



USER'S MANUAL

COGENTIX MEDICAL

Flexible Nasopharyngo-Laryngoscope

ENT-4000/4500

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

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How to Use This Manual

This User's Manual contains the recommended procedures for preparing and using the Cogentix Medical **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope. It is intended for physicians and other medical personnel who will come in contact with the endoscope before, during, and after any patient procedures performed with it. The manual also contains pertinent information on the proper care and handling of the endoscope. Please read and become familiar with this entire manual before using the endoscope.

This manual contains the following information:

- Description of the endoscope
- 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 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 **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope and compatible peripheral equipment. This chapter includes instrument diagrams, identifies components, and defines their functions.

Chapter 4, Preparation, Inspection and Operation – This chapter describes how to prepare the endoscope and peripheral equipment for use, and the assembly of 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 5, 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 6, 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 7, Troubleshooting – Describes possible problems that may be encountered with the endoscopic system, and suggests corrective actions to take towards resolving minor problems.

Chapter 8, 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 **ENT-4000/4500** Nasopharyngo-Laryngoscope, 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).

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1 Symbols and Terms

Symbols

The symbols listed below can be found on the **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope and on other components of the endoscopic system.



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



Alerts the user to the presence of important operating, maintenance, and service instructions. Refer to and become familiar with the user's manuals for all equipment used in the procedure.



Serial number of the endoscope



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



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 5, Reprocessing (Endoscope must feature the  symbol for compatibility to apply)



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

The following terms are used throughout this User's Manual:

- **"Laryngoscope", "Endoscope", or "ENT Scope"** - Refers to the Cogentix Medical **ENT-4000/4500 Nasopharyngo-Laryngoscope**.
- **"Sheath"** – Refers to the disposable **ENT Slide-On® EndoSheath® Technology** for the **ENT-4000/4500 Nasopharyngo-Laryngoscope**.

2 Important Information

The information in this chapter is essential for the correct and safe operation of the **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope. Please read and understand this information before preparing or using the endoscope or any peripheral equipment with which it will be used.

Intended Use

The Cogentix Medical **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope is intended to be used for flexible endoscopic examination of the upper airway, vocal cords and/or nasal passages.

NOTE: The **ENT-4000/4500** is not intended for electrosurgical procedures.

Do not use the endoscope for any purpose other than these intended uses.

User Qualifications

This equipment should only be used in a medical facility by or under the supervision of a physician trained in laryngoscopy.

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 device before use, and disassembly and proper cleaning after use, users should be adequately trained in the proper procedures. Failure to thoroughly understand these details, such as – but not limited to – **EndoSheath® Technology** installation and authorized disinfection 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, 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 5, **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 below. Warnings, Cautions and Notes will appear throughout this manual; carefully read and follow all statements.



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



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 safety to 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



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 or call the Cogentix Medical Customer Service Department.

All devices that are connected to the **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope 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.



NOTE: The Cogentix Medical ENT-4000 and ENT-4500 Flexible Nasopharyngo-Laryngoscopes and Slide-On® EndoSheath® Technology are not made with natural rubber latex.

During Use

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.

The **ENT-4000/4500** is not intended to be used with electrosurgical devices.

If any of the components 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 into 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.

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.

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 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

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

Use extreme care when reprocessing the endoscope. 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 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 **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscopes are designed to perform safe, sterile, and efficient endoscopy. This equipment has been designed for the examination of the upper airway from the nasal passages to the vocal cords, including the larynx. With proper use, the endoscope provides a thorough examination for more accurate diagnoses with minimal patient discomfort.

The **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope is shown in Figures 3-1 and 3-2 on pages 9 and 10. The endoscope does not have a working channel; it contains three fiberoptic light bundles and a fiberoptic image bundle.

The **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscopes are validated for use with the **Slide-On® EndoSheath® Technology**. The **ENT-4000/4500** endoscopes can be used with or without the **Slide-On® 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.

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, or fluid invasion of the endoscope.

Inspect the Standard Set



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 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.

