

INSTRUCTIONS FOR USE

IMPORTANT 

Before using these products, please read the following information thoroughly!

WARNING 

Reusable Ackermann products are delivered unsterile, indicated on the device label by the following symbol:



Prior to their first use, the devices need to be cleaned and sterilized as described in the reprocessing section of this document.

WARNING 

The instruments may only be used by trained and, if applicable, instructed physicians. Disinfection, cleaning and sterilization may only be performed by specially trained medical personal.

INTENDED USE

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

- Arthroscope: arthroscopic procedures
- Sinuscope: sinusopic procedures
- Otoscope: otoscopic procedures
- Laryngoscope: laryngoscopic procedures
- Laparoscope: laparoscopic procedures
- Hysteroscope: hysteroscopic procedures
- Cystoscope: cystoscopic 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.

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"

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.

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.

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.

TESTING, HANDLING & MAINTENANCE

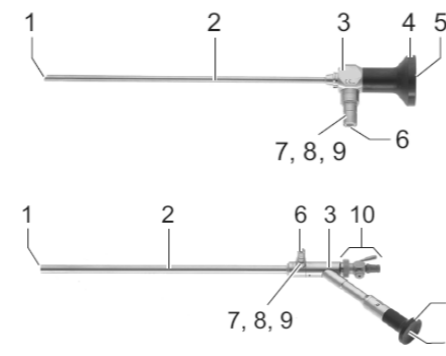
Endoscopes from Ackermann are precision medical instruments, and handling them requires great care.

- 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.

DEVICE DESCRIPTION



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 Ackermann / Storz / Olympus
- 10 For endoscopes with working channel: Adapter with stopcock

MARKING

- 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 Ackermann / Ackermann High Definition / Ackermann 4K

AVAILABLE DESIGNS & SIZES

The endoscopes are available in the following designs and sizes:

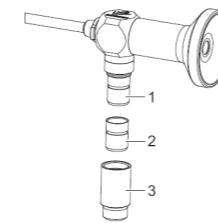
- Straight endoscopes
- Angled endoscopes
- Endoscopes with working channel
- Sheath diameter 1.9 – 11 mm
- Working channel diameter 5.1 – 6.4 mm

COMPATIBILITY

You can combine the endoscopes with existing camera systems and with illumination fibres and instruments from Ackermann.

PREPARATION OF THE DEVICE

ASSEMBLY & DISASSEMBLY

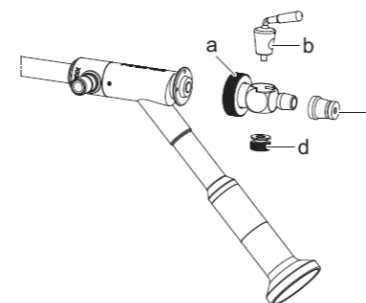


ASSEMBLY

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

- If necessary mount adapter for illumination fibre
- Ensure that the irradiation surface of the illumination fibre is clean
- Mount illumination fibre
- If required, adapt the camera

For endoscopes with working channel:



- a Union nut
- b Stopcock
- c Sealing cap
- d Stopcock nut

Note: 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.

DISASSEMBLY

WARNING 

Allow the illumination fibre to cool sufficiently before removing it. The ends can become very hot and cause serious burns.

- Remove illumination fibre.

Note:

- 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**.

PREPARATION FOR USE

VISUAL INSPECTION & FUNCTIONAL TEST

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 / see "Removing deposits from optical end surfaces"
- 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.

PROVISIONING

- Clean / disinfect and sterilise the endoscope prior to initial use as well as each additional use of the endoscope / See "Reprocessing"
- 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"
- Mount illumination fibre
- If required, adapt the camera

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.

GUIDELINES FOR CARE, MAINTENANCE & CLEANING

REPROCESSING

SAFE STORAGE & TRANSPORT

If possible, reprocessing endoscopes immediately after use is recommended. Endoscope containers and trays are reusable. Trays must be inspected for visible contamination and cleaned prior to use. They can be cleaned manually or in an automatic cleaning unit using a cleaning agent.

• Always store endoscope securely and transport it to processing in a closed container to prevent damage to the endoscope and contamination of the environment.

CLEANING & DISINFECTION

MANUAL CLEANING MANUAL PRE-CLEANING & DISINFECTION

WARNING

- Do not use fixating cleaning agents or hot water (>40 °C) as it can cause fixation of the contaminants and jeopardise successful cleaning.
- Do not scratch contaminants off with hard objects as this can cause damage to the optical end surfaces.
- Do not clean endoscope in an ultrasonic bath.

Prerequisite:

- Existing adapters are dismantled.
- For endoscopes with working channel: Adapter with stopcock is dismantled.
- For laryngoscopes: Handle is dismantled.

