Instruction manual for “Rigid endoscopes”

*GASTA-01B

English

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2 Applicability

This instruction manual applies to the product group of rigid endoscopes (class IIa) from EMOS Technology GmbH.
This instruction manual contains important information for the safe and effective use of these instruments. Prior to use, read the instructions for all devices employed during the procedure and use them accordingly. If you have questions or comments on the contents of this instruction manual, please contact EMOS Technology GmbH.
This instruction manual also contains processing instructions for rigid endoscopes (class IIa).

2.1 Product numbers

This instruction manual applies to the following article numbers:

AD40B.X*	AY40B.X*	LU100A.X*	SS40A.X*	UW40C.X*
AD40C.X*	AY40C.X*	LU100B.X*	SS40B.X*	
AL40B.X*	HC19A.X*	LU100G.X*	SS40C.X*	
AM29B.X*	HS28A.X*	LU20A.X*	SS40CUD.X*	
AO40B.X*	HC19A.X*	LU20B.X*	SS40D.X*	
AS19A.X*	HS28A.X*	LU50A.X*	SS40DUD.X*	
AS19B.X*	HS28B.X*	LU50B.X*	SS40G.X*	
AS24A.X*	HS28C.X*	LU50G.X*	SW40A.X*	
AS24B.X*	HS28F.X*	LU70C.X*	SW40B.X*	
AS28A.X*	HS40A.X*	LU70D.X*	US28A.X*	
AS28B.X*	HS40B.X*	OS28A.X*	US28B.X*	
AS40A.X*	HS40F.X*	OS28B.X*	US40A.X*	
AS40B.X*	HW27A.X*	OS40A.X*	US40B.X*	
AS40C.X*	HW27B.X*	OS40B.X*	US40C.X*	
AS40G.X*	HW40A.X*	SS19A.X*	US40F.X*	
AW40A.X*	HW40B.X*	SS19B.X*	UW27B.X*	
AW40B.X*	LS40CUD.X*	SS28A.X*	UW40A.X*	
AW40C.X*	LS40DUD.X*	SS28B.X*	UW40B.X*	

X* = Placeholder for colour variant of the endoscope

3 Symbols

	Observe instruction manual		Medical device
	Caution! (Warning)		Order number
	Information for proper handling		Serial number
	Manufacturer		Not sterile
	Date of manufacture		Latex-free
CE	European approval labelling		Keep out of sunlight
0483	Identification number of the Notified Body (mdc medical device certification GmbH)		Store dry

4 Warnings

⚠ The instructions for use and processing as well as the specifications regarding accessories or medical devices used in combination should be carefully read, observed, and stored

⚠ The endoscopes are not supplied sterile and must be cleaned, disinfected, and sterilised prior to first use as well as before every further use

⚠ The endoscopes may not be cleaned in an ultrasonic bath

⚠ The endoscopes may not be exposed to gamma rays

⚠ If there are signs of damage, the endoscope may not continue to be used in any case

⚠ If an unsuitable light source is selected, the light may be emitted from the light window with a high level of radiation energy and the temperature in the tissue may increase (> 41°C). Only light sources with max. 300 W (xenon) or 250 W (halogen) may be used. Overheated endoscopes may continue to be used only after adequate cooling

5 General application instructions

The instruction manual contains important information for the operation and proper function of the rigid endoscopes. These instructions do not serve as a guide for or explanation of relevant surgical and/or examination techniques.
Every individual endoscope of EMOS Technology GmbH was developed for a particular area of application and may be used only in this area of application.
The rigid endoscopes are to be used exclusively for their intended purpose and by trained and qualified professionals. The surgeon is responsible for the selection and proper application of the endoscopes. These instructions cannot replace the user's training, care, and state of the art. EMOS Technology GmbH can provide training in the safe application of the endoscopes, if needed.

The endoscopes of EMOS Technology GmbH must be used in accordance with recognised medical regulations for endoscopic procedures and endoscopy practices. We therefore assume familiarity with the relevant legal regulations, standards, and recommendations (such as of the RKI (Robert Koch Institute) or also of the AKI (Arbeitskreis Instrumentenaufbereitung (Instrument Reprocessing Working Group))). The applicable country-specific laws and regulations should always be observed.

