

- Rinse with running tap water for at least 30 seconds or until all solution is removed.
- Clean the scope with a detergent solution such as Steris Prolystica® 2X Concentrate Neutral Detergent at the mfg's recommendation concentration.
- Rinse with running tap water for at least 30 seconds or until all solution is removed.
- Dry cystoscope with a soft cloth.
- Carry out visual inspection, function check and servicing, see "Testing, handling and maintenance"

**!** Non-compliance with the manufacturer's specifications can result in damage to the cystoscope.

**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:

**i** Only clean with polishing paste if the image which you see through the cystoscope 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 and sterilize the cystoscope.
- Carry out visual inspection. If the deposits were not removed: send in cystoscope for repair.

**8.3 Sterilization**

- i** Prior to each sterilization, rigid cystoscopes must be cleaned according to the methods in these instructions for use.
- i** If a sterilization pouch is utilized, it must be cleared for use with the intended sterilization method and cycle.

- Sterilize cystoscopes in suitable packaging to prevent subsequent contamination.

**Steam sterilization (autoclaving)**

**!** Only cystoscopes 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 cystoscopes.

**Deviating process parameters could damage the cystoscope. In this case, the guarantee and warranty shall become void.**

**i** Autoclavable cystoscopes can be sterilized with the French cycle (134 °C, 18 minutes, 3.1 bar (absolute) without restrictions regarding material compatibility.

- Existing adapters are dismantled.
- Sterilize cystoscopes.
- When the sterilization process has ended, allow the endoscopes to cool gradually to room temperature.

**Fractionated pre-vacuum method**

The following process has been validated:

Temperature	132 °C (270 °F)
Time	3 minutes
Configuration	Wrapped
Drying	At least 10 minutes

**Gravitation method**

Temperature	132 °C (270 °F)
Time	15 minutes
Configuration	Double packed in sterilization bags
Drying	At least 10 minutes

**i** The cystoscopes have material compatibility with the gravitation method for a hold time of 15 minutes.

**Hydrogen peroxide sterilization (STERRAD® method)**  
Cystoscopes without working channels can be sterilized with the following STERRAD systems:  
- STERRAD 100S

- The following process has been validated:  
- STERRAD 100S, Full (short) cycle
- Observe specifications of the manufacturer (ASP) regarding the corresponding method.

**Ethylene oxide sterilization**

**i** The cystoscopes are material compatible with ethylene oxide (EO) sterilization.

- The following process has been validated:

Exposure Time	1 hour
Temperature	55 ± 2°C
EO Concentration	≥725 mg/L
RH	50% ± 5%
Aeration Time	8 hrs at 55 ± 2°C

**8.4 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 sterilization processes. Therefore, the standard methods for decontamination and sterilization 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.

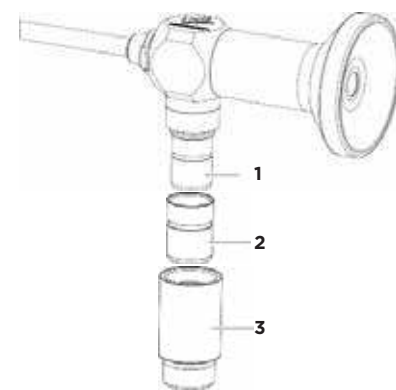
**8.5 Processing restrictions**

Repeated processing has only minimal effect on the cystoscopes. The service life of the units is usually determined by wear and damage.

The cystoscope can be damaged if the manufacturer's specifications are not observed.

**!** Do not clean cystoscope in an ultrasonic bath.

**9. Assembly**



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

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

**10. Disassembly**

**!** **WARNING**  
Risk of burns!

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

- Remove illumination fiber.
- !** Do not remove the ocular funnel because otherwise the cystoscope will be damaged.
- Unscrew existing adapters.

**11. 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 cystoscopes 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 cystoscope either in the original packaging or in a screen tray/container.
- Ensure that the cystoscope is stored securely.
- Observe the respective valid national provisions when storing in a sterile condition.

**12. Service and maintenance**

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

- Have the cystoscopes repaired by Emmy Medical only. For service, send the defective cystoscope to the address of the sales partner.
- Clean and sterilize the cystoscope thoroughly prior to returning it for repair.
- Ideally, send in the cystoscope in its original packaging. If this is not possible, package the cystoscope to secure it for transport.
- Emmy Medical is not liable for damage resulting from improper shipping.

