



USER'S MANUAL

COGENTIX MEDICAL

Flexible Video Esophagoscope

TNE-5000

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

©2008, 2009, 2011, 2012, 2013, 2015 Cogentix Medical, Inc. All rights reserved. Printed in the United States of America.

The information contained herein is the exclusive and confidential property of Cogentix Medical, Inc. No part of this manual may be disclosed or reproduced in whole or in part without permission from Cogentix Medical, Inc.

How to Use This Manual

This User's Manual contains the recommended procedures for preparing and using the Cogentix Medical **TNE-5000** Flexible Video Esophagoscope and 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 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 equipment.

This manual contains the following information:

- The endoscope's intended use
- Description of the endoscope and **Slide-On[®] EndoSheath[®] Technology**
- 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 **TNE-5000** Flexible Video Esophagoscope and compatible peripheral equipment. This chapter includes instrument diagrams, identifies components, and defines their functions.

Chapter 4, Installing and Removing Slide-On[®] EndoSheath[®] Technology – **Slide-On[®] EndoSheath[®] Technology** is a sterile, single-use barrier placed over

How to Use This Manual

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.

The **Appendix** contains the technical specifications for the **TNE-5000** Flexible Video Esophagoscope 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

How to Use This Manual	i
Organization of this Manual	i
Additional Information.....	ii
1 Symbols and Terms	1
Symbols.....	1
Terms.....	2
2 Important Information	3
Intended Use	3
User Qualifications	3
Reprocessing.....	3
Maintenance and Repair	4
Signal Words.....	4
Important Safety Precautions.....	4
Preparation, Inspection, and Assembly	4
During Use.....	6
Reprocessing	7
3 Endoscope and Accessories	9
Inspect the Standard Set.....	10
Equipment Diagrams.....	11
TNE-5000 Flexible Video Esophagoscope	11
TV-2.1 Slide-On® EndoSheath® Technology	14
TV-1.5 Slide-On® EndoSheath® Technology	16
DPU-5000/7000 Series Digital Video Processor	18
Installation Stand	19
Accessories	20
Video Processor.....	20
Light Sources	20
Leak Testing	20
Reprocessing	20
Therapeutic Accessories.....	20
4 Installing and Removing the Slide-On® EndoSheath® Technology	21
Install the Slide-On® EndoSheath® Technology	21
Prepare the Endoscope and Sheath.....	22

Table of Contents

Insert the Endoscope Into the Sheath	22
Connect Tubing / Complete Sheath Attachment	24
Complete System Assembly	24
Observe the Endoscopic Image.....	24
Remove the Slide-On [®] EndoSheath [®] Technology.....	25
5 Preparation, Inspection and Operation	27
Preparation and Inspection.....	27
Select an Installation Site	27
Endoscope Operation	29
Insufflation.....	30
Suction	30
Inserting Accessories.....	30
Electrosurgical Devices/Accessories	31
Laser Devices/Accessories	32
6 Reprocessing	33
Reprocessing Steps.....	34
Leak Testing.....	34
Attach the Leak Tester to the Endoscope.....	34
Pressurize the Endoscope.....	35
Cleaning, Disinfection, and Sterilization.....	37
Use of the Vent Cap.....	37
Cleaning After Slide-On [®] EndoSheath [®] Technology Usage	37
High-Level Disinfection and Sterilization	38
Recommended Disinfection and Sterilization Procedures	38
Acceptable Reprocessing Materials	39
Incompatible Methods	39
High-Level Disinfection Protocol	40
Pre-Cleaning	40
Disinfection	40
Rinsing	40
Ethylene Oxide (EtO) Gas Sterilization	41
EtO Gas Sterilization Parameters.....	41
After EtO Gas Sterilization	41
STERRAD [®] and STERIS [®] Sterilization.....	42
7 Care and Storage.....	43
Storage.....	43
Disposal	44

8 Troubleshooting 45

9 Warranty and Service 53

 Warranty Information.....53

 Cogentix Medical Service Information53

 Shipping to Cogentix Medical54

Appendix..... 55

 Specifications TNE-500055

 Infection Control Information.....56

 Electromagnetic Compatibility Declarations57

Index of Figures

Figure 2-1: Incorrect and Correct Sheath Alignment.....5

Figure 3-1: TNE-5000 Flexible Video Esophagoscope..... 11

Figure 3-2: TNE-5000 Flexible Video Esophagoscope – Control Body 12

Figure 3-3: TV-2.1 Slide-On® EndoSheath® Technology..... 14

Figure 3-4: TV-1.5 Slide-On® EndoSheath® Technology..... 16

Figure 3-5: DPU-5000/7000 Series Digital Video Processor..... 18

Figure 3-6: Installation Stand 19

Figure 4-1: Incorrect and Correct Sheath Alignment.....23

Figure 6-1: Leak Tester Connection 35

Figure 6-2: Opening the Vent Valve 37

Index of Tables

Table 3-1: TNE-5000 Flexible Video Esophagoscope – Components 10

Table 6-1: STERRAD® and STERIS® Validated Systems/Cycles 42

Table 8-1: Troubleshooting 46

Table A-1: Specifications..... 55

Table A-2: Electromagnetic Emissions Declaration.....57

Table A-3: Electromagnetic Immunity Declaration 58

Table A-4: Electromagnetic Immunity Declaration 59

Table A-5: Recommended Separation Distances.....60

1 Symbols and Terms

Symbols

The symbols listed below can be found on the **TNE-5000** Flexible Video Esophagoscope 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/or service instructions. Refer to the user's manuals for warnings and safety precautions associated with equipment used in the procedure.



The equipment 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



STERIS[®] and STERRAD[®] Reprocessing Compatibility
Refer to Chapter 6, Reprocessing (Endoscope must feature the  symbol for STERIS[®] / STERRAD[®] compatibility)



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:

"Esophagoscope", "Endoscope", or "Videoscope" - refers to the Cogentix Medical **TNE-5000** Flexible Video Esophagoscope.

"Slide-On[®] EndoSheath[®] Technology" or **"Sheath"** refers to the disposable **TV-2.1** or **TV-1.5 Slide-On[®] EndoSheath[®] Technology** for the **TNE-5000** Flexible Video Esophagoscope.

"Processor" refers to the **DPU-5000/7000 Series** Video Processors.

2 Important Information

The information in this chapter is essential for the correct and safe operation of the **TNE-5000** Flexible Video Esophagoscope. 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 **TNE-5000** Flexible Video Esophagoscope with **Slide-On® EndoSheath® Technology** is intended to be used for endoscopic access and examination of the larynx, esophagus, and gastro-esophageal junction. The equipment may also be used to assist in intubation.

Do not use the equipment 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 endoscopy. Use of the system does not require any deviation from standard esophagoscopy technique. However, the operator should have complete familiarity with the operation of the entire system prior to clinical use.

Only use the endoscope and peripheral equipment according to the instructions and 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 6, **Reprocessing**, for information on all 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; it should also 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



The **TNE-5000** 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 a 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.

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 endoscope should move freely without the application of force. Should **ANY** resistance be encountered, verify that the Sheath's channel is properly aligned.

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 a damaged endoscope; doing so could cause patient injury, and may result in further damage to the endoscope.

If the channel of the sheath is misaligned, straighten out the channel before continuing scope insertion, as shown in Figure 2-1 below. Also refer to Chapter 8, **Troubleshooting**, for further information. If the suggestions given in that chapter do not solve the alignment or insertion problems, contact your local distributor or Cogentix Medical Customer Service Department.



NOTE: The Cogentix Medical **TNE-5000** Flexible Video Esophagoscope and **Slide-On® EndoSheath® Technology** are not made with natural rubber latex.



MISALIGNED



ALIGNED PROPERLY

Figure 2-1: Incorrect and Correct Sheath Alignment

Important Information

CAUTION

All devices that are connected to the **TNE-5000** Flexible Video Esophagoscope and **DPU-5000/7000 Series** Video Processor 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, and Safety Requirements for Medical Electrical Equipment, IEC 60601-1-1.

DO NOT expose the Sheath to alcohol or other cleaning agents prior to use.

The Working Channel of the **TV-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 allow liquids to get inside the Sheath prior to use. Doing so could damage the Sheath and/or the endoscope.

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.

If any of the components of the endoscopic system malfunction 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.

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 and Videoscope Cable. 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 endoscope's 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 endoscope and/or the **Slide-On® EndoSheath® Technology**.

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.

