INSTRUCTION FOR USE

Precisely yours,

INVIDIA®
MEDICAL
GERMANY

Rigid medical endoscopes

INVIDIA Medical GmbH & Co. KG
Carl-Benz-Strasse 28
78576 Emmingen-Liptingen
Germany

CE

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1 About this document

1.1 Purpose

This document describes the correct handling and function of the rigid endoscope, as well as recommended processing methods.
This document may not be used to carry out endoscopic examinations or surgeries, nor may it be used for training purposes.
The respective current version of this document can be requested from INVIDIA.
If you as the user of this endoscope believe that you require more detailed information regarding the product's use and maintenance, please contact your representative.

1.2 Symbols used

The following symbols are used to make it easier for you to access the information:

	Instructions for preventing personal injury
	Instructions for preventing material damage
	Information to facilitate understanding or workflow optimisation
✓	Prerequisite
➢	Instruction

2 Intended use

Rigid medical endoscopes are used to visualize body cavities. Each endoscope was developed for diagnostic and surgical procedures in one of the following fields of application:

- Arthroscope: arthroscopic procedures
- Sinuscope: sinuscopic procedures
- Laparoscope: laparoscopic procedures
- Hysteroscope: hysteroscopic procedures
- Cystoscope: cystocscopic procedures

For the benefit and safety of patients, physicians must select a method which they consider suitable based on their experience.

If you as the user of this endoscope believe that you require more detailed information regarding the product's use and maintenance, please contact your representative.

3 Safety information

The endoscope may only be used by trained medical professionals in medical facilities.

- After delivery, inspect the endoscope for completeness and damage.
- Read, observe and keep the instructions for use.
- Use the endoscope only as intended, see “Intended use” on page 3.
- When endoscopic instruments are used together with other electromedical devices, the total patient current leakage may be additive. Ensure BF (CF) conditions are observed when using the endoscopic instruments with electromedical devices.
- The user and/or patient should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- Ensure that any modifications or repairs are carried out by persons authorized by INVIDIA. No modifications of this equipment is allowed by the user, or the warranty is void.

For storage, transport and processing, ensure that the endoscope is not subjected to mechanical strain, particularly to prevent damage to the sensitive lens system.

WARNING

Risk of infection to the patient or medical professionals!

The endoscopes are delivered non-sterile as reusable products.

The state of the art and national laws require the observance of validated processes. In general, users are responsible for the validation of their processes.

- **Ensure that the processing, material and personnel are suitable for achieving the results necessary.**
- **Observe any valid local operator regulations for all manual cleaning and drying processes.**
- **Clean / disinfect and sterilise the endoscope prior to initial use as well as each subsequent use of the endoscope.**
- **Bring the endoscope to the decontamination area after use. Observe valid protective measures to prevent contaminating the environment.**

WARNING

Risk of burns!

The optical fibres emit high-energy light at the distal end of the endoscope. This can cause the temperature of the body tissue to rise to 41 °C.

- **Avoid direct contact of the distal end with body tissue or flammable materials as it can cause burns.**
- **Reduce the light intensity of the cold light source when working near body tissue or flammable materials.**

WARNING

Risk of injury due to faulty endoscopes!

- **Carry out visual inspection and function check prior to each use.**
- **Only use endoscopes which are in perfect condition.**

4 Testing, handling and maintenance

Endoscopes from INVIDIA are precision medical instruments and handling them requires great care.

