Instructions for Use

Ergo-Flex

49-4930 EF-N (Ø3.4mm)
49-4928 EF-N Slim (Ø2.8mm)

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

pmnl117
Rev. 3
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 patients.**
- **All fiberoptic light sources should be medical-grade, electrically isolated, and not pose a heat risk to the patient.**
- **Ergo-Flex fiberoptic bundles are very 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 11 and throughout this manual.

DESCRIPTION & INDICATIONS FOR USE

JEDMED's Ergo-Flex 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. Ergo-Flex scopes are intended to be used by ENT physicians in an office setting for routine ENT procedures.

Ergo-Flex is available in two sizes: the 3.4mm standard insertion tube diameter (EF-N) and the 2.8mm diameter size for pediatrics (EF-N Slim). The ergonomic shape of this scope creates a well-balanced instrument, maximizing user comfort.

Ergo-Flex contains a high fiber-count image bundle producing exceptional, high-resolution images which are large, sharp and bright. An industry-standard "B-cup" endoscope eyepiece allows the user to look through the scope, directly, or to indirectly observe the field by attaching an optional video camera and endoscope coupler. Unsurpassed light transmission also makes this scope ideal for stroboscopic examinations.

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

> ➢ **NOTE**
>
> Ergo-Flex 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.

System: EF-N (3.4mm diameter)

Qty	Item	Item No.
1	49-4930	Scope (EF-N)
1	49-4980	Leakage Tester
1	49-4985	Ventilation Cap
1	49-4172	Karl Storz Adaptor
1	49-4170	Wolf Adaptor

OR

System: EF-N Slim (2.8mm diameter)

Qty	Item	Item No.
1	49-4928	Scope (EF-N Slim)
1	49-4980	Leakage Tester
1	49-4985	Ventilation Cap
1	49-4172	Karl Storz Adaptor
1	49-4170	Wolf Adaptor

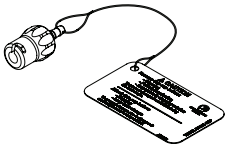
Refer to next page for illustrations.

