Cogentix
Medical

USER'S MANUAL

COGENTIX MEDICAL

Flexible Fiberoptic Cystoscope/Hysteroscope

CST-4000/4000*i*

and Slide-On® EndoSheath® Technology

NOTE: Federal (USA) law restricts this device to sale by, or on the order of, a physician or other appropriately licensed medical professional.

www.cogentixmedical.com

How to Use This Manual

This User's Manual contains the recommended procedures for preparing and using the Cogentix Medical **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope with the **Slide-On® EndoSheath® Technology**. It is intended for physicians and other medical personnel who will come in contact with the equipment before, during, and after any patient procedures with it. The manual also contains pertinent information on the proper care and handling of the equipment. Please read and become familiar with this entire manual before using the endoscope and accessories.

The manual contains the following information:

- Description of the endoscope and **Slide-On® EndoSheath® Technology**
- The endoscope's intended use
- Components and features of the endoscope and peripheral equipment used in conjunction with the endoscope
- Complete instructions on endoscope preparation, inspection, operation, reprocessing, and storage
- Warning and Caution statements that must be observed by endoscope users to ensure patient and user safety

If you are a **first time endoscope user**, Cogentix Medical strongly recommends that you read this manual from beginning to end and become intimately familiar with the endoscope and its use.

If you are an **experienced endoscope user**, select specific chapters and/or sections that pertain to features and procedures that you are using.

Organization of this Manual

Following is a list of the chapters included in this User's Manual. Each chapter's title is listed at the top of all pages after the title page, so that you can quickly access the information you need.

Chapter 1, Symbols and Terms — This chapter defines the symbols on the endoscope and peripheral equipment. There is also a brief list of the terms that are commonly used in the manual.

Chapter 2, Important Information — The information in this chapter is a summary of critical Warning and Caution statements in the manual. This information is essential to the safe operation and reprocessing of the endoscope. Cogentix Medical strongly recommends that this chapter be read thoroughly and completely understood by all users before working with the endoscope.

Chapter 3, Endoscope and Accessories — Introduces the **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope, the **Slide-On® EndoSheath® Technology,** and compatible peripheral equipment. This chapter includes instrument diagrams, identifies components, and defines their functions.

Chapter 4, Installing and Removing the Slide-On® EndoSheath® Technology — The **Slide-On® EndoSheath® Technology** is a sterile, single use barrier placed over the endoscope's Insertion Tube before the procedure, and removed and discarded after the procedure is completed. This chapter includes the procedures for installing the sheath prior to the procedure, and removing it when the procedure is over.

Chapter 5, Preparation, Inspection and Operation — This chapter describes how to prepare the endoscope and peripheral equipment for use, and how to assemble the equipment into a system. The chapter also leads you through a detailed inspection procedure to confirm that the equipment is undamaged and working properly before it is used in a procedure.

Chapter 6, Reprocessing — This chapter contains important instructions on the proper cleaning, disinfection, and sterilization of the endoscope before its first use and after each subsequent use. Strict adherence to the instructions in this chapter will render the endoscope "patient-ready" for each procedure.

Chapter 7, Care and Storage — If the equipment will not be used for a prolonged period, refer to this chapter for instructions on safe, secure storage.

Chapter 8, Troubleshooting — Describes possible problems that may be encountered with the endoscopic system, and suggests corrective actions to take towards resolving minor problems.

Chapter 9, Warranty and Service — This chapter contains the terms of the Cogentix Medical warranty on the endoscope, any restrictions that apply and user actions that may void the warranty if taken. This chapter also includes shipping instructions in case the endoscope must be returned to Cogentix Medical for repair or service.

The **Appendix** contains the technical specifications for the **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope, and infection control information.

Additional Information

The information in this User's Manual is subject to change without notice. If you have any questions regarding any of the material contained in this manual, or wish to confirm that this is the most comprehensive information available for these products, please contact your local distributor or Cogentix Medical Customer Service Department at 866 258-2182 (toll free in U.S.) or (+1) 952-426-6189 (international).

Table of Contents

Index of Figures

Index of Tables

1 Symbols and Terms

Symbols

The symbols listed below can be found on the **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope and on other components of the endoscopic system.

Type BF applied part (Safety degree specified by IEC 60601-1)

Alerts the user to the presence of important operating, maintenance, and service instructions. Refer to the user's manuals for warnings and safety precautions associated with equipment used in the procedure.

Equipment bearing this mark has been designed, tested, and certified as essentially compliant with all applicable European Union (EU) regulations and recommendations.

Serial number of the endoscope

Up position for the angulation lever

Down position for the angulation lever

Underwriters Laboratories Component Recognition Mark

STERIS® and STERRAD® Reprocessing Compatibility
(Refer to Chapter 6, Reprocessing)

Products do not contain natural rubber latex

Consult Instructions for Use

The presence of this symbol on the product or packaging indicates that the device is RoHS compliant.

Terms

Throughout this manual, the following terms are used:

"Endoscope", or **"Cystoscope/Hysteroscope"** refers to the Cogentix Medical **CST-4000/ 4000*i*** Cystoscope/Hysteroscope.

"Slide-On® EndoSheath® Technology" or **"Sheath"** refers to the disposable **CF-2.1 Therapeutic Slide-On® EndoSheath® Technology** or **CF-1.5 Diagnostic Slide-On® EndoSheath® Technology**.

2 Important Information

The information in this chapter is essential for the correct and safe operation of the **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope and **Slide-On® EndoSheath® Technology**. Please read and understand this information before preparing or using the endoscope or any peripheral equipment with which it will be used.

Intended Use

Cystoscopy:
The Cogentix Medical **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope and **Slide-On® EndoSheath® Technology** are intended to be used for endoscopic access to and examination of the lower urinary tract, including the bladder. When combined with accessory instruments, the endoscopic system allows the user to perform various diagnostic and therapeutic procedures.

Hysteroscopy:
The Cogentix Medical **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope and **Slide-On® EndoSheath® Technology** is also intended to be used for direct viewing of the cervical canal and the uterine cavity, for the purpose of performing diagnostic and therapeutic surgical procedures.

Do not use this equipment for any purpose other than these intended uses.

Contraindications for Hysteroscopy

The **CST-4000/4000*i*** endoscope and **Slide-On® EndoSheath® Technology** should not be used to perform hysteroscopy if any one of the following conditions exists. **Do not perform hysteroscopy using this equipment if**:

- The patient is pregnant or suspected to be pregnant
- The patient's cervix cannot be properly dilated
- The patient's uterus cannot be distended
- The patient has acute pelvic inflammatory disease (PID)
- The patient has invasive carcinoma of the cervix
- The patient has had a recent uterine perforation

User Qualifications

This equipment should only be used in a medical facility by or under the supervision of a physician trained in cystoscopy/hysteroscopy. Use of the system does not require any deviation from standard cystoscopy/hysteroscopy technique. However, the operator should have complete familiarity with the operation of the entire system prior to clinical use.

Only practitioners with appropriate training in hysteroscopy should perform hysteroscopic procedures. Cogentix Medical strongly recommends a thorough review of all relevant medical literature relative to techniques, complications, and hazards prior to undertaking any hysteroscopic procedure.

Only use the endoscope and peripheral equipment according to the instructions and under the operating conditions described in this manual. Failure to do so could result in compromised safety, equipment malfunction and/or instrument damage.

For preparation of the endoscope before use, and disassembly and proper cleaning after use, users should be thoroughly trained in the proper procedures. Failure to thoroughly understand these details, such as – but not limited to – **EndoSheath® Technology** installation and authorized disinfection or sterilization protocols, may pose an infection-control risk and/or cause equipment damage.

If training assistance is desired from either the manufacturer or a local distributor or representative, please contact Cogentix Medical Customer Service at 866 258-2182 (toll free in U.S.) or (+1) 952-426-6189 (international).

Reprocessing

The endoscope must be thoroughly cleaned, disinfected, and/or sterilized before its first use and after each subsequent use. This is the only way to ensure that a "patient-ready" endoscope is used in every procedure. See Chapter 6, **Reprocessing**, for information on reprocessing equipment and procedures.

Maintenance and Repair

The endoscope contains **no** user-serviceable parts; **never** attempt to modify or repair it. Doing so may cause further equipment damage and/or compromise patient safety if the endoscope is subsequently used in a procedure. The endoscope may only be serviced / repaired at an authorized Cogentix Medical facility.

The endoscope should be thoroughly inspected before each procedure, and should be periodically inspected to determine if there is damage or wear that requires attention.

Signal Words

Information included in this manual to warn users of the possibility of patient injury and/or equipment damage is signified by the Warning and Caution symbols shown in this section. Notes are also included, to advise of important information. Warnings, Cautions and Notes will appear throughout this manual; carefully read and follow all statements.

WARNING Alerts the user to situations which, if not avoided, could result in death or serious injury.

CAUTION Alerts the user to situations which, if not avoided, could result in moderate or minor injury to the user or patient. It is also used to alert the user to conditions and actions that could cause equipment damage.

NOTE: Indicates additional helpful information.

Important Safety Precautions

The following precautions should always be exercised when using the endoscope and all medical equipment to ensure the safety of all involved parties – user(s), patient(s), etc. They are summarized here in the order of the stages of the endoscope's use.

Preparation, Inspection and Assembly

WARNING

The **CST-4000/4000*i*** endoscope and **Slide-On® EndoSheath® Technology** are designed to operate as an integrated system. **Neither component can be used independently of the other.**

The **Slide-On® EndoSheath® Technology** is designed for single patient use only. Do not reuse or attempt to re-sterilize the Sheath. For installing the Sheath in a sterile environment, users should wear two (2) pairs of sterile gloves. Refer to Chapter 4, **Installing and Removing the Slide-On® EndoSheath® Technology**, for complete details.

Carefully inspect all equipment before using it in a procedure, and do not use any equipment that is damaged or excessively worn. Doing so could lead to patient injury and/or further damage to the equipment.

If inspection reveals difficulty in articulation of the endoscope's Distal Bending Section, the endoscope may be damaged. Do not use the endoscope in this case. Contact your local distributor, representative, or call Cogentix Medical Customer Service Dept.

All devices connected to the **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope must be Classified Medical Equipment. Before using any additional equipment, confirm that it complies with the appropriate end-product safety standard (such as IEC 60950-1) and the Standards for Medical Electrical Equipment (UL 60601-1 or IEC 60601-1).

CAUTION **Never drop the equipment or subject it to severe impact**, as it could compromise the functionality and/or safety of the equipment or system. Should the equipment be mishandled or dropped, do not use it. Immediately return it to an authorized Cogentix Medical service facility for inspection and repair.

While the Sheath is being installed, the Cystoscope/Hysteroscope should move freely without the application of force. Should **ANY** resistance be encountered, verify that the Sheath's channel is properly aligned.

If the channel is misaligned as shown in Figure 2-1, straighten the channel before continuing endoscope insertion. If the problem continues, refer to Chapter 8, **Troubleshooting** for further instructions. If this does not help solve the problem, contact your local distributor or call Cogentix Medical Customer Service Department. **DO NOT** expose the Sheath to alcohol or other cleaning agents prior to use.

Note: The Cogentix Medical CST-4000/4000*i* Cystoscope/ Hysteroscope and Slide-On® EndoSheath® Technology are not made with natural rubber latex.

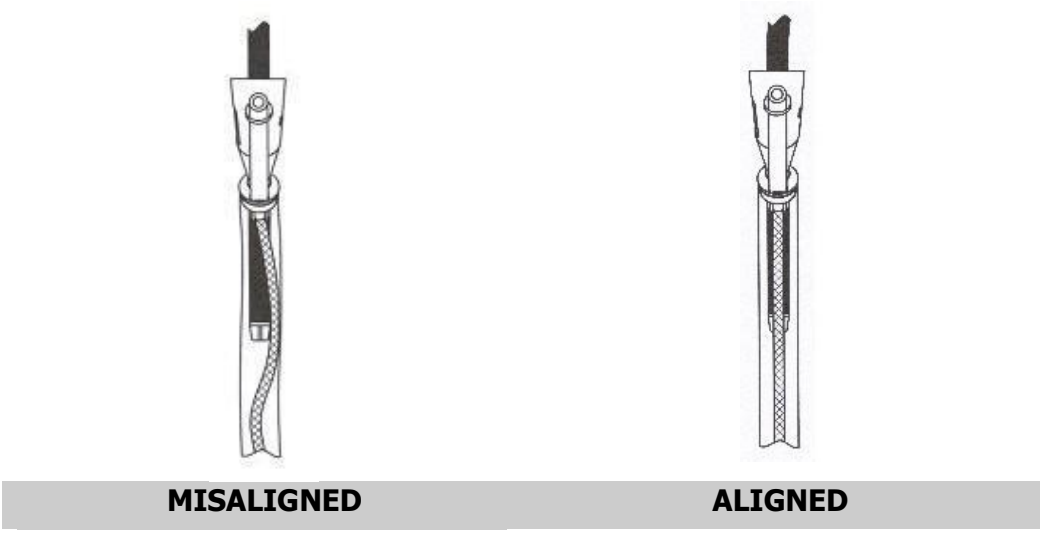


Figure 2-1: Incorrect and Correct Sheath Alignment

During Use - General

WARNING

Do not use this equipment in the presence of a flammable anesthetic mixture containing air, oxygen or nitrous oxide. There is a possibility of fire or explosion.