ENT-4000 NASOPHARYNGO-LARYNGOSCOPE STANDARD SET	
CATALOG NO.	DESCRIPTION
02-4202	ENT-4000 Endoscope
07-3060	Light Guide Cable, 1.8m
07-6015	Vent Cap
07-6180	Cogentix Medical ENT-4000/4500 Carrying Case
	ENT-4000/4500 User's Manual (this document)
ENT-4500 NASOPHARYNGO-LARYNGOSCOPE STANDARD SET	
02-4502	ENT-4500 Endoscope
07-3060	Light Guide Cable, 1.8m
07-6015	Vent Cap
07-6180	Cogentix Medical ENT-4000/4500 Carrying Case
	ENT-4000/4500 User's Manual (this document)
OPTIONAL ITEMS AND ACCESSORIES (NOT SHIPPED WITH ENDOSCOPE)	
07-6160	Installation Stand, Floor Model
07-6161	Installation Stand, Clamp Model
07-6162	Installation Stand, Wall Mount
07-6010	Endoscope Leak Tester
See List on Page 13	Light Guide Sleeve Adapter
07-3053*	BLS-1000 Battery Powered Light Source Set (with Batteries and Battery Charger)
07-3050	BLS-1000 Battery Powered Light Source (Replacement)
07-3058*	BLS-1000 Battery Charger (Replacement)
07-3059	BLS-1000 Batteries (2 Batteries) (Replacement)