PARTS IDENTIFICATION

Package Contents

Scope

Leakage Tester

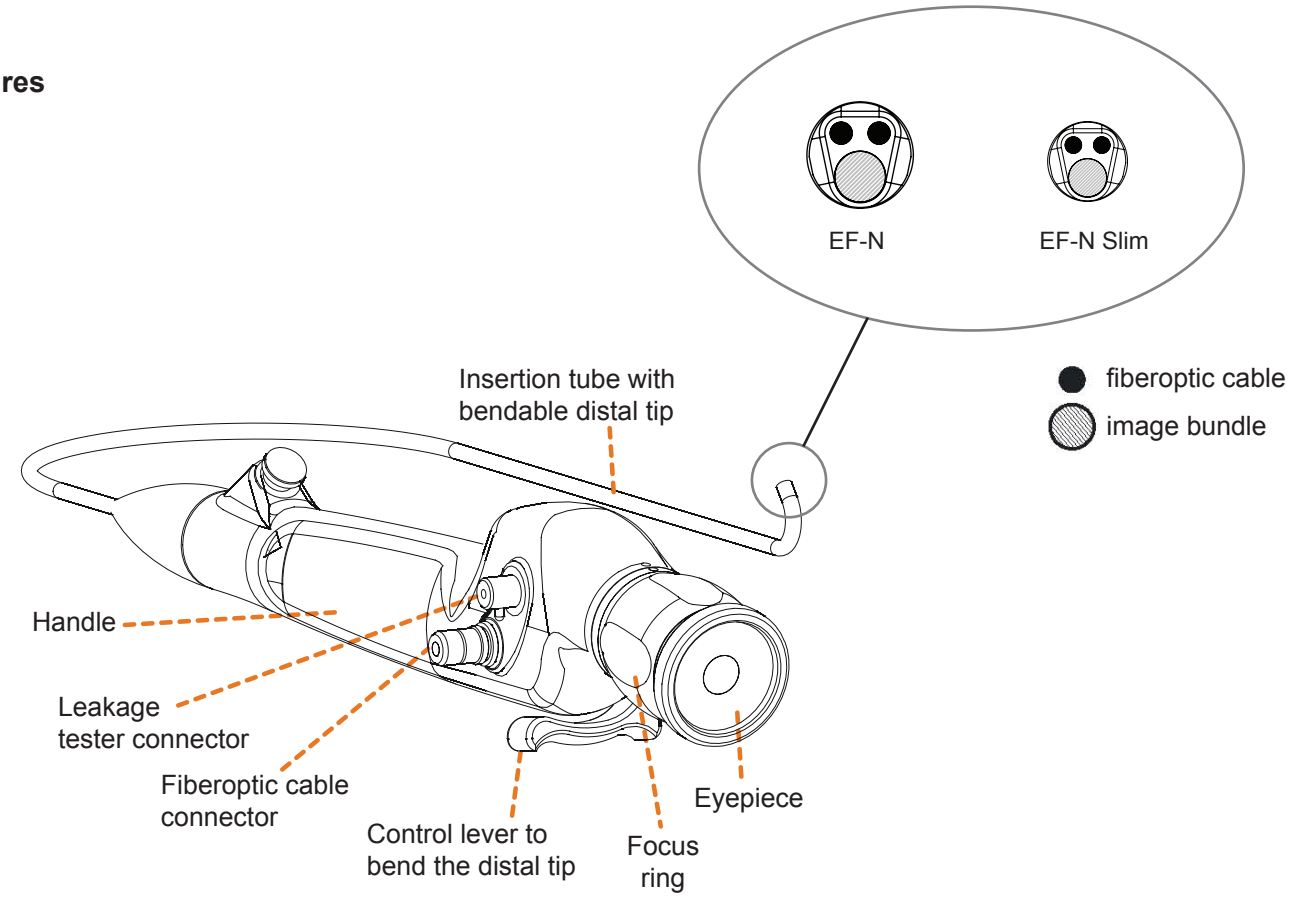


Ventilation Cap

Karl Storz Adaptor
(attached to scope)

Wolf Adaptor
(attached to scope)

