous product identification		Order number
	Global body: GS1		Medical device
	caution		Batch name
	Follow the instructions for use		Unsterile
	CE marking with notified body number		Under U.S. federal law, this product may only be sold to or on behalf of physicians or licensed professionals.
	Refers to the European registration mark		
	serial		
	Unit of measure		Data matrix code

2 PRODUCT DESCRIPTION

2.1 Arthrosopes

A rigid endoscope is a medical instrument for minimally invasive inspection and treatment of body cavities, especially joints (arthroscopy). The endoscope consists of a rigid optical tube, an eyepiece or camera system and optional working channels for instruments.

Structure and components:

- Rigid tube: High-quality metal or medical stainless steel, ensures stable guidance of the instrument.
- Optics: Glass or fiberglass lenses for clear visual access to the body cavity.
- Working channel (optional): For surgical instruments or rinsing/suction devices.
- Connection for light source/camera: Allows illuminated vision and recording of the procedure.
- Handle/handpiece: Ergonomic design for precise handling by the surgeon.

2.2 Information on quantitative and qualitative data on the material

2.2.1 Material information

The following table gives an overview of the materials used in the product groups of Anton Hipp GmbH and at the same time lists an assignment to the associated material standards.

Material standards

- (A) Stainless steel 1.4301, 1.4305, 1.4307, 1.4542
- (B) Bronze 2.1030
- (C) Nickel silver 2.1030
- (D) Car nickel silver 2.0771
- (E) Plastic PPSU

3 PURPOSE DETERMINATION

Product family	Purpose
arthroscopy	Arthroscopes are used on a temporary basis to visualize the interior of joints and are employed for examinations, diagnoses, and—in combination with endoscopically compatible accessories—for treatment. They are used specifically in the hand, elbow, shoulder, hip, knee, jaw, and ankle joints.

3.1 Indication / application restrictions

3.1.1 indications

Arthroscopes are indicated as diagnostic tools for examinations of the wrist, elbow, shoulder, hip, knee, temporomandibular, and ankle joints.

3.1.2 Application restrictions

The product is not intended for use on the central circulatory system or the central nervous system. (*Except vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior)

3.2 contraindication

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

Specific contraindications are:

- Local or Generalized Infections
- severe coagulation disorders
- immunosuppressive therapy (cortisone, etc.).

3.3 Patient population

Patients in whom an arthroscopic examination or treatment of a joint is medically indicated. Use after medical benefit-risk assessment.

3.4 users

users	attribution
Specialists	☒
doctors	☒
Medical professionals	☐
nurses	☐
Medical laypersons	☐
Patient (self-administration)	☐
Specialist in sterile goods supply	☒

Summary:

The users are qualified specialists in their special fields, e.g. orthopedists, oral and maxillofacial surgeons.

3.5 Application environment

The products must be used in a defined operating room/clinic or established practice in a sterile environment.

3.6 Warnings, application instructions

- Excessive force application or axial forces can lead to excessive stress, as a result of which the instruments can break.
- The medical devices are delivered non-sterile and must be cleaned, disinfected and sterilized before the first application.
- Defective products must not be used and must have gone through the entire reprocessing process before returning them.
- Please note additional information enclosed with the product
- Remove all protective covers and films before first use or preparation.
- The safe combination of devices with each other or with implants must be checked by the user before clinical use
- Avoid improper throwing or dropping of instruments.
- To avoid any contact corrosion, instruments with damaged surface must be discarded immediately
- In case of use of the products in patients with Creutzfeldt-Jakob disease or HIV infection, we reject any responsibility for reuse.

4 Lifetime, residence time

The service life of the products depends to a large extent on their sterility and functionality. The products themselves are insensitive to environmental conditions. Furthermore, a lifetime of the products in clinical use cannot be determined. Anton Hipp GmbH guarantees an unlimited retention period of product-specific records in order to meet our obligation as a manufacturer and distributor.

5 SAFETY INSTRUCTIONS

5.1 Undesirable side effects / complications / risks

5.1.1 Unwanted side effects / complications / risks

After contact with the instrument, hypersensitivity reactions can be triggered in a patient with material intolerances to stainless steel. In the course of the market observation, further potential complications / side effects could be identified:

1. Breakage of the instrument
2. Ingestion of components
3. Injury of vessels, tissues
4. thermal injury due to light source
5. Tissue damage due to sharp edges / damaged tube
6. limited visibility due to damaged optics
7. Infection in case of insufficient treatment
8. Breakage / detachment of components
9. Liquid ingress / leakage
10. Burns at fiber optic connection

5.2 Unsterile product

	Non-sterile
	The products are non-sterile and must undergo a reprocessing process before clinical application.