EMOS Technology GmbH endoscopes are precision instruments.
All metal parts are made of stainless steel. In patients with a hypersensitivity to components of high-alloy steels, it is the responsibility of the attending physician to clarify the patient’s possible allergic tendencies in an information discussion prior to use and to assess the residual risk or find alternatives.
The rigid endoscopes may not be used if, in the opinion of a responsible physician, such use could cause a hazard to the patient.

Please always handle your endoscope with utmost care.

After every cleaning/disinfection and before each use, the endoscopes are to be checked for cleanliness, function, and damage (see section 10).
Damaged or defective endoscopes may not be used. Damaged individual parts must be immediately replaced with original replacement parts. Damaged endoscopes are to be immediately taken out of service.
If a malfunction should occur during application on a patient, the application should be immediately discontinued.
If a trocar is used, the rigid endoscopes must always be introduced carefully to avoid damage to the working end. Bending stresses during introduction and removal should be avoided.

ℹ To avoid damage, the rigid endoscopes should not be bent!

- Protect the endoscope from direct sunlight
- Protect the endoscope from X-rays
- Protect the endoscope from vibrations
- Always handle the endoscope with utmost care (impact).

In the event of suspected or diagnosed Creutzfeldt-Jacob syndrome (CJD or vCJD), measures must be taken

immediately to prevent transfer to other patients, users, or third parties. The endoscopes may not be reused and are to be disposed of following thorough processing and sterilisation.
For reasons of infection prevention, shipping contaminated medical devices should on principle be strictly refused. The medical devices should therefore be decontaminated directly on site in order to avoid contact and airborne infections in staff.

EMOS Technology GmbH, as the company placing these devices on the market, does not assume any liability for direct damage or consequential damage that occurs due to improper use or handling, in particular due to a failure to observe the enclosed instruction manual or due to improper care or maintenance.

The applicable country-specific laws and regulations should always be observed.

6 Intended use

Rigid endoscopes are used in diagnostic and surgical endoscopy. They are used for examination, diagnosis, and/or therapy in connection with endoscopic accessories, including within the framework of the product-specific intended purposes listed below.

6.1 Intended purpose

Arthroscope: During examination, diagnosis, and/or in connection with accessories for treatment that can be used endoscopically, arthroscopes are used exclusively to visualise the inside of the wrist, elbow, shoulder, hip, knee, and ankle.

Hysteroscope: During examination, diagnosis, and/or in connection with accessories for treatment that can be used endoscopically, hysteroscopes are used exclusively to visualise the uterus and cervix.

Laparoscope: During examination, diagnosis, and/or in connection with accessories for treatment that can be used endoscopically, laparoscopes are used exclusively to visualise the abdominal cavity.

Cystoscope: During examination, diagnosis, and/or in connection with accessories for treatment that can be used endoscopically, cystoscopes are used exclusively to visualise the lower urinary tract, including the urethra and urinary bladder.

6.2 Medical indication

Arthroscope: Arthroscopes are indicated as an aid during examinations of the wrist, elbow, shoulder, hip, knee, and ankle.

Hysteroscope: Hysteroscopes are indicated as an aid during examinations of the uterus and uterine cervix.

Laparoscope: Laparoscopes are indicated as an aid during examinations of the abdominal cavity, including the abdominal organs.

Cystoscope: Cystoscopes are indicated as an aid during examinations and for visualisation of the lower urinary tract, including the urethra and urinary bladder.

6.3 Contraindication

The use of rigid endoscopes is generally contraindicated if the use of other surgical techniques is indicated.
In addition, the following represent contraindications in general:

- general inoperability
- a lack of willingness on the part of the patient
- if the technical preconditions are not met
- applications outside of the intended purpose
- Not for use at the central circulatory and nervous system within the meaning of the Medical Device Regulation

6.4 Specific contraindications:

Arthroscopy:
- Local or generalised infections
- Severe coagulation disorders
- Immunosuppressive therapy (cortisone, etc.)