Reprocessing

WARNING

The endoscope must be properly reprocessed, by cleaning, disinfecting and/or sterilizing, 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 (>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 recontaminate 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 **TNE-5000** Flexible Video Esophagoscope and **Slide-On® EndoSheath® Technology** are designed to perform safe, sterile, and efficient esophagoscopy procedures.

The two major components of the endoscopic system are:

- The **TNE-5000** Flexible Video Esophagoscope, which is shown in Figures 3-1 and 3-2 on pages 11 and 12. The endoscope's Insertion Tube has no working channel; it contains the video camera module and illumination bundles.
- The disposable **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. The sheaths also contain working channels through which insufflation, suction, and/or accessory equipment can be used.

There are two types of sheaths available for use with the **TNE-5000**:

- The **TV-2.1 Slide-On® EndoSheath® Technology** (see Figure 3-3 on page 14). This Sheath contains a 2.1mm (6.3Fr) channel through which air insufflation and suction can be performed, or accessory instruments inserted.
- The **TV-1.5 Slide-On® EndoSheath® Technology** (see Figure 3-4 on page 16) has a 1.5mm (4.5Fr) channel that supports insufflation and suction, but cannot accommodate the insertion of accessory devices.

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 ordered items listed in Table 3-1 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 replacement parts.

TNE-5000 ESOPHAGOSCOPE STANDARD SET	
COGENTIX MEDICAL CATALOG NO.	DESCRIPTION
03-5201 OR	TNE-5000 Flexible Video Esophagoscope, NTSC
03-5202	TNE-5000 Flexible Video Esophagoscope, PAL
07-6182	Cogentix Medical TNE-5000 Carrying Case
07-6015	Vent Cap
	TNE-5000 User's Manual (this document)
VIDEO PROCESSORS (NOT SHIPPED WITH ENDOSCOPE)	
07-5050	DPU-5050 Video Processor with LCD Display*
07-5051	DPU-5050A Video Processor with Air Pump and LCD Display*
07-7001	DPU-7000A Video Processor with LCD Display
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	Videoscope Leak Tester
ENDOSHEATH® TECHNOLOGY	
03-5101	TV-2.1 Slide-On® EndoSheath® Technology with 2.1mm (6.3Fr) Working Channel for the TNE-5000 Flexible Video Esophagoscope
03-5102	TV-1.5 Slide-On® EndoSheath® Technology with 1.5mm (4.5Fr) Air/Suction Channel for the TNE-5000 Flexible Video Esophagoscope