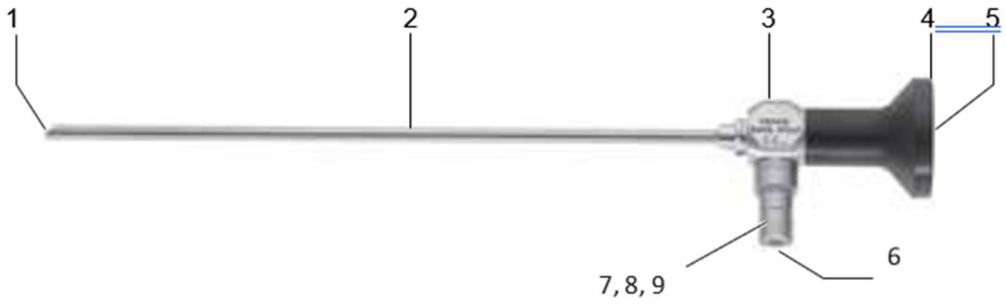
- Inspect the endoscope for damage prior to and after use.
- If the endoscope is damaged, discontinue use and contact the manufacturer.
- Do not subject the endoscope to impact.
- Put the endoscope down carefully.
- Hold endoscope only by the ocular funnel / main part and not by the sheath.
- Do not bend the sheath.
- Do not bend the body after inserting the endoscope into the body. A piece broken off the endoscope can become lodged in the soft tissue or no longer appear in the endoscope's field of vision and thus remain in the body.
- Transport endoscopes individually and store them safely by using a screen basket or container.

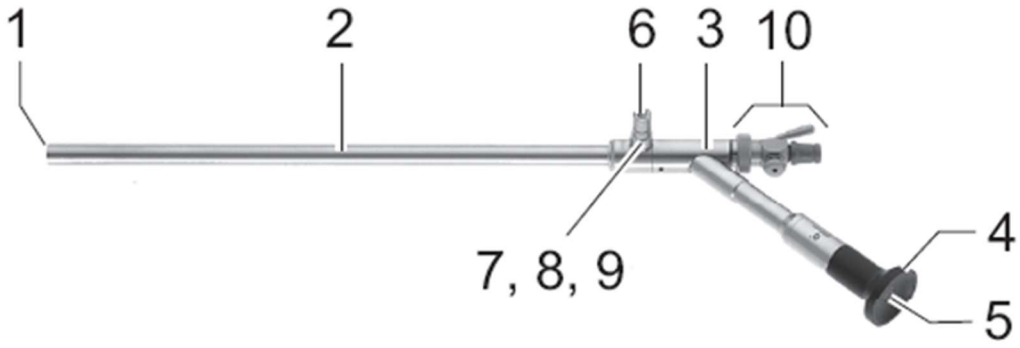
5 Guideline conformity

CE CE 0297	The CE marking of the medical product complies with the guideline 93/42/EWG. It applies only when the product and/or packaging features this marking. In addition, products of Class IIa and higher are labelled with the identification number of the respective notified body.

6 Description

6.1 Construction





1 Distal end
2 Sheath
3 Main part
4 Ocular funnel
5 Proximal end
6 Irradiation surface of the illumination fibres
7 Connection for illumination fibre, type ACMI
8 Adapter for illumination fibre, type Wolf, pre-assembled
9 Adapter for illumination fibre, type Storz / Olympus (assembly, see “Assembly” on page 14.)
10 For endoscopes with working channel: Adapter with stopcock (disassembly, see “Disassembly” on page 16.)

6.2 Markings

- Article number
- Serial number
- CE mark with identification number of the notified body where applicable: Endoscope conforms to the requirements of the guideline 93/42/EWG
- For autoclavable endoscopes: Writing "autoclavable"
- Specification of the direction of view
- Writing GERMANY
- Writing INVIDIA MEDICAL
- For large-screen lenses: Writing **HM**
- For high-resolution optics developed specifically for the latest Full HD camera generations: Writing 
- For endoscopes of the third INVIDIA HD generation: Writing 

6.3 Available designs and sizes

The endoscopes are available in the following designs and sizes:

- Straight endoscopes
- Angled endoscopes
- Endoscopes with working channel

6.4 Combinable products

You can combine the endoscopes with instruments from INVIDIA.
Endoscopes are generally compatible to camera systems and light sources that use interfaces according to ISO TS 18339.

7 Preparation for use

7.1 Visual inspection and function check

WARNING

Risk of injury due to faulty endoscopes!