Table 3-1: ENT-4000/4500 Nasopharyngo-Laryngoscope Standard Sets

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

Equipment Diagrams

ENT-4000/4500 Flexible Nasopharyngo-Laryngoscope

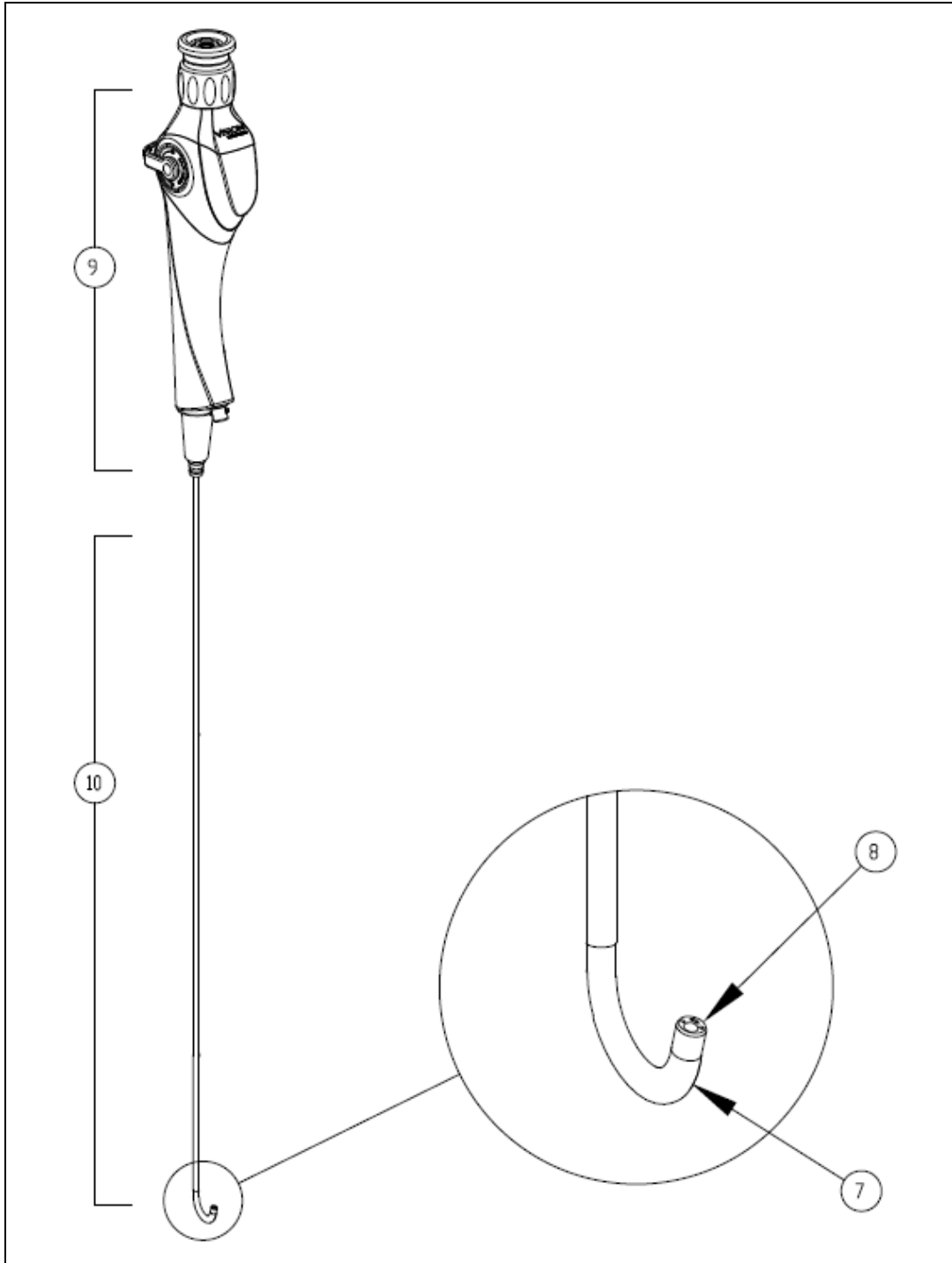


Figure 3-1: ENT-4000/4500 Nasopharyngo-Laryngoscope

ENT-4000/4500 Flexible Nasopharyngo-Laryngoscope

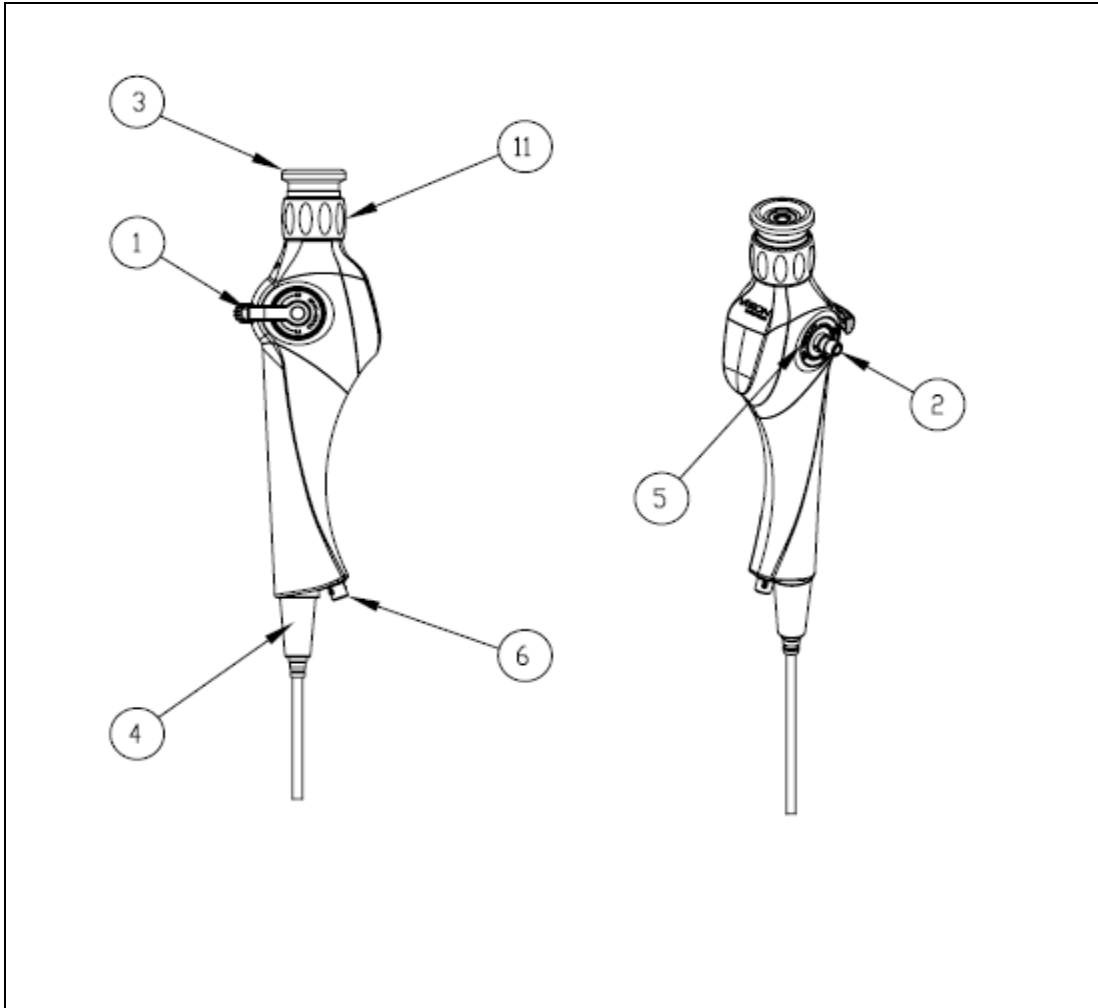


Figure 3-2: ENT-4000/4500 Nasopharyngo-Laryngoscope (Control Body)

Endoscope and Control Body:

1. **Angulation Lever:** This integral component of the Control Body controls the endoscope's Distal Tip deflection.
2. **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.
3. **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 system, or teaching attachment can be connected to the eyepiece, allowing the image to be displayed on a video monitor and/or photographed.

4. **EndoSheath® Interface:** Located at the base of the Control Body, this component secures the disposable Slide-On® EndoSheath® Technology to the endoscope.
5. **Identification Ring:** Includes the Serial Number, which is a unique number identifying the endoscope; and the (S) 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 that can be used in tandem with add-on components such as light sources and camera attachments.
6. **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.
7. **Distal Bending Section:** Deflects up and down when the Angulation Lever is actuated by the user.
8. **Distal Tip:** The terminating point of the image fiber bundle [Objective Lens] and the light guide fiber bundles [Light Guides].
9. **Control Body:** This segment allows physician control over endoscopic functions.
10. **Insertion Tube:** This component, along with the Distal Tip, is the part of the endoscope that is inserted into the patient.
11. **Diopter Adjustment Ring:** Located on the Control Body, this ring turns clockwise or counterclockwise to adjust the image until the image is clear. When a video camera, still photography systems, or teaching attachment is used, the white dot on the control body should 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, instead of 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.