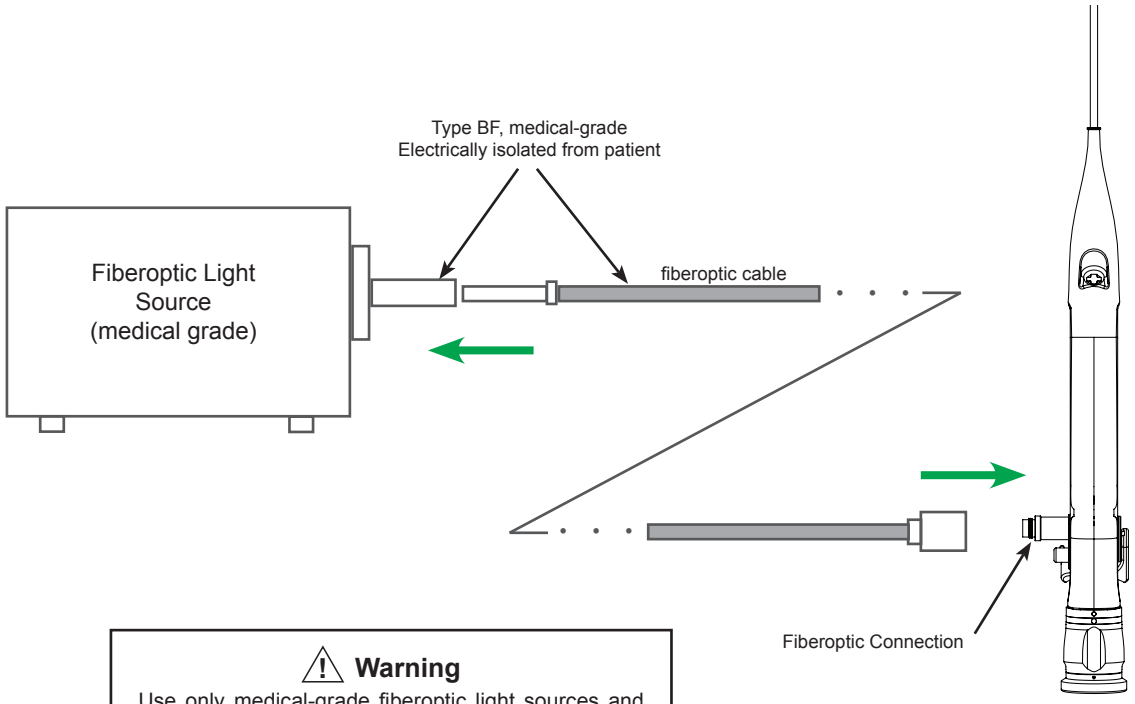
Features



Basic Connections

1. Connect suitable fiberoptic cable to Ergo-Flex.
   Scope will accept Karl Storz, Wolf or ACMI (see bottom of page)

2. Connect other end on fiberoptic cable to suitable
   fiberoptic light source.

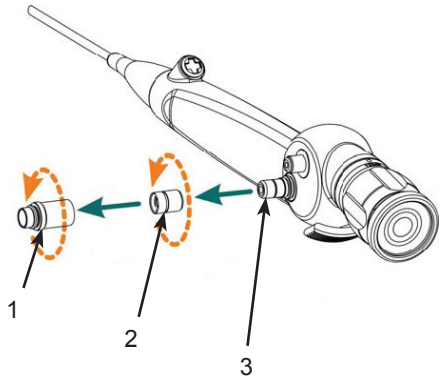


⚠ Warning
Use only medical-grade fiberoptic light sources and light cables to assure patient safety. See page 10-11.

Light Port Adaptors

1. Karl Storz adaptor (removable)
2. Wolf adaptor (removable)
3. ACMI port (fixed)

Simply screw adaptors on or off by hand.

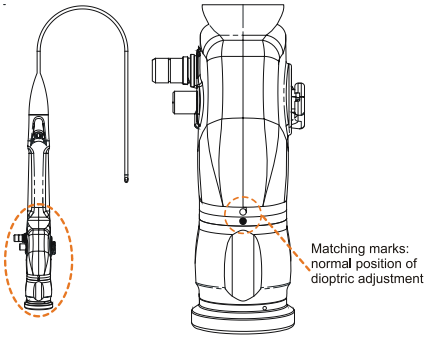


DEVICE OPERATION - Focusing

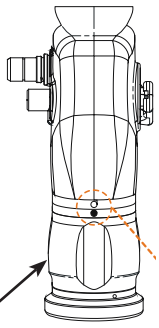
> ⚠ **WARNING**
>
> Scope is not aseptic, as received. Scope MUST be cleaned and disinfected before initial and every use.

Note: Focus settings will vary with each, individual user.

Users wearing glasses or contact lenses
(corrected vision)



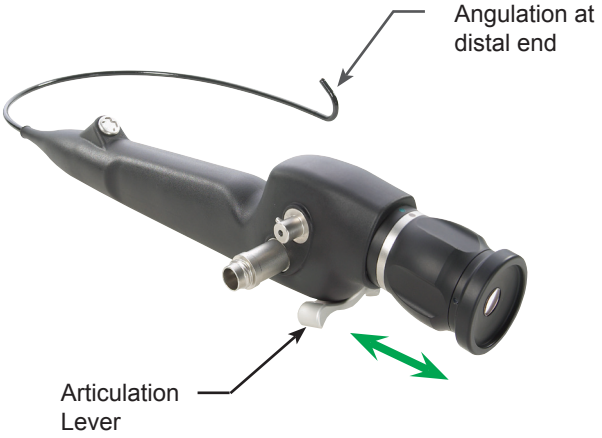
Users who remove glasses or contact lenses
(uncorrected vision)



Rotate focus ring to achieve sharpest image.

DEVICE OPERATION - Angulation

Hold scope comfortably in hand. Use thumb to gently rock articulation lever forward and backward. Observe corresponding angulation of the scope distal end. Movement should be smooth and symmetrical.



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 B-cup eyepiece interface. Rotate focus ring to align its dot to dot on scope body. 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 fiberoptic cable diameter 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 and fiberoptic cables 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). In addition, ALWAYS use an isolated fiberoptic cable (never use a fiberoptic cable which contains an internal, metal monocoil sheath or other means to electrically connect the two ends of the cable).

⚠ **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 14-15)

Clean and disinfect scope
(page 17)

Check Scope Functions

1. Connect scope to light source
(pages 7, 10)

2. Look through scope to observe bright, clear image.

3. Move articulation lever 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**
> Ergo-Flex must be cleaned and disinfected before each use.

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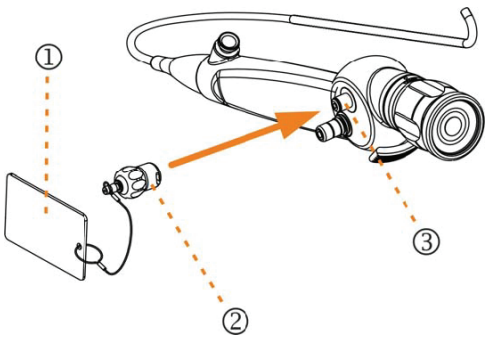
DEVICE OPERATION - Ventilation Cap

Overview

A 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 transporting the scope via air-cargo or if placing scope in any low-pressure chamber. Without venting, internal scope pressure could cause insertion tube sheath to expand and rupture.