Table 3-1: TNE-5000 Flexible Video Esophagoscope – Components

*Available in select markets only

Equipment Diagrams

TNE-5000 Flexible Video Esophagoscope

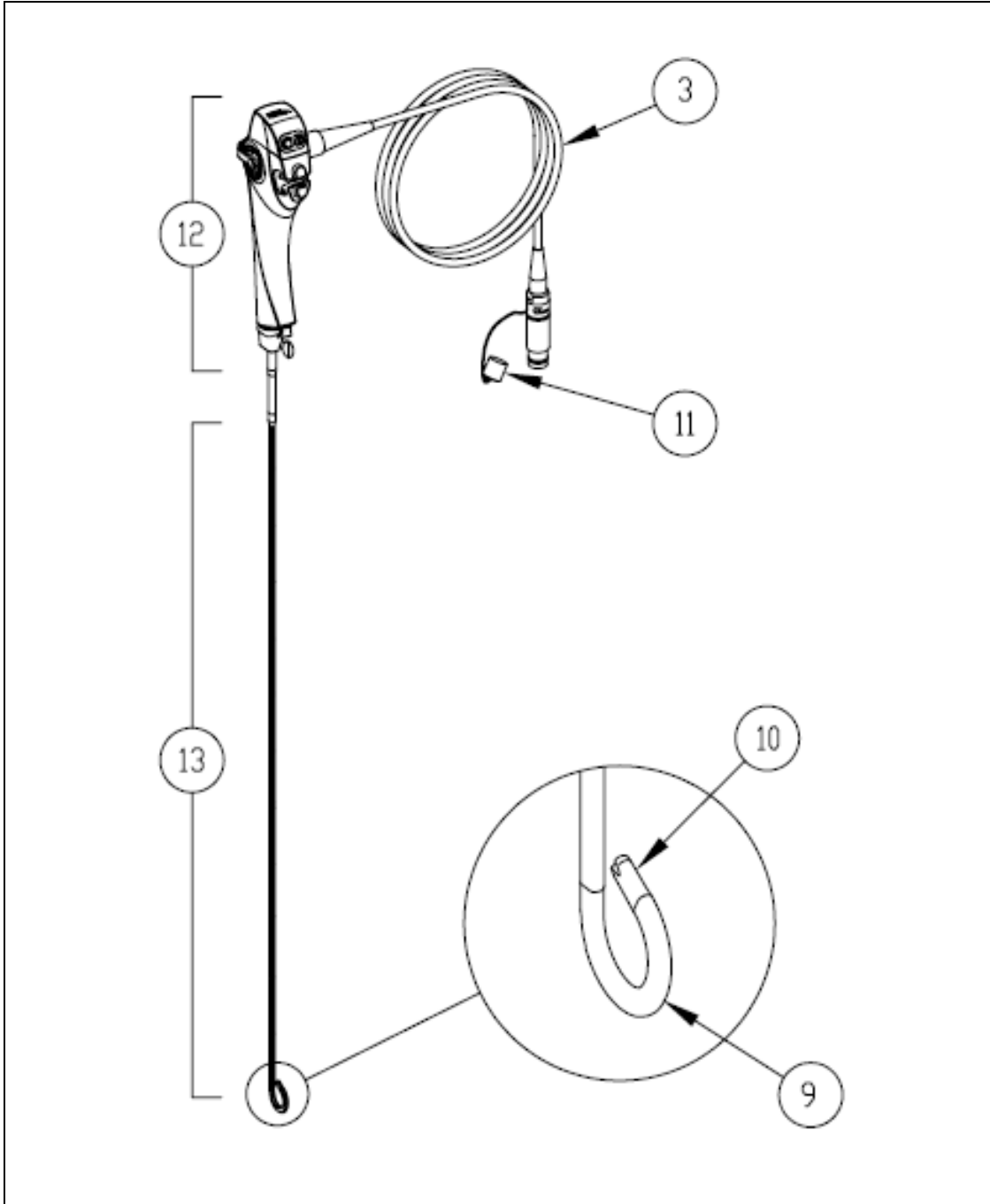


Figure 3-1: TNE-5000 Flexible Video Esophagoscope

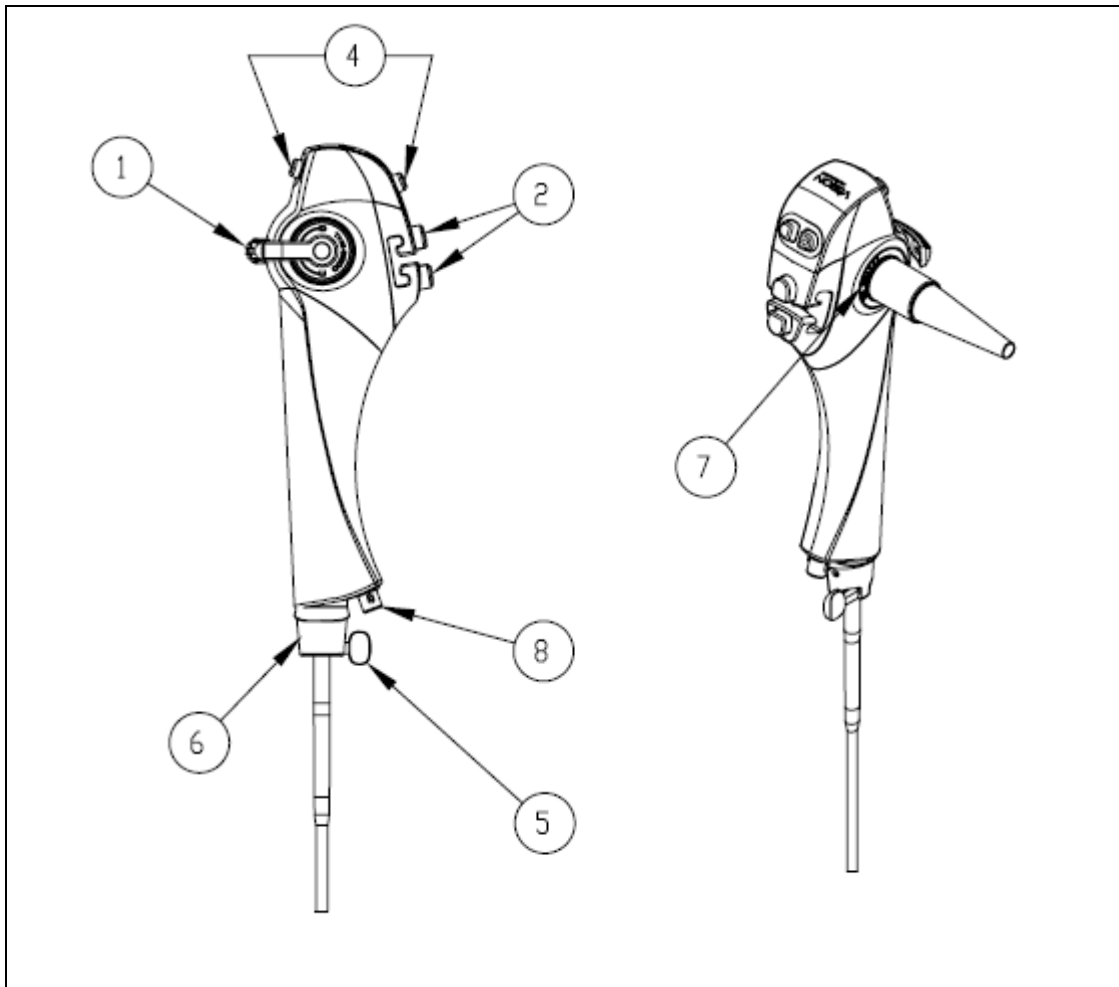


Figure 3-2: TNE-5000 Flexible Video Esophagoscope – Control Body

Instrument Components

1. **Angulation Lever:** Controls deflection of the endoscope's Distal Bending Section.
2. **Dual Pinch Valves:** Attach the Insufflation/Suction Tubing to the valves to regulate insufflation and suction during use.
3. **Videoscope Cable:** The connector (plug) at the end of the cable connects to the **DPU-5000/7000 Series** Digital Video Processor.
4. **Control Buttons:** Four programmable function buttons which allow the user to activate different functions of the video system. Consult the **DPU-5000/7000 Series** Video Processor User's Manual for instructions regarding the control functions and how to program the buttons.
5. **Locking Knob:** Mates with the EndoSheath[®] Rigid Connector to secure the **Slide-On[®] EndoSheath[®] Technology** to the endoscope.

6. **EndoSheath Interface:** Secures the disposable EndoSheath[®] cover to the endoscope body.
7. **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 Identification Ring in order for STERIS[®] / STERRAD[®] compatibility to apply.
8. **Vent Valve:** When the Vent Cap is connected, this valve allows access to the interior of the endoscope for EtO and STERRAD[®] gas sterilization, and should be connected during transport. The Vent Cap **must** be attached to the valve prior to EtO and 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.
10. **Distal Tip:** The terminating point of the video camera module and the light guide fiber bundles [Light Guides].
11. **Sealing Cap:** Seals the plug prior to soaking for leak testing or disinfection.
12. **Control Body:** This segment allows physician control over endoscopic functions.
13. **Insertion Tube:** This component, along with the Distal Tip, is the part of the endoscope that is inserted into the patient.

TV-2.1 Slide-On® EndoSheath® Technology

The **TV-2.1 Slide-On® EndoSheath® Technology** shown in Figure 3-3 is a sterile, disposable barrier for the Cogentix Medical **TNE-5000** Flexible Video Esophagoscope. The Sheath isolates the endoscope from contact with patient fluid and material during the procedure.

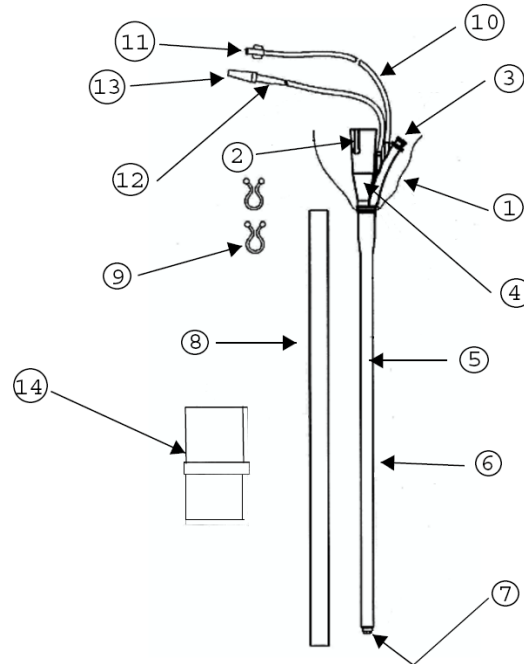


Figure 3-3: TV-2.1 Slide-On® EndoSheath® Technology

1. **Control Body Cover:** Covers and protects the endoscope's Control Body from contaminants during the procedure.
2. **Slot for Locking Knob:** Slides past the Locking Knob to secure the Sheath to the endoscope.
3. **Accessory Port with Removable Seal:** Allows rapid fluid injection and passage of accessories during procedures. A removable Accessory Port Valve Seal allows for secure Luer-Lock syringe attachment for fluid withdrawal.
4. **EndoSheath® Connector:** Secures the Sheath to the endoscope.
5. **Working Channel:** A solid, impermeable tubing that runs the length of the Sheath, allowing for maximum air insufflation and suction while also allowing the passage of accessory devices.
6. **Insertion Tube Barrier:** A flexible elastomeric sleeve that creates a barrier covering for the endoscope's Insertion Tube.

7. **Sheath Window:** A patented, optically clear window that covers the Distal Tip of the endoscope.
8. **Protector Tube:** Protects the Sheath from external damage during shipping, storage, and Sheath loading.
9. **Control Body Cover Clips (2):** Secure the Drape Bag on the Installation Stand, and secure the Control Body Cover to the Videoscope Cable and Suction/Insufflation Tubes.
10. **Air Insufflation Tube:** Provides air to the endoscope's Distal Tip for insufflation during the procedure.
11. **Luer Lock/Air Connector:** A standard Luer-Lock Fitting Cap to couple with the Air Pump Unit's tubing.
12. **Suction Tube:** Passes aspirated fluids out to a vacuum source.
13. **Suction Tube Connector:** Connect suction tubing from a vacuum source here.
14. **Drape Bag:** Covers the Installation Stand to prevent contamination. The Drape Bag can also be used to conveniently dispose of the Sheath.

TV-1.5 Slide-On® EndoSheath® Technology

The **TV-1.5 Slide-On® EndoSheath® Technology** shown in Figure 3-4 is a sterile, disposable barrier for the Cogentix Medical **TNE-5000** Flexible Video Esophagoscope. The Sheath isolates the endoscope from contact with patient fluid and material during the procedure, and supports air insufflation and suction.

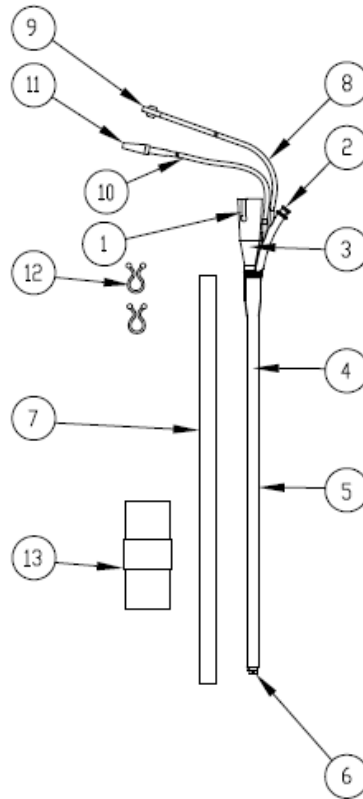


Figure 3-4: TV-1.5 Slide-On® EndoSheath® Technology

1. **Slot for Locking Knob:** Slides past the Locking Knob to secure the Sheath to the endoscope.
2. **Sealed Accessory Port:** On the **TV-1.5 Slide-On® EndoSheath® Technology**, the Accessory Port is sealed because standard accessory tools cannot be passed through the channel.
3. **EndoSheath® Connector:** Secures the Sheath to the endoscope.
4. **Insufflation Channel:** A 1.5mm channel that supports air insufflation and fluid aspiration. This channel does not support the passage of accessory tools.
5. **Insertion Tube Barrier:** A flexible, elastomeric sleeve that creates a barrier covering for the endoscope's Insertion Tube.
6. **Sheath Window:** A patented, optically clear window that covers the Distal Tip of the endoscope.