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 that the safety certifications have been performed in accordance with the appropriate standard (IEC 60601-1 and/or IEC 60601-1-1).

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 4, **Preparation, Inspection and Operation** for proper set-up and operation information. The **ENT-4000/4500** Endoscope is designed to be used with the **BLS-1000** Battery Powered Light Source.

Light Guide Cables

Additionally, the **ENT-4000/4500** Endoscope is designed to be compatible with various light sources when using the detachable Light Guide Cable. To ensure proper mating with the selected light source, be sure that the appropriate Light Guide Sleeve is securely threaded onto the Light Guide Cable. Refer to Figure 3-3 for a complete list and diagrams of the available Light Guide Sleeves.

Add-On Camera System

The **ENT-4000/4500** Endoscope features a "rigid" style eyepiece compatible with most manufacturers' Add-On Camera Systems. Ensure that the Camera System's coupler is designed for a "rigid" style eyepiece. If it is not, please contact Cogentix Medical for compatibility assistance.

Leak Testing

The **ENT-4000/4500** Endoscope may only be leak tested with a Cogentix Medical Endoscope Leak Tester.

Reprocessing

The **ENT-4000/4500** Endoscope may be reprocessed by a variety of methods. Refer to Chapter 5, **Reprocessing** for the accessories that will be used when reprocessing the endoscope. Contact Cogentix Medical Customer Service for advice on compatibility issues.

Light Source Adapters (Light Guide Sleeves)

The following Light Guide Sleeves are available to adapt Cogentix Medical endoscopes for use with other manufacturers' light sources when using a Detachable Light Guide Cable.

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.