5.3 Exclusion of reusability

The reusability of the arthroscopes is excluded for more than 101 processing cycles, visible defects, limited optical quality, leakage, corrosion, deformation or damage to optics, light connection or tube.

6 PREPARATION - CLEANING, DESINFECTION, CARE AND STERILISATION - OF PRODUCTS

6.1 GENERAL COMMENTS

All products must be cleaned, disinfected and sterilized before each application, especially for the first use after delivery, as all products are delivered non-sterile (cleaning and disinfection after removal of the transport protective packaging; sterilization after packaging). Effective cleaning and disinfection is an indispensable prerequisite for effective sterilization.

As part of your responsibility for the sterility of the products,

- that, in principle, only sufficiently device- and product-specific validated methods are used for cleaning/disinfection and sterilization,
- that the devices used (RDG, sterilizer, etc.) are regularly maintained, checked and calibrated, and
- that the validated parameters are complied with for each cycle.

It is the responsibility of the user to ensure compliance with the hygiene regulations of his facility, taking into account the requirements for reprocessing applicable in the respective country.

6.2 WARNINGS

The products are to be used exclusively by trained specialists.

The treatment may only be carried out by trained specialists in the central sterile goods supply department of the facility.

The facility is also responsible for selecting and applying the necessary protective equipment and hygiene measures.

6.3 CLEANING AND DISINFECTION

For cleaning and disinfection, a machine method (RDG (cleaning and disinfection device)) is preferable. Due to the significantly lower effectiveness and reproducibility, a manual process should only be used in the event of unavailability of a machine process or according to country-specific requirements (e.g. in Germany for critical B products, a mandatory machine process), but is not recommended and is not validated.

6.4 PRE-TREATMENT AT THE PLACE OF USE

Immediately after use (within a maximum of 1 hour), coarse impurities, corrosive solutions or medicines must be removed from the products. If this time cannot be met due to the duration of the application or as a result of organizational aspects, the user must define and validate measures on his own responsibility in order to prevent the dirt from drying through.

sequence

1. Disassemble disassemblable products as much as possible.

Note: For products where assembly/disassembly is not self-explanatory, specific instructions will be provided or prepared upon request.

2. Wipe the medical device with a lint-free, damp cloth or similar. Rinse the products under running water for at least 1 minute (temperature: 35 °C/95 °F). Move moving parts back and forth at least three times during pre-rinsing. Support pre-cleaning by completely brushing all internal and external surfaces with a suitable brush until no impurities are visible.

6.5 DEPOSIT (transport for processing (e.g. ZSVA))

6.5.1 Dry disposal

Transport to the processing unit takes place in closed systems. Dry disposal is always preferable as a gentle method in the direction of value preservation, whereby drying of substances must be avoided.

6.5.2 Wet disposal

In wet disposal, the instruments are preferably inserted into a solution of a detergent or a combined cleaning and disinfectant, which has no protein-fixing effect. Disinfectants containing aldehydes should be avoided as they have a fixing effect.

It is essential to comply with the manufacturer's specifications regarding concentration and exposure time and, where appropriate, addition of cleaning amplifiers.

6.6 MANUAL PRE-CERTIFICATION

Before the products undergo mechanical cleaning in the RDG, we recommend manual pre-cleaning in an ultrasonic bath using a suitable cleaning or disinfectant. For reasons of effective cleaning, make sure that the products are disassembled as far as possible (if necessary according to the manufacturer's instructions), are completely covered and do not touch. The screen trays, racks, brackets, etc. used must be designed in such a way that manual pre-cleaning and subsequent cleaning in the RDG is not obstructed by flushing shadows.

When selecting the detergent used, care must be taken to ensure that:

- it is generally suitable for cleaning invasive medical devices made of metals and plastics,
- the detergent is suitable for ultrasonic cleaning (no foam development),
- the detergent is compatible with the products (see chapter 'Material resistance');
- the detergent is aldehyde-free.

The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning and disinfectant as well as the requirements for rinsing must be strictly adhered to.

Example 'Neodisher MediClean forte (Dr. Weigert)':

Dosage: 0.5-2 % (depending on the degree of contamination)

Temperature: max. 40°C

Exposure time: 10 – 30 minutes in an ultrasonic bath.

rinsing: at least 10 seconds under running drinking water

Use only freshly prepared solutions and purified water (VE water, aqua purificata).