- **Carry out a visual inspection and function check prior to initial use as well as each additional use.**
- **Only use endoscopes which are in perfect condition.**
- **Clean / disinfect and sterilise the endoscope prior to initial use as well as each additional use of the endoscope. Contaminants on the irradiation surface of the illumination fibres can burn in during use, which impacts image quality.**
- **Ensure that the proximal end of the endoscope is dry to prevent the endoscope from fogging up during the examination / procedure.**
- **Ensure that no parts are missing or loose.**
- **Ensure that there are no residual cleaning agents or disinfectants on the endoscope.**
- **Inspect the entire endoscope, particularly the sheath, for contaminants and damage of any type, such as dents, scratches, cracks, bending and sharp edges.**
- **Inspect distal end, proximal end and irradiation surface of the illumination fibres for contamination and scratches. Make contaminants and scratches visible using light reflexes. Hold the connection of the optical fibres against the light and inspect whether the optical fibres illuminate evenly at the distal end.**
- **Check image quality: The image may not be blurry, clouded or dark. If necessary, remove deposits on the optical end surface using polishing paste provided.**
- **For endoscopes with locking device: Inspect between the sheath and the main part for contaminants and damage to ensure a fixed and secure connection.**
- **For endoscopes with working channel: Inspect all components of the adapter with stopcock for function and damage.**
- **Inspect free passage of the working channels.**

7.2 Provisioning

- Clean / disinfect and sterilise the endoscope prior to initial use as well as each additional use of the endoscope, see “Processing” on page 9.
- Ensure that the proximal end of the endoscope is dry to prevent the endoscope from fogging up during the examination/procedure.
- If necessary mount adapter for illumination fibre, see “Assembly” on page 14.
- Mount illumination fibre (see manufacturer's specifications).
- If required, adapt the camera (see manufacturer's specifications).

8 Use

WARNING
Risk of burns!
The optical fibres emit high-energy light at the distal end of the endoscope. This can cause the temperature of the body tissue to rise to 41 °C.

- **Avoid direct contact of the distal end with body tissue or flammable materials as it can cause burns.**
- **Reduce the light intensity of the cold light source when working near body tissue or flammable materials.**

For endoscopes with working channel:

- **If an instrument is inserted, do not move the lever on the stopcock because otherwise the instrument could be damaged or sheared off.**

- Prepare the endoscope for processing immediately after use to prevent surface drying of the contaminants.

9 Processing

These reprocessing instructions are provided in accordance with ISO 17664, AAMI TIR 12, AAMI TIR30, AAMI ST79, and AAMI ST81. While they have been validated as being capable of preparing the endoscope for re-use, it remains the responsibility of the processor to ensure that the reprocessing, as actually performed (using equipment, materials, and personnel in the reprocessing facility), achieves the desired result. This normally requires routine monitoring of the process.
INVIDIA recommends users observe these standards when reprocessing medical endoscopes.

Warnings

- Always store the endoscope securely and transport it to processing in a closed container to prevent damage to the endoscope and contamination of the environment.
- The endoscope must be cleaned and sterilized prior to the first use and after every subsequent use.
- The sterilization parameters presented in this document apply only to endoscopes sterilized outside of a sterilization tray. When using a sterilization tray, consult the instructions provided with the tray for proper sterilization parameters.

- For United States customers: Due to the limitations of using liquid chemical germicides for sterilizing medical endoscopes, the FDA recommends that liquid chemical sterilants be limited to reprocessing only critical endoscopes that are heat-sensitive and incompatible with other sterilization methods. Steam sterilization is the recommended method for the INVIDIA medical endoscopes.
- Use only the sterilization cycles outlined in this document. Using unspecified sterilization cycles may damage the endoscope or result in incomplete sterilization.
- Prior to cleaning or sterilization, remove any protective sheathing that was used to protect the endoscope during shipment.
- Prior to cleaning or sterilization, separate the camera head, coupler, endoscope, and scope end adapter. Be sure to also remove the light-post adapter, which comes pre-attached to the endoscope. If any of these components are cleaned, disinfected, or sterilized as a single unit, disconnecting the endoscopes during use will compromise the sterility of the products. (Refer to camera head and coupler product manuals for reprocessing instructions.)
- Wear appropriate protective equipment: gloves, eye protection, etc.