Hysteroscopy:
- Acute or chronic inflammation of the external and internal genitals and in the case of pelveoperitonitis
- Severe uterine bleeding
- Pregnancy

Laparoscopy:
- Severe cardiovascular and/or pulmonary diseases
- Severe coagulation disorder
- Infection of the abdominal wall
- Diffuse peritonitis (= inflammation of the peritoneum)

Cystoscopy:
- Acute inflammation of the urinary tracts/urinary bladder/prostate/epididymis (microbial transmission)
- Severe blood clotting disorders

6.5 Target group (intended user group)

The rigid endoscopes may be used exclusively for their intended use in medical fields, only in medical facilities, and by medical professionals trained and qualified to do so (physician, medical assistants under the supervision of a physician). The attending physician or the user/operator is responsible for selecting the instruments for certain applications or surgical use, the appropriate training and information, and sufficient experience in handling the instruments.
The processing and sterilisation of the endoscopes and accessories is permitted only by professionals with qualified training.

6.6 Intended patient population

Arthroscope: With regard to arthroscopes, there are no limitations or restrictions with regard to the patient population unless there is at least one contraindication.

Hysteroscope: Hysteroscopes are intended exclusively for use in women. There are further limitations and restrictions on the patient population beyond this if at least one contraindication is present.

Laparoscope: With regard to laparoscopes, there are no limitations or restrictions with regard to the patient population unless there is at least one contraindication.

Cystoscope: With regard to cystoscopes, there are no limitations or restrictions with regard to the patient population unless there is at least one contraindication.

The attending physician or the user/operator is responsible for selecting the instruments for certain applications or surgical use, the appropriate training and information, and sufficient experience in handling the instruments.

7 Scope of delivery

Name	Image	Article number
Rigid endoscope		see section 2.1
Wolf adapter		470.00049.00
Storz adapter		470.00882.00
Packaging / carton		270.00000.00 (arthroscope) 270.00001.00 (laparoscope, cystoscope, hysteroscope) 270.00072.00 (laparoscope bariatrics)
Foam inserts		270.00002.00; 270.00003.00 (arthroscope) 270.00004.00; 270.00005.00 (laparoscope, cystoscope, hysteroscope) 270.00073.00; 270.00074.00 (laparoscope bariatrics) 270.00067.00 (mini arthroscope)
Instruction manual		GASTA01-B
Guarantee certificate		ZERT01

8 Combination

When combined with electrically operated accessories that can be used endoscopically, there is a possible hazard due to excessively high voltages and currents.
Ensure that patient leakage currents are minimised in the case of combinations.
To avoid an electrical coupling between the patient and the device, EMOS Technology GmbH recommends using EMOS Technology GmbH devices and accessories.

Combine rigid endoscopes with other medical devices only if:

- the intended use in the user and operating instructions permits this
- the technical data in the user and operating instructions permit this
- the standard of the TV lenses or cameras corresponds to the general standard

8.1 Accessories / Replacement parts

Article number	Name
LC35XX* – LC48XX*	Light guide cable (various)
LCXX*	LE adapter (various)

All accessories and replacement parts are to be obtained exclusively from the manufacturer. Only the accessories recommended by EMOS Technology GmbH may be used together with the endoscopes.

More detailed information is available in the accessories catalogue (not included in the scope of delivery).

9 Assembly / Disassembly

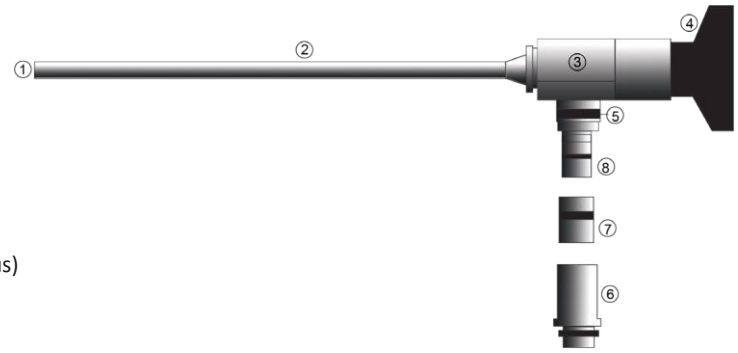
- Assemble and disassemble the light guide connection according to the figure
- Ensure that the adapters of the light guide cables correspond to the adapters of the rigid endoscopes (see figure, section 9.1) Corresponding connection systems only fit into the intended adapters
- Adapters for Storz®/Olympus® ⑥ and Wolf® ⑦ light guide connections are included in the scope of delivery as standard parts.
- Always hold the endoscope by the main body ③ or the eyepiece ④
- Ensure that glass surfaces are not touched by other instruments

