Instructions for Use

MACHIDA
Flexible Scope

49-5020 ENT-2L Pediatric (Ø2.1mm)
49-5030 ENT-3L Slim Line (Ø3.2mm)
49-5040 ENT-4L Standard (Ø4.2mm)

Operating / Service Manual

IMPORTANT: *Read all instructions before assembling or using this device.*

anthony products, inc.

Laryngo-Nasopharyngoscope

For decades, JEDMED Instrument Company has built its reputation on principles of quality, integrity, innovation and value. Continuous research and development coupled with exceptional customer service and a world-class quality system has placed JEDMED as an industry leader.

As always, our focus remains on you, our valued customer. Building rewarding and lasting relationships is the cornerstone of JEDMED's business philosophy. JEDMED is committed to delivering reliable and cost-effective solutions to medical professionals everywhere.

The employee-owners of JEDMED would like to take this opportunity to thank you for all your support. We are pleased and proud to serve the ever-changing medical community.

Sincerely,

JEDMED

pmnl041
Rev. 2
12-2015

CONTENTS

Note: *Specifications subject to change without notice.*

The following conventions are used throughout this manual:

⚠ **WARNING** Alerts user to the possibility of ***PERSONAL INJURY.***

❖ **CAUTION** Alerts user to the possibility of ***DAMAGE to the EQUIPMENT***.

➢ **NOTE** Alerts user to ***PERTINENT FACTS or CONDITIONS***.

❖ **CAUTION**

Federal (USA) law restricts this device to sale by or on the order of a physician.

➢ **NOTE**

This manual covers operation of this endoscope and is not a substitute for working-knowledge of the physician.

Safety Precautions

(general)

- Allow operation only by qualified personnel.
- Do not leave device(s) operating while unattended.
- **Scope is shipped in a non-aseptic condition. Scope must be cleaned and disinfected before use.**
- **Always use "Universal Precautions" when handling potentially infectious material.**
- **Always clean and disinfect endoscopes between each patient.**
- **All fiberoptic light sources should be medical-grade, electrically isolated, and not pose a heat risk to the patient.**
- **MACHIDA fiberoptic bundles are fragile. Use care cleaning, handling and storing.**
- **When using fiberoptic light sources, keep flammables away from light port, fiberoptic cable ends and endoscope tip.**
- Disconnect from power before cleaning, servicing or storing.
- All cleaning and disinfecting should only be performed by appropriately-trained individuals.
- Do not allow liquid to enter any part of this device.

Additional Precautions and Warnings are found on page 13 and throughout this manual.

DESCRIPTION & INDICATIONS FOR USE

MACHIDA's laryngo-nasopharyngoscope is a flexible fiberoptic endoscope designed for examining the larynx, nasal cavity and nasopharynx. These areas encompass the upper respiratory tract from the nasal passages to the vocal chords. MACHIDA scopes are intended to be used by ENT physicians in an office setting for routine ENT procedures.

MACHIDA scopes are available in three sizes: the 2.1mm pediatric insertion tube diameter (ENT-2L), the 3.2mm slim-line insertion tube diameter (ENT-3L) and the 4.2mm standard insertion tube diameter (ENT-4L).

An industry-standard endoscope eyepiece allows the user to look through the scope, directly, or to indirectly observe the field by attaching an optional endoscope coupler and video camera.

A MACHIDA scope is a quality-designed and manufactured medical device. Given reasonable care, this product will provide many years of trouble-free service.

> ➢ **NOTE**
> MACHIDA laryngo-nasopharyngoscope is also referred to as "device", "instrument" and/or "scope" throughout this manual.

CONTENTS

Carefully unpack all components. Verify contents and inspect for shipping damage.

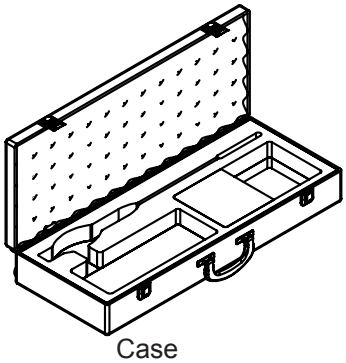
> ➢ **NOTE**
> Any shipping damage should be documented and reported immediately to the carrier or JEDMED.

> ➢ **NOTE**
> Ethylene Oxide Gas Sterilization is also referred to as "EtO", "EO" and/or "EOG" throughout this manual.

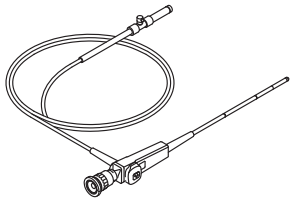
Item	Item No.	ENT-2L System (2.1mm diameter)	ENT-3L System (3.2mm diameter)	ENT-4L System (4.2mm diameter)
49-5020	Scope (ENT-2L)	1	0	0
49-5030	Scope (ENT-3L)	0	1	0
49-5040	Scope (ENT-4L)	0	0	1
49-4990	Case	1	1	1
49-5085	EOG/EtO Adaptor	1	1	1
49-51xx	Light Source Adaptor (See page 9)	1	1	1

Refer to next page for illustrations.

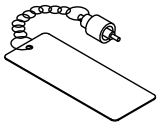
Package Contents



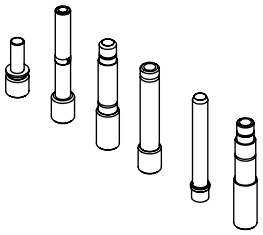
Case
(Actual case may be vary)