7. **Protector Tube:** Protects the Sheath from external damage during shipping, storage, and Sheath loading.
8. **Air Insufflation Tube:** Provides air to the endoscope's Distal Tip for insufflation during the procedure.
9. **Luer Lock/Air Connector:** A standard Luer-Lock Fitting Cap to couple with the Air Pump Unit's tubing.
10. **Suction Tube:** Passes aspirated fluids out to a vacuum source.
11. **Suction Tube Connector:** Connect suction tubing from a vacuum source here.
12. **Twist-Lock Clips (2):** Secures the Suction/Insufflation Tubing to the endoscope's Videoscope Cable.
13. **Drape Bag:** Covers the Installation Stand to prevent contamination. The Drape Bag can also be used to conveniently dispose of the Sheath.

DPU-5000/7000 Series Digital Video Processor

CAUTION

The **TNE-5000** Flexible Video Esophagoscope is not compatible with any other manufacturers' video processors. Attempting to connect the endoscope to or use it in conjunction with another manufacturer's video processor could cause damage to the endoscope and/or the video processor.

The **TNE-5000** Flexible Video Esophagoscope **must** be used in conjunction with a **DPU-5000/7000 Series** Video Processor (shown in Figure 3-5). Refer to the **DPU-5000/7000 Series** User's Manual for complete instructions on the operation of the unit.

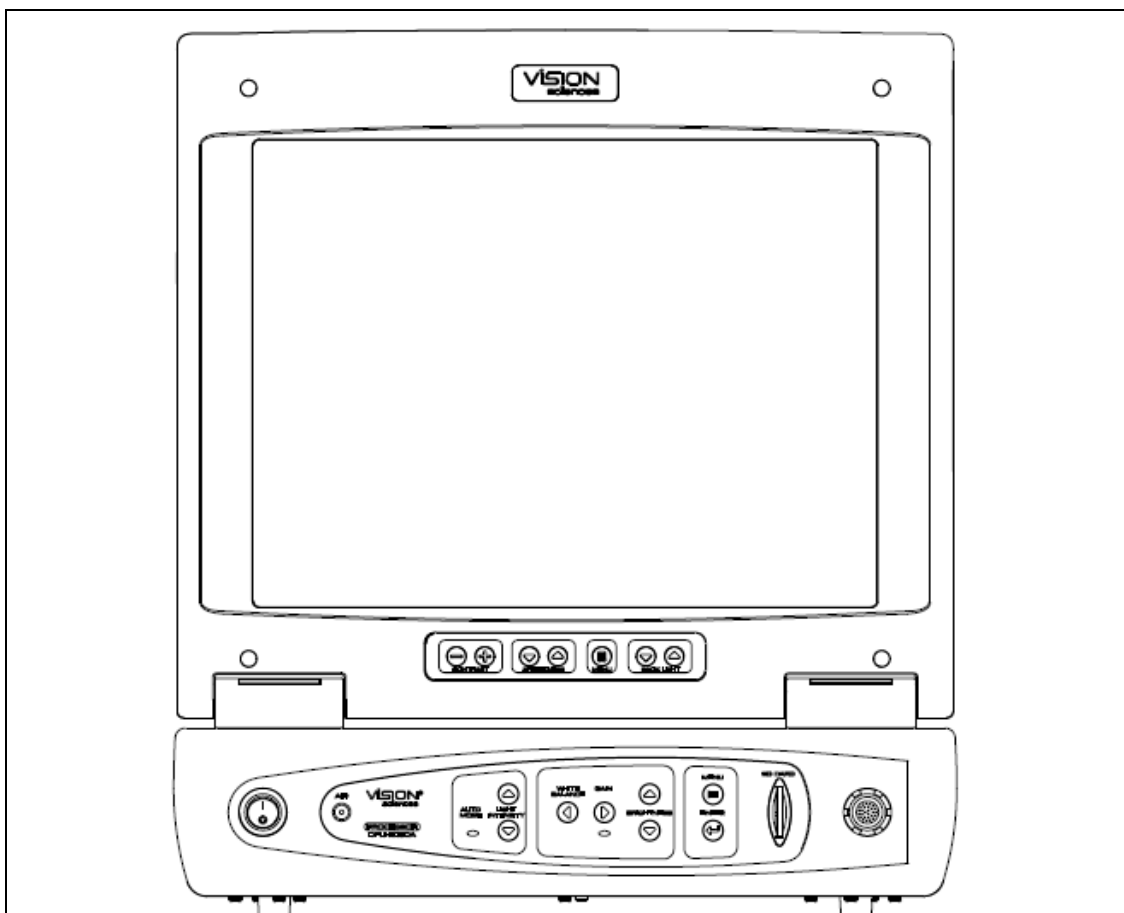


Figure 3-5: DPU-5000/7000 Series Digital Video Processor

Installation Stand

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

Refer to Figure 3-6 below and to the Installation Stand's Instructions-for-Use for information on the correct preparation and use of the stand.

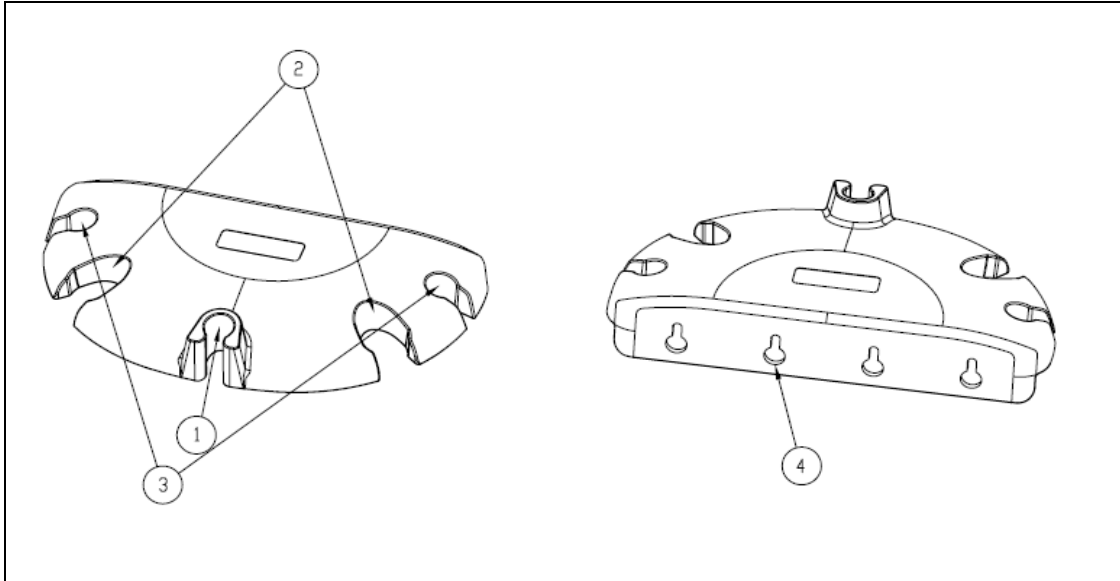


Figure 3-6: Installation Stand

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 Videoscope Cable when the endoscope is being stored.
4. **Wall-Mounting Bracket/Holes:** For mounting the Installation Stand on a wall or inside a cabinet for storage purposes.

Accessories



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 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.

Video Processor

The **TNE-5000** Flexible Video Esophagoscope is designed to work with the Cogentix Medical **DPU-5000/7000 Series** Video Processors. The endoscope is not compatible with any other manufacturers' video processors.

Light Sources

The **TNE-5000** Flexible Video Esophagoscope has an integrated, solid-state light source which is controlled by the **DPU-5000/7000 Series** Video Processors. No external light source is required for the **TNE-5000** Flexible Video Esophagoscope.

Leak Testing

The **TNE-5000** Flexible Video Esophagoscope may only be leak tested with a Cogentix Medical V1 Endoscope Leak Tester.

Reprocessing

The **TNE-5000** Flexible Video Esophagoscope 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 Accessories

The **TV-2.1 Slide-On® EndoSheath® Technology** features a 2.1mm working channel for the passage of therapeutic tools. Laryngoscopy tools and accessories that are compatible with a 2.1mm channel should be compatible with this system.

The **TV-1.5 Slide-On® EndoSheath® Technology** has a 1.5mm Insufflation/ Suction Channel which supports aspiration and air insufflation, **but does not support the passage of accessory tools.**

For further information regarding Tools and Accessories, please contact your local distributor or Cogentix Medical Customer Service Department.

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

CAUTION Installation and removal of the **Slide-On[®] EndoSheath[®] Technology** onto and from the Esophagoscope 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 Esophagoscope, 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.