- To prevent the endoscope from becoming fogged during the surgery, the proximal end of the lens must be completely dry before attaching the camera or the camera adapter. To ensure a firm and secure connection of the individual components, ensure that the fastener of the endoscope and that of the adapter are not soiled or damaged

ⓘ When disassembling contaminated endoscopes, there is a risk of infection

9.1 Assembly

① Lens with sapphire cover glass
② Sheathing
③ Main body
④ Eyepiece
⑤ Colour coding ring (corresponds to viewing direction)
⑥ Adapter for light guides, can be unscrewed (Storz/Olympus)
⑦ Adapter for light guides, can be unscrewed (Wolf)
⑧ Connection piece for light guides (ACMI)



10 Inspection and maintenance

Before each testing and maintenance, allow endoscopes and accessories to cool to room temperature. Assemble detachable endoscopes and accessories.

10.1 Inspection (visual inspection)

- After each cleaning and disinfection, check endoscopes and accessories for protein residues and contamination. Clean contaminated endoscopes and accessories once again. The endoscopes may not have any residues of cleaning agents and disinfectants.
- Before every sterilisation and every use, the endoscopes are to be checked for cleanliness, function, and damage.
- The entire endoscope should be free of any damage, such as loose, bent, deformed, fractured, cracked, rough, broken-off parts, worn surfaces, sharp edges, defective insulation, etc.
- Damaged, defective, stained or cloudy endoscopes and accessories should be taken out of service and replaced. Defective cables must be replaced immediately.
- Ensure that no parts are missing or have become loose (e.g. sealing rings) and that the connection elements between the instruments are working properly and are firmly seated or latched.
- Do not continue to use a device with damaged glass surfaces or stubborn deposits that cannot be removed by cleaning.
- Visual inspection of the glass surfaces (lens window, eyepiece window, light guide connection) with the aid of reflected light or a loupe: The surfaces must be clean, smooth and intact.
- A further inspection comprises image quality (clear and free of distortion) and the light transmission through the glass fibres. To do this, hold the light guide connection against glare-free light. If the glass fibres at the distal end appear as dark dots, glass fibres are broken and adequate illumination may no longer be ensured.

If one of the deviations mentioned occurs, the endoscope may not be used further and must be sent to the manufacturer or an authorised service centre for repair (see section 14) or be properly disposed of (see section 16).

10.2 Maintenance and servicing

Rigid endoscopes and accessories are maintenance-free. They do not contain any components that need to be maintained by the user or manufacturer.

ⓘ Regular cleaning of the optical surfaces with 70% alcohol (ethanol, isopropyl alcohol) prevents deposits from becoming set/burned in

11 Processing and disinfection

⚠ The endoscopes are not supplied sterile and must be cleaned, disinfected, and sterilised prior to first use as well as before every further use

⚠ Endoscopes may not be cleaned in an ultrasonic bath

⚠ Endoscopes may not be exposed to gamma rays

General application instructions for safe processing

- After every cleaning/disinfection and before each use, the endoscopes are to be checked for cleanliness, function, and damage (see section 10). Damaged or defective endoscopes may not be used. Damaged individual parts must be immediately replaced with original replacement parts. Damaged endoscopes are to be immediately taken out of service
- Process contaminated endoscopes and accessories as quickly as possible
- Manual or machine (automatic) cleaning and disinfection are to be performed after each use Observe manufacturer's information (e.g. dosing)
- Do not apply any strong pressure by hand
- Ensure that endoscopes and accessories do not touch each other during cleaning
- Use only cleaning agents for the complete dissolution of proteins
- Avoid any fixation of proteins before and during the processing
- Do not use any abrasive cleaning agents or metal brushes
- The parameters indicated by the manufacturer for the cleaning agent and disinfectant with regard to concentration, temperature, service life, and contact time must be observed and automatic metering devices must be controllable
- If there are elevated chloride concentrations in the water, pitting and stress corrosion on the instruments can occur. Such corrosion can be minimised through the use of demineralised water or alkaline cleaning agents
- The selection of the cleaning agent and disinfectant is based on the properties of the instruments and national guidelines and recommendations
- The applicable country-specific laws and regulations should always be observed
- Follow instructions for processing and sterilisation