Cautions

- Do not use brushes or pads with metal or abrasive tips during manual cleaning, as permanent scoring or damage could result.
- To minimize galvanic corrosion, avoid soaking dissimilar metals in close proximity.
- Do not use fixating cleaning agents or hot water (> 40° C) as it can cause fixation of the contaminants and jeopardize successful cleaning.
- Allow the endoscope to air cool following steam sterilization. Rapid cooling or "quenching" in a liquid will damage the endoscope and void the warranty.

Limitations on reprocessing

- Using multiple sterilization methods may significantly reduce the performance of the endoscope and is not recommended.
- Damage incurred by improper processing will not be covered by the warranty

9.1 Instructions for reprocessing

Point of use

- Wipe excess soil from the endoscope using disposable paper towels or lint free cloth.
- The automated cleaning method should be preferred compared to the manual cleaning method.
- If an automated reprocessing method will be used, rinse any channels in the endoscope (if existing) with sterile distilled water immediately after use.

Containment and transportation

- Reprocess the endoscope as soon as reasonably practical following use.

Brush/Rinse

- Rinse the endoscope by immersing them in cold tap water (≤ 23 °C) for at least 120 seconds.
- Brush the endoscope with a soft-bristled brush under cold tap water (≤ 23 °C) for at least 60 seconds.
- If the endoscope has a lumen or stopcocks, clean each lumen and stopcocks with an appropriately sized lumen brush

Soak/Brush

- Prepare an enzymatic detergent according to the manufacturer's recommendations. (The detergent Neodisher® MediClean forte of Dr. Weigert was used for the validation (5 ml per liter using warm tap water (31 °C - 40 °C)).)
- Fully immerse the endoscope into the prepared detergent.
- Allow the endoscopes to soak for a minimum of 10 minutes.

Brush/Rinse

- After the soak time leave the endoscope in the prepared detergent.
- Brush the endoscope with a soft-bristled brush for at least 60 seconds until all visible soil is removed. (For the validation a soft-bristled M-16 brush was used.)
- If the endoscope has a lumen or stopcocks, clean each lumen and stopcocks with an appropriately sized lumen brush for at least 60 seconds.
- Rinse the endoscope under running tap water for 30 seconds.
- For endoscopes with lumen, stopcocks , holes and threads: Rinse the lumen, stopcocks, holes and threads with a water pistol for 20 seconds each at a pressure of at least 1.7 bar (25 psi).

Brush

- Dry the endoscope with lint-free cloth and by using compressed air for 60 seconds (1.7 bar/25 psi).

Automated cleaning

Pre-cleaning

- Rinse the endoscope under cold running tap water (≤ 23 °C) for at least 120 seconds.
- While rinsing, clean the endoscope using a soft-bristled brush. Particularly pay attention to grooves, crevices, mated surfaces and any hard-to-reach areas.
  (For the validation a soft-bristled M-16 brush was used.)
- For endoscopes with lumen and stopcocks: Clean each lumen and stopcock with an appropriately sized lumen brush for at least 60 seconds.

Inspecting

- Visually inspect the endoscope, including all internal surfaces, for remaining soil.
- If soil remains, repeat manual or automated cleaning procedure, focusing on those areas.

Automated wash

- Place the endoscope in an automated washer on an incline to facilitate drainage.
  (The automated cleaning was validated with the STERIS® Reliance® Genfore™. For use with another washer/disinfector make sure that it is also in compliance with EN ISO 15883-2.)
- Program the washer with the following parameters, then activate the wash:

Phase	Recirculation time	Water temperature	Detergent type
Pre Wash 1	2 minutes	Cold tap water (≤ 23 °C)	N/A
Pre Wash 2	5 minutes	Cold tap water (≤ 23 °C)	N/A
Wash 1	8 minutes	55 °C (set point)	Enzymatic detergent 1)
Wash 2 (neutralized)	5 minutes	43 °C (set point)	Neutralizer 2)
Rinse 1	4 minutes	43 °C (set point)	N/A

1) The detergent Neodisher® MediClean forte of Dr. Weigert was used for validation.
2) The neutralizer Neodisher® Z of Dr. Weigert was used for the validation.