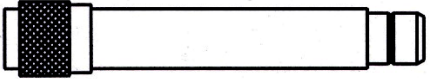
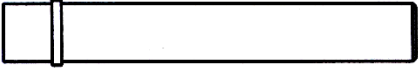
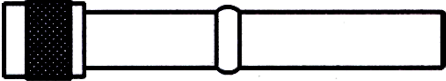
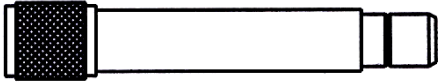
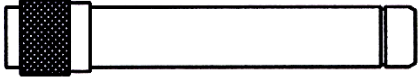
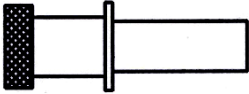
LIGHT GUIDE SLEEVE DIAGRAM	CATALOG NUMBER & COMPATIBLE LIGHT SOURCES
	<p><u>06-6019</u>: Cogentix Medical HLS-1500 / XLS-3000, Circon and ACMI Light Sources</p>
	<p><u>06-6009</u>: Cogentix Medical LS-150 and Pentax Light Sources</p>
	<p><u>06-6044</u>: Olympus Light Sources</p>
	<p><u>06-6020</u>: Smith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

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

4 Preparation, Inspection and Operation

WARNING

If an abnormality is detected during endoscope preparation, do not use the endoscope. Refer to the tables in Chapter 7, **Troubleshooting**. If the problem cannot be solved using the information in that chapter, contact your regional distributor or Cogentix Medical Customer Service. Refer to Cogentix Medical Service Information (Chapter 8, **Warranty and Service**) in this manual.

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.

If you are not using the **Slide-On® EndoSheath® Technology**, ensure that the endoscope has undergone the appropriate disinfection process. Refer to Chapter 5, **Reprocessing**, for compatible reprocessing methods and procedures.

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.

During the procedure, the temperature at the distal end of the endoscope may exceed 41°C (106 °F) due to intense endoscopic 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 end of the endoscope in close proximity to mucous membranes for a long period of time.

Preparation, Inspection and Operation

If using the **Slide-On® EndoSheath® Technology** and image glare is present, lower light source intensity until glare disappears.

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 present.

1. Check the 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 can damage the internal components.

3. Check for full Distal Tip deflection by actuating the Angulation Lever up and down.

CAUTION Avoid applying excessive pressure when using the Angulation Lever. Doing so could damage the angulation mechanism.

4. Clean the Lens on the endoscope's 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.

5. Ensure that the proper Light Guide Adapter is securely connected to the Light Guide Cable.
6. Securely insert the Light Guide Cable into the light source.
7. Look through the Eyepiece and rotate the Diopter Adjustment Ring until the fiber pattern is clearly focused.
8. 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.

Endoscope Operation with BLS-1000 Battery Powered Light Source

1. Prior to use, the **BLS-1000** should be reprocessed. Please refer to the **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 cover fit, 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 outer body of 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. 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.

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.

7. 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.

8. Prepare the patient using normally acceptable clinical practice prior to endoscope insertion.
9. Lubricate the outside of the endoscope (or Sheath, if used) before inserting the endoscope into the patient. Cogentix Medical recommends that the endoscope (or Sheath, if used) be lubricated with water or a water-based lubricant just prior to insertion.
10. Introduce the endoscope into the patient using normally acceptable clinical practice. Operate the Angulation Lever as necessary for advancement and observation.
11. 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.
12. When the procedure is finished, rotate the outer body of the **BLS-1000** to the OFF position, and confirm that the light is off.

Endoscope Operation – Other Light Source

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 the 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. If the endoscope will be inserted into the patient's mouth, first place a bite block into the patient's mouth to prevent bite damage.
8. Lubricate the outside of the endoscope (or Sheath, if used) before inserting the endoscope into the patient. Cogentix Medical recommends that the endoscope (or Sheath, if used) be lubricated with water or a water-based lubricant just prior to insertion.
9. Introduce the endoscope into the patient using normally acceptable clinical practice. Operate the Angulation Lever as necessary for advancement and observation.
10. 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.

5 Reprocessing

The **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope can be used either with or without the **Slide-On® EndoSheath® Technology***. Cogentix Medical recommends the use of the **Slide-On® EndoSheath® Technology**; 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 an endoscope, and benefits both user and patient by providing an Insertion Tube covered with a sterile Sheath for every procedure. For cleaning and disinfection procedures when using the **Slide-On® EndoSheath® Technology**, see **Cleaning After Slide-On® EndoSheath® Technology Use** on page 23.

WARNING

The endoscope must be properly reprocessed by cleaning, disinfection and/or sterilization, before its first use and after each subsequent use according to the protocols in this section. 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 cleaning 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.

