Symbol Descriptions (Glossary)

Do Not Reuse	Do not Resterilize	Consult Instructions for Use
Batch Code	Not made with Natural Rubber Latex	Warning
Catalog Number	Do not expose product to radiation and UV light	Keep Away from Sunlight
Manufacturer	Use by Date	Do Not Use if Package is Damaged
Quantity: 1	Sterilization Using Ethylene Oxide	Storage Temperature 60-80°F (15-25°C)

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Manufactured for:
Emmy Medical, LLC
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Holliston, MA 01746
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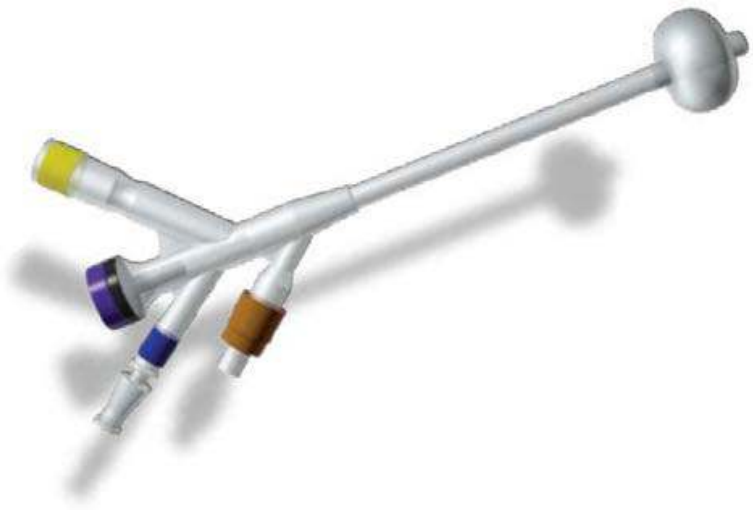
www.cystosure.com

Emmy Medical

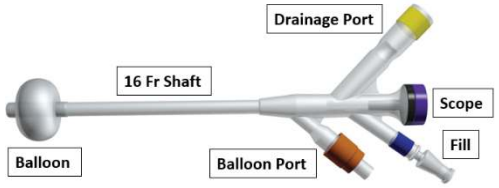
CystoSure®
A **Vision** for Better Medicine



Instructions for Use

CystoSure® Plus/XL Catheters, 10-400/10-600
Caution:
Federal (USA) law restricts this device to use by or on the order of a physician.

Contents of Package:
1 – CystoSure® Silicone access catheter



Product Description: The CystoSure® silicone catheters are intermittent (short-term) flexible tubes retained in the bladder for the purpose of continuous drainage.

The length of the CystoSure® catheters is 258 (Plus) & 288 (XL) mm. Catheter and balloon are made out of 100% silicone material. The catheters are 16 Fr and are design to maximize patient comfort with the smallest possible size that prevents urine leakage, while at the same time capable of providing adequate drainage and irrigation with the additional scope access port.

The purpose of the small balloon, i.e. 5 ml/cc is simply to retain the catheter and prevent it from slipping out of the bladder. It is used primarily for routine drainage during the procedure.

The CystoSure® catheters come with four ports: 1) a port for passage of the endoscope (purple), 2) a port for bladder drainage (yellow), 3) a port for inflow of clear fluids (blue) and 4) a balloon inflation channel (red). The CystoSure® Plus catheter is used intra-operatively on patients undergoing pelvic procedures such as hysterectomy, pelvic prolapse and suburethal sling placements and for short-term post-operative bladder drainage.

Intended Use/Indications for Use: The CystoSure® catheters provide access and visualization for the female urinary bladder.

The single-use CystoSure® catheters provide urethral urinary catheterization and postoperative bladder irrigation/lavage with the addition of a sealed port for passage of the endoscope. They are suitable for medium- to long-term use, up to 30 days.

Contraindications: These devices are not intended to be used in pediatrics, adult male patients or in situations where urethral obstructions, erosion or hemorrhage is present.

Warnings – CystoSure® Plus & XL Catheters

- 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.

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 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”.

Precautions: This device should only be used for its intended purpose by or under the supervision of trained healthcare professionals with a comprehensive understanding in clinical principles, procedures and risks associated with urinary catheters. It is recommended to adhere to the instructions for use provided with this device, the urinary instructions for the healthcare facility and instructions recommended by physicians.

Product Benefits: The CystoSure® Plus & XL catheters are a latex-free option that is ideal for users with latex allergy and for healthcare providers who have a latex-free product selection policy. The elimination of the removal and reinsertion of the catheter for diagnostic visualization reduces risk of urinary tract infection and hospital-acquired infections (HAIs).

The CystoSure® Plus & XL catheters were developed as flexible and strong catheters that conform to the urethra. They minimize irritation and improve patients’ comfort during use. The all-silicone catheters come with a precise tip length that reduces risk of painful and irritating contact with the bladder wall. The tip is smoothened to eliminate any excess material that could potentially cause irritation during catheterization and contain a hole to enable passage of the scope.