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.

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 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 **TV-2.1** and **TV-1.5** Sheaths.

Prepare the Endoscope and Sheath

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.

1. Before installing the Sheath, clean the endoscope's lens on the Distal Tip with an alcohol prep pad. Do not use abrasive materials to clean any part of the endoscope, particularly the lens at the Distal Tip of the scope. Doing so could damage the lens and impair the endoscope's imaging capability.
2. Connect the **TNE-5000** video cable to the **DPU-5000/7000 Series** video processor, and turn the processor on.
3. Check the EndoSheath® disposable packaging for defects or damage.
4. Put on two pairs of sterile gloves.
5. Open the Sheath's package carefully, remove the plastic Drape Bag, unfold the Drape Bag, remove adhesive strip backing, and secure the Drape Bag to the Installation Stand with a plastic clip if necessary.
6. Remove the Sheath from the package. The Sheath should remain in the Protector Tube during installation.
7. Remove the two Control Body Cover Clips from the package and place them on a clean surface.
8. Place the Sheath into the Installation Stand with the Accessory Port facing outward (towards you). **Note:** the sheath fits into the stand in only one direction.
9. Fold back the Control Body Cover to expose the top opening of the EndoSheath® Connector.

Insert the Endoscope Into the Sheath

10. Take the endoscope in hand; make sure that the Distal Bending section of the endoscope is straight.
11. 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).**
12. Gently slide the endoscope's Insertion Tube into the Sheath. Keep the Insertion Tube as straight as possible, aligned with the shape of the insertion hole. **DO NOT TWIST** the insertion tube during insertion, doing so will cause resistance.

IMPORTANT NOTE: If there is resistance in loading the endoscope into the sheath, remove the protective tube to verify that the sheath channel is properly aligned. If the channel is misaligned, straighten channel and continue scope insertion.

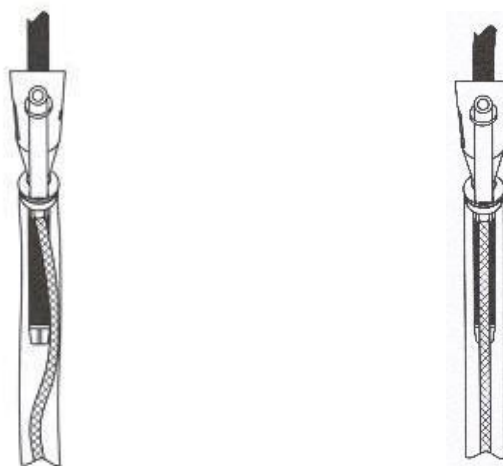
Installing and Removing the Slide-On® EndoSheath® Technology

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.

CAUTION 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 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 and the Biopsy Port on the EndoSheath® Connector during installation and removal. If there is resistance in loading the endoscope into the Sheath, remove the protective tube to verify proper alignment of the channel. If the channel is misaligned, straighten the channel and continue endoscope insertion.



MISALIGNED

ALIGNED PROPERLY

Figure 4-1: Incorrect and Correct Sheath Alignment

13. Make sure the endoscope's Locking Knob is in a vertical position.
14. Align the Locking Knob on the endoscope with the vertical slot on the EndoSheath® Connector, and continue to slide the endoscope into the Sheath until the Locking Knob is fully seated at the base of the slot.
15. Rotate the Locking Knob on the endoscope to a horizontal position. This will ensure a secure fit between the EndoSheath® Connector and the endoscope.

Connect Tubing / Complete Sheath Attachment

16. Connect the Air Insufflation Tubing to the front of the Pinch Valve Mechanism by pressing the front button and stretching the tubing against the tubing slot. When the tubing is seated in the valve, release the button. This will squeeze the Air Insufflation Channel closed.
17. Connect the Air Insufflation Tubing to the Cogentix Medical Air Source.
18. Connect the Suction Tubing to the scope's Pinch Valve Mechanism by pressing the button and stretching the tubing against the tubing slot. When the tubing is seated in the valve, release the button. This will squeeze the Suction Channel closed.
19. Connect the Suction Tubing to the external suction source.
20. Remove outer pair of gloves.

Complete System Assembly

21. Pull the Control Body Cover up over the endoscope's Control Body.
22. Secure the Control Body Cover, Air Insufflation Tubing and Suction Tubing to the videoscope cable using the Cover Clips.
23. Press the Pinch Valve to turn on and off; confirm that it operates properly.
24. Carefully remove the Sheath from the protective tube and discard the tube. DO NOT reinstall the protective tube onto the Sheath, or damage to the Sheath may result.
25. Visually inspect the window of the Sheath to confirm that the endoscope's Distal Tip is flush with the Sheath's window; if a gap is observed between the Distal Tip and the Sheath's window, move the angulation lever 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 gently to fully seat the Sheath. If the Sheath window is not fully seated, the image may be impaired.

CAUTION: DO NOT articulate the Bending Section while the protective tube is on.

26. Turn on the external Air Source and Suction Source. Verify systems are functioning properly.
27. The system is ready for use.

Observe the Endoscopic Image

The Sheath's window should now be in direct contact with the Insertion Tube's Distal Tip. To confirm this, view an endoscopic image with illumination 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 in the endoscopic image, 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 gently 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, and assure the Drape Bag is completely covering the Installation Stand.
2. Slide the sheathed endoscope into the draped Installation Stand (port facing you).
3. Disconnect the Air Insufflation Luer from the Air Source Tubing before disconnecting the Suction Tubing.
4. Disconnect the Suction Connector from the Suction Source.
5. Remove the Control Body Cover Clips and discard them. 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. Remove the Air Tube from the Pinch Valve Mechanism by pressing the front button and pulling the tubing free.
8. Remove the Suction Tubing from the Pinch Valve Mechanism by pressing the back button and pulling the tubing free.
9. Rotate the Locking Knob into the vertical position so that it is aligned with the slot on the EndoSheath® Connector.
10. Using the angulation lever, articulate the Distal Bending Section of the endoscope into the straight/neutral position.
11. Ensure the working channel is not wrapped around the insertion tube by straightening the channel with gloved fingers.
12. Hold the endoscope's Control Body in one hand. Slowly and gently withdraw the scope from the Sheath. If resistance is encountered, use the hanging outside portion of the Drape Bag as a barrier between your fingers and the Sheath, and gently grasp the Sheath's window. Then slowly and gently continue to withdraw the endoscope from the Sheath.

CAUTION

Do not rotate 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.

13. Place the endoscope in a non-contaminated area. Power off the Video Processor, Air Source and Suction Pump.
14. 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, providing that 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 Chapter 6, **Reprocessing**.
15. Collect the contaminated Sheath in the Drape Bag and remove it from the Installation Stand. Carefully discard the Drape Bag and Sheath per hospital/facility policy.
16. Proceed to the Recommended Cleaning Procedure detailed in Chapter 6, **Reprocessing**, to prepare the endoscope for the next procedure.

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 in that chapter, contact your Regional Distributor, Territory Manager, 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.

During the procedure, the temperature at the distal end of endoscope may exceed 41°C (106 °F) due to the 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 time.

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 an acute infection-control risk to the next patient.

A complete review and understanding of the **DPU-5000/7000 Series** User's Manual is recommended before using the **TNE-5000** Flexible Video Esophagoscope.

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:

Select an Installation Site

It is important to select an appropriate location in which to install the Video Processor.

- Place the Video Processor on a stable rigid surface such as a cart, counter-top, or solid stand.
- The location must not contain explosive or flammable gases.

Preparation, Inspection and Operation

- Place the **TNE-5000** Videoscope and Video Processor away from radios, televisions, cell phones, or any other devices that emit electromagnetic energy. These can interfere with proper operation. Avoid stacking the videoscope or the Video Processor on other equipment to avoid possible electromagnetic interference.
- Place the Video Processor in a dry place, and avoid contact with liquids.
- Do not allow the Video Processor's vents to be obstructed; full ventilation is necessary for proper operation. Vents are located on the bottom and back of the unit.

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 of the Insertion Tube.

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. The **DPU-5000/7000 Series** Video Processor should be powered on and ready for the procedure.

CAUTION **Turn off** the Video Processor's power switch before connecting or disconnecting the Videoscope Cable. Connecting or disconnecting the cable with the power on could damage both the endoscope and the Video Processor.