**13. Accessories / spare parts**

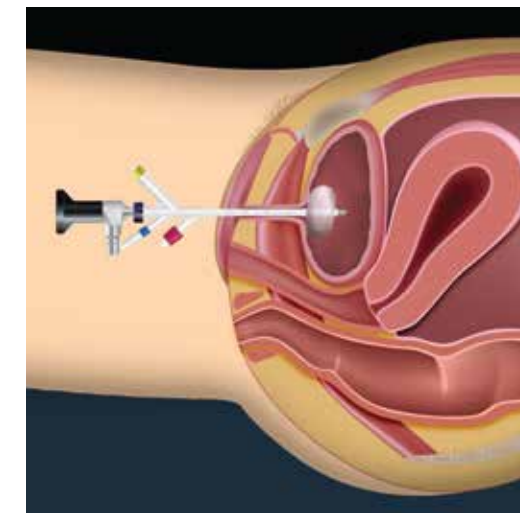
Designation	Article Number
Polishing paste	8101001000
Adapter type Wolf	89530738
Adapter type Storz / Olympus	89542801

**14. Disposal**

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

**15. System Illustration**

Figure 1 CystoSure Setup



Note: Scope must be withdrawn from catheter when using either inflow or outflow ports.



Instructions for Use



Manufactured for:  
Emmy Medical, LLC  
18 Hillside Drive  
Holliston, MA 01746

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**1. About this document**

**1.1 Purpose**  
 This document describes the correct handling and function of the rigid cystoscope, 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 Emmy Medical. If you as the user of this cystoscope 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:

	<b>Instructions for preventing personal injury</b>
	<b>Instructions for preventing material damage</b>
	<b>Information to facilitate understanding or workflow optimization</b>
	<b>Prerequisite</b>
	<b>Instruction</b>

**2. Intended use**

The CystoSure® Urinary Access System provides access and visualization for the female urinary bladder. The reusable CystoSure® rigid metal scope is used to visualize the female urinary bladder for diagnostic procedures. The single-use CystoSure® access catheter accessory provides urethral urinary catheterization and postoperative bladder irrigation/lavage with the addition of a sealed port for passage of the CystoSure® scope. It is suitable for medium- to long-term use, up to 30 days. 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 cystoscope believe that you require more detailed information regarding the product's use and maintenance, please contact your representative. An illustrated diagram of the system is provided in the Figure 1 of Section 16.

**3. Safety information**

The cystoscope may only be used by trained medical professionals in medical facilities. After delivery, inspect the cystoscope for completeness and damage. Read, observe and keep the instructions for use. Use the cystoscope only as intended, see "Intended use" above. For storage, transport and processing, ensure that the cystoscope is not subjected to mechanical strain, particularly to prevent damage to the sensitive lens system.

**Warnings – CystoSure® Cystoscope**

- WARNING**  
**Risk of infection to the patient or medical professionals!**  
**The cystoscope is delivered non-sterile as a reusable product.**  
**The state of the art and national laws require the observance of validated 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 and sterilize the cystoscope prior to initial use as well as each subsequent use of the cystoscope.**  
**Bring the cystoscope to the decontamination area after use. Observe valid protective measures to prevent contaminating the environment.**

- WARNING**  
**Risk of burns!**  
**The optical fibers emit high-energy light at the distal end of the cystoscope. 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 light source when working near body tissue or flammable materials.**

- WARNING**  
**Risk of injury due to faulty cystoscopes!**  
**Carry out visual inspection and function check prior to each use.**  
**Only use cystoscopes which are in perfect condition.**

**Contraindications – CystoSure® Catheter**

- This device is not intended to be used in pediatrics, adult male patients or in situations where urethral obstructions, erosion or hemorrhage is present.

**Warnings – CystoSure® Catheter**

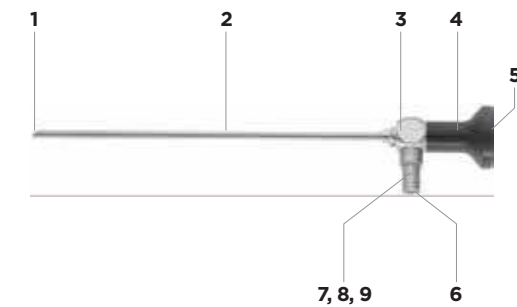
- Do not re-sterilize or reprocess this medical device as this may have an adverse effect on the known characteristics of the structural integrity, performance and biocompatibility of the device.
- Do not use if package has been opened or damaged.
- Do not use petroleum-based lubricants on catheter.
- Do not use needle to inflate balloon; use 5 cc luer slip syringe.
- Do not use glycine for inflation.
- Do not clamp catheter shaft, since this may damage catheter and prevent deflation and use sterile catheter outflow valve to stop urine flow.
- Avoid contact with oil-based antiseptic phenols or their derivatives, greases, spirit, paraffin or other related compounds.
- For single patient use only; do not reuse this medical device as this may increase the risk of contamination leading to transmission of infectious diseases which has the potential of resulting in patient injury, illness or death.
- Do not use with connectors found in the following medical devices/healthcare applications:
  - Intravascular devices;
  - Hypodermic applications;
  - Breathing systems and driving gas devices;
  - Limb cuff inflation devices;
  - Neuraxial devices
- Once used, dispose of packaging and package contents in accordance with healthcare institution guidelines and/or local government policy.