Scope

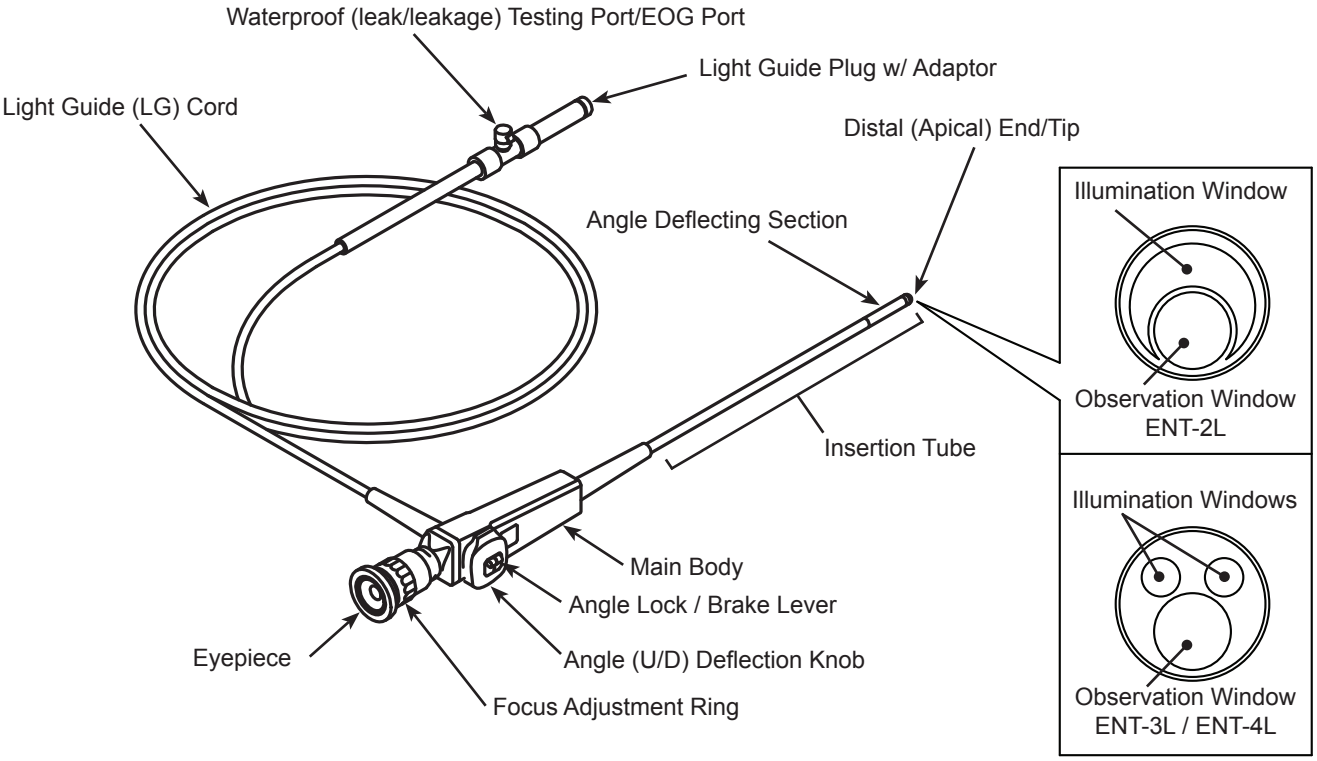


EOG Adaptor/
Ventilation Cap



Light Source
Adaptor
(one adaptor included, customer choice)

Features



Functions:

Eyepiece

Lens system used to enlarge and image the object in view. When looking through the eyepiece, a "V"-shaped pointer can be seen. This pointer indicates the "up" side of the scope and aids in the orientation of the viewed object.

Focus Adjustment Ring

Focus adjustment ring which moves the eyepiece in and out to allow for a clear, focused image. Alignment of colored dot (on ocular) and colored line (on focus ring) put scope at infinity focus.

Angle Deflection Knob

Knob that controls the direction and degree of deflection at the distal end. Turning this dial in either the "U" (up) or "D" (down) direction will cause the tip of the scope to be deflected up or down respectively.

Angle Lock/Brake Lever

Cam action lever which engages the brake. Turning this lever to "E" (engage) will cause the deflection to be fixed at any desired position. When the lever is moved to "F" (free), the deflection will no longer be fixed and the scope will return to the straight (at rest) position.

❖ **CAUTION**
Never apply external force to scope distal end when brake is engaged. Permanent damage to scope may result.

Main Body

Plastic housing containing internal components. Sealed to withstand soaking.

Insertion Tube

Flexible protective tubing containing angle controlling wires, fiberoptic image guide and light guide. This part is inserted into the patient's nasal cavity.

❖ **CAUTION**
All scopes are delicate instruments. Never forcefully twist, pull or bend the insertion tube and avoid excessive shock.

Angle Deflecting Section

Flexible portion of the scope which articulates when the angle deflection knob is rotated.

Distal (Apical) End

This part incorporates the objective lens, control wire attachments and illumination/observation windows.

Light Guide/Universal Cord

A reinforced protective jacket containing the fiberoptic illumination bundles. This transmits light from the light source to the distal end of the scope.

Waterproof Testing/EOG Aeration Terminal

A spring ball luer-lock used for both waterproof testing and for aeration during sterilization using Ethylene Oxide Gas.

> ❖ **CAUTION**
>
> Do not modify a waterproof test terminal.

Light Guide Plug w/Plug Sleeve

Metal connector for attachment to light source. The removable sleeves are designed for multiple types of light source adaptors including: Karl Storz, ACMI/Olympus, Wolf/Dyonics, Machida, Pentax and Kay.

Light Guide/Illumination Windows

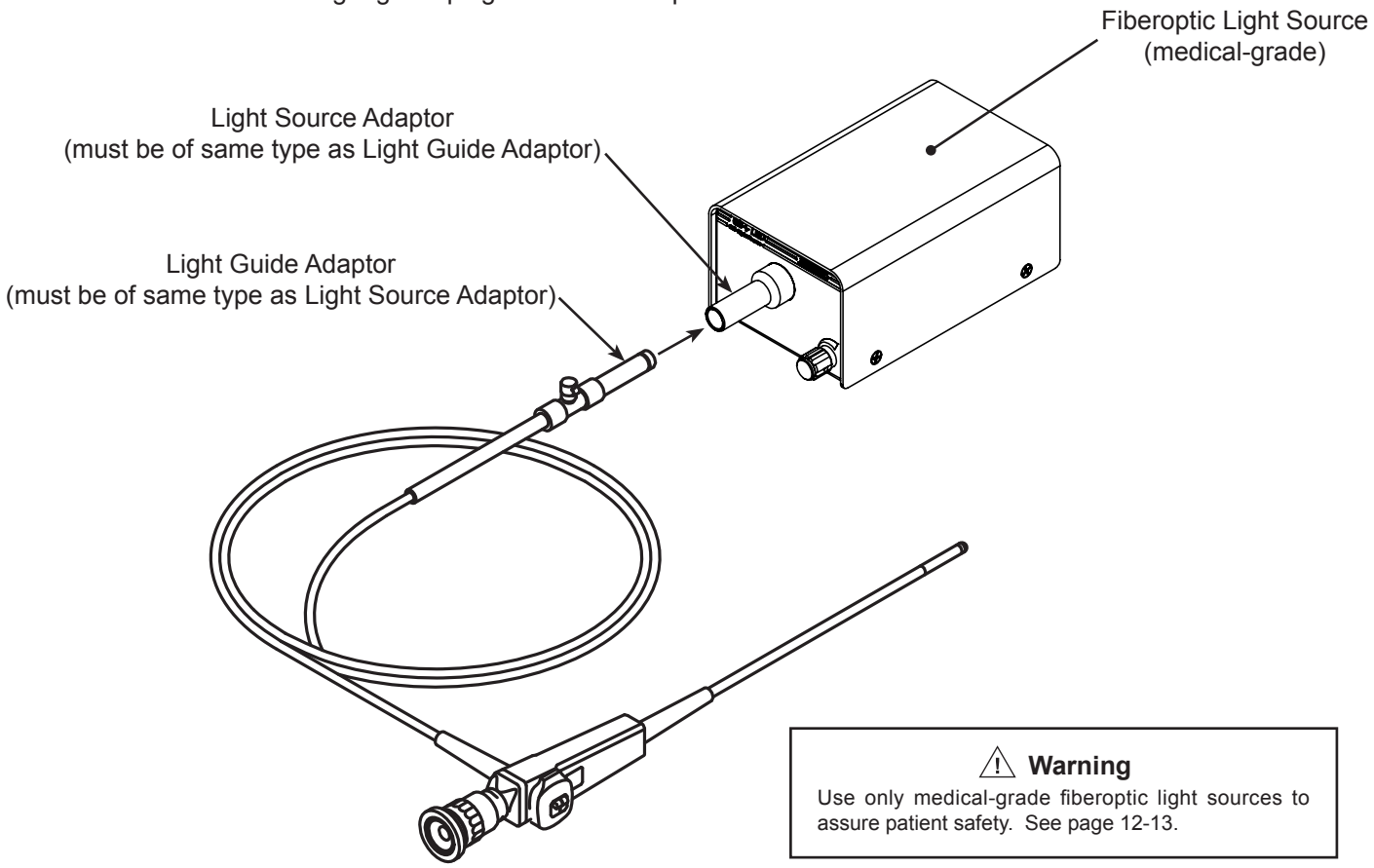
Termination point of the fiberoptic illumination bundle which produces the illumination field.