ℹ
- Immediately clean with water in the event of contact with corrosive agents. Use demineralised water, if possible.
- Improper cleaning can lead to material damage.
- Autoclave only endoscopes and accessories that are marked with "autoclave"

Always perform machine (automatic) cleaning after contact with:

- Blood
- Wounds
- Internal tissue
- Organs

11.1 Preparation of the instruments and precleaning

11.1.1 Preparation of the instruments at the place of use

- Remove visible surgical residues and surface contamination as completely as possible using a clean, damp, lint-free cloth.
- All light guide adapters are to be removed prior to processing (see section 9)

ℹ Do not use warm water (> 40°C) or fixing disinfectants since this can lead to fixation of the residues on the device (risk of protein coagulation or denaturing) which can affect the success of the subsequent processing steps.

11.1.2 Transport

- The instruments can be transported to the respective processing rooms in either wet or dry condition
- For safe, easy transport for processing, we recommend using the storage systems provided for this (such as disposal containers)

ℹ Residues should not be allowed to dry in any case

11.1.3 Manual precleaning

Precleaning must always be performed prior to manual or machine (automatic) cleaning:

1. Disassemble detachable endoscopes and accessories into individual parts. Disassemble the endoscope as much as possible (see section 9). Remove the light guide adapter prior to processing.
2. To remove adhered grime, place the device in cold municipal water (< 40°C, according to the Drinking Water Ordinance (TrinkwV)) for at least 5 minutes.
3. Using a soft cleaning brush (natural bristles), clean the device under running municipal water (< 40°C) until all visible contamination has been removed.
4. Rinse cavities, lumens, narrow gaps, and slits using a water gun (or syringe) intensively (min. 30 seconds) with cold municipal water.
5. Clean the optical surfaces (proximal eyepiece, distal tip, light guide cable connection) with a lint-free cleaning cloth and carefully rinse them under cold running municipal water (< 40°C). Do not use any cleaning brushes since this can leave scratch marks. Contamination and scratch marks that impair the optical quality can be made visible by reflecting light on the optical surface.

ℹ If residues remain on the surface of the optical fibres after cleaning, these residues can be burned onto the surface when a light source is used and thus impair the fibre transmission (light transmission)

11.2 Manual processing

11.2.1 Manual cleaning

Validated with the alkaline cleaning agent neodisher® MediClean forte

1. Place the instruments completely in the alkaline cleaning bath (e.g. 0.5% neodisher® MediClean forte for 5 min). Observe the contact time according to the manufacturer's information
2. It must be ensured that the cleaning solution reaches all areas of the instrument. Movable parts on the instrument must be moved several times (min. 3 x) in the cleaning bath. In the cleaning bath, rinse through and around cavities, lumens, narrow gaps and slits using a syringe (without cannula) several times (min. 3 x 20 ml)
3. After the necessary contact time, the instruments undergo post-cleaning under cold, running municipal water (< 40°C) using a soft brush. Rinse through and around cavities, lumens, narrow gaps, and slits once again using the water gun (or syringe) (min. 30 sec)
4. Then rinse the endoscopes once again under cold, running municipal water (< 40°C) and perform post-cleaning with a brush until the cleaning agent has been completely removed (min. 30 sec)

11.2.2 Manual disinfection

Validated with the aldehyde-free disinfectant Korsolex® plus

1. Immerse instruments in an RKI- or VAH-listed disinfectant (e.g. 3% Korsolex® plus for 15 min). In doing so, follow the instructions of the disinfectant manufacturer.
2. It must be ensured that the disinfectant reaches all areas of the instrument. Movable parts on the instrument must be moved several times (min. 3 x) in the disinfectant bath. In the disinfectant bath, rinse through and around cavities, lumens, narrow gaps and slits using a syringe (without cannula) several times (min. 3 x 20 ml).
3. After the contact time, rinse off the instrument carefully using cold demineralised water (min. 30 sec). Cavities and lumens must be flushed with demineralised water multiple times (min. 3 x 20 ml) using a syringe (without cannula).
4. Dry manually using a disposable, lint-free cloth. To largely prevent water from remaining in cavities, it is recommended to blow out cavities using sterile, oil-free compressed air.

11.3 Machine processing (automatic cleaning and thermal disinfection)

Only special methods for lenses that are tested and approved for this purpose may be used
(e.g. thermal disinfection). The use of a cleaning and disinfection device in accordance with the recommendations according to standards series ISO 15883 is recommended. Suitable pH-neutral or alkaline cleaners are to be used as cleaning agents for machine cleaning.