Note:

As part of the validation of this preparation manual, manual pre-treatment was omitted in order to take into account a worst-case approach. We strongly recommend manual pre-cleaning.

6.7 MACHINE CLEANING/DESINFECTION

(RDG = CLEANING AND DESINFECTION DEVICE)

When selecting the RDG, it is important to ensure that:

- the RDG generally has a proven effectiveness (e.g. DGHM or FDA approval / clearance / registration or CE marking according to DIN EN ISO 15883),
- a tested thermal disinfection programme (A0 value > 3000 or, for older equipment, at least 5 min at 90 °C/194 °F) is used (Note: In case of chemical disinfection, risk of disinfectant residues on the products),
- the programme used is suitable for the products and contains sufficient rinsing cycles (at least two depleting steps after cleaning);

- only purified water (VE water, aqua purificata) is used for rinsing,
- the air used for drying is filtered (free of oil / water, low in germs and particles) and
- the RDG is regularly maintained, checked and calibrated.

When selecting the detergent system used, care must be taken to ensure that:

- it is generally suitable for cleaning invasive medical devices made of metals and plastics,
 - if no thermal disinfection is used (not recommended) - additionally a suitable disinfectant with proven efficacy (e.g. VAH/DGHM or FDA/EPA approval / clearance / registration or CE marking) is used and that this is compatible with the cleaning agent used and
- the chemicals used are compatible with the products (see chapter 'Material resistance').

Note: The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning and disinfectant, if any, as well as the requirements for rinsing must be strictly adhered to.

sequence

1. Disassemble disassemblable products as much as possible.
Note: For products where assembly/disassembly is not self-explanatory, specific instructions will be provided or prepared upon request.
2. Insert the disassembled products into the RDG. Make sure that the products do not touch each other. If necessary, enable active flushing by connecting to the flushing connection of the RDG.
3. Start the program. (see table Cycle parameters)
4. Remove the products from the RDG after the end of the program.
5. Check and pack the products as soon as possible after removal (see chapter "Control", "Maintenance" and "Packaging", if necessary after additional night drying in a clean place).

The demonstration of the fundamental suitability of the products for effective mechanical cleaning and disinfection was carried out by an independent test laboratory accredited according to DIN EN ISO 17025 and ZLG-approved using RDG PG8536 (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the pre-cleaning and cleaning agent Neodisher MediClean forte (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above has been taken into account.

Validated cycle parameters

step	denomination	medium	temperature (°C)	Duration (minutes)
1	Pre-rinse	water	Not tempered (< 30°C)	2
2	emptying	-	-	-
3	cleaning	Alkaline detergent: Neodisher Medi-Clean forte (Dr. Weigert GmbH & Co. KG, Hamburg) Concentration: 0,5%	50°	10
4	emptying	-	-	-
5	Rinse I	Deionized water	Not tempered (< 30°C)	2
6	emptying	-	-	-
7	Rinsing II	Deionized water	Not tempered (< 30°C)	2
8	emptying	-	-	-

9	Disinfection (thermal)	A0 > 3000; or ⇔	at least 90°C	min. 5
10	drying	Hot air	100°	20

6.8 CONTROL / LIVING PERIOD OF PRODUCTS

Products that are still dirty must be cleaned and disinfected again.

Unless expressly indicated otherwise, the products can be used several times. The influence of repeated reprocessing was validated by 101 cycles. The validation has shown that repeated reprocessing does not cause damage to the products. The product lifespan is thus fundamentally determined by damage and signs of wear due to use.

In order to be able to prove the suitability of the reuse of the products, they should be checked after each preparation in accordance with the requirements of DIN 96298-4. The following characteristics must be checked:

- cleanliness
- Miscellaneous parts
- fracture
- deformation
- Surface changes such as corrosion, discoloration, cracks, changes in coatings
- marking
- Leakage test
- Fibre optic connection test

The lifespan of the products is terminated when:

- it can no longer fulfil its intended purpose and thus also its function (e.g. breakage or strong deformation)
- traceability is no longer guaranteed (e.g. labeling, UDI code no longer readable)
- the surface is so damaged that the product can no longer be used safely (e.g. rust formation, burr, sharp edges)

If the end of the product's life is reached, the products must be marked as no longer functional and sorted out. After the products have been prepared, they must be repaired by the manufacturer or disposed of as usual at the hospital.