6. If not already connected, connect the Air Pump Unit's tubing to the Sheath's Air Tube. Turn on the Air Pump, press the Air Flow Button on the endoscope's Control Body, and confirm that air flows from the nozzle at the Distal Tip.
7. If not already connected, connect the Suction Tubing to the Suction Pump. Turn on the Suction Pump, press the Suction Button, and confirm that there is suction at the Distal Tip. If the tubing is not seated properly in the valve, suction will not be available.

Endoscope Operation

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. 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 and pass Accessory Devices.
2. The **DPU-5000/7000 Series** Digital Video Processor should be on; adjust the settings to the desired level using the Processor's controls.
3. Perform the White Balance procedure.
4. Prepare the patient using normally acceptable clinical practice prior to endoscope insertion.
5. 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.
6. 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.
7. Introduce the sheathed endoscope into the patient using normally acceptable clinical practice. Operate the Angulation Lever as necessary for advancement and observation.
8. When using the system through an endotracheal tube (for intubation assistance), it is extremely important to maintain proper alignment between the tube and the endoscope's Distal Bending Section.



NOTE: The four (4) buttons on the endoscope's Control Body may be programmed on the Video Processor to perform designated image-control functions. These functions include:

- Image Freeze
- Image Capture
- Image Enhancement
- Remote Activation (Copy/Print)
- Gain

Refer to the **DPU-5000/7000 Series** Video Processor User's Manual for further information on available control functions and instructions on programming the Control Buttons.

Preparation, Inspection and Operation

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.

Insufflation

Press the Air Button on the endoscope's Control Body to activate insufflation. Release the Air Button to stop insufflation.

Suction

Press the Suction Button on the endoscope's Control Body to activate suction. Release the Suction Button to stop suction.



NOTE: Recommended Suction Pressure Settings: 160 – 180 mmHg (6.3–7.1 inHg or 3.1–3.5 psi) for optimal levels, increasing in slight increments if stronger suction power is needed.

Depending on the gauge design, the suction pressure level may be displayed as either a negative (true) or positive number. Due to differences in suction equipment and accessories, suction settings may need to be adjusted to meet specific procedural needs. However, excessive suction pressure settings may collapse tubing, which will impair suction performance. The **Slide-On® EndoSheath® Technology** is validated to an upper limit of 580 mmHg (22.8 inHg or 11.2 psi).

Inserting Accessories



This section only applies to the **TV-2.1 Slide-On® EndoSheath® Technology**. **The TV-1.5 Slide-On® EndoSheath® Technology does not support tool passage.**

Do not continue advancing an accessory if excessive resistance is encountered during insertion. Excessive force may result in damage to the Sheath, endoscope, and/or accessory.

Confirm that the accessory is compatible with the Sheath's 2.1 mm Working Channel prior to insertion. If the accessory is too large, it could damage the Sheath and may compromise the integrity of the barrier.

1. Before inserting an accessory, straighten the endoscope's Distal Bending Section.
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 on the video monitor.
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 again 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 **TNE-5000** Flexible Video Esophagoscope and **Slide-On® EndoSheath® Technology** may be used with high-frequency (HF) electrosurgical 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.

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.

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

- CUT: 560 V_p
- COAG: 775 V_p
- SPRAY: 1,700 V_p

Always utilize the lowest output setting necessary on the Electrosurgical Unit. This reduces the potential for patient injury or equipment damage.

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

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

Preparation, Inspection and Operation

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

To best determine the necessary minimum output, operators should conduct basic tests before electro-surgery according to the User's Manual of the Electro-surgical Unit.

Laser Devices/Accessories

WARNING

Before using any laser devices, users 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.

Always confirm that the Distal Tip section of the laser fiber accessory is an appropriate distance from the Distal Tip of the endoscope and that the laser fiber tip is clearly in view. If the Distal Tip of the fiber is in close proximity to the endoscope's Distal Tip, or not advanced far enough beyond the Sheath, or still within the Channel during use, the endoscope and **Slide-On® EndoSheath® Technology** may be damaged and patient injury may occur.

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

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

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

CAUTION

Before inserting or removing the 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® EndoSheath® Technology**.

6 Reprocessing

The **TNE-5000** endoscopic system works in tandem with 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 an endoscope and ensures an Insertion Tube is covered with a sterile Sheath for every procedure, thus providing optimal benefit for medical personnel and patients. See **Cleaning After EndoSheath® Technology Usage** on page 37 for cleaning/disinfection procedures when using the **Slide-On® EndoSheath® Technology**.

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 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 Dept. to verify the compatibility of a cleaning method not listed in this manual and/or a complete list of functionally compatible agents.

The endoscope must be cleaned 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 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 discrete steps, each of which is essential to successful reprocessing. The steps are listed below in their proper order, and the complete instructions for each step are given in greater detail in this chapter.

- **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 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 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 37.
- **High-Level Disinfection** – If the user suspects the endoscope has become 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. It must then be thoroughly aerated to ensure that all 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 **TNE-5000** Flexible Video Esophagoscope must be evaluated for possible leaks in the Control Body and/or the Insertion Tube before immersion in any fluid. The Leak Tester accessory should be used for this test (Cogentix Medical Leak Tester is required). Follow the steps given below.

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 Leak Tester’s connector clockwise until it locks.

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.

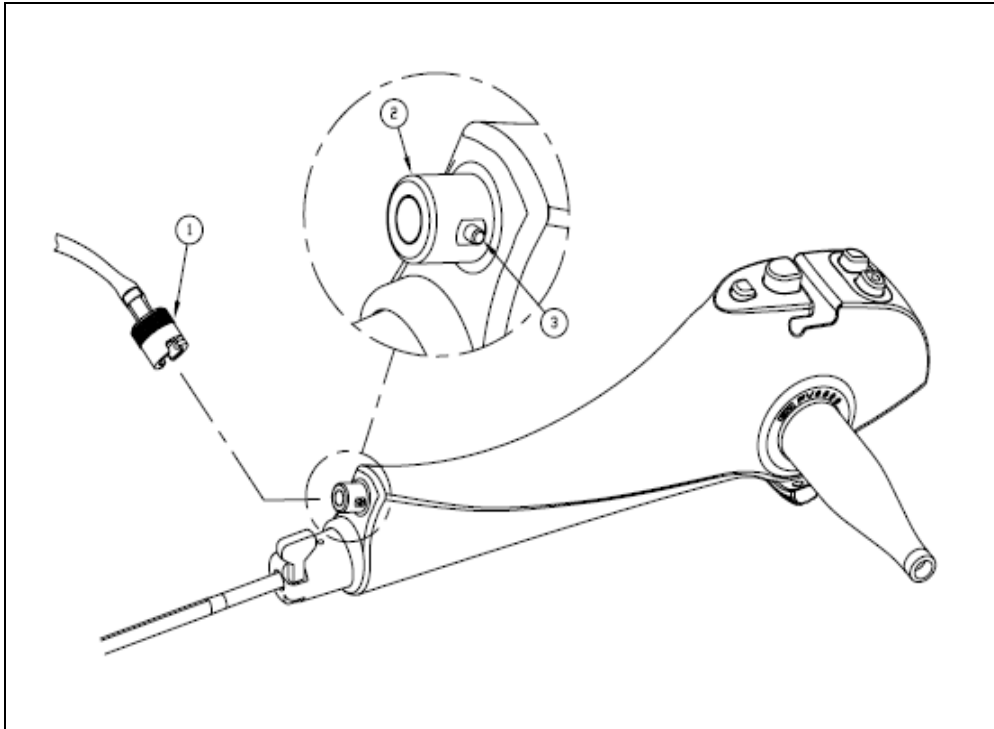


Figure 6-1: Leak Tester Connection

Leak Tester Connection Components

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

Pressurize the Endoscope

CAUTION

The Videoscope Cable's Sealing Cap must be attached to the plug end of the Videoscope Cable Connector prior to leak testing or immersion of the endoscope into water or disinfecting solution.

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 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 Sealing Cap of the Videoscope Cable may not be secured onto the plug; or the Leak Tester to endoscope connection may be loose. Check the Pressure-Relief Valve on the Leak Tester, it may still be open, and should be closed. Make sure the Sealing Cap is securely placed on the plug; remove and reattach the Leak Tester to the endoscope and repeat Steps 1 through 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 to Cogentix Medical, 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 it 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 to Cogentix Medical, 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 covering.