Fiberoptic Image Guide/Observation Window

Termination point of the fiberoptic image guide which produces the field of view.

Basic Connections

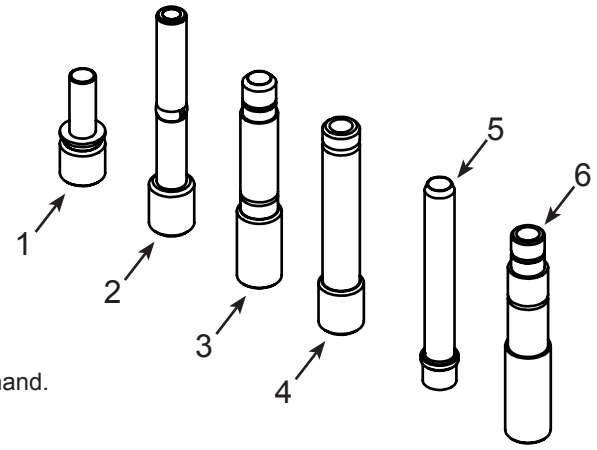
1. Screw on light guide adaptor that is of the same type as the light source adaptor (Machida to Machida, K. Storz to K. Storz,...).
2. Connect light guide plug with adaptor to suitable fiberoptic light source. Do not use light guide plug without an adaptor.



⚠ Warning
Use only medical-grade fiberoptic light sources to assure patient safety. See page 12-13.

Light Port Adaptors

1. 49-5102 Karl Storz adaptor
2. 49-5104 Olympus/ACMI adaptor
3. 49-5106 Wolf/Dyonics adaptor
4. 49-5108 Machida adpator
5. 49-5110 Pentax adaptor
6. 49-5112 Kay Elemetrics adaptor

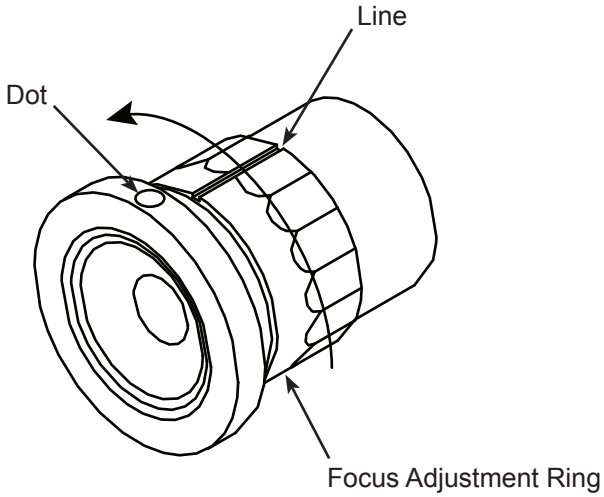


Simply screw adaptors on or off by hand.

> ⚠ **WARNING**
>
> Scope is not aseptic, as received. Scope MUST be cleaned and disinfected before initial use and between each patient.

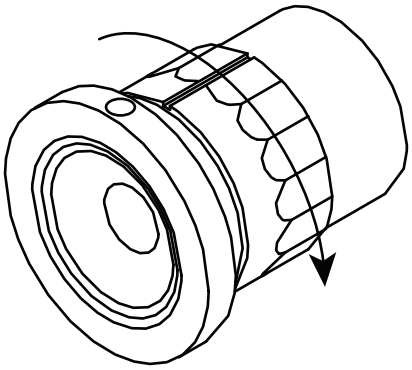
> ➢ **NOTE**
>
> Focus settings will vary with each individual user.

Users wearing glasses or contact lenses
(corrected vision)



Rotate focus adjustment ring counter-clockwise until it stops to align dot with line (infinity focus).

Users who remove glasses or contact lenses
(uncorrected vision)



Rotate focus adjustment ring clockwise to achieve sharpest image (starting from infinity focus).

DEVICE OPERATION - Angulation

Ensure angle lock lever is in the “F” (free) position.

Hold scope comfortably in hand. Use thumb to gently rotate angle deflection knob clockwise and counter-clockwise. Observe corresponding angulation of the scope distal end. Movement should be smooth.

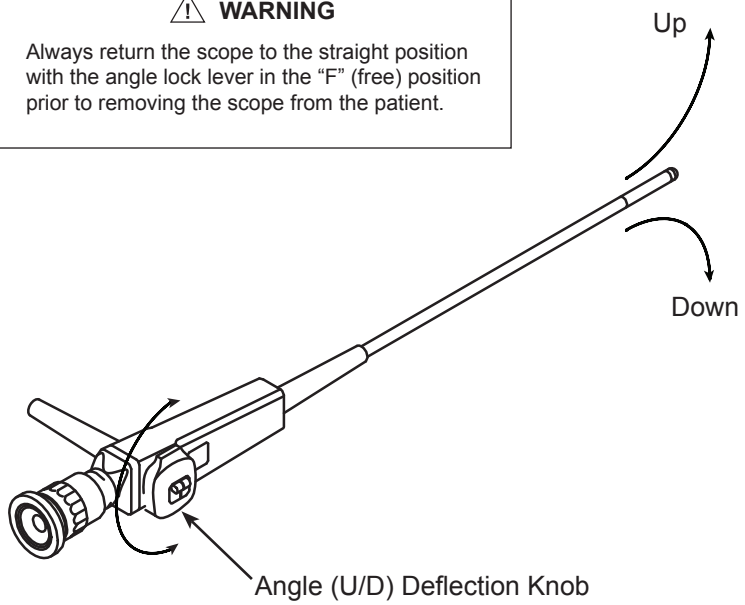
Moving angle lock lever to “E” (engage) position will lock deflection angle of distal tip. Moving angle lock lever back to “F” (free) position will unlock deflection angle.