*Cogentix Medical Slide-On® EndoSheath® products for ENT endoscopes are covered by the following U.S. patents: 6,350,231; 6,530,881; 6,733,440. These products may be covered by other U.S. or international patents.

Reprocessing Steps

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

Note: The **ENT-4000/4500** endoscope may only be leak tested with a Cogentix Medical Endoscope Leak Tester.

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 invasion. 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 fluid invasion.

- **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 is sufficient to prepare it for the next procedure.
- **Intermediate-Level Disinfection** – After use with **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 23. For procedures without utilizing the **EndoSheath® Technology**, intermediate-level disinfection is not an adequate level of reprocessing.
- **High-Level Disinfection** – For procedures where the endoscope comes in direct contact with the patient, or following any procedure during which the user suspects the endoscope became contaminated, it is necessary to immerse the endoscope in a high-level disinfectant. Sterilization is also recommended. See the **High-Level Disinfection Protocol and Sterilization** section in this chapter.
- **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. Endoscope **must** feature the (S) symbol for STERRAD® / STERIS® compatibility.

Leak Testing

The **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope must be evaluated for possible leaks in the Control Body and/or the 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 5-1). 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.

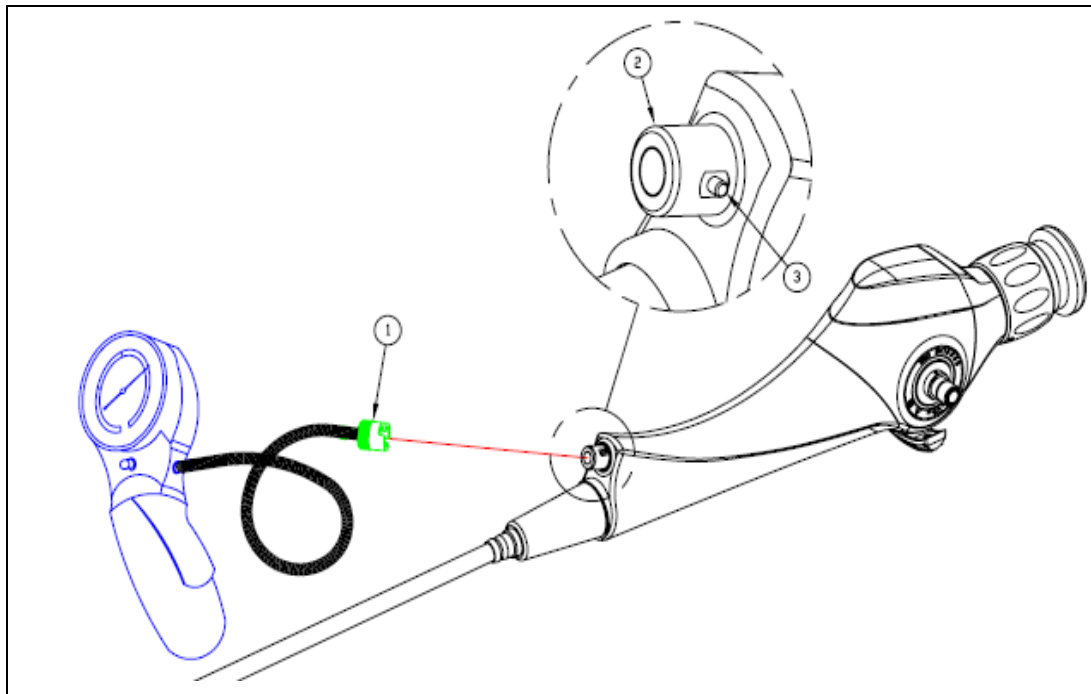


Figure 5-1: Leak Tester Connection

Leak Test 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.

Reprocessing

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 lead to damage to the endoscope.

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 8, **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 neutral 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 8, **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.

Cleaning/Disinfection/Sterilization

Use of the Vent Cap

CAUTION

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

1. Gas Sterilization
2. Aeration
3. Shipping

Remove the Vent Cap from the endoscope **before** the following:

1. Patient Use
2. Immersion in Fluids

FAILURE TO COMPLY WITH THE ABOVE MAY RESULT IN DAMAGE TO THE ENDOSCOPE AND MAY VOID THE PRODUCT WARRANTY.