Scope is vented when ventilation cap is installed.

1 - Instruction Card
2 - Ventilation Cap
3 - Leak test connector

Installing ventilation cap:

- Align cap to connector on scope.
- Gently push inward while turning 1/8 turn.

Reverse procedure to remove cap.

❖ 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

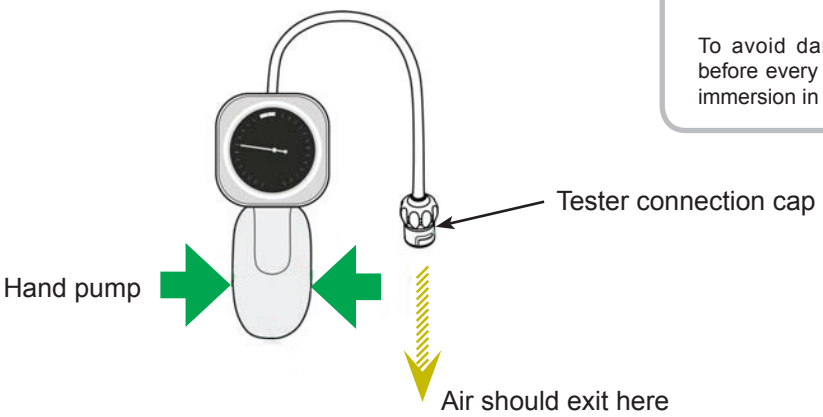
Check Components

1. Check venting connector - ensure connector had no scratches, defects or residues

2. Check leak tester - check for cracks, scratches, defects or residues.
   - squeeze hand pump bulb (verify air exits connector)

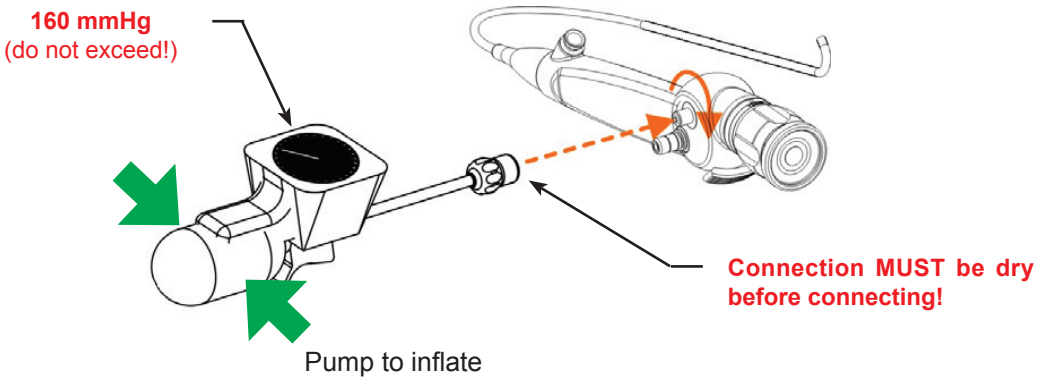
❖ CAUTION

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



DEVICE OPERATION - Leak Testing (continued)

1) Connect Tester to Scope



Procedure

1. Connect leak tester connection to scope (align pin to notch, push inward firmly, gently turn 1/8 turn clockwise). This creates an air-tight connection.

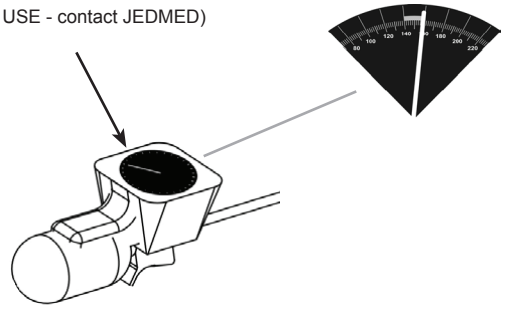
2. Squeeze hand bulb slowly until pressure on gauge reads 160 mmHg. Do not over-inflate. Note: Angulation section of insertion tube (rubber sleeve) normally bulges slightly while inflated.

3. Observe gauge. If pressure reading drops more than 10 mmHg within 1 minute, DO NOT USE; scope must be returned to JEDMED for service (see page 25).