⚠ WARNING

Always return the scope to the straight position with the angle lock lever in the “F” (free) position prior to removing the scope from the patient.

❖ CAUTION

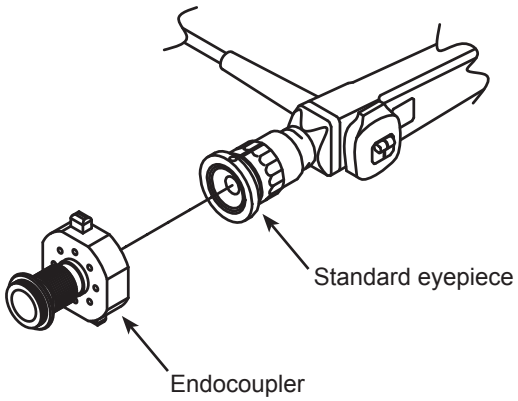
Never apply external force to scope distal end when brake is engaged. Permanent damage to scope may result.



DEVICE OPERATION - Video Cameras

Connection

To connect scope to a video camera, first connect video camera to any standard endocoupler. Next, connect the endocoupler to the scope at the common eyepiece interface. Rotate focus adjustment ring to align white line to white dot on eyecup. Focus as needed using focus ring on endocoupler.



Moiré

Moiré effects may occur whenever a fiber scope is viewed on a video camera. It displays as an odd, interference pattern on the video monitor. Moiré results from the pattern of the image fibers aligning with the pattern of pixels on the image chip of the camera.

To minimize moiré effects, rotate endocoupler slightly on eyepiece of scope to un-align fibers with pixels. Slightly defocusing the image may also be effective.

All video cameras should be medical-grade!

Background

High-intensity light sources used for endoscope illumination may pose multiple risks to the patient and/or user. Primary risks include patient burns, fire and electrical shock. It is important to understand and limit these risks in all cases.

Many types and manufacture of fiberoptic light sources are readily available. Common types include: halogen (incandescent), light-emitting diode (LED), metal-halide, and xenon-arc. In general, all light sources and cables must be medical-grade to ensure patient safety.

Heat / Burn Hazards

Each light source emits different amounts of heat associated with the light, depending on the nature of the light and type of construction. LED sources typically emit the least heat, while xenon-arc sources generally emit the most.

Emitted light may cause the tip of the scope to heat, at times, significantly. Additionally, the emitted light may be absorbed by tissue or material upon which it is shining, also causing significant heating. Broken or missing heat filters, incorrect lamps in sources and incorrect fiberoptic cable adaptors can also affect heat at the distal tip.

Before use, be sure to test any light source with the scope to determine that the tip temperature remains as cool as possible (ideally under 41ºC/106ºF) and that the emitted light does not cause excessive heating of tissue. Tip temperatures exceeding 41ºC/106ºF may be allowable, in some instances, depending on location of viewing, type of tissue contact and duration of use, among others.

In all cases, it is imperative to assure that tip heat and/or emitted light does not cause an unacceptable risk to the patient or user.

Fire Hazards

Along with patient burns, extreme light output at the tips of endoscopes can also be a fire hazard. Always keep scope tip away from flammable materials and turn off light source when not in use.
Never leave light operating while unattended.

Electrical Shock Hazard

Leakage current is always present on some level in mains (ac) powered equipment. In some cases, leakage current can be felt by the patient as a tingling sensation on sensitive tissue such as mucus-lined nasal passages. To minimize any possibility of macro or micro shock from fiberoptic light sources, all sources used must be Type BF and medical-grade. BF indicates that each device is “floating” and not electrically connected to the patient in any fashion.

⚠ WARNING

Explosion Hazard - Do NOT use in the presence of flammable anesthetics!

Due to the extreme nature of arc-lamps, JEDMED does not recommend using xenon-arc sources with this endoscope.

DEVICE OPERATION - List of Warnings

⚠ **WARNING -** Endoscope tip may become hot depending on the particular fiberoptic light source used. ALWAYS test tip temperature and heat emitted from scope tip before use. ALWAYS ensure either condition does not cause an unacceptable risk to the patient or user.

⚠ **WARNING -** High-intensity, radiated light may be transmitted from the light emission window at the front of the scope. To minimize potential heat-related issues, ALWAYS observe the following:

- Turn off or minimize light source intensity when scope is not in use.
- Before use, always test temperature of light emitted from scope tip to determine adequacy.
- Do not allow light emitted from scope tip near sensitive tissue or near flammable objects.
- Do not use more light than required to complete the task at hand.
- Do not leave light source operating while unattended.

⚠ **WARNING -** In the event of a scope malfunction (example: loss of light or angulation function) ALWAYS terminate examination as soon as possible and carefully remove scope from patient so as to minimize any risk or harm to the patient.

⚠ **WARNING -** ALWAYS verify any fiberoptic light source used contains the manufacturer's specified lamp and any associated optical filters.

⚠ **WARNING -** This endoscope is intended to be "floating" or electrically isolated from any other equipment it is attached to. In order to achieve this, any fiberoptic light sources, video cameras or other equipment attached to the scope MUST be medical-grade and type BF (floating or electrically isolated connections).

⚠ **WARNING -** Before each use, ALWAYS inspect outer surface of scope to ensure there are no unintended rough surfaces, sharp edges or protrusions which could cause harm.

⚠ **WARNING -** When using a video camera on this endoscope, ALWAYS verify a live video image is being observed (as opposed to a stored image in memory) before beginning an examination. Likewise, after storing a video image in memory, always verify a live video image is being observed before continuing examination.

⚠ **WARNING -** NEVER use this endoscope (or any high-frequency cautery or endotherapy device) in the presence of flammable or explosive concentrations of medical gases or anesthetics.

⚠ **WARNING -** All electrical equipment connected to this equipment will produce patient leakage currents which are additive.

⚠ **WARNING -** In the case where this endoscope is used along with LASER equipment, ALWAYS observe all pertinent safety precautions governing laser devices including, but not limited to:

- User should wear suitable, laser-filtering, eye protection.
- Never shine a laser beam directly into any person's eye(s)

⚠ **WARNING -** Before using with accessories or other endoscopic devices, check compatibility of this scope with the criteria for safe use as defined in the equipment's instructions for use.