If any component of the endoscopic system malfunctions during the procedure, or if the endoscopic image is lost or compromised, immediately move the endoscope's Distal Bending Section to the neutral position and slowly withdraw the endoscope from the patient. Using an endoscope that is not functioning properly could cause patient injury and/or further damage to the equipment.

DO NOT use any accessory instrumentation that is damaged. Doing so may result in instrumentation malfunction during the procedure, which could cause serious patient injury and/or further damage to the Cystoscope/Hysteroscope.

CAUTION

Always wear appropriate personal protective equipment when using the endoscope and/or sheath, such as a gown, gloves, and face and eye shields.

Avoid excessive bending or twisting of the endoscope's Insertion Tube. Although they are designed to bend, excessive bending can damage the fiber bundles and internal components. Should the endoscope develop a severe kink or bend, do not attempt to straighten the Insertion Tube. Contact Cogentix Medical Customer Service for assistance.

DO NOT apply excessive pressure to the angulation lever, as it could damage the endoscope and lead to patient injury.

DO NOT look directly at the intense light emitted from the endoscope tip to avoid the possibility of eye injury.

If resistance is encountered when inserting an instrument into the Sheath, do not force it, as it could damage the instrument, the Cystoscope/Hysteroscope and/or the **CF-2.1 Slide-On® Endo-Sheath® Technology**.

The Irrigation Working Channel of the **CF-2.1 Slide-On® EndoSheath® Technology** accommodates instrumentation indicated by the accessory manufacturer to be compatible with a 2.1 mm or smaller working channel. All instrumentation must be tested for compatibility with the channel prior to clinical use. If assistance is needed to determine compatibility, contact your local distributor or Cogentix Medical Customer Service.

DO NOT attempt to advance an exposed needle or other sharp instruments through the working channel. Doing so could damage the sheath's channel.

A thorough understanding of the principles and techniques involved in laser, electrosurgical and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device and other medical instruments. Ensure that insulation or grounding is not compromised.

During Use - Hysteroscopy

WARNING

Prior to performing a hysteroscopic procedure, it is extremely important that the user review the following information which may be critical to ensuring patient safety.

Continuous CO_2 Flow Hysteroscopy

If CO_2 gas is used as a distention medium, operative hysteroscopy is contraindicated due to the risk of gas embolization, with the exception of non-electrosurgical polypectomy or directed biopsy. CO_2 gas may be used for diagnostic procedures**. It is extremely important that a hysteroscopic insufflator is used.** Death has been reported when laparoscope CO_2 insufflators were used during hysteroscopy. The CO_2 flow rate should be limited to less than 100 ml/min, and the patient's intrauterine pressure should not exceed 100 mm Hg.

Potential complications of continuous flow hysteroscopy with CO_2 include:

- CO_2 embolization
- Circulatory collapse
- Death

Continuous Fluid Flow Hysteroscopy

If a liquid distention medium is used, strict fluid intake and output surveillance should be maintained to ensure that fluid deficit is known at all times. Depending on whether a non-electrolytic or an electrolytic solution is being used, when excessive fluid deficit occurs, consideration should be given to stopping further infusion and concluding the procedure.

When using a fluid distention medium, closely monitor fluid intake/output. Excessive intake of distention fluid can lead to fluid overload and complications.

Potential complications of continuous flow hysteroscopy with fluid distention media include:

- Hyponatremia
- Hypothermia
- Uterine perforation resulting in possible injury to bowel, bladder, major blood vessels and ureter
- Pulmonary edema

- Cerebral edema
- Death

If pregnancy is suspected, perform a pregnancy test prior to performing hysteroscopy. **DO NOT** perform hysteroscopy if the patient is pregnant.

If performing Endometrial Ablation or Hysteroscopic Myomectomy, verify that the patient does not have procedural contraindications.

CAUTION Vaginal ultrasonography before hysteroscopy may identify clinical conditions that will alter patient management.

Gravity fed intrauterine fluid distention can usually be accomplished with pressures in the range of 35-75 mm Hg. Hanging the fluid distention medium 42 inches above the patient can generate intrauterine pressure of approximately 80 mm Hg. Unless the systemic blood pressure is excessive, it is seldom necessary to use pressures greater than 75-80 mm Hg.

NOTE: Hysteroscopes are used as tools to access the uterine cavity and are not, in and of themselves, a method of surgery.

Diagnostic hysteroscopy can be used to evaluate numerous conditions including the following:

- Abnormal uterine bleeding
- Infertility
- Evaluation of abnormal hysterosalpingogram or sonohysterogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain

Operative hysteroscopy is used to perform numerous procedures including the following:

- Directed endometrial biopsy
- Polypectomy
- Submucous Myomectomy
- Transection of Intrauterine Adhesions
- Transection of Intrauterine Septa
- Endometrial Ablation

Reprocessing

WARNING

The endoscope must be properly reprocessed, by cleaning, disinfection and/or sterilization, before its first use and after each subsequent use. Using an endoscope that has not been properly reprocessed in a procedure presents an acute infection-control risk to both the patient and medical personnel performing or assisting in the procedure.

CAUTION

Always wear appropriate personal protective equipment when reprocessing the Cystoscope/Hysteroscope. Personal protective equipment includes items such as a gown, gloves, and face and eye shields.

Use extreme care when reprocessing the Cystoscope/ Hysteroscope. Do not forcefully pull, push, or drag wipes, towels, or cloths along the Insertion Tube. The use of excessive force could damage the endoscope.

DO NOT immerse the endoscope in disinfectant solution for long periods of time (**in excess of one 1 hour**). Prolonged immersions may damage the outer coverings of the endoscope and allow fluid infiltration.

DO NOT place the endoscope in or near contaminated areas after it has been reprocessed. Doing so can re-contaminate the endoscope and require reprocessing to be repeated.

DO NOT place the endoscope in awkward or confining areas between procedures as this could result in equipment damage.

3 Endoscope and Accessories

The Cogentix Medical **CST-4000/4000*i*** Cystoscope/Hysteroscope and **Slide-On® EndoSheath® Technology** are designed to perform safe, sterile, and efficient cystoscopic/hysteroscopic procedures.

The two major components of the endoscopic system are:

- The **CST-4000/4000*i*** Cystoscope/Hysteroscope, which is shown in Figures 3-1 and 3-2 on pages 13 and 14. The endoscope's Insertion Tube has no working channel; it contains the fiberoptic image and illumination bundles only.

  - Be sure to handle the endoscope with care during use, reprocessing and storage. The fiberoptics are comprised of thin glass fibers which can be damaged by physical trauma, extreme temperatures, high humidity, and/or fluid invasion of the scope.

- The disposable **EndoSheath® Technology**. The sterile, disposable Sheaths are installed over the endoscope's Insertion Tube, acting as a protective barrier to protect patients and users from the spread of potentially pathogenic materials. The Sheaths also contain working channels through which irrigation and/or accessory equipment can be used. There are two types of Sheaths available for use with the **CST-4000/4000*i***:

  - The **CF-2.1 Therapeutic Slide-On® EndoSheath® Technology** (see Figure 3-3 on page 17). This Sheath contains a channel through which irrigation fluids can be instilled into the patient, or accessory instruments can be inserted.

  - The **CF-1.5 Diagnostic Slide-On® EndoSheath® Technology** (see Figure 3-4 on page 19) has a smaller channel that supports irrigation, but cannot accommodate the insertion of accessory devices. This Sheath is intended purely for diagnostic purposes.

Inspect the Standard Set

WARNING Do not use any equipment that is observed to be damaged or excessively worn. Doing so could lead to patient injury and/or further damage to the equipment.

When the endoscope is received from Cogentix Medical, immediately confirm that all of the items listed in Table 3-1 below have been shipped, and inspect them for damage. If any item is missing or damaged, do not use the endoscope. Contact Cogentix Medical to obtain a replacement part.

CST-4000/4000*i* CYSTOSCOPE/HYSTEROSCOPE STANDARD SET	
COGENTIX MEDICAL CATALOG NO.	**DESCRIPTION**
08-4201 OR	**CST-4000** Flexible Cystoscope/Hysteroscope
08-4202	**CST-4000*i*** Flexible Cystoscope/Hysteroscope
07-3060	Detachable Light Guide Cable, 1.8m
07-6180	Cogentix Medical CST-4000/4000*i* Carrying Case
07-6015	Vent Cap
	CST-4000/4000*i* User's Manual (this document)
OPTIONAL ITEMS AND ACCESSORIES (NOT SHIPPED WITH ENDOSCOPE)	
07-6010	Endoscope Leak Tester
07-6160	Installation Stand, Floor Model
07-6161	Installation Stand, Clamp Model
07-6162	Installation Stand, Wall Mount
See List on Page 23	Light Guide Sleeve Adapter
07-3053*****	BLS-1000 Battery Powered Light Source Kit (includes Batteries and Battery Charger)
07-3050	BLS-1000 Battery Powered Light Source (Replacement)
07-3058*****	Battery Charger (Replacement)
07-3059	Batteries (2 batteries) (Replacement)
SLIDE-ON® ENDOSHEATH® TECHNOLOGY (NOT SHIPPED WITH ENDOSCOPE)	
08-4101	**CF-2.1 Therapeutic Slide-On® EndoSheath® Technology** (2.1mm Working Channel) for the **CST-4000/4000*i*** Cystoscope/Hysteroscope
08-4102	**CF-1.5 Diagnostic Slide-On® EndoSheath® Technology** (1.5mm Channel) for the **CST-4000/4000*i*** Cystoscope/Hysteroscope