- Instruments must be placed on instrument holders suitable for the machine such that they can be easily rinsed
- The instrument holders (e.g. mesh baskets) must be designed such that subsequent cleaning in the cleaning and disinfection device is not prevented by ”dead zones” that cannot be reached by water
- The instruments should be secured in the cleaning basket at a minimum distance from each other
- Overlapping with one another should be avoided to prevent damage to the instruments by the cleaning process
- The instructions of the device and cleaning agent manufacturers must always be followed

Automatic processing process validated with the cleaning and disinfection device Miele G7835 CD, programme “Des-Var-TD”, alkaline cleaning agent neodisher® MediClean forte, neutralising agent neodisher® Z:

1. 1 minute of precleaning with cold municipal water < 40°C
2. Drain water
3. 3 minutes of precleaning with cold municipal water < 40°C
4. Drain water
5. 5 minutes of cleaning at 55°C +/- 2°C with alkaline cleaning agent (e.g. 0.5% neodisher® MediClean forte)
6. Drain water
7. 3 minutes of neutralisation (e.g. 0.1% neodisher® Z) with warm municipal water (40°C +/- 2°C)
8. Drain water
9. 2 minutes of rinsing with warm demineralised water (40°C ± 2°C)
10. Automatic thermal disinfection in the cleaning and disinfection equipment, taking the national requirements regarding the A0 value into account (e.g. > 90°C (A0 > 3000), 5 min)
11. Automatic drying according to the automatic drying process of the cleaning and disinfection equipment (e.g. 90°C +/- 2°C, 30 min).
12. If needed, manual drying can then additionally be performed using a lint-free cloth or by blowing out lumens using sterile, oil-free compressed air.

i After machine cleaning, take the endoscopes out of the cleaning device immediately in order to avoid corrosion

i Accelerated cooling of the instrument should be avoided

12 Sterilisation

⚠ The endoscopes are not supplied sterile and must be cleaned, disinfected, and sterilised prior to first use as well as before every further use.

i Before each sterilisation, the endoscopes are to be thoroughly cleaned (manual or machine) and disinfected (see section 11)

i Before each sterilisation, the endoscopes should be checked for cleanliness, function and damage (see section 10)

- Sterilise endoscopes individually packed into suitable sterilisation containers
- Ensure that the entire surface is in contact with sterilisation medium
- Ensure that the fastening elements securely accommodate the endoscopes
- The endoscopes may not be exposed to any mechanical stress since this could damage the sensitive optics
- The tip of the endoscope may not be in direct contact with the metal container. The heat of the container will otherwise be transferred directly to the endoscope and this would damage the optics
- After the end of the sterilisation process, the endoscopes should cool slowly to room temperature The endoscope may not be rinsed with cold water or other liquids for cooling since this can lead to damage of the lenses

12.1 Sterilisation methods

- Only methods that are tested and approved for this purpose may be used
- Sterilise endoscopes according to the generally applicable hospital method
- Observe manufacturer’s information for the aids used

- Ensure that devices are packed for sterilisation according to ISO 11607 and EN 868

⚠ Endoscopes may not be exposed to gamma rays

Recommended sterilisation methods (validated methods):

- Steam sterilisation / autoclaving (validated parameters, see section 12.2)

It is possible that sterilisation methods not listed in these instructions are also compatible with the endoscopes.

When using methods other than those listed in these instructions as being validated, the operator is responsible for the sterility.

12.2 Steam sterilisation (autoclaving)

Perform sterilisation according to DIN EN 13060/DIN EN ISO 17665-1. In doing so, take relevant national requirements into account.
The sterilisation result depends on various factors, such as how the sterilised instrument was packaged or stored or how the instrument is arranged in the autoclave. Check the degree of sterilisation using suitable indicators.