Before Use

Leak test scope to verify no leaks
(pages 15-17)

Clean and disinfect scope
(pages 18-21)

Check Scope Functions

1. Connect scope to light source
   (pages 9, 12)
2. Look through scope to observe bright, clear image.
3. Move angle deflection knob and observe corresponding movement of angulation section.
4. Inspect insertion tube and distal tip to verify both are smooth and unblemished.
5. Test eyepiece focus adjustment.
6. Place scope near representative (anatomical) target and verify colors observed by naked eye under ambient light appear consistent with those observed through scope using intended fiberoptic illumination.
7. Verify high-intensity light exiting distal tip windows is cool so as not to burn patient.

Scope is now ready for use.

> ⚠ **WARNING**
>
> Scope is not aseptic, as received. Scope MUST be cleaned and disinfected before initial use and between each patient.

DEVICE OPERATION - Ventilation Cap

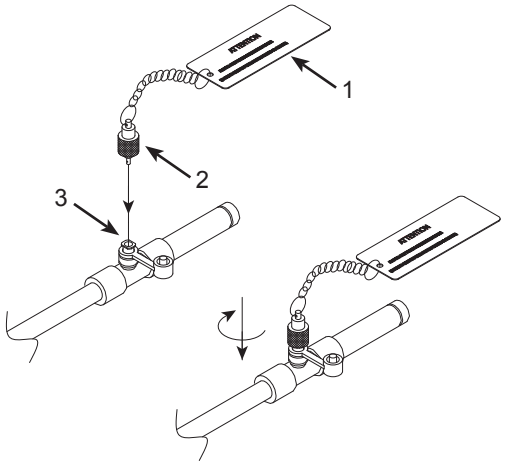
Overview

An EOG adaptor/ventilation cap is used to open an airway to the inside of the scope. When the cap is connected to the scope, internal and external atmospheric pressures are allowed to equalize. Pressure equalization is required when placing scope in any low-pressure chamber. Without venting, internal scope pressure could cause insertion tube sheath to expand and rupture.

Installing ventilation cap:

- Align cap to connector on scope.
- Gently push inward while turning 1/8 turn. (luer-lock connection)

Reverse procedure to remove cap.



Scope is vented when ventilation cap is installed.

1 - Instruction Card
2 - EOG Adaptor/Ventilation Cap
3 - Waterproof testing port/EOG port

> ❖ **CAUTION**
> Ventilation cap will allow fluids to enter scope. Ventilation cap MUST be removed from scope before immersing scope in any liquid.

DEVICE OPERATION - Leak Testing

The Leakage Tester is designed to check the airtightness of the endoscope by pressurizing the endoscope internally while the operator observes the gauge and endoscope for air leaks. Air leaks are indicated by a drop in pressure (needle slowly drops on gauge) and from bubbles emitting from the scope (wet leak test).

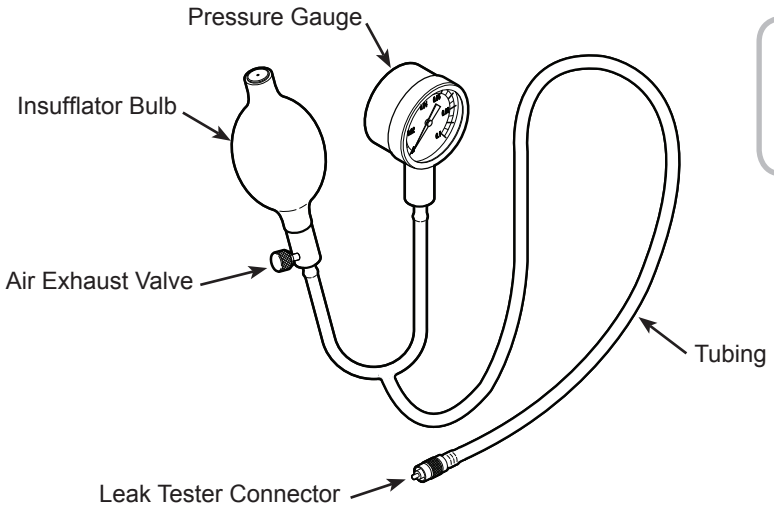
> ❖ **CAUTION**
> The pressure gauge and insufflator bulb with valve are not waterproof. Only immerse the leak tester connector and tubing, otherwise, it may cause damage to the leak tester and/or endoscope.

Check Components

1. Check leakage tester connector and the waterproof testing terminal (on scope)
   - ensure connector has no scratches, defects or residues.

2. Check leak tester
   - check for cracks, scratches, defects or residues.
   - squeeze insufflator bulb (verify air exits connector and no liquid is present)

DEVICE OPERATION - Leak Testing (continued)



❖ CAUTION

To avoid damage to scope, perform leak test before every cleaning, disinfection, sterilization or immersion in any liquid.

Procedure

1. Prepare a sink or container with water (enough to cover endoscope by several inches).

2. Close air exhaust valve on leakage tester (turn clockwise until it stops); this will close the valve.

3 Connect leak tester connector to scope (insert leak tester connector firmly into waterproof testing port and turn clockwise, 1/8 turn). This creates an air-tight connection.

4. Squeeze insufflator bulb slowly until pressure on gauge reads 0.015 -0.02 MPa (staying in the green zone) . Do not over-inflate.

5. Observe gauge. If pressure reading drops, DO NOT USE; scope and leak tester must be returned to JEDMED for service (see page 28).

   If pressure remains constant after 1 minute, instrument passes dry leak test.

6. Upon success of dry leak test the scope can now be immersed in water (wet leak test). Scope should be fully immersed leaving a few inches above the scope. Begin by slowly immersing the light guide cable and then the insertion tube. If no bubbles are escaping (air leaking) from the immersed sections proceed to immersing the body. Observe the scope for 1 minute, if no bubbles are present the scope has passed the wet leak test. If at anytime during the leak test bubbles are detected, immediately remove the scope from the water and return the scope and leak tester to JEDMED for service (see page 28).