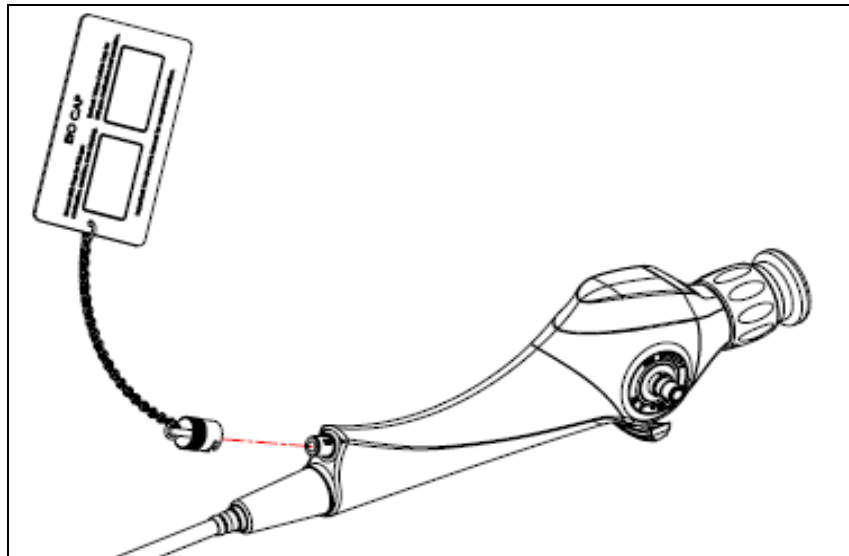


Figure 5-2: Opening the Vent Valve

Cleaning and Intermediate Level Disinfection 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. 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 used, 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 and/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 **ENT-4000/4500 Flexible Nasopharyngo-Laryngoscope**:

- **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 procedures are given in the **Ethylene Oxide (EtO) Gas Sterilization** section on page 27.
- **Sterilization by STERRAD®:** The endoscope may be sterilized using a validated **STERRAD®** protocol. Refer to Table 5-1 on page 28 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 5-1 on page 28 for the approved system suitable for use with this endoscope.



Disinfection and sterilization methods not listed here may be harmful to the endoscope and exposure could result in extensive 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	<ul style="list-style-type: none"> • Soft Material Lint-Free Gauze (4x4) • Enzymatic Cleaner • Instrument Grade Detergent
Intermediate Level Disinfection	<ul style="list-style-type: none"> • 70% Isopropyl Alcohol or • 70% Ethyl Alcohol
High Level Disinfection	<ul style="list-style-type: none"> • 2.4% Glutaraldehyde-based solution
Sterilization	<ul style="list-style-type: none"> • EtO Gas Sterilization • STERRAD® 100S, NX, 100NX* • STERIS® System 1E*

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

Incompatible Methods

The high-level disinfection and sterilization chemicals and methods shown below are NOT compatible with the **ENT-4000/4500** Nasopharyngo-Laryngoscope; **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, representative, or the Cogentix Medical Customer Service Center.

Incompatible High Level Disinfection and Sterilization Methods/Chemicals		
High Level Disinfection Chemicals	DO NOT USE	<ul style="list-style-type: none"> • Chlorines • Formaldehyde • Iodophors
Sterilization Methods	DO NOT USE	<ul style="list-style-type: none"> • 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. Contact Cogentix Medical Customer Service to arrange for repair and/or service of the endoscope.

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 visible 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.

High-Level 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 **ENT-4000/4500** Nasopharyngo-Laryngoscope 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 opened 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 softer materials of the endoscope.

EtO Gas Sterilization Parameters

Temperature: 125° ± 5°F (52°C ± 3°C)

Humidity: 50 ± 10%

Exposure Time: 3 hours + 1/-0 hour

EtO Concentration: 600 mg/liter

Post-Sterilization Aeration: 12 hours at 130°F (55°C) or 72 hours at 75°F (24°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 and completely cleaned and dried according to the High-Level Disinfection Protocol.

CAUTION

Failure to properly clean the endoscope may inhibit the EtO Gas Sterilization process.

Prior to Gas Sterilization, the Vent Valve must be opened (as shown in Figure 5-2 on page 23) to accommodate the heat and pressure changes of the sterilization process. To open the Valve, press the red Vent cap onto the Vent Valve of the endoscope, 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 be used to confirm effective sterilization.