Table 3-1: CST-4000/4000*i* Standard Set

***Contact distributor for region-specific configuration**

Equipment Diagrams

CST-4000/4000*i* Flexible Cystoscope/Hysteroscope

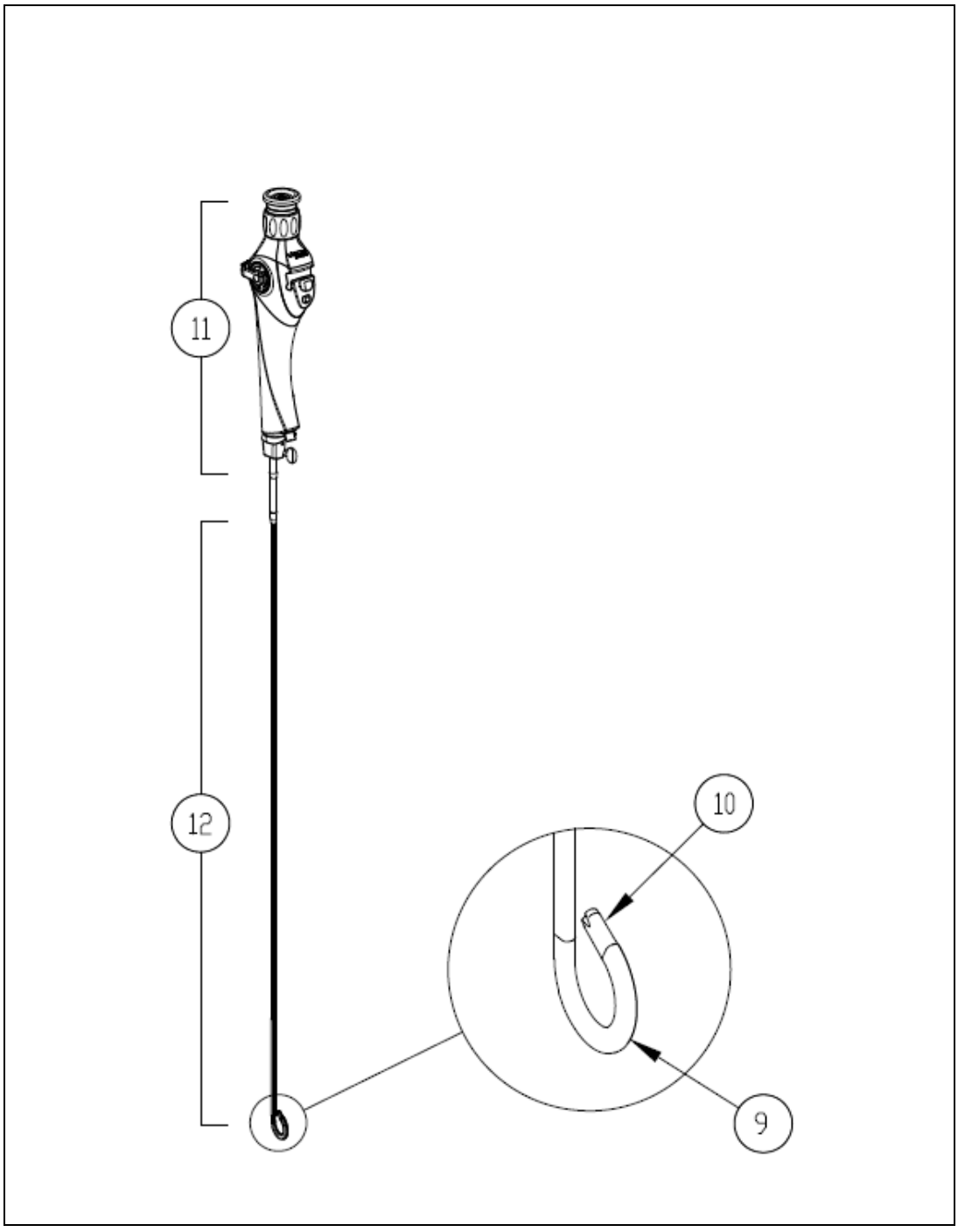


Figure 3-1: CST-4000/4000*i* Flexible Cystoscope/Hysteroscope

CST-4000/4000*i* Flexible Cystoscope/Hysteroscope Control Body

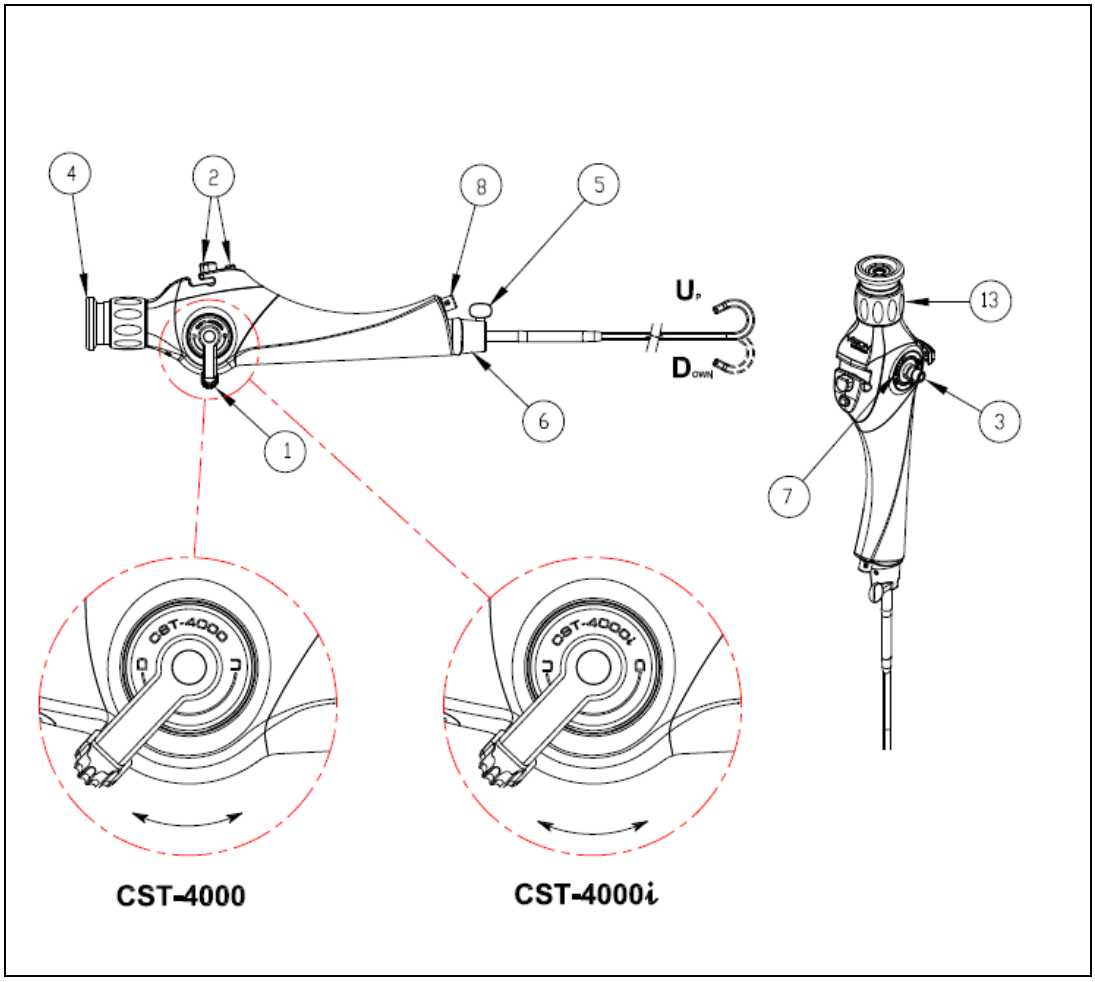


Figure 3-2: CST-4000/4000*i* Flexible Cystoscope/Hysteroscope (Control Body)

Instrument Components
Endoscope and Control Body:

1. **Angulation Lever:** This integral component of the Control Body controls the endoscope's Distal Tip deflection. There is only one difference between the **4000** and **4000*i*** Models: the Up and Down conventions are reversed in the Angulation Lever and its effect on articulation/deflection in the Distal Bending Section.

   - **CST-4000 Model**:
   The Angulation Lever on the **CST-4000** provides control of the bending section in the "traditional" directions. This indicates that when the Angulation Lever is moved toward the "top" of the Control Body, the Distal Bending Section will articulate in the visual "down" direction. When the Angulation Lever is moved toward the Insertion Tube, the Distal Bending Section will articulate toward visual "up" direction.

- CST-4000*i* Model:
The Angulation Lever on the **CST-4000*i*** provides control of the bending section in the "intuitive" directions. This indicates that when the Angulation Lever is moved toward the "top" of the Control Body, the Distal Bending Section will articulate in the visual "up" direction. When the Angulation Lever is moved toward the Insertion Tube, the Distal Bending Section will articulate in the visual "down" direction.

2. **Flow Control Valve:** This Control Body component secures the EndoSheath® Irrigation Tubing to regulate irrigation during use, with Open Flow and Close Flow buttons.

3. **Light Guide Cable Connector (Light Post):** One end of the Detachable Light-Guide Cable is inserted into the external Light Source to allow light to be projected to the endoscope's Distal Tip; the other end of the Cable is attached to this Connector on the Control Body.

4. **Eyepiece/Ocular:** Located at the top of the Control Body, this feature allows the user to view the image directly. Alternatively, a standard video camera, still photography systems, or teaching attachment can be connected to the eyepiece, allowing the image to be displayed on a video monitor and/or photographed.

5. **Locking Knob:** Located at the base of the Control Body, this knob mates with the EndoSheath® Connector to secure the **Slide-On® EndoSheath® Technology** to the Cystoscope/Hysteroscope.

6. **EndoSheath® Interface:** Also located at the base of the Control Body, this component secures the Sheath to the endoscope.

7. **Identification Ring:** Includes the Serial Number, which is a unique number identifying the endoscope; and the Ⓢ symbol, which indicates the endoscope can be sterilized using a validated STERIS® or STERRAD® system. The endoscope must feature this symbol on the ID ring in order for STERIS® or STERRAD® compatibility to apply. Also includes a UL symbol (Underwriters Laboratories), which indicates the fiberscope is recognized as a component which can be used in tandem with add-on components such as light sources and camera attachments.

8. **Vent Valve:** When the Vent Cap is connected here, this Valve allows access to the interior of the endoscope for EtO or STERRAD® Gas Sterilization, and should be connected during transport. The Vent Cap **must** be attached to this Valve prior to EtO or STERRAD® Gas Sterilization and prior to shipping. The valve is also used as a Leak Tester Connector for Leak Testing.

9. **Distal Bending Section:** Deflects up and down when the Angulation Lever is actuated by the user.

10. **Distal Tip:** The terminating point of the endoscope's image fiber bundle (objective lens) and light-guide fiber bundles (light guides).

11. **Control Body:** This segment allows physician control over endoscopic functions.

12. **Insertion Tube:** This component, along with the Distal Tip, is the part of the endoscope that is inserted into the patient.

13. **Diopter Adjustment Ring:** Located on the Control Body, this ring turns clockwise or counterclockwise to adjust the image until the focus is clear. When a video camera, still photography system, or teaching attachment is used, the white dot on the control body must be aligned with the white dot on the Diopter Adjustment Ring. When using an add-on camera, use the Focus Ring on the camera to adjust focus, rather than the Diopter Adjustment Ring.

Not Shown in Diagram:

Detachable Light Guide Cable: Standard 1.8m cable shipped with endoscope.

Light Guide Sleeve: Adapts the Light Guide Cable to make it compatible with different light sources.

CF-2.1 Slide-On® EndoSheath® Technology

The **CF-2.1 Slide-On® EndoSheath® Technology** (shown in Figure 3-3 below) is a sterile, disposable barrier for the Cogentix Medical **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope. This Sheath isolates the Cystoscope/ Hysteroscope from contact with patient fluid and material during the procedure, and supports accessory instrument passage.

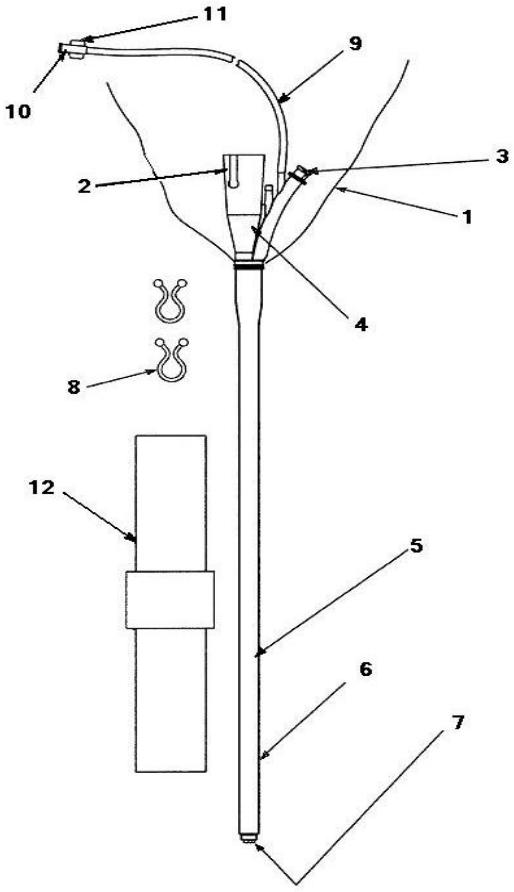


Figure 3-3: CF-2.1 Slide-On® EndoSheath® Technology

CF-2.1 Sheath Components

1. **Control Body Cover:** Protects the Cystoscope/Hysteroscope's Control Body from becoming contaminated with patient material during the procedure.
2. **Slot for Locking Knob:** The Cystoscope/Hysteroscope's Locking Knob slides into this slot to secure the Sheath to the Cystoscope/Hysteroscope.
3. **Accessory Port with Removable Seal:** Allows fluid injection and the passage of accessory instruments during endoscopic procedures. The removable seal allows a Luer-Lock syringe to be attached for fluid withdrawal.

4. **EndoSheath® Connector:** Secures the Sheath to the Cystoscope/ Hysteroscope.

5. **Working Channel:** Running the length of the Sheath, this impermeable channel allows maximum fluid irrigation and evacuation, as well as the passage of accessory devices for access through the Distal Tip.

6. **Insertion Tube Barrier:** A flexible, elastomeric sleeve that creates a barrier over the Cystoscope/Hysteroscope's Insertion Tube.

7. **Sheath Window:** An optically clear window that covers the Distal Tip of the Cystoscope/Hysteroscope.

8. **Control Body Cover Clips (2):** The clips secure the Control Body Cover to the Light Guide Cable and Irrigation Tube.

9. **Irrigation Tube:** Provides access for irrigation to the Distal Tip.

10. **Irrigation Tube Connector:** A standard Luer-Lock fitting allows an irrigation tube to be connected here.

11. **Luer Cap:** A standard Luer Lock Fitting Cap is attached here to prevent internal contamination of the Irrigation tube prior to making a connection.

12. **Drape Bag:** A polyethylene bag with an adhesive strip that protects the Installation Stand from contamination, collects post-procedural bodily fluids, and will contain the used Sheath for disposal.

CF-1.5 Slide-On® EndoSheath® Technology

The **CF-1.5 Slide-On® EndoSheath® Technology** (shown in Figure 3-4 below) is also a sterile, disposable barrier for the Cogentix Medical **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope. The Sheath isolates the Cystoscope from contact with patient fluid and material during the procedure, supports irrigation, but **does not support accessory instrument passage**.

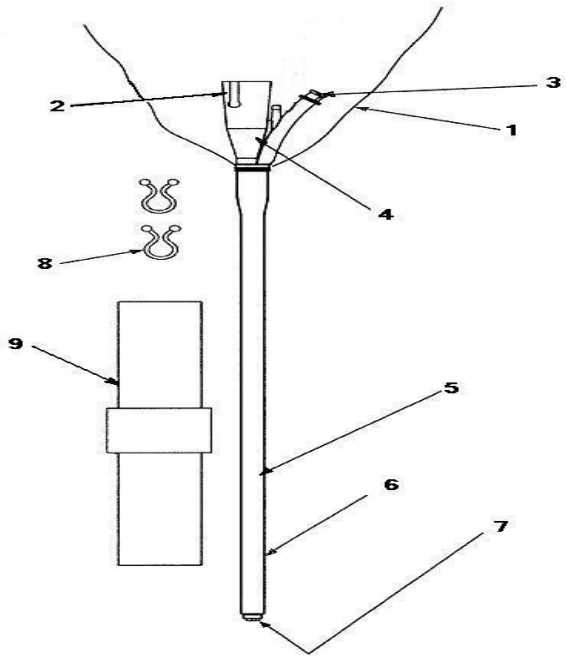


Figure 3-4: CF-1.5 Slide-On® EndoSheath® Technology

CF-1.5 Sheath Components

1. **Control Body Cover:** Protects the Cystoscope/Hysteroscope's Control Body from becoming contaminated with patient material during the procedure.