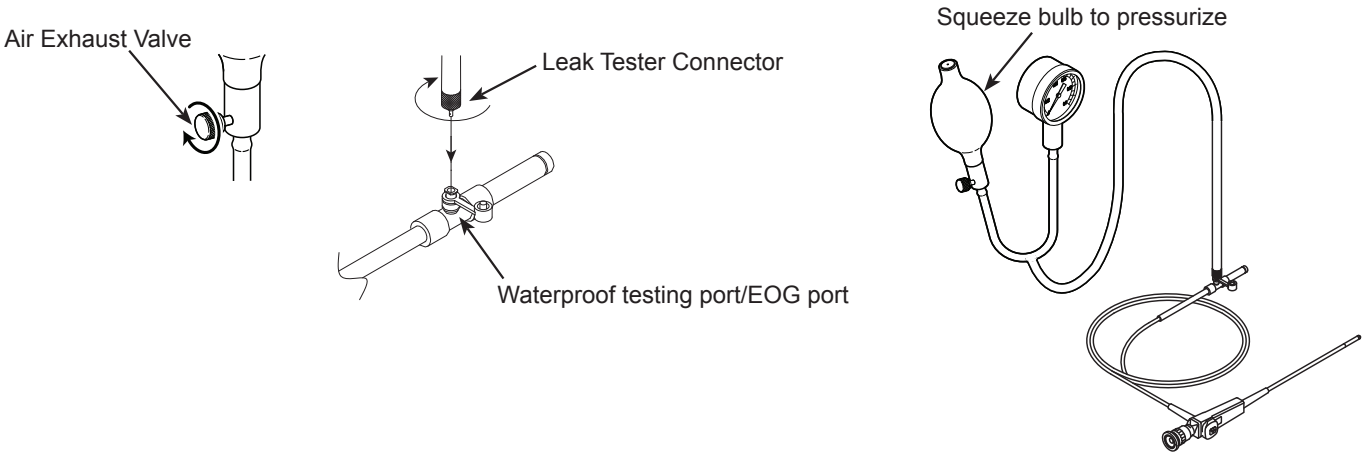
7. Remove the scope from the water and carefully dry the entire scope. Pay particular attention to drying any water near the waterproof testing port/leak tester connection.

8. Turn the exhaust vent counter-clockwise to release the pressurized air from the scope. The needle gauge should drop to 0 MPa.

9. Confirm no water is present at the leak tester connection and then remove the leak tester by turning counter-clockwise and withdrawing connector.

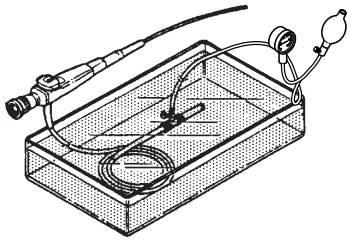
DEVICE OPERATION - Leak Testing (continued)

1) Connect Tester to Scope and Pressurize

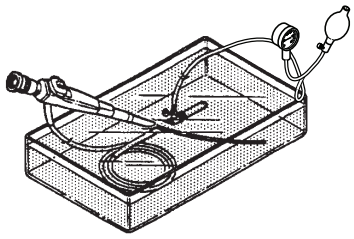


2) Immerse Scope in Water and Observe

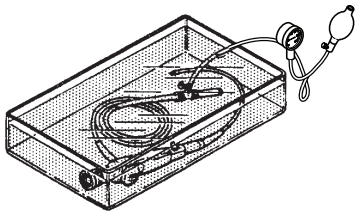
Immerse light guide cable first.



Immerse insertion tube next.

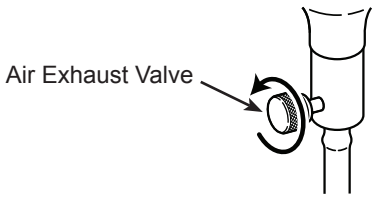


Immerse body last.

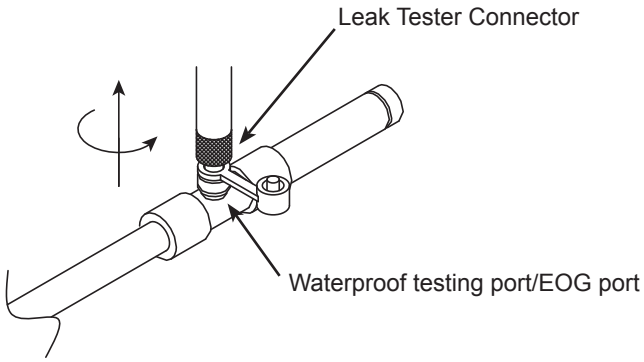


If pressure remains constant after 1 minute, instrument passes wet leak test.

3) Disconnect Scope



Release Pressure



Remove Leak Tester

Under the medical device classification requirements the flexible endoscope is classified as a semi-critical device. By definition, a semi-critical device makes contact with mucous membranes but does not ordinarily penetrate normally sterile areas of the body. Semi-critical devices should be sterilized whenever practical, otherwise high-level disinfection is acceptable.

The following table lists approved methods for cleaning, disinfecting (high-level) and sterilizing flexible scopes.

Cleaning:		
Alcohol	Ethyl (70-90% by volume)	Wipe with gauze
Alcohol	Isopropyl (70-90% by volume)	Wipe with gauze
Enzymatic Detergent	Proteolytic Enzymes	Follow manufacturer's instructions.
High-Level Disinfectant:		
Glutaraldehyde*	Glutaraldehyde* (2.4%)	Minimum 45 minutes at 25°C (77°F) Follow manufacturer's instructions
Ortho-phthalaldehyde	Ortho-phthalaldehyde (0.55%)	Minimum 12 minute soak time at 20°C (77°F) for manual processing. Follow manufacturer's instructions.
Sterilant:		
Glutaraldehyde*	Glutaraldehyde* (2.4%)	Minimum 10 hours at 25°C (77°F) Follow manufacturer's instructions.
Ethylene Oxide Gas	EO/HCFC-124 (10:90 mixture)	PreConditioning Temperature: 52.4-56.4°C (126.3-133.5°F) PreConditioning Time: 30 minutes Initial Vacuum: 0.088 MPa Humidity Set Point: 50 ±10% Temperature at Gas Dwell: 52.4 ~ 56.4°C (126.3 ~ 133.5°F) Gas Exposure Set Point: 0.076 MPa Gas Exposure Time: 120 minutes Gas Concentration: 500±5.mg/L, 600±5.mg/L Re-Evacuation Set Point: 0.088 MPa Post-Exhaustive Vacuum: 3 intervals Air Wash: 20 minutes Aeration: 12 hours
Peracetic Acid	S40™ Sterilant Concentrate	23 minute cycle time Follow manufacturer's instructions.

* Machida flexible scopes have been tested and found compatible with Cidex® glutaraldehyde. As recommended by the manufacturer, glutaraldehyde solutions that do not contain surfactants are more appropriate for flexible scopes. Always follow manufacturer's instructions.

Cleaning

After use, immediately perform the following:

1. Gently wipe all debris off insertion tube with a moistened gauze or disinfectant towelette. Ensure all debris has been removed from the insertion tube, deflecting section, and illumination/observation windows.

2. Thoroughly (but gently) wash the entire outer surface of the scope with a mild pH enzymatic detergent pre-cleaner. A mild soapy solution may also be used, however, enzymatic detergents are designed to breakdown organic matter. (Note: Always follow manufacturer's instructions)

3. Thoroughly rinse scope with potable water and gently dry.

4. Proceed with one of the following:
   a) Gas Sterilization
   b) Chemical Sterilization
   c) Chemical High-Level Disinfection

> ➢ **NOTE**
> Follow all necessary procedures including the use of rubber gloves to ensure proper sterilization/high-level disinfection.