Cleaning, Disinfection, and 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

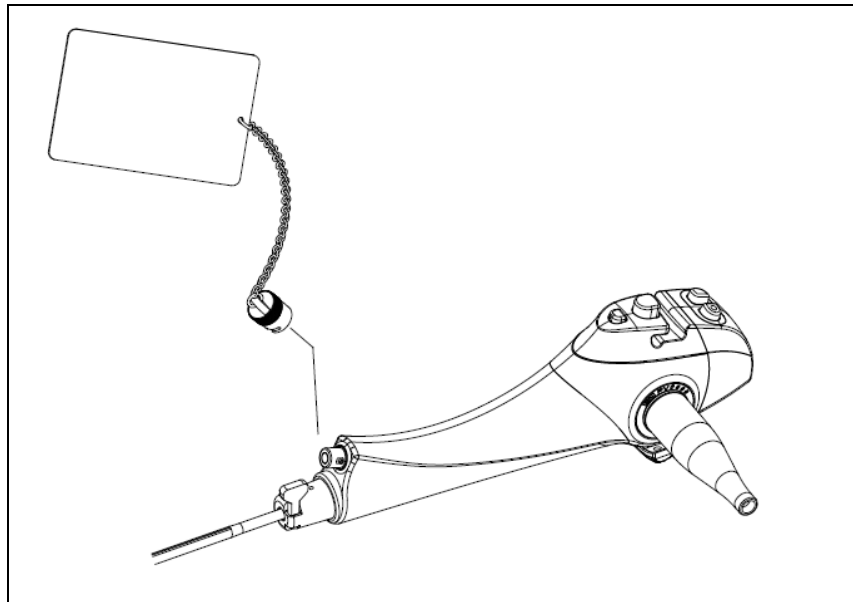


Figure 6-2: Opening the Vent Valve

Cleaning After Slide-On[®] EndoSheath[®] Technology Usage

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.



NOTE: Because the possibility exists that a Sheath could be torn, or that the endoscope or Sheath could come into contact with contaminated surfaces, the user should develop and follow a prophylactic routine which includes exercising care when handling a sheathed or unsheathed endoscope.

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 and cleaning 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. It could present an infection-control risk if not handled properly.

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 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 Disinfection and Sterilization Procedures

The following procedures have been determined by Cogentix Medical to be compatible with the **TNE-5000** Flexible Video Esophagoscope.

- **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 **Ethylene Oxide (EtO) Gas Sterilization** section on page 41.

- **Sterilization by STERRAD®:** The endoscope may be sterilized using a validated **STERRAD®** protocol. Refer to Table 6-1 on page 42 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 42 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	<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 STERIS® / STERRAD® compatibility

Incompatible Methods

The high-level disinfection and sterilization chemicals and methods shown below are not compatible with the **TNE-5000** Flexible Video Esophagoscope; **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	<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 interfere with proper disinfection. **In the event that the endoscope fails the leak test, do not immerse the endoscope in liquids and do not use it in a procedure. Return the endoscope to the manufacturer for repair.**

Make sure that the sealing cap is securely attached to the Videoscope Cable prior to immersion. **Failure to do so will lead to fluid invasion and severe equipment damage.**

Pre-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 gross 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 **TNE-5000** Flexible Video Esophagoscope 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/or softer materials of the endoscope.

The Videoscope Cable's Sealing Cap must be removed from the Videoscope Cable Connector prior to EtO gas sterilization.

EtO Gas Sterilization Parameters

Temperature: $125^{\circ} \pm 5^{\circ}\text{F}$ ($52^{\circ}\text{C} \pm 3^{\circ}\text{C}$)

Relative Humidity: $50\% \pm 10\%$

EtO Concentration: 600 mg/liter

Exposure Time: 3 hours + 1/-0 hour

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, pre-cleaned and dried as described for the High-Level Disinfection Protocol.

CAUTION

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 Fig 6-2 (page 37) 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 **TNE-5000** Flexible Video Esophagoscope 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 videoscope 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

Compatibility applies **only** to endoscopes which feature the (S) symbol located on the Identification Ring on the Control Body.

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 such circumstances.

Storage

Follow the instructions below when storing the **TNE-5000** Flexible Video Esophagoscope:

- **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 Videoscope Cable may be stored either straight or neatly coiled to prevent kinking or bending.
- The endoscope should be completely clean and dry before storing.
- This equipment 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 intended 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 repairs using the information given in Chapter 9, **Warranty and Service**.

The **TNE-5000** Flexible Video Esophagoscope requires a video processor to process and display images. In order to identify issues related to image problems, you may also have to refer to the Troubleshooting chapter in the **DPU-5000/7000 Series** Video Processors User's Manual.

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 9, 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 9, 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 9, 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 videoscope'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 9, Warranty and Service. ⇒ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.

Table 8-1: Troubleshooting

PROBLEM	PROBABLE CAUSE	ACTION
No image	<ul style="list-style-type: none"> • Video processor is not powered on. • Connection between the endoscope and the Video Processor is lost. • No video output signal to a monitor. 	<ul style="list-style-type: none"> ⇒ Check the power cord connection and fuses, or connect the Video Processor to a different mains outlet. ⇒ Check the cable connection between the endoscope and the Video Processor. ⇒ Check the video output cable connections when using an external monitor. Replace the cable if necessary. ⇒ If the problem cannot be corrected, send the endoscope and Video Processor to Cogentix Medical for repair.
Poor quality image from an unsheathed endoscope	<ul style="list-style-type: none"> • Patient debris or other material on the Objective Lens. • Improper settings on the Video Processor or display. • Damaged optics, sensors or electronics in the endoscope. 	<ul style="list-style-type: none"> ⇒ 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 the settings on the Video Processor or display. Perform a White Balance procedure on the Video Processor. ⇒ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.

Table 8-1: Troubleshooting (cont'd)

Troubleshooting

<p>Loss of illumination</p>	<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. • Internal light source is deteriorating. 	<ul style="list-style-type: none"> ⇒ Clean the Distal Tip with an alcohol prep pad to remove material or stains. Excess staining may not be correctable and the lens may require replacement. ⇒ Adjust the Light Intensity setting. ⇒ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service. ⇒ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.
<p>Wrinkles and/or folds in the Insertion Tube</p>	<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. 	<ul style="list-style-type: none"> ⇒ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.
<p>Insertion Tube is dented</p>	<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]. 	<ul style="list-style-type: none"> ⇒ Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.
<p>Loss of pressure during the leakage test</p>	<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. 	<ul style="list-style-type: none"> ⇒ 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.

Table 8-1: Troubleshooting (cont'd)

<p>Cannot insert endoscope into the Sheath</p>	<ul style="list-style-type: none"> • 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. • The Sheath's Window is not aligned with the Insertion Tube. • The flat portion of the D-shaped Insertion Tube is not aligned with the Biopsy Port during insertion. • The Sheath is torn or punctured. 	<ul style="list-style-type: none"> ⇒ Straighten the channel before continuing scope insertion. ⇒ Make sure that the Locking Knob is positioned vertically. Align the Locking Knob with the slot and fully seat the endoscope into 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. ⇒ 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. ⇒ Align the flat side of the Insertion Tube with the Sheath's Accessory Port. ⇒ Replace the Sheath.
<p>Cannot remove the endoscope from the Sheath</p>	<ul style="list-style-type: none"> • The Locking Knob not rotated. • The endoscope has become twisted during removal. • Sheath is torn or punctured. • The Sheath's channel is wrapped around the Insertion Tube. 	<ul style="list-style-type: none"> ⇒ Rotate the Locking Knob to the vertical position. ⇒ Align the flat side of the endoscope's Insertion Tube with the Sheath's Accessory Port during removal. ⇒ Contact your regional distributor or Cogentix Medical Customer Service Department for removal instructions. ⇒ Straighten the channel before gently removing the Sheath.

Table 8-1: Troubleshooting (cont'd)

Troubleshooting

<p>Cannot remove the endoscope from the Sheath (cont'd)</p>	<ul style="list-style-type: none"> • The Sheath has been attached to the endoscope for an extended period of time, causing it to adhere to the Insertion Tube. • The Distal head is lodged in the Sheath. 	<ul style="list-style-type: none"> ⇒ 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 for removal instructions. Disinfect / sterilize the endoscope. ⇒ Gently grasp the Sheath's 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.
<p>Glare in the endoscopic image</p>	<ul style="list-style-type: none"> • The sheath's Window is not in contact with the Distal Tip of the endoscope due to: <ul style="list-style-type: none"> - Incomplete insertion into the Sheath. OR - The endoscope's tip is damaged and/or enlarged. 	<ul style="list-style-type: none"> ⇒ 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. ⇒ Remove the endoscope from the Sheath. Return the endoscope to Cogentix Medical for repair. Refer to Chapter 9, Warranty and Service.
<p>Suction or insufflation is observed without the Pinch Valve Button pressed</p>	<ul style="list-style-type: none"> • The Control Body Cover is draped too tightly around the Suction Valve. • Suction/Insufflation Tubing is not properly positioned in the Pinch Valves. • The Sheath's Window is damaged. 	<ul style="list-style-type: none"> ⇒ Relieve tension on the Suction Valve by adjusting the Control Body Cover. ⇒ Properly position the Suction/Insufflation Tubing in the Pinch Valve. ⇒ Remove the Sheath and install a new one.