- Remove coarse contamination from the endoscope. Clean the endoscope with a soft brush under cold tap water until all visible contaminants have been removed.
- For working channels, holes and threads: Rinse with a water pistol for at least 10 seconds at a pressure of at least 3.8 bar (absolute).

Note: The endoscopes have material compatibility with the Steris™ System 1 process.

- Disinfect endoscope. In doing so, observe the specifications of the disinfectant solution manufacturer regarding temperature, concentration and application time.

WARNING

Non-compliance with the manufacturer's specifications can result in damage to the endoscope!

- Rinse endoscope with running water.
- If necessary, rinse working channel with a water pistol for at least 10 seconds at a pressure of at least 3.8 bar (absolute).
- If necessary, dry working channel with compressed air.
- Dry endoscope with a soft cloth.
- Carry out visual inspection, function check and servicing / see "Testing, handling and maintenance"

MACHINE CLEANING & THERMAL DISINFECTION

The rigid endoscopes from Ackermann are suitable for prevalent machine methods of cleaning and thermal disinfection. In doing so, use gentle cycles for rigid endoscopes and suitable cleaning agents and disinfectants. The instructions of the machine, cleaning agent and disinfectant manufacturers must be observed. The cleaning and disinfectant result must be confirmed by the machine, cleaning agent and disinfectant manufacturers in cooperation with the user.

The following methods have been validated by Ackermann for the following rigid endoscopes:

- without working channel
- with working channel (dia. ≥5 mm)

• Fix the endoscope to the loading rack in such a way that damage is prevented during cleaning. The following materials and machines were used for the validation:

Cleaning agent:

- Alkaline: Neodisher FA; Dr. Weigert; Hamburg
- Enzymatic: Endozime, Ruhof

Neutraliser:

- Neodisher Z; Dr. Weigert, Hamburg

Cleaning and disinfecting unit:

- Miele G 7736 CD

Loading rack:

- Loading rack E 327-06
- MIC rack E 450

Start cleaning process:

- Pre-rinse with cold water for 1 minute
- Drain
- Pre-rinse with cold water for 3 minutes
- Drain
- Clean with 0.5% alkaline cleaning agent for 5 minutes at 55 °C or with 0.5% enzymatic cleaning agent at 45 °C
- Drain
- Neutralise for 3 minutes with warm tap water (<40 °C) and neutraliser
- Drain
- Intermediate rinse for 2 minutes with warm tap water (<40 °C)
- Drain

- Carry out machine thermal disinfection considering the national requirements regarding the Ao value (see DIN EN ISO 15883).
- Ensure that the exteriors of the endoscope are dry. If necessary, dry with a soft cloth.
- If necessary, dry working channels with compressed air.
- Carry out visual inspection, function check and servicing / See "Testing, handling and maintenance"

REMOVING DEPOSITS FROM OPTICAL END SURFACES

If deposits are found when checking the image quality, they can be removed with the provided polishing paste as follows:

Note: Only clean with polishing paste if the image which you see through the endoscope is cloudy and blurry.

- Apply polishing paste to a clean cotton swab.
- For large end surfaces: press cotton swab lightly on the end surface to be cleaned and rub it over the glass.
- For small end surfaces: place cotton swab lightly on the end surface to be cleaned and turn it.



- Clean all optical end surfaces with warm water and mild detergent to remove all polishing paste residue.
- Rinse optical end surfaces under running water.
- Dry optical end surfaces with a soft cloth.
- Clean / disinfect and sterilise the endoscope.
- Carry out visual inspection. If the deposits were not removed: send in endoscope for repair.

STERILIZATION

Note: Prior to each sterilisation, rigid endoscopes must be cleaned and disinfected according to the methods in these instructions for use.

- Sterilise endoscopes in suitable packaging to prevent subsequent contamination.

STEAM STERILIZATION

Autoclaving

In general, users are responsible for the validation of their processes.

Only endoscopes which are marked with the writing "autoclavable" are intended for autoclaving. The permissible processing methods are explained in the instructions at hand.

When selecting the processing method, observe the valid national hygienic regulations and local provisions for hospital hygiene.

- Comply with specified process parameters. The specified parameters have been validated to ensure the sterility of the endoscopes. Deviating process parameters could damage

the endoscope. In this case, the guarantee and warranty shall become void.

Note: Autoclavable endoscopes can be sterilised with the French cycle (134 °C, 18 minutes, 3.1 bar (absolute) without restrictions regarding material compatibility.

Prerequisite:

- Existing adapters are dismantled.
- For endoscopes with working channel: Adapter for stopcock is dismantled.
- Sterilise endoscopes.
- When the sterilisation process has ended, allow the endoscopes to cool gradually to room temperature.