Drying

- Dry the endoscope completely with lint free cloths and filtered pressurized air for 60 seconds (1.7 bar/25 psi) prior to sterilization.
- For endoscopes with lumen, stopcocks, holes and threads: Make sure that those areas are dried with high attention.

Inspecting

- Visually inspect the endoscope, including all internal surfaces, for remaining soil.
- If soil remains, repeat manual or automated cleaning procedure, focusing on those areas.

Maintenance, inspection and testing

- Inspect the endoscope on a continual basis. If a problem is observed or suspected, the endoscope should be returned for repair.
- Inspect all components for cleanliness. If fluid or tissue buildup is present, repeat the above cleaning and disinfection procedures.

Sterilization

After performing the cleaning instructions specified above, perform the following sterilization cycle:

Steam

	Pre-vacuum 3)
Wrapping 4)	Double
Temperature	132 °C (270 °F)
Time	4 minutes 5)
Dry time	45 minutes
	Warning: Drying time depends on several variables, including: altitude, humidity, type of wrap, preconditioning, size of chamber, mass of load, material of load, and placement in chamber. Users must verify that drying time set in their autoclave yields dry surgical equipment
Open door time	45 minutes

3) The sterilization validation was validated with the STERIS Amsco® Lab 250 sterilizer.

4) The Halyard Health H300-510(k) K082554 wrap was used for the validation.

5) 18 minutes is the maximum time that should be used for the pre-vacuum cycle.

NOTE: Rapid cooling, or "quenching," the endoscopes after autoclaving will result in product damage.

Packaging

The endoscopes are delivered non-sterile in sealed plastic or in a protective box/foam packaging. Transport packaging is not suitable for sterilization.

9.2 Special precautions: Pathogens of Transmissible Spongiform Encephalopathy

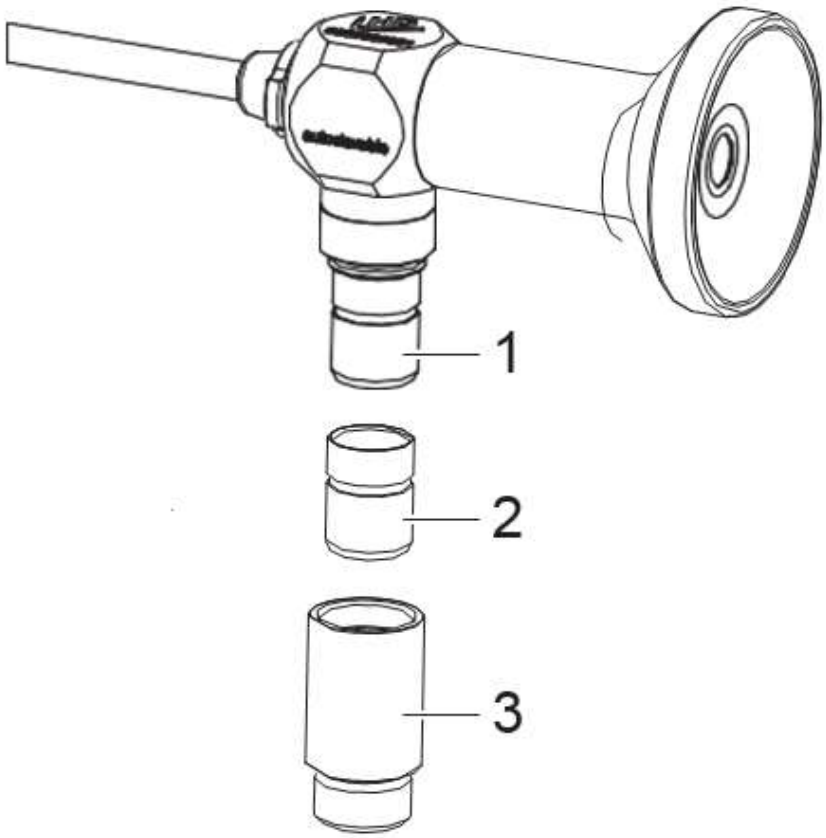
A comprehensive explanation of the necessary preventative measures with regard to agents of Transmissible Spongiform Encephalopathy (TSE) would go beyond the scope of this document.
It is assumed that pathogens of the Creutzfeldt Jakob Disease cannot be killed using normal disinfection and sterilisation processes. Therefore, the standard methods for decontamination and sterilisation are not sufficient if there is a risk of transferring Creutzfeldt Jakob Disease.
In general, only tissue with a low potential of TSE infection comes into contact with surgical instruments. In spite of this, special preventative measures must be taken for instruments which are used to treat patients with a known or suspected infection of TSE, as well as for patients at risk.