**4. Testing, handling and maintenance**

- The cystoscope from Emmy Medical is a precision medical instrument, and handling it requires great care.
- Inspect the cystoscope for damage prior to and after use.
  - If the cystoscope is damaged, discontinue use and contact the manufacturer.
  - Do not subject the cystoscope to impact. Put the cystoscope down carefully.
  - Hold cystoscope only by the ocular funnel / main part and not by the sheath.
  - Do not bend the sheath.
  - Do not bend the cystoscope after inserting the into the access catheter. A piece broken off the cystoscope can become lodged in the soft tissue or no longer appear in the cystoscope's field of vision and thus remain in the body.
  - Transport cystoscopes individually and store them safely by using a screen basket or container.

**5.0 Description**

**5.1 Construction**



- 1. Distal end
- 2. Sheath
- 3. Main part
- 4. Ocular funnel
- 5. Proximal end
- 6. Irradiation surface of the illumination fibers
- 7. Connection for illumination fiber, type ACMI
- 8. Adapter for illumination fiber, type Wolf, pre-assembled
- 9. Adapter for illumination fiber, type Storz / Olympus (assembly, see "Assembly".)

**5.2 Markings**

- Article number
- Serial number
- Writing "autoclavable"
- Specification of the direction of view
- Writing GERMANY
- Writing CYSTOSURE

**5.3 Available design and size**

- The cystoscope is available in the following design and sizes:
- Straight with 185 or 270 mm working length
  - Angled 30° and 70°

**5.4 Combinable products**

You can combine the cystoscopes with existing camera systems and with illumination fibers.

**6. Preparation for use**

**6.1 Visual inspection and function check**

- WARNING**  
**Risk of injury due to faulty cystoscopes!**
- Carry out a visual inspection and function check prior to initial use as well as each additional use.
- Only use cystoscopes which are in perfect condition.
- Clean and sterilize the cystoscope prior to initial use as well as each additional use of the cystoscope.
- Contaminants on the irradiation surface of the illumination fibers can burn in during use, which impacts image quality.
- Ensure that the proximal end of the cystoscope is dry to prevent the cystoscope from fogging up during the examination / procedure.
- Ensure that no parts are missing or loose.
- Ensure that there are no residual cleaning agents on the cystoscope.
- Inspect the entire cystoscope 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 fibers for contamination and scratches. Make contaminants and scratches visible using light reflexes. Hold the connection of the optical fibers against the light and inspect whether the optical fibers 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".

**6.2 Provisioning**

- Clean and sterilize the cystoscope prior to initial use as well as each additional use of the cystoscope, see "Processing".
- Ensure that the proximal end of the cystoscope is dry to pre-vent the cystoscope from fogging up during the examination/ procedure.
- If necessary mount adapter for illumination fiber, see "Assembly".
- Mount illumination fiber (see manufacturer's specifications).
- If required, adapt the camera (see manufacturer's specifications).

**7. Use**

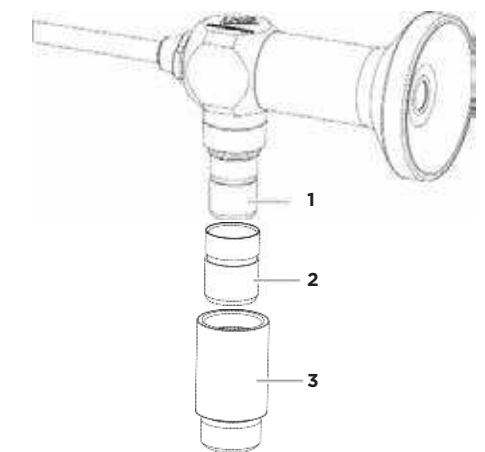
- WARNING**  
**Risk of burns!**
- **The optical fibers emit high-energy light at the distal end of the cystoscope. This can cause the temperature of the body tissue to rise to 41 °C.**
- **Avoid direct contact of the distal end with body tissue or flammable materials as it can cause burns.**
- **Reduce the light intensity of the light source when working near body tissue or flammable materials.**
- Prepare the cystoscope for processing immediately after use to prevent surface drying of the contaminants.

**8. Processing**

- 8.1 Safe storage and transport**  
 If possible, reprocessing cystoscopes immediately after use is recommended. Cystoscope 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 cystoscope securely and transport it to processing in a closed container to prevent damage to the endoscope and contamination of the environment.

**8.2 Cleaning**

- Manual cleaning / pre-cleaning**
- Do not use fixing cleaning agents or hot water (>40 °C) as it can cause fixation of the contaminants and jeopardize successful cleaning.
  - Do not scratch contaminants off with hard objects as this can cause damage to the optical end surfaces. Do not clean cystoscope in an ultrasonic bath.
  - ✓ Existing adapters are dismounted as shown below.



- 1. Connection for illumination fiber, type ACMI
- 2. Adapter type Wolf
- 3. Adapter type Storz / Olympus
- Remove coarse contamination from the cystoscope using running water until all visible contaminants have been removed.
- Soak the cystoscope in an enzymatic solution such as Steris Polystica® 2X Concentrate Enzymatic Presoak and Cleaner at the mfg's recommendation concentration scrubbing all crevices with a soft brush working beneath the liquid level for 2 minutes or until cystoscope is visibly clean.