2. **Slot for Locking Knob:** The Cystoscope/Hysteroscope's Locking Knob slides into this slot to secure the Sheath to the Cystoscope/Hysteroscope.

3. **Irrigation Port:** A Luer-Lock syringe attachment allows for fluid irrigation and withdrawal.

4. **EndoSheath® Connector:** Secures the Sheath to the Cystoscope/ Hysteroscope.

5. **Channel:** A tube that runs the length of the Sheath and allows for fluid irrigation and evacuation.

6. **Insertion Tube Barrier:** A flexible, elastomeric sleeve that creates a barrier over the Cystoscope/Hysteroscope's Insertion Tube.

7. **Sheath Window:** An optically clear window that covers the Distal Tip of the Cystoscope/Hysteroscope.

8. **Control Body Cover Clips (2):** The clips secure the Control Body Cover to the Light Guide Cable.

9. **Drape Bag:** A polyethylene bag with an adhesive strip that protects the Installation Stand from contamination, collects post-procedural bodily fluids, and will contain the used Sheath for disposal.

Installation Stand

CAUTION Installation and removal of the **Slide-On® EndoSheath® Technology** onto and from the Cystoscope/Hysteroscope should **always** be performed using the Installation Stand. Failure to do so may cause installation difficulty and/or equipment damage.

Refer to Figure 3-5 below and the Installation Stand's Instructions For Use for information on the correct preparation and use of the stand.

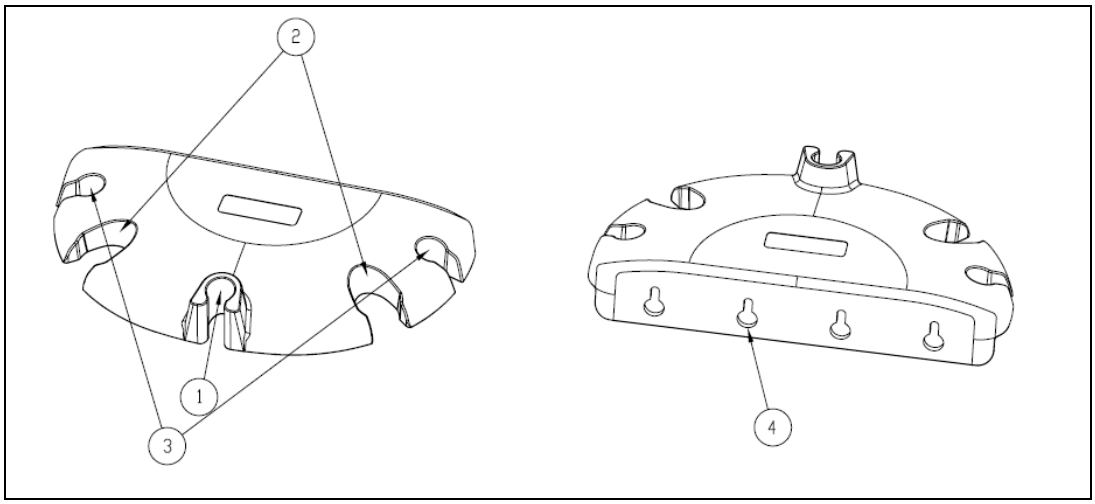


Figure 3-5: Installation Stand

1. **EndoSheath® Slot/Holder:** The slot that securely holds the EndoSheath® Connector, which is designed to fit with its Accessory Port facing out.

2. **Endoscope Storage Slots:** Post-procedure slots for hanging endoscopes. (Not intended for long-term storage unless the Installation Stand is wall-mounted.)

3. **Cable Storage Slots:** For securing the Light Guide Cable when the endoscope is not in use (if **BLS-1000** Light Source is used, these slots are not needed).

4. **Wall-Mounting Bracket/Holes:** For mounting on a wall or inside a cabinet for storage purposes.

Accessories

WARNING

Do not use any accessories that are not in compliance with the equivalent safety requirements of this equipment. Doing so may reduce the operational safety of the system and could cause patient and/or user injury. For all accessories, confirm the safety certifications have been performed in accordance with the appropriate standard (IEC 60601-1 and/or IEC 60601-1-1).

The use of accessories not specified in this manual or sold by Cogentix Medical may result in increased electromagnetic emissions or decreased immunity of the equipment or system.

Light Sources

BLS-1000 Battery Powered Light Source

An LED light source that allows for endoscopic illumination without a Light Guide Cable. Refer to Chapter 5, **Preparation, Inspection and Operation** for proper set-up and operation information. The **CST-4000/4000*i*** is designed to be used with the **BLS-1000** Battery Powered Light Source.

Light Guide Cables

Additionally, the **CST-4000/4000*i*** Cystoscope/Hysteroscope is designed to be compatible with various light sources when using the detachable Light Guide Cable. The Light Guide Connector (Light Post) on the **CST-4000/4000*i*** will accept Light Guide Cables made by other manufacturers with an ACMI-style connection/adapter. To ensure proper mating with the light source, be sure that the appropriate Light Guide Sleeve is securely threaded onto the Light Guide Cable. Refer to Figure 3-6 for a complete list and diagrams of the available Light Guide Sleeves.

Add-On Camera Systems

The **CST-4000/4000*i*** Cystoscope/Hysteroscope features a "rigid" style eyepiece that is compatible with most manufacturers' add-on camera technologies. Ensure that the selected camera systems coupler is compatible with a "rigid" style eyepiece. If it is not, please contact Cogentix Medical for compatibility assistance.

Leak Testing

The **CST-4000/4000*i*** Cystoscope/Hysteroscope may only be leak tested with a Cogentix Medical Endoscope Leak Tester.

Reprocessing

The **CST-4000/4000*i*** Cystoscope/Hysteroscope may be reprocessed by a variety of methods. Refer to Chapter 6, **Reprocessing** for the accessories that will be used when reprocessing the endoscope. Contact Cogentix Medical Customer Service for advice on compatibility issues.

Therapeutic/Diagnostic Accessories

The **CF-2.1 Slide-On® EndoSheath® Technology** features a 2.1mm working channel. Cystoscopy/Hysteroscopy tools and accessories that are compatible with a 2.1mm channel should be compatible with this system. For further information regarding tools and accessories, please contact your local distributor or Cogentix Medical Customer Service Department.

CAUTION The **CF-1.5 Diagnostic Slide-On® EndoSheath® Technology does not support** accessory tool passage. Attempting to insert an accessory or tool may damage this Sheath.

Light Source Adapters (Light Guide Sleeves)

A number of different Light Guide Sleeves are available to adapt Cogentix Medical endoscopes for use with other manufacturers' light sources. Figure 3-6 shows diagrams of all compatible adapters, lists the light sources with which they are compatible, and gives the Cogentix Medical Catalog Number for each one.

CAUTION Using an incorrect or incompatible adapter could result in impaired operation and viewing, and could cause damage to the endoscope, light-guide cable and/or light source.

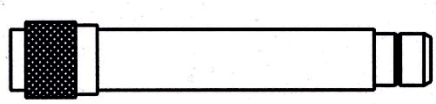
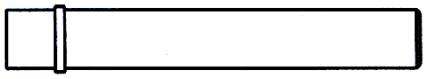
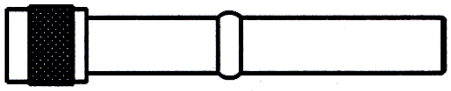
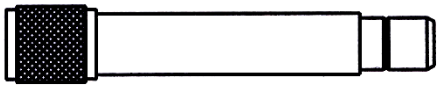
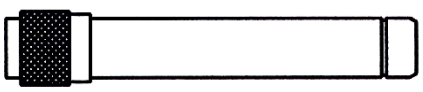
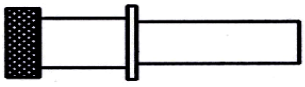
LIGHT GUIDE SLEEVE DIAGRAM	CATALOG NUMBER & COMPATIBLE LIGHT SOURCES
	**06-6019: Cogentix Medical HLS-1500 & XLS-3000, Circon and ACMI Light Sources**
	**06-6009: Cogentix Medical LS-150 and Pentax Light Sources**
	**06-6044: Olympus Light Sources**
	**06-6020: Smith & Nephew, Gyrus, and Richard Wolf Light Sources**
	**06-6029: Machida Light Sources**
	**06-6023: Karl Storz Light Sources**

Figure 3-6: Light Guide Adapters (Light Guide Sleeves)

4 Installing and Removing the Slide-On® EndoSheath® Technology

CAUTION Installation and removal of the **Slide-On® EndoSheath® Technology** onto and from the Cystoscope/Hysteroscope should always be performed with the Installation Stand. **Failure to utilize the installation stand for setup and preparation may lead to difficulty in installation and ultimately equipment damage.**

Ensure that the endoscope is clean and dry prior to installing the **Slide-On® EndoSheath® Technology**. Any moisture on the endoscope prior to installation may result in difficulty removing the endoscope from the **Slide-On® EndoSheath® Technology** after the procedure.

Wear appropriate protective gear when using the **Slide-On® EndoSheath® Technology** and cystoscope/hysteroscope, including gown, gloves, and face and eye shields. To maintain a sterile field during installation, it is recommended that users wear two (2) pairs of sterile gloves.

Install the Slide-On® EndoSheath® Technology

WARNING Before installing the Sheath, carefully inspect the endoscope's Insertion Tube for any damage or defects. If any irregularities are found, do not use the endoscope. Using a damaged or defective endoscope could damage the Sheath, cause further damage to the endoscope itself, and/or cause patient or user injury.

The **Slide-On® EndoSheath® Technology** is supplied sterile, and is intended for a **single use only**. Do not reuse or attempt to re-sterilize the Sheath, as it could become damaged, which could in turn cause damage to the endoscope and/or present an infection-control risk to the patient and/or user.

CAUTION The endoscope and Sheath do not have any user-serviceable parts. Do not attempt any repairs. If malfunction occurs, refer to the Troubleshooting section of this manual or call Cogentix Medical for assistance.

Do not expose the interior or exterior of the sheath to alcohol or other cleaning agents prior to use.

NOTE: Refer to **Instructions for Use** for CF-2.1 and CF-1.5 Sheaths.

CAUTION **Do not** use this equipment in the presence of a flammable anesthetic mixture containing air, oxygen, or nitrous oxide. There is a possibility of fire or explosion.

Prepare the Endoscope and Sheath

1. Before installing the Sheath, clean the endoscope's eyepiece and the lenses on its distal tip with an alcohol prep pad.

CAUTION **Do not** use abrasive materials to clean any part of the endoscope, particularly the eyepiece or Distal Tip lens. Doing so could damage these components and impair the endoscope's imaging capability.

2. Check the EndoSheath® disposable packaging for defects or damage.
3. Open the Sheath's package carefully; put on two pairs of sterile gloves.
4. Remove the Drape Bag from the tray, open it, remove adhesive strip backing and secure it to the back of the Installation Stand. Secure the Drape Bag with a plastic clip if necessary.
5. Carefully remove the Sheath from the package.
6. Place the Sheath into the Installation Stand. The Sheath must be placed in the Stand with the Accessory Port facing toward you. NOTE: the Sheath fits in the stand in only one direction.
7. Discard the disposable packaging.
8. Fold back the Control Body Cover to expose the top opening of the EndoSheath® connector.

Insert the Endoscope Into the Sheath

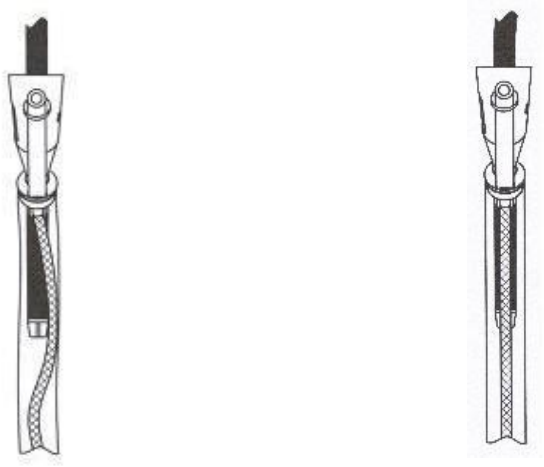
9. Take the endoscope in hand and verify that the distal bending section of the endoscope is straight. Hold the endoscope vertically above the Sheath. Align the endoscope's D-shaped Insertion Tube with the D-shaped opening of the EndoSheath® Connector – the flat portion of the Insertion Tube should face toward the Sheath's Accessory Port (toward you).
10. Gently slide the Insertion Tube into the Sheath, keeping the flat side of the D-shaped Insertion Tube aligned with the Accessory Port of the Sheath. Do not rotate the Insertion Tube during insertion (this will cause resistance).

CAUTION When inserting the endoscope into the Sheath, avoid excessive bending of the Insertion Tube, as it could damage the Sheath and/or the endoscope.