6.9 MAINTENANCE

Reassemble disassembled products.

Note: For products where assembly/disassembly is not self-explanatory, specific instructions will be provided or prepared upon request.

Instrument oils or fats shall not be used. An exception applies in the case of joint oiling, taking into account the maximum applied sterilisation temperature, only instrument oils (white oil, without any other additives) which are approved for steam sterilisation and have a proven biocompatibility and only a small amount of the joints are used shall be used.

6.10 PACKAGING

Standard-compliant packaging must be selected that meets the following requirements (material/process):

- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- Suitable for steam sterilization (temperature resistance 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 (sterilization containers)

- A maximum weight of 10 kg per package/content of the sterilization container must not be exceeded.

6.11 STERILISATION

NOTE: Only the sterilisation methods listed below shall be used for sterilisation, other sterilisation methods shall not be permitted.

6.11.1 Steam sterilization

- fractional vacuum process (at least 3 vacuum steps), (with sufficient product drying)
- Steam sterilizer 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 and product-specific performance assessment (PQ))
- maximum sterilization temperature 134 °C (273 °F; plus tolerance according to DIN EN ISO 17665)
- Sterilization time (exposure time at sterilization temperature):

land	fractional vacuum method
Germany	At least 5 minutes at 134 °C (273 °F)
USA	at least 4 minutes at 132 °C (270 °F), drying time at least 20 minutes
France / Switzerland	At least 5 minutes at 134 °C (273 °F) when required for prion inactivation sterilization time 18 minutes
Other countries	at least 5 minutes at 132 °C (270 °F) / 134 °C (273 °F)

sequence

1. Place the packaged product in the steam sterilizer.
2. Start the sterilization program.
3. Remove the product after the end of the program and successful steam sterilization.

NOTE: Do not use gravitational sterilization, lightning sterilization, hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, and plasma sterilization.

The proof of the basic suitability of the products for effective steam sterilisation was provided by an independent test laboratory accredited and ZLG-approved in accordance with DIN EN ISO 17025 using the steam steriliser 3870 EHS (Tuttnauer) and using the fractionated vacuum process and the instrument oil 'RUCK Instrument Care Oil' (oils of the joints and friction surfaces). Typical conditions in the clinic and doctor's office as well as the procedure described above were taken into account.

6.12 STORAGE

After sterilization, the products must be stored dry and dust-free in the sterilization packaging.

6.13 MATERIAL RESISTANCE

When selecting cleaning and disinfecting agents, make sure that the following ingredients are not included:

- organic, mineral and oxidising acids (minimum pH 5,5)
- alkalis/strong alkalis (neutral/enzymatic cleaner (maximum permissible pH value 8.5, mandatory for products made of aluminium or other alkali-sensitive materials) or alkaline cleaner (maximum permissible pH value 11, mandatory for products with intended application in critical areas, e.g. according to Appendix 7 of the KRINKO RKI BfArM recommendation for preparation) recommended)

- organic solvents (e.g. alcohols, ethers, ketones, gasoline)
- Oxidants (e.g. hydrogen peroxides)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

Never clean all products, sterilization trays and sterilization containers with metal brushes or steel wool.

All products, sterilization trays and sterilization containers may only be exposed to temperatures not higher than 134 °C (280 °F).

6.14 REUSABILITY & LIMITATION

<i>The instructions listed above have been validated by the medical device manufacturer as suitable for preparing a medical device for its use. The reprocessor is responsible for ensuring that the actual reprocessing carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired result. This requires verification and/or validation and routine monitoring of the process.</i>

7 COMBINATION WITH OTHER PRODUCTS

7.1 instruments

- **Fiber optic cables**
- **Compatible camera**
- **Light source**
- **Trocar / shaft / rinsing and extraction systems**
- **Use only compatible connections**
- **Thermal risks of high-performance light sources**

8 EXCLUSIONS OF LIABILITY & GUARANTEE

The products are made of high-quality materials and are subjected to quality control before delivery. If you still experience errors, please contact our service. However, we cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself. We cannot accept any liability for accidental or consequential damage.

All product liability expires,

- in case of damage due to improper storage, handling,
- in case of incorrect cleaning and sterilization,
- in case of non-observance of these instructions for use

ANTON HIPPI GMBH DOES NOT MAKE ANY LIABILITY IF DEMONSTRABLY DISTRIBUTED AGAINST THIS USE INSTRUCTIONS.