The CystoSure® Plus & XL catheters and endoscope combinations offer great visualization of the bladder lining and drainage flow from the ureteral openings.

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Potential Risk: Complications and adverse events associated with device use include, but are not limited to unintended catheter dislodgement, clogging and kinking.

To avoid risk of urinary tract infection and hospital-acquired infections (HAIs), aseptic technique must be practiced in all instances when using the catheter.

Care must be taken when inflating balloon. Catheter balloon must be inflated with only the prescribed volume of sterile water. Catheter balloon that is over-inflated will burst and may slip out if under-inflated.

Catheter must not come in contact with oil-based antiseptic phenols or their derivatives, greases, spirit, paraffin or other related compounds, as it will affect product properties and cause balloon to burst. Such being the case, use only water-based lubricants on catheter instead of petroleum-based lubricants to prevent deterioration of silicone material.

Do not clamp or kink catheter shaft as this will seal the inflation lumen and cause non-deflation of balloon or blockage of drainage and inflow lumen.

Storage Recommendations

Store at room temperature (e.g., 15-25ºC or 60-80ºF) and avoid exposure to elevated temperatures.

Do not expose the product to radiation, direct sunlight or UV lights as it may impact the product performance.

Instructions for Use

An illustrated diagram of the system is provided in the Figure 1 below. Use aseptic technique using sterile gloves for the following steps:

Device Inspection

1. Remove catheter from packaging. Take care not to contaminate the catheter tube.
2. Insert luer tip syringe into the balloon inflation valve with a firm push and twist motion.
3. Inflate balloon with prescribed 5cc of sterile water.
4. While holding syringe plunger check for leakage or deflation.
5. Release syringe plunger and allow balloon to deflate.
6. Use only gentle aspiration, if necessary, to deflate balloon.
7. Do not use if balloon leaks or fails to fully deflate, and if visual defects or imperfections are visible prior to use.

Device Placement

8. Apply appropriate water-based sterile lubricant as per local policy.
9. Carefully insert catheter shaft into the urethra until balloon is appropriately positioned in the bladder; this is normally indicated by urine flow.
10. Once appropriate balloon position is confirmed, inflate balloon with the prescribed volume of sterile water.
11. Gently pull catheter shaft to ensure balloon is correctly positioned at the neck of the bladder.

Bladder Inspection

12. Use red clamp to occlude the drainage port (yellow ring).
13. Attach irrigation tubing to irrigation port (blue ring).
14. Instill fluid to distend bladder.
15. Insert endoscope into catheter via scope port (purple) until bladder is observed.
16. Rotate the scope as necessary to visualize the bladder and ureteral orifices (UO’s).
17. In some patients, it may be necessary to deflate balloon and retract catheter together with the cystoscope when UO’s and trigonal ridge are near the ureteral meatus.
18. After inspection of the bladder and ureteral orifices is complete, if the catheter is to be removed, the balloon should be deflated and the endoscope and CystoSure® catheter should be withdrawn slowly, visualizing the urethral-vesicle junction and urethra as devices are removed. Alternatively, if the catheter is to remain in-dwelling, the balloon should remain inflated and only the cystoscope should be withdrawn.

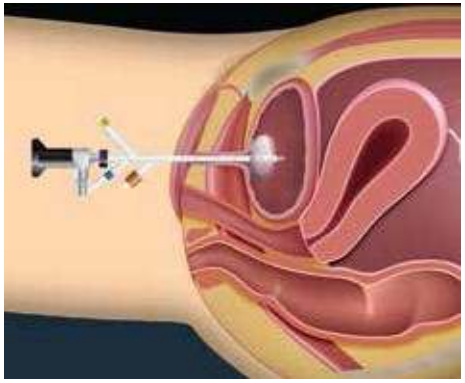
Device Removal (Balloon Deflation)

19. Insert luer slip syringe into balloon inflation valve with a firm push and twist motion. Release syringe plunger and allow balloon to deflate. Use only gentle aspiration, if necessary, to deflate balloon.
20. If device cannot be removed, it is possible that deflation has not occurred.
21. Repeat aspiration using syringe plunger to force deflation. If necessary, inject additional fluid into balloon and aspirate again.
22. If device still cannot be removed, sever the side arm below the balloon inflation port or bisect catheter shaft to enable any residual fluid in the balloon to empty and remove the device. Dispose of used catheter into clinical waste bag or according to clinical waste protocol, e.g., incineration.

Limitations of Use: The 100% silicone Foley catheters are suitable for long-term use, i.e. up to 30 days indwelling time and they should not be used past this recommended period.

Should the use of the product cause any irritation or discomfort, discontinue use and consult a physician.

Figure 1 CystoSure Setup



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