DO NOT apply excessive force to install the Sheath onto the endoscope if insertion is found to be difficult. If you experience difficulty installing the Sheath, refer to Chapter 8, **Troubleshooting.** If the recommended actions

given there do not ease endoscope insertion, call your local distributor, representative, or Cogentix Medical Customer Service at 866 258-2182 (toll free in U.S.) or (+1) 952-426-6189 (international) for further instruction.

NOTE: It is extremely important to maintain the alignment between the flat portion of the Insertion Tube with the port on the EndoSheath® Connector during installation and removal. If there is resistance in loading the endoscope into the Sheath, verify that the Sheath channel is properly aligned. If channel is misaligned, straighten channel before continuing scope insertion.



MISALIGNED **ALIGNED**

Figure 4-1: Incorrect and Correct Sheath Alignment

11. Ensure the Locking Knob on the endoscope is in a vertical position. Align the Locking Knob with the vertical slot on the EndoSheath® Connector.
12. Continue sliding the endoscope into the Sheath until the Locking Knob is fully seated at the base of the slot.
13. Rotate the Locking Knob to the horizontal position (locked position). This will ensure a secure fit between the EndoSheath® Connector and the scope.
14. Using the angulation lever, articulate the bending section in both directions to ensure proper Sheath fit. Visually inspect the Sheath and confirm that the endoscope's Distal Tip is flush with Sheath's Window. If the Distal Tip is not flush with the Sheath's window, articulate the Distal Bending Section until the window is seated properly.

Connect Irrigation Tubing / Complete Sheath Attachment

15. When using the **CF-2.1 EndoSheath® Technology**: Connect the Irrigation Tubing to the endoscope's Flow Control Valve by pressing the Open Flow button and stretching the tubing into the slot of the Valve. This allows the Flow Control Valve to secure the tubing in place. Do not pull the Irrigation Tubing too tightly. Ensure that the tubing is placed into slot completely, then press the Close Flow button.

16. When using the **CF-2.1 Slide-On® EndoSheath® Technology**, remove the Sterile Cap from the Irrigation Tubing.

NOTE: The Flow Control Valve may be bypassed and a stopcock used for on-off fluid management.

17. Connect a fluid management accessory to the Sheath Irrigation Tube Luer fitting when desired. The irrigation tube's standard luer fitting may be used to permit irrigation while an accessory device is inserted into or attached to the accessory port.

18. Remove outer pair of gloves.

19. Pull the Sheath's Control Body Cover up over the endoscope's Control Body and the Light Guide Cable to completely cover them.

20. Align the Eyepiece opening of the Control Body Cover with the endoscope's Eyepiece and pull down on the cover so that the eyepiece extends through the opening.

21. Secure the Control Body Cover and Irrigation Tubing using the Control Body Cover Clips.

NOTE: Fluid withdrawal and irrigation may also be accomplished by connecting to the standard luer fitting on the Sheath's Accessory Port.

22. Turn the Flow Control Valve on and off; confirm that it operates properly.

Observe the Endoscopic Image

The Sheath's window should be in direct contact with the Insertion Tube's Distal Tip. To confirm this, view an endoscopic image with a light source on; there should be no glare. If a gap is observed between the Distal Tip and the Sheath's window, or if glare is observed, move the Angulation Lever up and down several times to articulate the Distal Bending Section. This process should properly seat the Sheath.

In some cases it may be necessary to hold the edge of the optical window **(while wearing gloves**) and move it to fully seat the Sheath.

Remove the Slide-On® EndoSheath® Technology

When the endoscopic procedure is complete, the **Slide-On® EndoSheath® Technology** must be removed and disposed of properly to eliminate the possibility of infection-control risks.

CAUTION Wear appropriate personal protective equipment when removing the Sheath from the endoscope, to prevent the possibility of infection from contact with patient material. Cogentix Medical strongly recommends that a double set of gloves be worn for this procedure.

Always use the Installation Stand to remove the endoscope from the Sheath. Attempting to remove the endoscope without using the Installation Stand could cause damage to the endoscope.

1. Put on two (2) pairs of sterile gloves.
2. Ensure that the Drape Bag completely covers the Installation Stand.
3. Slide the endoscope and Sheath into the Installation Stand with the Accessory Port facing toward you. The contaminated, sheathed Insertion Tube must be contained within the Drape Bag to capture and contain any patient material and/or fluids.
4. Disconnect the irrigation tubing from source.
5. Remove the Control Body Cover Clips and discard them in the Drape Bag. Keeping your hands on the outside of the contaminated Control Body Cover, pull the Cover forward and down off of the endoscope.
6. Remove the outer set of gloves. **Do not** handle the endoscope's Control Body with contaminated gloves.
7. Disconnect the Irrigation Tubing from the Flow Control Valve by pressing the Open Flow button, and then stretch the tubing while pulling it away from the base of the slot at the front of the valve. Continue pulling on the tubing until it is clearly out of the valve.
8. Rotate the Locking Knob into the vertical position so that it is aligned with the slot on the EndoSheath® Connector.
9. Using the Angulation Lever, articulate the Distal Bending Section of the endoscope into the straight/neutral position.
10. Hold the endoscope's Control Body in one hand. Using the bottom outside portion of the Drape Bag as a barrier between your fingers and the Sheath, gently and carefully grasp the Sheath's window, then slowly and gently withdraw the scope from the Sheath.

CAUTION **Do not twist the endoscope** when removing it from the sheath. Doing so can damage the Insertion Tube.

If you experience difficulty removing the endoscope from the Sheath, **do not** use excessive force in trying to remove it. Refer to Chapter 8, **Troubleshooting**, for further instructions.

11. After the endoscope's Distal Bending Section has emerged from the Sheath, release the window of the Sheath and slowly remove the endoscope.
12. Place the endoscope in a non-contaminated area.
13. Inspect the Insertion Tube and Distal Tip, and confirm that these areas are dry. If moisture is observed, there may have been a leak into the Sheath during the procedure, provided that the endoscope was dry when the Sheath was attached. In this case, the endoscope must be high-level disinfected or sterilized following the instructions given in Chapter 6, **Reprocessing**.

14. Fold the top end of the contaminated Drape Bag over the EndoSheath® Connector and remove it from the Installation Stand. Carefully discard the contaminated Sheath per hospital/facility policy.
15. The endoscope should then undergo the recommended cleaning and disinfecting procedure detailed in Chapter 6, **Reprocessing**.

5 Preparation, Inspection and Operation

WARNING If an abnormality is detected during endoscope preparation, do not use the equipment; refer to the tables in Chapter 8, **Troubleshooting**. If the problem cannot be solved using the information found there, contact your regional distributor or Cogentix Medical Customer Service.

When using the **Slide-On® EndoSheath® Technology** with the endoscope, refer to the Instructions for Use that are shipped with the system. These instructions will provide complete details on preparing, installing and removing the disposable sheath.

The **Slide-On® EndoSheath® Technology** is shipped sterile and intended for a **single use only**; do not reuse it. When the procedure is complete, remove the sheath from the endoscope and dispose of it. Reusing the sheath can damage it, and in turn cause endoscope damage. In addition, a reused sheath presents a marked infection-control risk to the next patient.

During the procedure, the temperature at the Distal Tip of the endoscope may exceed 41°C (106°F) due to the intense endoscope illumination. Surface temperatures over 41°C (106°F) may cause mucosal burns. Always use the minimum level of illumination necessary for adequate viewing. Whenever possible, avoid close stationary viewing and do not leave the Distal Tip of the endoscope in close proximity to mucous membranes for a long time.

Preparation and Inspection

Follow the inspection steps listed below **before** connecting any equipment or using the system. Do not use the equipment if abnormalities are detected:

1. Check the endoscope's Insertion Tube for holes, superficial cuts or abrasions.
2. Lightly run your fingertips over the entire length of the Insertion Tube to confirm that it is smooth and does not exhibit looseness or bagging.

CAUTION Do not apply excessive pressure to the endoscope's Insertion Tube. Doing so could damage the internal components of the Insertion Tube.

3. Check the distal end of the Sheath's Working Channel for any sharp edges, being careful to minimize contact with the clear window.

4. Check for full Distal Tip deflection by moving the Angulation Lever up and down.

CAUTION Do not apply excessive pressure when moving the Angulation Lever. Doing so could damage the angulation mechanism.

5. Clean the Lens on the Distal Tip with an alcohol prep pad.

CAUTION Do not use abrasive materials to clean the Lens. Doing so could damage the Lens and impair the endoscope's imaging capability.

6. Ensure that the proper Light Guide Adapter is securely connected to the Light Guide Cable.
7. Securely insert the Light Guide Cable into the light source.
8. Look through the Eyepiece and rotate the Diopter Adjustment Ring until the fiber pattern is clearly focused.
9. When using a video camera, still photography system, or teaching attachment with the endoscope, make sure that the white dot on the Control Body is aligned with the white dot on the Diopter Adjustment Ring.
10. Connect an irrigation source to the Sheath's Irrigation Tube (when using the **CF-2.1** EndoSheath®) or the Accessory Port.

Endoscope Operation with BLS-1000 Battery Powered Light Source

1. Prior to use, the **BLS-1000** should be reprocessed. Please refer to **BLS-1000** Battery Powered Light Source User's Manual for proper Reprocessing procedures and compatibilities.
2. If necessary, insert charged or new batteries into the **BLS-1000**.
3. Verify the **BLS-1000** is in proper working condition before attaching to the endoscope by examining the outer cover for damage, secure fit of cover, and, with Light Source powered OFF, verify that the window over the bulb is clear and not obstructed.
4. Thread the **BLS-1000** onto the endoscope Light Post. Verify that the Light Source is OFF until needed.
5. Just prior to the procedure, rotate the **BLS-1000** to the ON position.

CAUTION Point the light-emitting area of the Light Source away from eyes before turning on the light.

6. Turn on the **BLS-1000**; or, if using the detachable light guide cable, insert light guide cable into the light source (snap the light guide cable in securely) and turn on the light source.

7. Verify light emission by viewing through the eyepiece. While viewing through the eyepiece, rotate the Diopter Adjustment Ring clockwise or counter-clockwise until the fiber pattern in the image field is clearly focused.

WARNING

Do not handle the **BLS-1000** with contaminated gloves. If the **BLS-1000** becomes contaminated, it must be reprocessed per the protocols in the **BLS-1000** Battery Powered Light Source User's Manual.

8. If using a video camera, still photography system or teaching attachment with the endoscope, be sure the white dot on the Control Body is aligned with the white dot on the Diopter Adjustment Ring.

9. Hold the endoscope so that the control body fits comfortably in your hand, allowing easy manipulation of the Angulation Lever. The other hand is free to manipulate the Insertion Tube of the endoscope.

CAUTION

Excessive angulation or excessive pressure on the Angulation lever may cause equipment damage. Do not exert force to move the lever beyond its natural limits.

10. Prepare the patient using normally acceptable clinical practice prior to endoscope insertion.

11. Lubricate the outside of the Sheath before inserting the endoscope into the patient. Cogentix Medical recommends that the Sheath be lubricated with water or a water-based lubricant just prior to insertion.

12. Introduce the sheathed endoscope into the patient using normally acceptable clinical practice. Operate the Angulation Lever as necessary for advancement and observation.

13. Upon completion of the procedure, withdraw the endoscope under direct visualization without holding the Angulation Lever. This will allow the Distal Bending Section to move freely during withdrawal.

14. When the procedure is finished, rotate the **BLS-1000** to the OFF position.

Endoscope Operation - Other Light Source

CAUTION Avoid excessive bending or twisting of the endoscope's insertion tube, particularly at the distal end. While the tube is designed to bend, excessive pressure can damage the fiber bundles and internal components.

Excessive angulation or excessive pressure placed on the Angulation Lever may cause equipment damage. Do not exert force to move the lever beyond its natural limits.

1. Connect the light guide cable to the endoscope.
2. Secure the appropriate light guide sleeve to the cable.
3. Connect light guide cable to light source.
4. Hold the endoscope so that the Control Body fits comfortably in your hand, allowing you to manipulate the Angulation Lever. The other hand is free to manipulate the Insertion Tube.
5. Turn the light source on. Adjust the brightness to the desired level using the light source's brightness adjustment controls.
6. Prepare the patient using normally acceptable clinical practice prior to endoscope insertion.
7. Lubricate the outside of the Sheath before inserting the endoscope into the patient. Cogentix Medical recommends that the Sheath be lubricated with water or a water-based lubricant.
8. Introduce the sheathed endoscope into the patient using normally acceptable clinical practice. Operate the Angulation Lever as necessary for advancement and observation.
9. When the procedure is completed, withdraw the endoscope under direct visualization without holding the Angulation Lever. This will allow the Distal Bending Section to move freely during withdrawal.

Aspirating Fluids

1. Attach a syringe to the Sheath's Accessory Port. When using the **CF-2.1 Slide-On® EndoSheath® Technology**, first remove the Accessory Port Seal.
2. Aspirate fluids by withdrawing the syringe's plunger.
3. To aspirate fluids via the CF-2.1 Sheath's irrigation tubing, confirm that the Accessory Port Seal is in place, and then open the endoscope's Flow Control Valve. Move the valve's lever to the closed position to stop aspiration.

Instilling Fluids

To inject anesthesia, saline or other fluids, attach a syringe to the Sheath's Accessory Port. When using the **CF-2.1 Slide-On® EndoSheath® Technology**, the syringe tip may be inserted directly into the Accessory Port Seal's opening.