STERRAD[®] and STERIS[®] Sterilization

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

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 (S) symbol on the Control Body.

The **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope 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 5-1: STERRAD[®] and STERIS[®] Validated Systems/Cycles

6 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 such circumstances.

Storage

Follow the instructions below when storing the **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope:

DO NOT store the endoscope with **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.

7 Troubleshooting

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

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 repair and/or service using the information given in Chapter 8, **Warranty and Service**.

Troubleshooting

PROBLEM	PROBABLE CAUSE	SUGGESTED ACTION
Angulation feels stiff	<ul style="list-style-type: none"> Damaged Distal Bending Section causing impaired angulation. 	⇒ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 8, Warranty and Service.
Angulation alignment is no longer up/down	<ul style="list-style-type: none"> Insertion Tube has become twisted. 	⇒ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 8, Warranty and Service.
Loss of angulation	<ul style="list-style-type: none"> Angulation wires have been stretched or broken during use. 	⇒ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 8, Warranty and Service.
Cloudy or foggy images when the endoscope is unsheathed	<ul style="list-style-type: none"> Patient debris or other material on the Objective Lens. Fluid incursion into the endoscope's optical system. The Lens at the Distal Tip has become damaged. 	⇒ 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. ⇒ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 8, Warranty and Service. ⇒ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 8, Warranty and Service.
Loss of illumination	<ul style="list-style-type: none"> Patient material or other substance on the Light Guides. Light Intensity is set too low. Damaged light guide fiber bundles. 	⇒ 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. ⇒ Adjust Light Intensity setting. ⇒ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 8, Warranty and Service.

Table 7-1: Troubleshooting

PROBLEM	PROBABLE CAUSE	SUGGESTED ACTION
Wrinkles and/or folds in the Insertion Tube	<ul style="list-style-type: none"> • 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 8, Warranty and Service.
Insertion tube is dented	<ul style="list-style-type: none"> • 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 8, Warranty and Service.
Loss of pressure during leak test	<ul style="list-style-type: none"> • 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 8, Warranty and Service.

8 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 **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope 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 **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope 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 the **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope 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

ENT-4000/4500 Flexible Nasopharyngo-Laryngoscopes are serviced at authorized Cogentix Medical 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@kogentixmedical.com

Warranty and Service

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 **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope has been used in a clinical setting, disinfect all system components before shipping as described in Chapter 5, **Reprocessing**. Shipping contaminated equipment could present an acute infection-control risk for those handling the endoscope, both during shipping and at Cogentix Medical.

If the **ENT-4000/4500** Flexible Nasopharyngo-Laryngoscope 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 5, **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

ENT-4000/4500		
Distal Tip Diameter	ENT-4000 ENT-4500	3.35 mm 2.40 mm
Insertion Tube Diameter	ENT-4000 ENT-4500	3.45 mm 2.4 mm
Insertion Tube Working Length		300 mm
Field of View	ENT-4000 ENT-4500	90° 80°
Direction of View		0°
Depth of Field		3 - 50 mm
Environmental Effects on Optical Performance		None
Maximum Angulation		140° up/down
Operating Environment Temperature		50° to 104° F (10° to 40° C)
Relative Humidity		30 to 85%
Air Pressure		700 to 1060 hPa
Storage Environment Temperature		14° to 140° F (-10° to +60° C)
Relative Humidity		0 to 95%
Air Pressure		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 (Body Floating)
Degree of Protection Against Fluid Invasion		IPX7: Fully Immersible (per Reprocessing Instructions)

Table A-1: Specifications

Infection Control Information

The **ENT-4000/4500 Flexible Nasopharyngo-Laryngoscopes** are validated for use with the **Slide-On[®] EndoSheath[®] Technology**. This equipment is designed to offer practitioners the ability to perform safe, efficient endoscopy. The **Slide-On[®] EndoSheath[®] Technology** has been proven to be an effective barrier to micro-organisms as small as 27 nanometers¹. Efficacy testing for barrier qualities has been performed by an independent laboratory per FDA required guidelines². All **Slide-On[®] EndoSheath[®]** 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 and the **Slide-On[®] EndoSheath[®] Technology**.

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

² Per 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

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