> ➢ **NOTE**
> Machida flexible scopes are designed to be highly reliable. With any delicate instrument proper care, cleaning, and maintenance will extend the life of the product and minimize repairs.

Gas Sterilization

> ⚠ **Warning**
> Clean, rinse and dry scope thoroughly prior to gas sterilization, chemical sterilization, or high-level disinfection. Insufficient preparation may reduce the effectiveness of the procedure.

1) Connect the EOG adaptor to the waterproof testing terminal (see page 15).

> ❖ **CAUTION**
> Ventilation cap will allow fluids to enter scope. Ventilation cap MUST be removed from scope before immersing scope in any liquid.

2) Place the scope on a plastic tray or wrap with gauze to prevent the scope from touching the internal metal casing walls directly.

3) Follow the manufacturer's recommendations along with the guidelines from page 18.

4) Be sure to aerate the scope adequately after sterilization.

5) Disconnect the EOG adaptor.

> ⚠ **Warning**
> Remaining/residual gas from sterilization may cause an adverse effect to the human body. Proper aeration is essential after gas sterilization.

Chemical Sterilization

1) Perform leakage test to ensure scope seal has not been compromised (Refer to pages 15-17 or to leakage tester instruction manual for proper procedures).
2) Prepare the chemical sterilant as recommended by the manufacturer along with guidelines from the previous table.
3) Prepare the proper container for the sterilization and pour the solution into it.
4) Immerse the scope for the manufacturer's recommended time for sterilization.

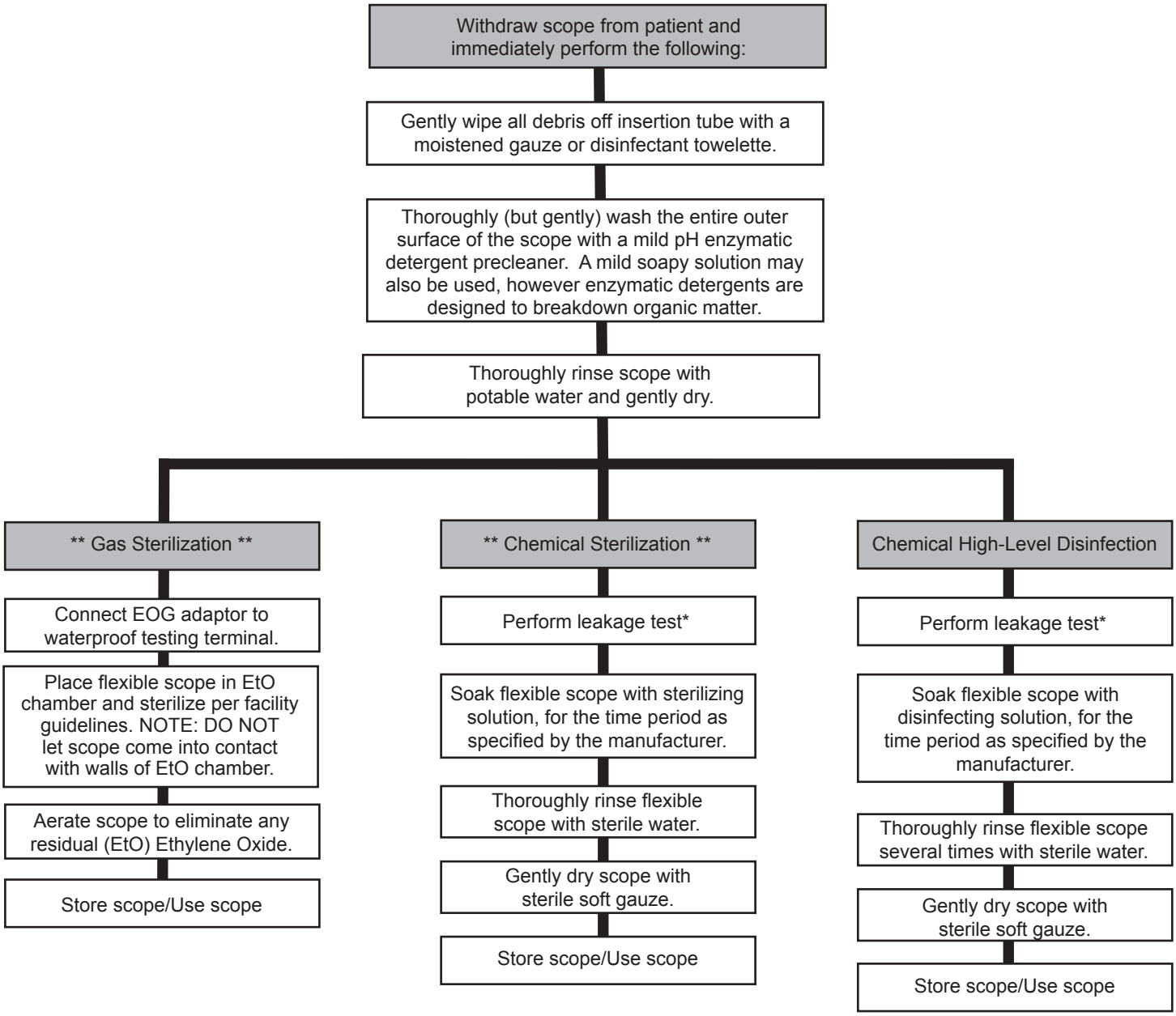
> ❖ **CAUTION**
>
> Immersion of flexible scope in a chemical solution for extended periods of time beyond manufacturer's recommendations may cause damage to the insertion tube, observation and/or illumination windows.

5) Remove scope from chemical solution.
6) Rinse scope completely using sterile water.
7) Dry scope thoroughly using sterile gauze.

High-Level Disinfection

1) Perform leakage test to ensure scope seal has not been compromised (refer to pages 15-17 or to leakage tester instruction manual for proper procedures).
2) Prepare the high-level disinfectant as recommended by the manufacturer along with the guidelines from page 18.
3) Prepare the proper container for the high-level disinfectant and pour the solution into it.
4) Immerse the scope for the manufacturer's recommended time for high-level disinfection.
5) Remove scope from chemical solution.
6) Rinse scope thoroughly using sterile water.
7) Dry scope thoroughly using sterile gauze.