CAUTION Make sure that the syringe is seated properly and straight in the Sheath's Accessory Port. Otherwise, the seal may be compromised and fluid may not flow smoothly into the Working Channel.

Inserting Accessories

CAUTION Accessories may only be inserted when using the **CF-2.1 Slide-On® EndoSheath® Technology**. The **CF-1.5 Diagnostic Sheath does not** support accessory tool passage.

Before inserting an accessory into the Sheath, confirm that it is compatible with a 2.1 mm diameter Working Channel. If the accessory is too large, it will damage the Sheath and may compromise the integrity of the barrier.

Do not continue advancing an accessory if excessive resistance is encountered, and do not use excessive force to try and advance it. The use of excessive force may result in damage to the Sheath and/or the endoscope.

1. Before inserting an accessory, straighten the endoscope's Distal Bending Section, and look through the Eyepiece to confirm that there is a clear lumen.
2. Insert the tip of the accessory through the Sheath's Accessory Port. Using straight, steady strokes, pass the accessory through the Working Channel until the tip of the accessory is visible when looking through the Eyepiece.
3. If resistance is encountered while inserting the accessory, withdraw the accessory, straighten the endoscope's Distal Bending Section, and attempt to insert the accessory again. If resistance is still felt, confirm that the accessory's diameter is compatible with the size of the Working Channel. Refer to Chapter 8, **Troubleshooting**, for additional suggestions.

Electrosurgical Devices / Accessories

The **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope and **Slide-On® EndoSheath® Technology** may be used with high-frequency (HF) electro-surgical devices. Operators utilizing HF devices and accessories should follow all manufacturer and facility guidelines for proper and safe use. Refer to the user manuals of all HF devices being used in the procedure, and closely follow all indications, instructions, and safety precautions.

WARNING

Before using any electrosurgical devices for high frequency cauterization, users should be thoroughly familiar with all guidelines, safety precautions, and proper use of the equipment. Follow all manufacturer instructions on proper equipment preparation and use. Accessories should be inspected for damage before and after each procedure.

Before electrosurgery, inspect the endoscope for any physical damage to surfaces and components. If damage is discovered, discontinue use and contact Cogentix Medical for repair. Continued use of damaged equipment during electrosurgery may lead to equipment damage and/or patient injury.

A thorough understanding of the principles and techniques involved in electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and prevent damage to the device and other medical instruments. Ensure that insulation or grounding is not compromised.

Do not immerse electrosurgical instruments in liquids unless the instruments are specifically designed and labeled to function in liquids.

Do not supply oxygen or use in presence of combustible gases during electrosurgery. There is the potential for combustion during cauterization.

WARNING

Set the high-frequency (peak) voltage level of the electrosurgical unit no higher than the voltages given below for the respective operating modes:

- CUT: 1,300 V_p
- COAG: 3,000 V_p
- SPRAY: 3,950 V_p

Always utilize the lowest output setting necessary on the electro-surgical unit. This reduces the potential for patient injury or equipment damage.

When the recommended voltages shown in the instructions for electrosurgical accessories differ from normally acceptable limits, always use the lowest recommended voltage.

Always confirm that the electrode section of the electrosurgical accessory is an appropriate distance from the Distal Tip of the endoscope and that the electrode is clearly in view. If the electrode is in close proximity to the Distal Tip or still within the **Slide-On® EndoSheath® Technology** during use, the endoscope and/or **Slide-On® EndoSheath® Technology** may be damaged and patient injury may occur.

Cogentix Medical recommends the use of isolated electrosurgical accessories. Use of non-isolated accessories may result in operator injury.

To best determine the necessary minimum output, operators should conduct basic tests before electrosurgery according to the User's Manual of the Electrosurgical Unit.

Laser Devices / Accessories

WARNING

Before using any laser devices, user should be thoroughly familiar with all guidelines, safety precautions, and proper use of the equipment. This includes, but is not limited to, proper eye and skin safety guidelines.

Do not use a damaged laser fiber accessory. Utilizing a probe with a damaged cover or distal end may result in patient injury and/or equipment damage.

Always confirm that the distal tip of the laser fiber accessory is an appropriate distance from the Distal Tip of the endoscope and the laser fiber tip is clearly in view. If the distal tip of the accessory is in close proximity to the endoscope's Distal Tip or still within the **Slide-On® EndoSheath® Technology** during use, the endoscope and/or **Slide-On® EndoSheath® Technology** may be damaged and patient injury may occur.

Do not supply oxygen when performing laser surgery, or do so in the presence of combustible gases. There is the potential for combustion during cauterization.

Follow all manufacturer instructions on proper equipment preparation and use. Accessories should be inspected for damage before and after each procedure.

CAUTION

Before inserting or removing a laser fiber accessory, ensure that the endoscope's Distal Bending Section is in the neutral position and straight. If the Distal Bending Section is articulated, there is a risk of damaging the Instrument Channel of the **Slide-On® Endo-Sheath® Technology**.

6 Reprocessing

The **CST-4000/4000*i* Flexible Cystoscope/Hysteroscope** utilizes the **Slide-On® EndoSheath® Technology.** The **Slide-On® EndoSheath® Technology** is a sterile, disposable protective covering which limits the need for elaborate chemical disinfection or sterilization procedures after every endoscopy procedure. The complete system enables the user to implement a fast and effective method of reprocessing the endoscope, and benefits both user and patient by providing an Insertion Tube covered with a sterile Sheath for every procedure. For cleaning/ disinfection procedures when using the **EndoSheath® Technology**, see **Cleaning After Slide-On® EndoSheath® Technology Use** on page 43.

WARNING

The endoscope must be properly reprocessed by cleaning, disinfection and/or sterilization, before its first use and after each subsequent use. Using an endoscope in a procedure that has not been properly reprocessed presents an acute infection-control risk to both the patient and medical personnel performing or assisting in the procedure.

CAUTION

Some methods of disinfection and sterilization may be harmful to the endoscope and exposure to them could result in extensive equipment damage. Please contact Cogentix Medical Customer Service to verify the compatibility of a reprocessing method not listed in this manual and/or a complete list of functionally compatible agents.

Clean the endoscope immediately after use in a procedure. Failure to do so may allow patient debris to harden on the endoscope's external surfaces, which can become difficult to remove and could inhibit subsequent disinfection/sterilization processes.

Do not use an endoscope that has been determined to have a leak, and do not immerse such an endoscope in any fluids. Fluid entry into the endoscope can cause equipment damage and render the endoscope unfit for patient use.

Always wear appropriate personal protective equipment when reprocessing the endoscope or any of its components. Appropriate protective equipment includes items such as a gown, gloves, and face and eye shields.

Complete and thorough reprocessing of the endoscope is the only way to ensure that a "patient-ready" endoscope is used in all patient procedures. Closely adhere to the reprocessing instructions given in this chapter.

Reprocessing Steps

The endoscope reprocessing procedure is made up of a series of steps, each of which is essential to successful reprocessing.

- ***Leak Testing* –** The reprocessing procedure requires exposing the endoscope's surface to and immersing the endoscope itself in fluids. If there is a leak in any part of the endoscope, the internal components of the endoscope are vulnerable and will likely be damaged by fluid infiltration. Before cleaning, disinfecting and/or sterilizing the endoscope, it is essential to perform a leak test to ensure the interior of the endoscope is resistant to fluids.
- ***Cleaning* –** Visible debris is removed from the surface of the endoscope in this procedure, which uses water and an instrument-grade detergent. When the **Slide-On® EndoSheath® Technology** is used and inspection after the procedure confirms that the Sheath was not compromised, surface cleaning and intermediate level disinfection of the endoscope should be sufficient to prepare it for the next procedure.
- ***Intermediate-Level Disinfection* –** After use with an **EndoSheath® Technology** and proper cleaning, the endoscope should undergo intermediate-level disinfection. For the complete routine, see **Cleaning After Slide-On® EndoSheath® Technology Use** on page 43.
- ***High-Level Disinfection* –** If the endoscope has been contaminated, it will be necessary to immerse the endoscope in a high-level disinfectant.
- ***Sterilization* –** In addition to high-level disinfection, the endoscope may be sterilized using ethylene oxide (EtO) gas. Following sterilization, the endoscope must be thoroughly aerated to ensure that all EtO gas residues have been removed. The endoscope may also be sterilized using a validated STERRAD® or STERIS® system. Refer to the STERRAD®/STERIS® section in this chapter.

Leak Testing

The **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope must be evaluated for possible leaks in the Control Body and/or Insertion Tube before immersion in any fluids. The Leak Tester accessory should be used for this test (Cogentix Medical Leak Tester is required). Follow the steps given in this chapter.

WARNING

It is essential that gloves be worn when performing the leak test procedure, in case the endoscope's Insertion Tube has been contaminated and requires further disinfection or sterilization. An endoscope in this condition can present an infection-control risk to the person(s) reprocessing the endoscope.

Attach the Leak Tester to the Endoscope

Connect the Leak Tester to the endoscope's Vent Valve (see Figure 6-1). Align the slot on the Leak Tester's connector with the pin on the Vent Valve, then push down and rotate the connector clockwise until it locks.

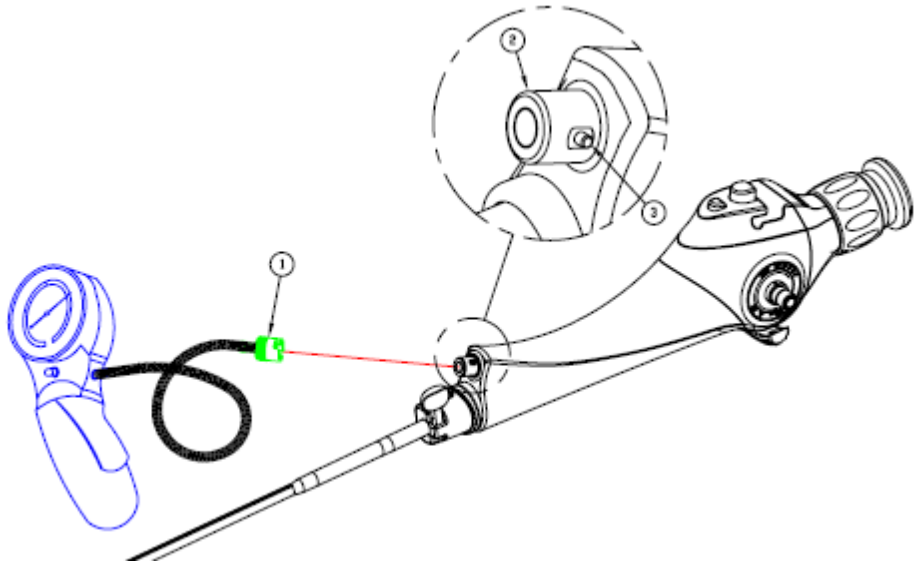


Figure 6-1: Leak Tester Connection

Leak Tester Connection Components

1. Connector
2. Vent Valve
3. Alignment Pin (align with slot in Connector)

Pressurize the Endoscope

1. Make sure that the Leak Tester's Pressure-Relief Valve is closed by moving the button to the "out" position.

2. Pump the hand bulb of the Leak Tester until the pressure gauge's needle reaches **the green zone**. Due to the size of the internal space of the endoscope, 2-3 pumps of the hand bulb may be required to pressurize the entire chamber. After the first pump, the needle may drop out of the green zone and reach a stable position in the white zone. Continue with additional pumps until the needle no longer falls back into the white zone.

CAUTION Do not over-pressurize the interior of the endoscope (do not allow the needle to go above the green area on the gauge). Over-pressurizing the interior of the endoscope can damage the light-transmission and/or optical system components.

3. Maintain the pressure for ten (10) seconds, observing the position of the needle on the pressure gauge. If the pressure decreases, the Leak Tester/endoscope connection may be loose or the Pressure-Relief Valve on the Leak Tester may still be open and should be closed. In this case, remove and reattach the Leak Tester and repeat Steps 1-3.

   If the pressure decreases after the connections are restored, the endoscope has a damaged seal. **Do not continue to use the endoscope or immerse it in fluids in this condition**. Contact your regional distributor or the Cogentix Medical Customer Service Center to arrange for evaluation and/or repair. When returning the endoscope, follow the instructions given in Chapter 9, **Warranty and Service**.

4. If the needle's position remains steady on the Leak Tester, immerse the entire endoscope in water, and observe it for thirty (30) seconds. Angulate the Distal Bending Section up and down while the endoscope is immersed, as holes in the soft covering of the Distal Bending Section may not be evident while it is in a relaxed position.

5. A steady stream of air bubbles at a given location indicates a small leak in the endoscope that was not detected by the pressure gauge. If a leak is detected, the air pressure in the endoscope will prevent water from entering through the leak. However, immediately remove the endoscope from the water and do not immerse it in any more fluids.

CAUTION **Do not continue to use an endoscope if leaks are detected.** Contact your local distributor or the Cogentix Medical Customer Service Center to arrange for evaluation and/or repair. When returning the endoscope, follow the instructions given in Chapter 9, **Warranty and Service**.