Validated sterilisation parameters:
Steam sterilisation with fractionated vacuum method (in the sterilisation container) and sufficient product drying according to DIN EN ISO 17665-1:

Fractionated prevacuum steps	3
Temperature	134°C (273°F)
Exposure time	5 minutes
Drying time	20 minutes
Packaging	Sterilisation film

Acceptance criterion:
According to EN ISO 14937, Annex D, a sterilisation process in a half-cycle method is considered to be effective if a reduction by at least a factor of 10^6 of the viable microorganisms is achieved (sterility assurance level (SAL): 10^{-6}). The process is considered to be passed if it meets the following criteria:

Description	Acceptance criterion	Passed: yes/no
Sterility assurance level (SAL) 10^{-6}	≥ 10^{-6}	Yes

The proof of fundamental suitability of the endoscopes for effective steam sterilisation was provided by an independent accredited test laboratory utilising the steam steriliser “3870 EHS Type B, Tuttnauer” with the use of the fractionated vacuum method. The method described above was taken into account here.

13 Storage and packaging

- Before storage, the endoscopes must be completely dry
- Store and pack endoscopes only individually
- Store endoscopes in a dry, clean, low-germ, dust-free, and well-ventilated environment and in a protected place at room temperature (free of corrosive vapours). To avoid the formation of condensate, major temperature fluctuations should be avoided
- The endoscopes must be reprocessed no later than after 7 days of storage

13.1 Packaging

- Always process and store rigid endoscopes in disposable sterilisation packaging and/or sterile goods packaging or sterilisation containers that are suitable for steam sterilisation (adequate temperature resistance, air and steam permeability; in accordance with DIN EN ISO/ANSI AAMI ISO 11607)
- The packaging must ensure optimal protection of the sterile endoscopes during transport and storage
- Reusable sterilisation containers must be serviced according to the manufacturer’s specifications The endoscopes must be secured inside them and protected from damage
- The transport packaging of the endoscopes is not intended for cleaning, sterilisation and storage, therefore do not store the endoscopes in the transport packaging

13.2 Transport

- For transport, the endoscope is to be kept protected from contamination in suitable closed containers, in order to avoid recontamination
- Transporting endoscopes in transport packaging for examinations at outside facilities is not permissible The transport packaging may be used only to ship a defective device to the manufacturer for repair (see section 15)

14 Service and repair

To ensure operational safety of the endoscopes:

- Have repairs performed only by the respective dealer or a qualified customer service centre authorised by EMOS Technology GmbH
- Use only original replacement parts for the repairs
- The guarantee and warranty claim becomes void in the case of repairs that are not performed by service centres not authorised by EMOS Technology GmbH
- Information on repairs and guarantees is available from EMOS Technology GmbH representatives or an authorised customer service centre

14.1 Shipment

- Returning used medical devices is permitted only if the devices are in a cleaned and sterilised condition with documented proof.
- When returning devices, always use the original transport packaging. The packaging must ensure optimal protection of the endoscopes during transport.

15 Service life

- Rigid endoscopes are reusable instruments
- The service life of the endoscopes depends on the frequency of use and on maintenance and careful handling
- When used properly, rigid endoscopes can be used and reprocessed for 100 cycles without maintenance/breakage
- Before each use, the endoscope should be checked for cleanliness, function and damage (see section 10)
- After the end of the life cycle, dispose of the endoscope properly, if necessary (see section 16)

16 Disposal

Irreparable or non-processable devices should be passed on for disposal as per regular hospital procedures.
When disposing of endoscopes, the following should be observed:

- Before disposal, thoroughly clean and sterilise endoscopes
- Dispose of packaging and used parts according to country-specific regulations
- Protect endoscopes from being accessed by unauthorised persons

17 Loss of warranty

The use of damaged and/or soiled endoscopes is under the sole responsibility of the user. Failure to follow these instructions for use and processing leads to the loss of guarantee and warranty claims. We accept no liability in the event of improper handling, incorrect or deficient processing, or unauthorised repairs.

18 Reporting incidents

In the event of a serious incident that occurs in connection with the device, the user and/or the patient must report this immediately to the manufacturer and the competent authority of the member state in which the user and/or patient is located.

19 Compliance with regulations

This medical device is provided with a CE mark in accordance with Medical Device Regulation (MDR) 2017/745.
If an identification number follows the CE mark, this indicates the competent Notified Body.

The rigid endoscopes correspond to ordinance (EU) 2017/745 (MDR) class IIa.

Devices of class IIa are additionally labelled with the identification of notified body no. 0483 “mdc medical device certification GmbH”. CE 0483

More information on the technical data is available from our service hotline:
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