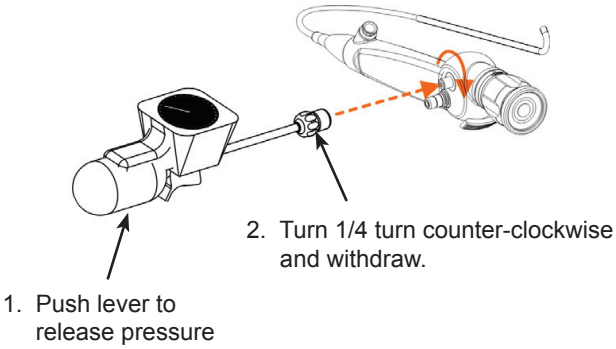
   If pressure remains constant after 1 minute, instrument passes leak test.

2) Observe Pressure After 1 Minute

If pressure drops more than 10 mmHg within 1 minute, scope fails!
(DO NOT USE - contact JEDMED)



3) Disconnect Tester



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Cleaning / Disinfecting Procedure

Ergo-Flex Laryngo-Nasopharyngoscopes

Read and follow these instructions completely!

Step 1

LEAK TESTING

1. **Wipe Insertion Tube**
   and distal tip immediately after removal from patient using alcohol wipe.

2. **Remove All Parts**
   Fiberoptic cable
   Fiberoptic adaptors
   Video equipment

3. **Perform Leak Test (dry)**
   Attach leak tester to scope
   Pump up to 160mmHg
   Wait one (1) minute

If pressure falls more than 10mmHg in one (1) minute scope fails.
Do not use (contact JEDMED)

If scope passes go to Step 2



Effective cleaning and disinfecting is absolutely required to avoid cross-contamination between patients.

Step 2

PRE-CLEANING

Clean scope immediately after use.*
Do NOT allow debris to dry on scope.

Remove all Loose Material Deposits

Hold scope under lukewarm, running tap water.

Gently wipe with cloth from scope body to distal tip.

Concentrate on insertion tube and distal tip windows.

Do not twist insertion tube!

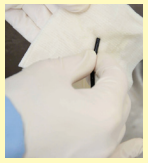
Use soft toothbrush or similar on difficult areas.

Rinse thoroughly.

Pat dry** with cloth.

Immediately go to Step 3





Step 3

CLEANING

ENZOL® Enzymatic Detergent

1. **Prepare Enzymatic Detergent / Clean Scope**

Follow manufacturer's instructions carefully.

Do not over-dilute or under-dilute.

Completely immerse scope in detergent bath.

Brush and wipe scope until no visible debris remain.

Continue brushing/wiping for two (2) additional minutes.

Pay special attention to insertion tube, distal tip windows, heavily soiled areas and physician contact areas.

2. **Rinse Thoroughly**
   Immerse scope in clean basin of fresh, lukewarm tap water. Agitate gently. Remove and rinse under lukewarm running tap water. Rinse until all detergent has been removed.

3. **Dry Thoroughly**
   Dry with medical-grade forced air until completely dry**.

4. **Re-Inspect**
   Visibly re-inspect and re-clean if any debris is found.




Do NOT use ultrasonic cleaner!

Step 4

DISINFECTION
(High-Level)

CIDEX® 2.4% Activated Dialdehyde | **CIDEX® OPA**

STERIS® Revital-Ox™ Resert® High-Level Disinfectant
(USA-Australia-New Zealand-Europe-Middle East)

1. **Fully Immerse Scope**
   in high-level disinfectant solution.

Follow manufacturer's instructions carefully.

Allow scope to soak specified time (use timer).

Remove scope from disinfectant.

2. **Rinse Thoroughly**
   Immerse in basin of sterile or clean tap water. Agitate gently. Discard water. Repeat above two (2) additional times. Rinse until all disinfectant has been removed.

3. **Dry Thoroughly**
   Dry with medical-grade forced air until completely dry**.

4. **Functionally Test Scope**

Steris 1E® Processing

1. **Disinfect / Rinse Scope**

Follow manufacturer's instructions carefully.

2. **Dry** Thoroughly**
   Dry with medical-grade forced air until completely dry**.

3. **Functionally Test Scope**

Step 5

STORAGE

1. **Assure Scope is Completely Dry**

2. **Store Scope**
   in a covered drawer, enclosed storage cabinet or original storage case. Area should be well-ventilated and dust-free.