NOTE: Do not mistake the release of trapped air from the crevices on the endoscope's outer surface for a leak. Trapped air can be released by tapping the endoscope gently after immersing it in water.

6. The absence of air bubbles confirms that the endoscope is watertight. Remove it from the water and open the Leak Tester's Valve.

7. Make sure that the needle on the pressure gauge falls to zero (0), and **disconnect** the Leak Tester from the endoscope. The endoscope can now be safely immersed in cleaning solutions.

CAUTION Failure to discharge/depressurize the endoscope after leak testing may place stress on the soft covering of the Insertion Tube, potentially producing a "rolling over" of the rubber.

Gloves must be worn when performing the Leak Test procedure.

Cleaning / Disinfection / Sterilization

Use of the Vent Cap

CAUTION Failure to follow the instructions given in this section regarding the use of the Vent Cap may result in damage to the endoscope. Any such damage will void the product warranty.

The Vent Cap is to be **attached** to the endoscope prior to **all** of the following procedures in order to prevent damage to the endoscope caused by changes in pressure and temperature:

- Gas Sterilization
- Aeration
- Shipping

The Vent Cap is to be **removed** from the endoscope prior to:

- Patient Procedures
- Immersion in Fluids

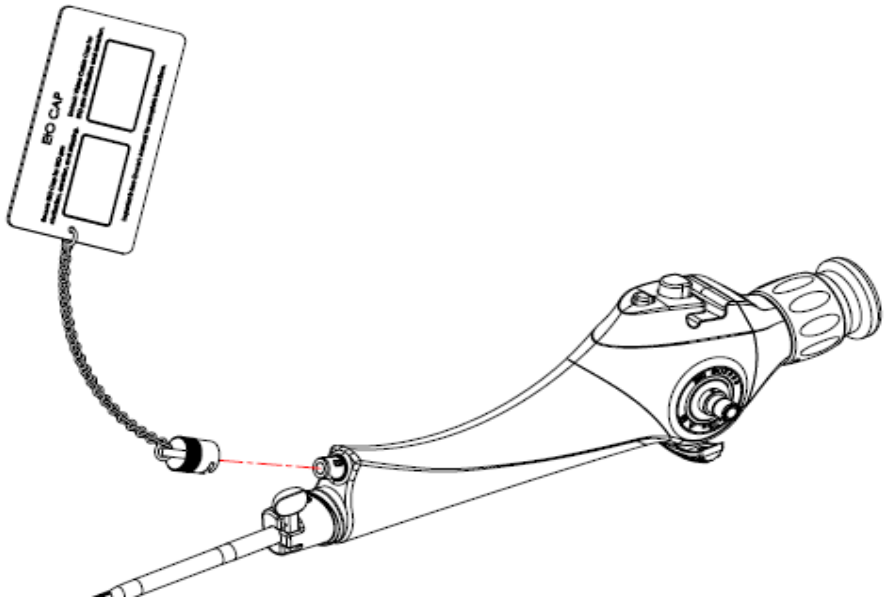


Figure 6-2: Opening the Vent Valve

Cleaning After Slide-On® EndoSheath® Technology Use

WARNING The **Slide-On® EndoSheath® Technology** is intended for a **single use only**; do not reuse it. When the procedure is complete, remove the Sheath from the endoscope and dispose of it as described in Chapter 4, **Installing and Removing the Slide-On® EndoSheath® Technology**. Reusing the Sheath can present an acute infection-control risk to the user and the next patient on whom the endoscope is used.

After a procedure in which the **Slide-On® EndoSheath® Technology** was attached over the endoscope's Insertion Tube, Cogentix Medical recommends performing the following prophylactic cleaning and intermediate disinfection routine between endoscopic procedures:

CAUTION Because of the possibility that a sheath could be torn, or that the endoscope or sheath could come in contact with contaminated surfaces, the user should exercise care when handling the endoscope, whether sheathed or unsheathed.

1. After removing the Sheath, inspect the Insertion Tube and Distal Bending Section, and confirm that these areas are dry. If moisture is observed, there may have been a leak into the Sheath during the procedure, providing the endoscope was dry when the sheath was attached. In this case, the endoscope must be high-level disinfected or sterilized following the instructions given in this chapter.
2. **For Cleaning** - Gently wash all external surfaces of the endoscope with an appropriate instrument-grade detergent. An ample size basin must be used for cleaning the endoscope. If the basin is too small, the endoscope may inadvertently be kinked or damaged during cleaning.
3. After washing, thoroughly rinse the outside of the endoscope with clean, lukewarm water and place it on a clean, dry surface.
4. **For Intermediate Level Disinfection** - Wipe down the entire endoscope with a soft, lint-free cloth or gauze soaked in 70% ethyl or isopropyl alcohol.
5. Ensure that all external surfaces of the endoscope are thoroughly dried prior to attaching another Sheath or storing the endoscope.

High-Level Disinfection and Sterilization

In the event that the endoscope is contaminated, it should be high-level disinfected or sterilized after cleaning. Use caution when cleaning and then high-level disinfecting or sterilizing the endoscope.

Recommended High Level Disinfection and Sterilization Procedures

The following procedures have been determined by Cogentix Medical to be compatible with the **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope.

- **High-Level Disinfection in Glutaraldehyde**: All Cogentix Medical endoscopes are validated for high-level disinfection in 2.4% glutaraldehyde solutions. Perform the **High-Level Disinfection Protocol** described in this chapter.
- **Sterilization by Ethylene Oxide (EtO) Gas**: The endoscope may be sterilized using a validated EtO protocol. The acceptable processing parameters and procedure are given in the **EtO Gas Sterilization** section in this chapter.

- **Sterilization by STERRAD®**: The endoscope may be sterilized using a validated **STERRAD®** protocol. Refer to Table 6-1 on page 48 for the approved systems / cycles suitable for use with this endoscope.
- **Sterilization by STERIS®**: The endoscope may be sterilized using a validated **STERIS®** protocol. Refer to Table 6-1 on page 48 for the approved system suitable for use with this endoscope.

CAUTION Disinfection and sterilization methods not listed here may be harmful to the endoscope and could cause extensive equipment damage. Please contact Cogentix Medical Customer Service to determine the compatibility of a disinfection or sterilization method not listed in this manual and/or a complete list of functionally compatible agents.

Acceptable Reprocessing Materials

Cleaning	• Soft Material Lint-Free Gauze (4x4) • Enzymatic Cleaner • Instrument Grade Detergent
Intermediate Level Disinfection	• 70% Isopropyl Alcohol or • 70% Ethyl Alcohol
High Level Disinfection	• 2.4% Glutaraldehyde-based solution
Sterilization	• EtO Gas Sterilization • STERRAD® 100S, NX, 100NX***** • STERIS® System 1E*****

***** Endoscope **must** feature the Ⓢ symbol for STERIS® / STERRAD® compatibility

Incompatible Methods

The high-level disinfection and sterilization chemicals and methods shown below are not compatible with the **CST-4000/4000*i*** Flexible Cystoscope/ Hysteroscope. **DO NOT USE THEM**, as they could cause extensive damage to the endoscope. If you have any questions regarding the compatibility of a given disinfection or sterilization method, please contact your local distributor or the Cogentix Medical Customer Service Center.

Incompatible High Level Disinfection and Sterilization Methods/Chemicals		
High Level Disinfection Chemicals	**DO NOT USE**	• Chlorines • Formaldehyde • Iodophors
Sterilization Methods	**DO NOT USE**	• Autoclave • Ultrasonic

High-Level Disinfection Protocol

If the endoscope was determined to be free of leaks, it may be immersed in a glutaraldehyde solution for the amount of time recommended by the disinfectant manufacturer to achieve high-level disinfection.

CAUTION It is imperative that the endoscope be leak tested and cleaned prior to immersion in high-level disinfectant. Failure to do so may not detect leaks that could allow fluid ingress and damage the endoscope. Failure to clean the endoscope may allow gross debris to remain on external surfaces, which could impair proper disinfection. **If the endoscope fails the leak test, do not immerse it in fluids and do not use the endoscope in a procedure. Return the endoscope to the manufacturer for repairs.**

Cleaning

1. Gently pat down the Insertion Tube and wipe the Distal Bending Section with a soft, lint-free cloth or gauze (4x4) to remove debris.
2. Perform the Leak Test procedure.
3. Gently wash down all external surfaces with an enzymatic cleaning solution and soak the endoscope in the enzymatic cleaning solution for the time recommended by the enzymatic solution's manufacturer.
4. Remove the endoscope from the cleaning solution and rinse it thoroughly with clean, lukewarm water.
5. Dry all external surfaces of the endoscope.

Disinfection

1. Immerse the endoscope in the disinfectant solution at the temperature recommended by the disinfectant manufacturer.
2. Allow the endoscope to remain immersed in the disinfectant solution for the period of time recommended by the disinfectant manufacturer.
3. Following disinfection, remove the endoscope from the solution.

Rinsing

1. Immerse the endoscope in a container of clean, lukewarm water.
2. Thoroughly rinse the outside of the endoscope with clean, lukewarm water and place it on a clean, dry surface.
3. Wipe all external surfaces of the endoscope with a soft, lint-free cloth or gauze (4x4) until it is completely dry.
4. Confirm that the Lens at the endoscope's Distal Tip is free of disinfectant residue.

Ethylene Oxide (EtO) Gas Sterilization

The **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope may be sterilized using a validated ethylene oxide (EtO) gas sterilization protocol, following the processing parameters given below.

CAUTION If the Vent Valve is not open during gas sterilization, the increased heat and pressure from the sterilization process will cause pressure to build up inside the endoscope and could rupture the watertight seals and/or softer materials of the endoscope.

EtO Gas Sterilization Parameters

Temperature: $125^{o} \pm 5^{o}F$ ($52^{o}C \pm 3^{o}C$)
Relative Humidity: 50% ± 10%
EtO Concentration: 600 mg/liter
Exposure Time: 3 hours + 1/-0 hour
Post-Sterilization Aeration: 12 hours at $130^{o}F$ ($55^{o}C$) or 72 hours at $75^{o}F$ ($24^{o}C$)

NOTE: EtO Gas Sterilization at the above parameters has been validated by Cogentix Medical and will sterilize the device to a sterility assurance level (SAL) of 10^{-6}.

Prior to EtO Gas Sterilization, the endoscope must be leak tested, pre-cleaned and dried as described for the High-Level Disinfection Protocol. Failure to properly pre-clean the endoscope may inhibit the EtO gas sterilization process.

Prior to Gas Sterilization, the Vent Valve must be opened as shown in Figure 6-2 (page 43) to accommodate the heat and pressure changes of the Gas Sterilization process. To open the Valve, press the red Vent Cap onto the Vent Valve, and rotate it clockwise until it is seated and locked.

After EtO Gas Sterilization

Effective aeration must be completed after EtO gas sterilization. Cogentix Medical recommends following the instructions-for-use supplied by the manufacturer of the gas sterilizer, and that a biological indicator is used to confirm sterilization efficacy.

STERRAD® and STERIS® Sterilization

Prior to STERRAD® and STERIS® Sterilization, the endoscope must be leak tested, cleaned and dried as described in this chapter.

The **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope has been validated for material and functional compatibility with the following sterilization systems/cycles:

STERRAD® 100S	STERRAD® NX	STERRAD® 100NX	STERIS® System 1E
✓ Short and Long Cycles	✓ Short and Long Cycles	✓ Flex Cycle Only	✓

Table 6-1: STERRAD® and STERIS® Validated Systems/Cycles

Refer to the STERRAD® or STERIS® Sterilization User's Manual for complete details on instructions for use.

CAUTION Failure to properly clean the endoscope may inhibit the STERRAD® or STERIS® sterilization process.

CAUTION The Vent Cap **must** be **attached** for the STERRAD® sterilization process. The Vent Cap must be **removed** for the STERIS® sterilization process.

CAUTION STERRAD® and STERIS® sterilization compatibility applies only to endoscopes which feature the Ⓢ symbol on the Control Body's Identification Ring.

7 Care and Storage

Follow the instructions in this chapter if you anticipate that the endoscope will not be used for a prolonged period of time. Do not leave the endoscope exposed to the elements in these circumstances.

Storage

Follow the instructions below when storing the **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope:

- **DO NOT** store the endoscope with the **Slide-On® EndoSheath® Technology** installed on the Insertion Tube. Over time, the Sheath material may adhere to the Insertion Tube and become difficult to remove.
- When storing the endoscope, be sure to keep the Insertion Tube as straight as possible.
- The equipment should be completely clean and dry before storing.
- The endoscope should be maintained in a clean condition during storage so that it is ready for subsequent use.
- The endoscope should be stored in a dry, well ventilated environment – avoid high humidity, direct sunlight, and temperatures below -10°C or above 60°C.
- Do not store the endoscope in its carrying case. This case is only intended for endoscope transport; it is not properly ventilated for storage.
- Avoid storing the endoscope in heavily trafficked areas where there is a chance that it may sustain physical damage.

CAUTION The endoscope should **NEVER** be stored in areas where it could be exposed to liquids or environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, etc., which could adversely affect its operation.

The endoscope should **NEVER** be stored in the presence of flammable or explosive gases or chemicals.

Disposal

The equipment should be returned to Cogentix Medical for disposal. Contact your local Cogentix Medical representative or service facility for further information.