Table 8-1: Troubleshooting (cont'd)

<p>Insufficient or no suction during procedure</p>	<ul style="list-style-type: none"> • Suction level is set too low or the unit is malfunctioning. • Suction/Insufflation Tubing is too tight in the Pinch Valve. • Suction tubing is kinked or crushed. • Suction tubing is open to the atmosphere. • The wall of the Working Channel is occluded with foreign matter. 	<ul style="list-style-type: none"> ⇒ Confirm that the suction pump is set properly. Disconnect the suction line from the Sheath and test the suction level through the tubing. Reconnect the suction line. ⇒ Relieve tension on the tubing by repositioning it to create more slack. ⇒ Straighten out the suction tubing. Make sure that the plastic clips are holding the tubes to the umbilical. Take care not to apply tension to the suction tubes. ⇒ The suction tubing may have become disconnected. Re-attach the tubing to the suction pump. ⇒ Stop applying suction. Attempt to clear the channel by passing air through it. Re-try suction. OR: Remove the endoscope from patient and inject 10cc of saline through the channel. If, after repeated attempts, the channel remains blocked, remove the endoscope from the Sheath and install a new Sheath.
---	--	--

Table 8-1: Troubleshooting (cont'd)

Troubleshooting

<p>Insufficient or no air during the procedure</p>	<ul style="list-style-type: none"> • Pressure level of air source set too low or the unit is malfunctioning. • Tubing is not seated properly in the Pinch valve. • The Sheath's Air Channel is occluded. 	<p>⇒ Confirm the settings of your air pump. Disconnect the air line from the Sheath and test the pressure level through the tubing.</p> <p>⇒ Seat the tubing properly.</p> <p>⇒ Actuate the air valve to clear the nozzle. Check air tubing for leaks or blockages. If, after repeated attempts, the channel remains blocked, remove the Sheath from endoscope and install a new Sheath.</p>
<p>Accessory will not pass through the Sheath's Suction/ Working Channel</p>	<ul style="list-style-type: none"> • Accessory is too large. • The channel is occluded by patient debris. • The endoscope's Distal Bending Section is angulated. 	<p>⇒ Check the diameter of accessory. Make sure that the accessory is compatible with a 2.1 mm Working Channel.</p> <p>⇒ 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.</p> <p>⇒ Maneuver the endoscope's Distal Tip to an area of the anatomy in which it can safely be straightened out. Insert the accessory until its tip can be seen on the endoscopic image. Now angulate the endoscope's Distal Bending Section and proceed to the desired area.</p>

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 **TNE-5000** Flexible Video Esophagoscope 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 **TNE-5000** Flexible Video Esophagoscope 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 **TNE-5000** Flexible Video Esophagoscope 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

TNE-5000 Flexible Video Esophagoscopes 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: customer care@cogentixmedical.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 **TNE-5000** Flexible Video Esophagoscope 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 Cogentix Medical or authorized facility.

If the **TNE-5000** Flexible Video Esophagoscope 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 down the endoscope 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 TNE-5000

Insertion Tube Diameter (Nominal)	TV-2.1 Sheath (Cat. No. 03-5101)	5.6 mm (with sheath)
	TV-1.5 Sheath (Cat. No. 03-5102)	5.2 mm (with sheath)
Insertion Tube Working Length		650 mm
Field of View		110°
Direction of View		Forward
Depth of Field		3 - 50 mm
Environmental Effects on Optical Performance		None
Angulation		215° down/140° up
Working Channel Diameter	TV-2.1 Sheath (Cat. No. 03-5101)	2.1 mm (6.3 Fr.)
	TV-1.5 Sheath (Cat. No. 03-5102)	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
Electromagnetic Compatibility		IEC 60601-1-2
Degree of Protection Against Electrical Shock		Type BF
Degree of Protection Against Ingress of Liquids		Fully Immersible (as per Reprocessing Instructions)

Table A-1: Specifications

Infection Control Information

The **Slide-On® EndoSheath® Technology** for the **TNE-5000** Flexible Video Esophagoscope 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 microorganisms 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® Barriers** 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"

Electromagnetic Compatibility Declarations



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.

Guidance and manufacturer's declaration – electromagnetic emissions		
The TNE-5000 Flexible Video Esophagoscope with the DPU-5000/7000 Series Video Processor [the "System"] is intended for use in the electromagnetic environments specified below. The customer or the user of the System should ensure that it is always used in such environments.		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The System is suitable for use in all non-domestic establishments, excepting those directly connected to a public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table A-2: Electromagnetic Emissions Declaration

Guidance and manufacturer's declaration – electromagnetic immunity			
The TNE-5000 Flexible Video Esophagoscope with the DPU-5000/7000 Series Video Processor [the "System"] is intended for use in the electromagnetic environments specified below. The customer or the user of the System should ensure that it is always used in such environments.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for input/output lines	±2kV for power supply lines ±1 kV for input/output lines	Mains power quality should be the equivalent of that in a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be the equivalent of that in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% dip U_T for 0.5 cycle 60% dip U_T for 5 cycles 30% dip U_T for 25 cycles 95% dip U_T for 5 sec	Compliant with all levels of voltage dips for $U_T = 100$ VAC and $U_T = 240$ VAC	Mains power quality should be the equivalent of that in a typical commercial or hospital environment. If the user of the System requires continued operation during power mains interrupts, it is recommended that the System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a standard commercial or hospital environment.

Table A-3: Electromagnetic Immunity Declaration


Guidance and manufacturer’s declaration – electromagnetic immunity				
The TNE-5000 Flexible Video Esophagoscope connected to the DPU-5000/7000 Series Video Processor [the “System”] is intended for use in the electromagnetic environment specified below. The customer or the user of the System should assure that it is always used in such environments.				
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment	– guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V		Portable and mobile RF communications equipment should be used no closer to any part of the System, including cables, than the recommend separation distance calculated from the equation applicable to the frequency of the transmitter. Recommend separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80MHz to 800MHz $d = 2.33\sqrt{P}$ 800MHz to 2.5GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m		where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies.				
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the System is used exceeds the applicable RF compliance level above, the System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary such as re-orienting or relocating the System.				
^b Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 v/m.				

Table A-4: Electromagnetic Immunity Declaration

Recommended separation distances between portable and mobile RF communications equipment and the System			
<p>The TNE-5000 Flexible Video Esophagoscope connected to the DPU-5000/7000 Series Video Processor [the "System"] is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below according to the maximum output power of the communications equipment.</p>			
Radiated maximum output power of transmitter	Separation distance according to frequency of transmitter		
	m		
W	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$D = [3.5/V_1]\sqrt{P}$	$D = [3.5/E_1]\sqrt{P}$	$D = [7/E_1]\sqrt{P}$
0.01	D = 0.12	D = 0.12	D = 0.23
0.1	D = 0.37	D = 0.37	D = 0.74
1	D = 1.17	D = 1.17	D = 2.33
10	D = 3.69	D = 3.69	D = 7.38
100	D = 11.67	D = 11.67	D = 23.33
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance, d, in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p>			
NOTE 1:	At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.		
NOTE 2:	These guidances may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

Table A-5: Recommended Separation Distances

Cogentix

Medical



Cogentix Medical, Inc.
40 Ramland Road South
Orangeburg, NY 10962 USA
Tel.: 866 258-2182 (toll free in U.S.)
Tel.: (+1) 952 426-6189 (international)
Fax: 866 255-4522 (toll free in U.S.)
Fax: (+1) 952 426-6199 (international)
email: customercare@kogentixmedical.com

www.kogentixmedical.com

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



MedPass International Ltd.
Windsor House, Bretforton
Evesham, Worcestershire
WR11 7JJ, United Kingdom



© 2008, 2009, 2011, 2012, 2013, 2015 Cogentix Medical, Inc. Slide-On and EndoSheath are registered trademarks of Cogentix Medical, Inc.

EndoSheath® products in this manual are covered by one or more of the following U.S. Patents: 6,350,231; 6,530,881; 6,733,440. Other U.S. and international patents pending.

(10/15) 09646-EN Rev. E (12315)