FRACTIONATED PRE-VACUUM METHOD

The following process has been validated:

Temperature: 132 - 137 °C (270 - 278 °F)

Time: At least 3 minutes

Configuration: Double packed in sterilisation bags

Drying: At least 10 minutes

GRAVITATION METHOD

Note: The endoscopes have material compatibility with the gravitation method for a hold time of 15 minutes.

HYDROGEN PEROXIDE STERILIZATION

STERRAD® method

Endoscopes without working channel and with working channel with a dia. ≥5 mm can be sterilised with the following STERRAD systems:

- STERRAD 100S
- STERRAD NX
- STERRAD 100NX

- Observe specifications of the manufacturer (ASP) regarding the corresponding method.

ETHYLENE OXIDE STERILIZATION

Note: The endoscopes are material compatible with ethylene oxide sterilisation.

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.

RE-PROCESSING RESTRICTIONS

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

WARNING

Do not clean endoscope in an ultrasonic bath.

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:

- Temperature: -10 °C to +40 °C
- Humidity: 10% to 90%

- 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.

SERVICE & MAINTENANCE

Ackermann does not supply original parts to independent workshops or other endoscope manufacturers. Thus only Ackermann 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 Ackermann products shall become void if repairs are carried out by an

workshop not authorised by Ackermann. In this case Ackermann is also no longer responsible for the technical specifications or safety of the product.

- Have the endoscopes repaired by Ackermann 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. Ackermann is not liable for damage resulting from improper shipping.

REPAIRS

In spite of application in compliance with intended use, medical products are subject to variable wear and tear depending on the intensity of the application. Wear is technically inevitable.

- Do not repair. Service and repairs must be carried out by the manufacturer or by authorized personnel
- Medical products have to be cleaned, disinfected and sterilized prior to sending for repair. Soiled or contaminated medical products should not be shipped

DISPOSAL

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

RELEVANT NOTE

In these IFUs have been reported info concerning to Class I devices. However, Class I devices are not under Notified Body responsibility. The Class I devices have been reported for descriptive information only.

COMPATIBILITY

COMBINATION PRODUCTS FOR THE ARTICLES LISTED IN THE APPEDIX

SCOPE-SIDE ADAPTERS

11-1146-100 11-1146-200 11-1146-300

LIGHTSOURCE-SIDE ADAPTERS

11-1147-100 11-1147-300 11-1147-400
11-1147-200

SCOPES FOR LAP, MINILAP, ARTHRO, URO, HYS & ENT

FIBRE LIGHT CABLES

11-1150	11-1151	11-1167
11-1151	11-1152	
11-1152	11-1161	

ANTI-FOGGING LUBE

11-1121

LIGHT CABLE TESTERS

11-16000CB	11-16000CBOLYWA
11-16000CBWOLF	

ADDITIONAL INFORMATION

Do not exceed maximum loading capacity of the sterilizer when processing multiple instruments in one sterilization cycle.

APPENDIX

All product codes covered by these instructions are listed below:

LAPAROSCOPES

11-1120	11-1126UHD
11-1120-45	11-1130
11-1120-45HD	11-1130-45
11-1120-45UHD	11-1130-45HD
11-1120HD	11-1130-45UHD
11-1120UHD	11-1130HD
11-1125	11-1130UHD
11-1125-45	11-1135
11-1125-45HD	11-1135-45
11-1125-45UHD	11-1135HD
11-1125HD	11-1135UHD
11-1125UHD	11-1136
11-1126	11-1136HD
11-1126-45	11-1136UHD
11-1126-45HD	11-1140
11-1126-45UHD	11-1145
11-1126HD	

ARTHROSCOPES

17-1750	17-1755	17-1760
17-1750HD	17-1755HD	17-1760HD
17-1750UHD	17-1755UHD	17-1760UHD
17-1751	17-1756	17-1761

HYSTEROSCOPES

18-2340HD	18-2343HD	18-2346HD
18-2341HD	18-2344HD	
18-2342HD	18-2345HD	

ENT SCOPES

22-2711	22-2718	22-2901
22-2712	22-2719	22-2905
22-2713	22-2721	22-2906
22-2716	22-2890	
22-2717	22-2900	


MINILAPAROSCOPES


23-3060HD	23-3062HD
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CYSTOSCOPES


32-4000HD	32-4015HD	32-4030HD
32-4002HD	32-4020HD	
32-4010HD	32-4022HD	


SYMBOLS USED ON LABELLING (ACC. DIN EN ISO 15223-1)


 Legal manufacturer


 Manufacturing date


 Consult instructions for use


 Serial number


 Product number


 Quantity


 Caution, consult accompanying documents


 Do not use if package is opened or damaged

 Non-sterile

 Keep out of direct sunlight

 Protect against moisture

 Prescription use only

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70191 Stuttgart, Germany

CONTACT DETAILS

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