8 Troubleshooting

The information in this chapter is designed to help users diagnose problems that may occur during operation of the endoscope. The tables include some of the problems that could arise during operation, possible causes for those problems, and suggested corrective action.

CAUTION If the problem persists even after the corrective action has been taken, or a problem occurs that is not covered in the tables, do not use the endoscope. Contact Cogentix Medical for service or repairs using the information given in Chapter 9, **Warranty and Service**.

Troubleshooting

PROBLEM	PROBABLE	ACTION
Angulation feels stiff	• Damaged Distal Bending Section causing impaired angulation.	⇨ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.
Angulation alignment is no longer up/down	• Insertion Tube has become twisted.	⇨ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.
Loss of angulation	• Angulation wires have been stretched or broken during use.	⇨ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.
Cloudy or foggy images when the endoscope is unsheathed	• Patient debris or other material on the Objective Lens.	⇨ Clean the Objective Lens with an alcohol prep pad to remove material or stain. Excess staining may not be correctable and the lens may require replacement.
	• Fluid incursion into the endoscope's optical system.	⇨ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.
	• The lens at the Distal Tip has become damaged.	⇨ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.
Loss of illumination	• Patient material or other substance on the Light Guides.	⇨ Clean the Distal Tip with an alcohol prep pad to remove material or stain. Excess staining may not be correctable and the lens may require replacement.
	• Light Intensity is set too low.	⇨ Adjust Light Intensity setting.
	• Damaged light guide fiber bundles.	⇨ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.

Table 8-1: Troubleshooting

PROBLEM	PROBABLE	ACTION
Wrinkles and/or folds in the Insertion Tube	• These may be a result of excessive force applied to the Insertion Tube during cleaning or Sheath removal, or the long-term effects of repeated immersion in chemical disinfecting solutions, which could stretch and weaken the outer coverings.	⇨ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.
Insertion tube is dented	• Dents can be caused by physical trauma to the endoscope [e.g., closing the case on the Insertion Tube].	⇨ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.
Loss of pressure during leak test	• The Leak Tester is not connected properly to the Vent Valve. • The Leak Tester's Pressure-Relief Valve is open. • A hole or crack has broken the endoscope's watertight seal.	⇨ Re-connect the Leak Tester and perform the test again. ⇨ Close the Pressure-Relief Valve. ⇨ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.
Cannot insert endoscope into the sheath	• The Sheath's channel is misaligned. • The endoscope's Locking Knob is not aligned with the slot. • The endoscope's Insertion Tube has been damaged and its diameter has increased. • The Angulation Lever has been actuated.	⇨ Straighten the channel before continuing scope insertion. ⇨ Make sure the Locking Knob is positioned vertically. Align Locking Knob with slot and fully seat the endoscope in the sheath. Rotate the Locking Knob clockwise until it is horizontal. ⇨ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service. ⇨ Place the Angulation Lever in the neutral position so the Distal Bending Section of the endoscope is straight.

⇨ **Table 8-1: Troubleshooting** (cont'd)

PROBLEM	PROBABLE	ACTION
Cannot insert endoscope into sheath (cont'd)	• The Sheath's Window is not aligned with the Insertion Tube.	⇨ Articulate the Insertion Tube back and forth several times to fully seat the Sheath. ⇨ Gently manipulate the edges of the Sheath's Window to fully seat it.
	• The D-shaped opening of the EndoSheath® Connector is not aligned with the Insertion Tube.	⇨ Align the opening of the EndoSheath® Connector with the Insertion Tube.
	• The Sheath is torn or punctured.	⇨ Replace the Sheath.
Cannot remove the endoscope from the sheath	• Locking Knob not rotated.	⇨ Rotate Locking Knob to the vertical position.
	• The Sheath is torn or punctured.	⇨ Contact your regional distributor or Cogentix Medical Customer Service for removal instructions. Disinfect / sterilize the endoscope.
	• The Sheath has been attached to the endoscope for an extended period of time, causing it to adhere to the Insertion Tube.	⇨ Use a syringe without a needle to introduce small amounts of 70% alcohol into the opening at the proximal end of the EndoSheath® Connector. When the liquid reaches the Distal Tip of the endoscope/sheath, carefully attempt to remove the endoscope from the Sheath. If necessary, contact your Regional Distributor or Cogentix Medical Customer Service for removal instructions. Disinfect/sterilize the endoscope.
	• The flat portion of the Insertion Tube is not properly aligned with the Biopsy Port.	⇨ Align the flat portion of the Insertion Tube with the Biopsy Port and then remove the endoscope from the Sheath.
	• The Distal Head of the Insertion Tube is lodged in the Sheath.	⇨ Gently grasp the Sheath's Optical Window using the hanging drape bag as a barrier between your fingers and the Sheath. Then slowly and gently withdraw the endoscope from the Sheath.

⇨ **Table 8-1: Troubleshooting** (cont'd)

PROBLEM	PROBABLE	ACTION
Glare evident when viewing through the sheath	• The Sheath's window is not in contact with the Distal Tip of the endoscope due to:	
	- Incomplete insertion into the Sheath.	⇨ Move the Distal Bending Section back and forth several times to fully seat the Sheath. ⇨ Gently manipulate the edges of the Sheath's Window to properly seat the endoscope.
	OR	
	- The endoscope's tip is damaged and/or enlarged.	⇨ Remove the endoscope from the Sheath. Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.
Insufficient or no irrigation during procedure	• The stopcock is closed.	⇨ Open the stopcock.
	• The Irrigation/ Suction tubing is kinked, crushed, or open to the atmosphere.	⇨ Straighten out or relieve any tension on the tubing.
	• Irrigation/Suction Tubing is tightly positioned in the endoscope's Flow Control Valve.	⇨ Relieve tension on the tubing by repositioning it to provide more slack ahead of the Flow Control Valve.
	• The Flow Control Valve is closed.	⇨ Open the Flow Control Valve.
Cannot inject fluid through the Accessory port	• The Suction/Working Channel is clogged	⇨ Remove the endoscope from the patient and inject 10cc of saline through the channel. If the channel remains blocked, remove the Sheath from the endoscope and install a new Sheath.
	• The Syringe is not fully seated into or aligned with the Accessory Port.	⇨ Insert the syringe tip fully and straight into the Accessory Port.

Table 8-1: Troubleshooting (cont'd)

PROBLEM	PROBABLE	ACTION
The Accessory will not pass through the Sheath's Working Channel	• Accessory is too large.	⇨ Verify that the **CF-2.1 Slide-On® EndoSheath® Technology** is being used. Check the diameter of the accessory. Make sure that the Accessory is compatible with a 2.1 mm Working Channel.
	• The Channel is occluded by patient debris.	⇨ Remove the endoscope from the patient and inject 10cc of saline through the Channel. If, after repeated attempts, the channel remains blocked, remove the Sheath from the endoscope and install a new one. Do not force the Accessory through the working Channel as this may damage the Channel and compromise the integrity of the barrier.
	• The endoscope's Distal Bending Section is angulated.	⇨ Maneuver the endoscope's Distal Tip to an area of the anatomy in which it can safely be straightened. Insert accessory until its tip can be seen when looking through eyepiece. Now angulate the endoscope's Distal Bending Section, proceed to desired area.

Table 8-1: Troubleshooting (cont'd)

9 Warranty and Service

Warranty Information

NOTE: Alterations or repairs done by persons not authorized by Cogentix Medical will void this warranty.

Cogentix Medical is not liable for any damages to the **CST-4000/ 4000*i*** Flexible Cystoscope/Hysteroscope resulting from misuse, negligence, or improper cleaning or storage. The warranty defined herein shall apply only to the original buyer. In no event shall Cogentix Medical be liable for anticipated profits, consequential damages or loss of time incurred by the buyer with the purchase or use of this equipment.

NOTE: Cogentix Medical sells many of its products through regional distributors. Before sending equipment to Cogentix Medical contact your regional distributor for repair/return procedures.

Cogentix Medical warrants that the **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope and its accessories will be free from defects in materials and workmanship **for a period of one year from the date of the invoice**. Replacement parts are warranted **for a period of ninety (90) days from the date of the invoice**.

All non-warranty repairs will be warranted to be free from defects in materials and workmanship **for a period of ninety (90) days from the date of the invoice**.

Upon receipt of a **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope for repair, Cogentix Medical will evaluate the instrument and make the final decision as to the warranty status.

The above warranties are in lieu of all other warranties, either expressed or implied, including warranties of fitness or merchantability.

Cogentix Medical Service Information

CST-4000/4000*i* Flexible Cystoscopes/Hysteroscopes are serviced at authorized Cogentix Medical repair facilities only. Use the following procedure to expedite returned goods for repair or replacement:

1. Telephone your Regional Distributor, Territory Manager, or Cogentix Medical Customer Service Monday through Friday from 8:00 AM to 7:00 PM EST.

   USA customers call 866-258-2182 (toll free in U.S.)

   International customers call (+1) 952-426-6189 for Cogentix Medical Customer Service or call your regional distributor.

   Fax 866 255-4522 (toll free in U.S.)

   Fax (+1) 952 426-6199 (international)

   Email: customercare@cogentixmedical.com

2. Provide a detailed description of the problem.

3. If troubleshooting cannot solve the problem, a Returned Goods Authorization (RGA) number will be issued.

4. Complete an Incident Report Form and send it to Cogentix Medical along with the returned goods. Returned merchandise will only be accepted with an RGA number.

Shipping to Cogentix Medical or Distributor

WARNING

If the **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope has been used in a clinical setting, disinfect all system components before shipping as described in Chapter 6, **Reprocessing.** Shipping contaminated equipment could present an acute infection-control risk for those handling the endoscope, both during shipping and at the Cogentix Medical authorized repair facility.

If the **CST-4000/4000*i*** Flexible Cystoscope/Hysteroscope has been used in a clinical setting but cannot be disinfected before shipping, **place a red biohazard label** on the shipping container to indicate that the contents are contaminated, in accordance with OSHA standards 29 CFR 1910.1030.

Observe the following precautions before shipping the endoscope:

1. Attach the Vent Cap to the endoscope's Vent Valve in preparation for shipping.

2. If the endoscope has a leak or tear or fails the leak test, or for some other reason cannot be disinfected properly as described in Chapter 6, **Reprocessing,** wipe the endoscope down with 70% alcohol to remove debris. Indicate on the outer package that the contents are contaminated.

3. Ship the endoscope in its carrying case. Place the carrying case inside a corrugated box containing protective shipping material to prevent damage during shipment.

Regardless of warranty status, all shipping charges to and from an authorized Cogentix Medical facility are the responsibility of the customer.

NOTE: The customer will be contacted and advised of the estimated repair costs. Repairs will not begin on any equipment until authorization or a purchase order has been issued indicating approval of the charges.

Appendix

Specifications

CST-4000 and CST-4000*i*		
Insertion Tube Diameter (Nominal)	**CF-2.1 Sheath**	5.6mm (16.8 Fr) with sheath
	CF-1.5 Sheath	5.2mm (15.6 Fr) with sheath
Insertion Tube Working Length		370 mm (w/ sheath)
Overall Endoscope Length (Distal Tip – End Eyepiece)		688 mm
Field of View		120° (air) 87° (water)
Direction of View		Forward
Depth of Field		3 - 50 mm
Environmental Effects on Optical Performance		None
Angulation		215° Up /140° Down
Working Channel Diameter	**CF-2.1 Sheath**	2.1 mm (6.3 Fr)
	CF-1.5 Sheath	1.5 mm (4.5 Fr)
Operating Environment **Temperature** **Relative Humidity** **Air Pressure**		 50° to 104° F (10° to 40° C) 30 to 85% 700 to 1060 hPa
Storage Environment **Temperature** **Relative Humidity** **Air Pressure**		 14° to 140° F (-10° to +60° C) 0 to 95% 700 to 1060 hPa
Mode of Operation		Continuous
Electrical Safety		IEC 60601-1 & IEC 60601-2-18
Thermal Safety		IEC 60601-1 & IEC 60601-2-18
Degree of Protection Against Electrical Shock		Type BF
Degree of Protection Against Invasion of Liquids		IPX7: Fully Immersible (as per Reprocessing Instructions)

Table A - 1: Specifications

Infection Control Information

The **Slide-On® EndoSheath® Technology** for the **CST-4000/4000*i*** Cystoscope/Hysteroscope is designed to offer practitioners the ability to perform safe, efficient endoscopy. The **EndoSheath® Technology** is a proven effective barrier[1] to microorganisms as small as 27 nanometers. Efficacy testing for barrier qualities has been performed by an independent laboratory per FDA required guidelines[2]. All **EndoSheath® Technology** units undergo a rigorous quality assurance process to ensure the utmost in product quality and efficacy.

Please contact Cogentix Medical Customer Service for a detailed information packet regarding infection-control issues related to the **EndoSheath® Technology**.

[1] Viral challenge testing performed with bacteriophage 27 nanometers in size, per FDA guidance.

[2] As required by FDA clearance requirements, barriers must be tested by the guidelines set within the "FDA Guidance for Manufacturers Seeking Marketing Clearance of … Endoscope Sheaths Used as Protective Barriers"

Cogentix
Medical

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For additional product information or questions pertaining to sales and service, please contact the local distributor or the manufacturer.

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