9.3 Processing restrictions

Repeated processing has only minimal effect on the endoscopes. The lifetime of the units is usually determined by wear and damage.
The endoscope can be damaged if the manufacturer's specifications are not observed.

- **Do not clean endoscope in an ultrasonic bath.**

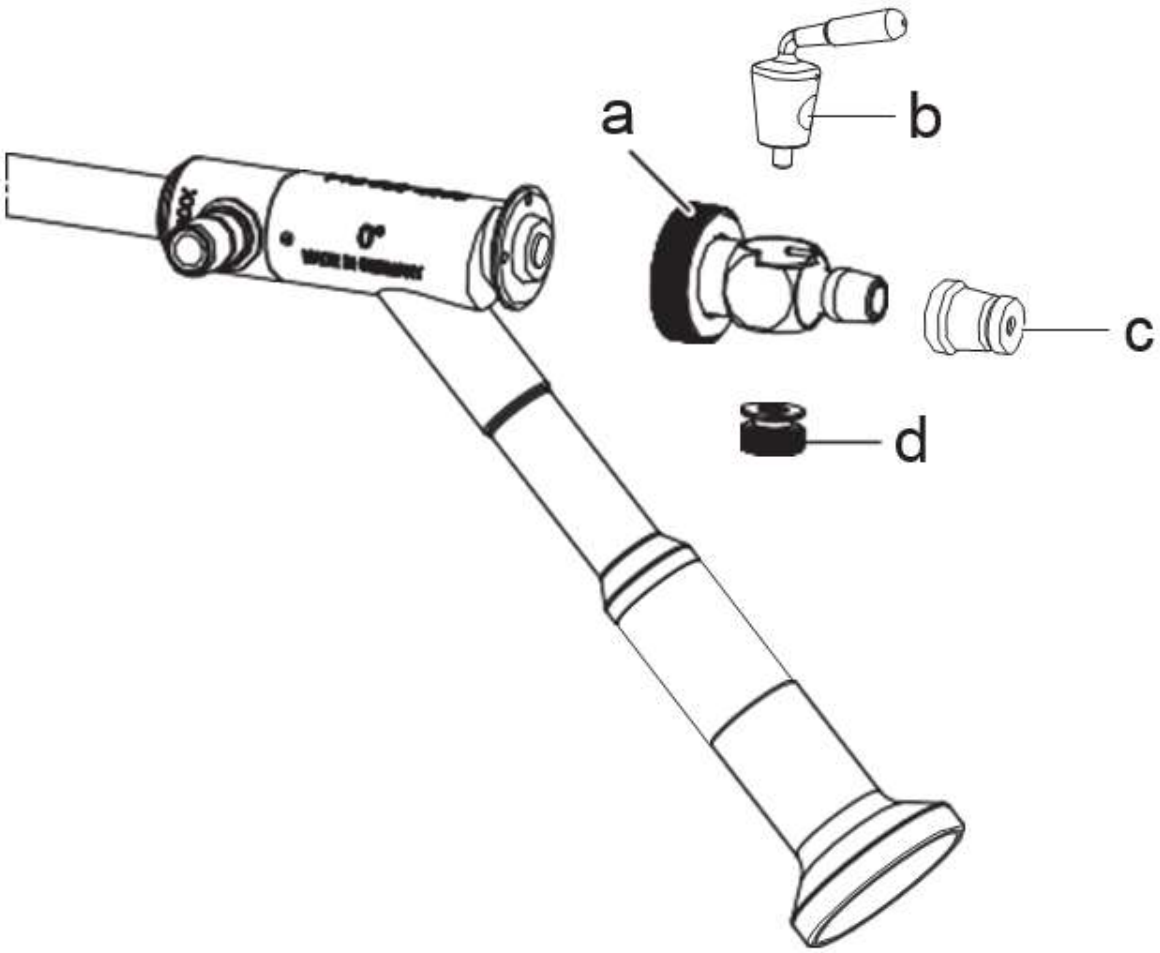
10 Assembly



1 Connection for illumination fibre, type ACMI
2 Adapter type Wolf
3 Adapter type Storz / Olympus

- If necessary mount adapter for illumination fibre
- Ensure that the irradiation surface of the illumination fibre is clean.
- Mount illumination fibre (see manufacturer's specifications).
- If required, adapt the camera (see manufacturer's specifications).

For endoscopes with working channel:



a Union nut
b Stopcock
c Sealing cap, green
d Stopcock nut

➢ **In order to ensure sterility, only use grease which is suitable for medical instruments for the stopcock.**

➢ Lubricate stopcock **b**.
➢ Mount stopcock **b** and fix with stopcock nut **d**.
Remove excess grease.

11 Disassembly

WARNING
Risk of burns!
Allow the illumination fibre to cool sufficiently before removing it. The ends can become very hot and cause serious burns.
➢ **Remove illumination fibre.**

➢ **Do not remove the ocular funnel because otherwise the endoscope will be damaged.**

➢ Unscrew existing adapters.
➢ For endoscopes with working channel, disassemble the adapter with stopcock.
- Remove sealing cap **c**.
- Loosen union nut **a**.
- Loosen stopcock nut **d**.
- Disassemble stopcock **b**.

12 Storage

Unsterile metal units must be stored in a clean, dry environment. The storage time of unsterile units is not limited; the units are made of a non-degradable material which maintains its stability when stored under the recommended conditions.