Quick Reference: Cleaning, Disinfection and Sterilization Flowchart



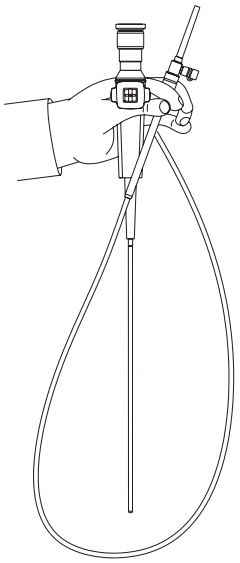
* Refer to pages 15-17 or to leakage tester instruction manual for proper procedures.
** SPECIAL NOTE: Sterile procedures must be followed when performing these guidelines.

Maintenance

This device is maintenance-free.

Handling

When handling a scope, handle as illustrated below:



❖ **CAUTION**

Machida flexible scopes (and accessories) are constructed of precise and delicate components that they should be handled and operated in a manner which will not cause damage.

Transport

Instrument should be transported only in its original packaging.

Temperature ..... 50°-104°F (10°-40°C)
Humidity..... 30-75%
Atmospheric Pressure ..... 10.2-15.4 PSI (0.07-0.106 MPa)

Storage

Scope and accessories should be thoroughly cleaned, disinfected, and dried before storing. Keep the instrument lying flat or hanging with the insertion tube and the angulation tip straight (confirm angle lock lever is in “F” (free) position). Store instrument in transport case or hanging, with protection from dust and contact.

Light cable should be loosely coiled.

Storage area should be dry, well-ventilated, and maintain a temperature of 50-104ºF / 10°-40ºC.

Replacement / Accessory Items

Flexible Scopes

49-5020 ..... Pediatric ENT-2L Scope (Ø2.1mm)
49-5030 ..... Slim Line ENT-3L Scope (Ø3.2mm)
49-5040 ..... Standard ENT-4L Scope (Ø4.2mm)

Light Source Adaptors

49-5102 ..... Karl Storz Adaptor
49-5104 ..... ACMI/Olympus Adaptor
49-5106 ..... R. Wolf/Dyonics Adaptor
49-5108 ..... Machida Adaptor
49-5110 ..... Pentax Adaptor
49-5112 ..... Kay Elemetrics/Pentax Adaptor

Miscellaneous

49-4990 ..... Carrying Case
49-5080 ..... Leakage Tester
49-5085 ..... EOG Adaptor
RA01103..... Ocular Cap (For International Standard Ocular)
RA01017 ..... EOG Aeration Rubber Cap (Luer Cover)
- - ..... Endoscope Adaptor (Various Models Available, Contact JEDMED for information)

Contact Information

For additional information or to order replacement parts contact your Regional Sales Representative or JEDMED Technical Service. Refer to inside of back cover.

SPECIFICATIONS

	49-5020 ENT-2L (Ø2.1mm)	49-5030 ENT-3L (Ø3.2mm)	49-5040 ENT-4L (Ø4.2mm)
Total Length	524mm	534mm	534mm
Working Length	310mm	300mm	300mm
Distal Tip Diameter	ø2.0mm	ø3.2mm	ø4.2mm
Flexible Part Diameter	ø2.1mm	ø3.2mm	ø4.2mm
Angle Deflection Up	130°	130°	130°
Angle Deflection Down	100°	100°	100°
Field of View	75°	80°	80°
Depth of Focus (Fixed)	3-50mm	3-50mm	3-50mm
Length of Light Guide	1.5m	1.5m	1.5m
Weight (use)	7oz.	7oz.	7oz.
Weight (Shipping)	6 lbs.	6 lbs.	6 lbs.

Use Specifications

Temperature ..... 50°-104°F (10°-40° C)

Humidity..... 30-75%

APPROVED DETERGENTS, DISINFECTANTS & STERILANTS

Product Trade Name	Detergent	High-Level Disinfectant	Sterilant
ENZOL® Enzymatic Detergent Solution	✓	--	--
CIDEX® Activated Glutaraldehyde Solution (2.4% glutaraldehyde)	--	✓**	✓**
CIDEX® OPA	--	✓	--
Steris® S40™ Sterilant Concentrate*	--	--	✓

*Steris S40 Sterilant to be used only with the Steris 1E® liquid chemical sterilant processing system.
**Follow manufacturer's instructions for either High-Level Disinfection or Sterilization.

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SERVICE INFORMATION

> ⚠ **WARNING**
>
> Always remove all electrical accessories before cleaning, disinfecting, maintenance or service.

- Service should only be performed by a qualified technician. Contact JEDMED for further information.
- Only authorized personnel and original repair parts are to be used for service of this instrument.
- Any attempt to disassemble the instrument by unauthorized personnel will void product warranty.
- Model and serial number are required when requesting service or replacement parts.
- **Before returning to JEDMED for service, instrument must be cleaned, disinfected and labelled accordingly.** If scope has failed leak testing and cannot be immersed for cleaning, see page 30 for returning a soiled scope.
- Scope may be damaged if shipped incorrectly. Refer to page 22 for transporting information.

Contact Information

For additional information or to order replacement parts contact your Regional Sales Representative or JEDMED Technical Service. Refer to inside of back cover.

TROUBLESHOOTING

Problem / Condition	Possible Cause	Solution
Light guide plug (with adaptor) will not fit into light source port (or fits loosely).	Incorrect adaptor on light guide plug.	Screw-on appropriate adaptor. See page 9.
Image observed through scope is out of focus (blurry).	Focus ring on scope is not adjusted properly.	Set focus ring line to align with dot for no optical correction. Rotate focus ring to achieve best focus. Varies per user. See page 10.
Image observed through scope is dim.	Debris on tip of scope. Fiberoptic cable not fully inserted into light source or scope connection. Broken fibers in illumination bundle. Debris or fingerprints on eyepiece.	Clean tip of scope. Verify good connections. Return to JEDMED for service. Clean eyepiece.
Scope tip becomes warm.	Debris on scope tip covering light emitting window(s). Improper lamp in light source. Improper heat filtering of fiberoptic light source.	Clean scope tip. Install proper lamp. Check for broken or missing heat filter in fiberoptic light source.
Angulation of tip is limited, not symmetrical, requires effort, or does not return to center when released.	Internal angulation mechanism is out-of-adjustment.	Return to JEDMED for service.

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Returning Endoscopes for Service

Normally, all scopes should be **cleaned**, **disinfected** and **dried** before returning to JEDMED for service.
If the scope presents a leak and cannot be submerged, please follow directions below.

1

A protective plastic sheet is supplied for return of soiled flexible endoscopes.

2

Unfold sheet and cover carrying case foam with protective sheet as a soil barrier.

3

➢ **NOTE**
Observe “Universal Precautions”

Wipe endoscope lightly with alcohol wipe.

Carefully place endoscope into carrying case.

4

Fold protective sheet over several times to fully enclose endoscope.

Include note stating: “**Bio-Hazard - Not disinfected**” along with a description of the problem and contact information.

Return to JEDMED for service.

NOTES

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