   Keep insertion tube and angulation section straight.



All cleaning and disinfecting to be performed only by appropriately-trained individuals.

Always use "Universal Precautions" and protective attire when working with potentially infectious material.

Only the aforementioned methods and products have been validated. Do not deviate.

All cloths and brushes should be clean, lint-free and single-use.

Be particularly careful not to damage fiber bundle or optics while cleaning.

Refer to Ergo-Flex Instruction Manual for additional information.

* Note: Clean scope immediately after use. Do NOT allow bio-materials to dry on scope, as cleaning is much more difficult. Residual bio-burden significantly decreases effectiveness of disinfectants. Effective cleaning is the most important part of the disinfection process.

** Note: Drying is critically important to minimize formation of biofilm. Biofilm will form on any surface containing non-sterile water. Biofilms significantly decrease effectiveness of disinfectants.

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12-2015 Rev 2

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Maintenance

This device is maintenance-free.

Transport

Instrument should be transported only in its original packaging. In the event of transporting via airlines, make sure to install the ventilation cap onto the connection port for the leak tester. This opens the scope sheath to allow pressure equalization and guard against the sheath bulging due to reduced atmospheric pressure. Refer to page 14.

❖ **CAUTION**

If transporting by airlines, scope must have ventilation connector installed. This allows pressure to equalize and avoids damage to insertion tube.

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. Store instrument in transport case or hanging, with dust protection.

Light cable should be loosely coiled.

Storage area should be dry, well-ventilated, and maintain a temperature of 64-73ºF / 18-22ºC.

Replacement / Accessory Items

Order #	Description
49-4980	Leakage Tester
49-4985	Ventilation Cap
49-4172	Karl Storz Adaptor
49-4170	Wolf Adaptor
49-4104	ACMI / OLYMPUS Adaptor for fiberoptic cable (light source end)
49-4990	Carrying Case
99-8056	Fiberoptic cable: Karl STORZ instrument and light source ends
99-8090	Fiberoptic cable: STORZ instrument (90º end) and WOLF extended light source end
99-8060	Fiberoptic cable: Universal (selectable ends)

> ➢ **NOTE**
>
> Refer to the assembly drawings located at the back of this manual for replacement parts.

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

EF-N

Sheath Diameter	3.4mm
Working Length	320mm
Bend Angle (up/down)	130º
Bending Radius	8mm
Optical Field of View	80º
Depth of Field	1 - 50mm
Weight	230g (8 oz.)

EF-N Slim

Sheath Diameter	2.8mm
Working Length	320mm
Bend Angle (up/down)	130º
Bending Radius	8mm
Optical Field of View	80º
Depth of Field	1 - 50mm
Weight	230g (8 oz.)

APPROVED DISINFECTANTS & DETERGENTS

Product Trade Name	High-Level Disinfectant	Detergent
ENZOL® Enzymatic Detergent Solution	--	✓
CIDEX® Activated Dialdehyde Solution (2.4% glutaraldehyde)	✓	--
CIDEX® OPA	✓	--
Steris® S40 Sterilant Concentrate *	✓	--
Rivital-Ox Resert® High Level Disinfectant (US/Aus/NZ/EU/Middle East)	✓	--
Rivital-OX Resert® High Level Disinfectant - Chemosterilant (Canada)	✓	--
Resert XL HLD (Rest of the World-Latin America/Asia Pacific)	✓	--

*Steris S40 Sterilant to be used only with the Steris 1E® liquid chemical sterilant processing system.

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 next page for returning a soiled scope.
- Scope may be damaged if shipped incorrectly. Refer to page 19 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.

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An Employee-Owned Company

Returning Endoscopes for Service

Normally, all scopes should be **cleaned**, **disinfected** and **dried** before returning to JEDMED for service.
If the scope fails leak testing and cannot be immersed, 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

⚠ 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.

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TROUBLESHOOTING

Problem / Condition	Possible Cause	Solution
Fiberoptic cables will not fit onto scope.	Incorrect adaptor on light post on scope.	Screw-on appropriate adaptor. See pages 6-7.
Image observed through scope is out of focus (blurry).	Focus ring on scope is not adjusted properly.	Set focus ring to align with dot for no optical correction. Rotate focus ring to achieve best focus. Varies per user. See page 8.
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 fiberoptic cable. Debris or fingerprints on eyepiece.	Clean tip of scope. Verify good connections. Replace fiberoptic cable. 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.

NOTES

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Website: www.anthonyproducts.com