As long as endoscopes are stored unsterile in the original packaging, the following storage conditions apply:
➢ Avoid direct sunlight.
➢ Store endoscope either in the original packaging or in a screen tray/container.
➢ Ensure that the endoscope is stored securely.
➢ Observe the respective valid national provisions when storing in a sterile condition.

13 Ambient conditions

	Operation	Transport and storage
Temperature	10 °C - 40 °C	-40 °C - 70 °C
Relative humidity	5 % - 75 %	5 % - 95 %
Atmospheric pressure	70 kPa – 106 kPa	70 kPa – 106 kPa

14 Service and maintenance

INVIDIA does not supply original parts to independent workshops or other endoscope manufacturers. Thus only INVIDIA is in a position to carry out repairs using original parts. The original technical specifications and the operational safety of the endoscope can only be guaranteed by using original parts. The warranty for INVIDIA products shall become void if repairs are carried out by an workshop not authorised by INVIDIA. In this case INVIDIA is also no longer responsible for the technical specifications or safety of the product.

- Have the endoscopes repaired by INVIDIA only. For service, send the defective endoscope to the address of the sales partner.
- Clean, disinfect and sterilise the endoscope thoroughly prior to returning it for repair.
- Ideally, send in the endoscope in its original packaging. If this is not possible, package the endoscope to secure it for transport.

INVIDIA is not liable for damage resulting from improper shipping.

15 Accessories / spare parts

Designation	Article number
Polishing paste	72-999-01
Adapter type Wolf	72-900-02
Adapter type Storz / Olympus	72-900-00

16 Disposal

- Observe country-specific regulations and laws for the disposal of medical products.