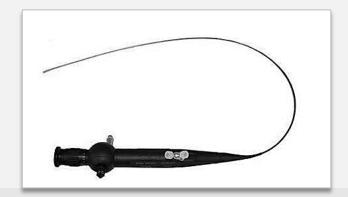


- ☐ Patient Safety
- **□**Economics
- ☐Scope Anatomy
- ☐ How to identify Damage
- ☐ Proper Care and Handling

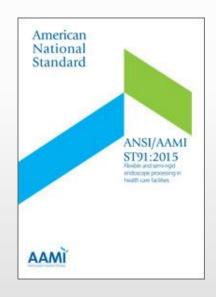






Patient Safety

Improper leak testing, manual cleaning or disinfection methods can result in increased infections and cross contamination among multiple patients



Manufacturer Instructions for Use







The Public Eye-PATIENT SAFETY

Patients warned of dirty endoscope risk at USAFA clinic

A bungled cleaning procedure could put 267 patients at risk for hepatitis or HIV

September 23, 2016 Comment Email Print

skipped a "precleaning" step.

CRE on dirty scopes kills 11 at Seattle hospital

A superbug infection (CRE) at a Seattle hospital caused 35 patients to fall ill and 11 to die

Contaminated endoscopes eyed in 'superbug' outbreak at Ronald Reagan

UCLA Medical Center Deaths of 2 patients in Los Angeles hospital-CRE

Dirty Endoscope Used at Pa. Hospital

Published: April 3, 2017

Nurse did not follow policies for disinfecting endoscopes prior to reuse.

Massachusetts-Based Hospital The Latest To Reveal Endoscope-Related Infection

Risk

Feb 2018-50 pts contacted-Air/water channel was not cleaned (second scope related outbreak)

Economics

Poor leak testing, reprocessing, care and handling and storage methods can unnecessarily increase repair costs.

Fluid invasion



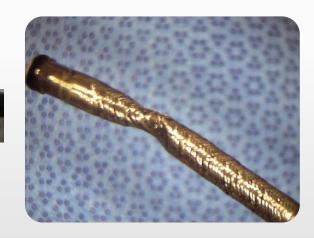
Average cost of repair: \$500+

Crushed insertion tube



Average repair: \$150+ Replace: \$4000+

Crushed bending end



Average cost to rebuild: \$2000+

Parts & Components



Light Connector

Connects into the video processor which provides the imagery

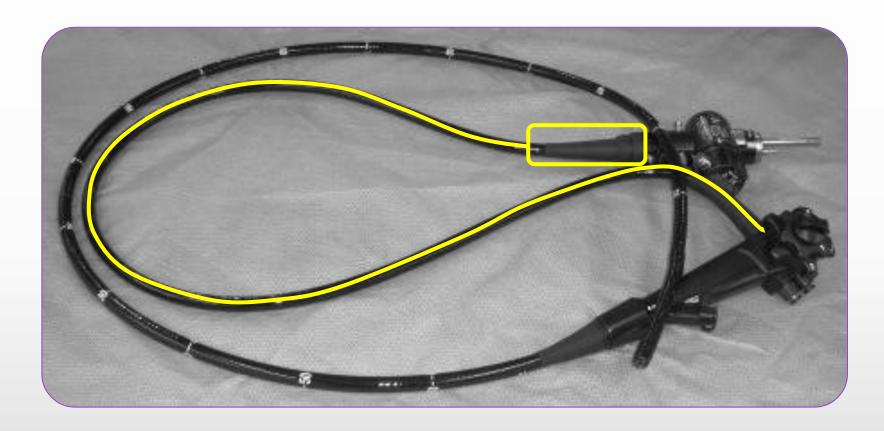
Company Confidential-Please Do Not Distribute



Olympus 130,140,160,180 gastroscopes

190 series-no cap needed
All Fuji & Pentax require caps

Video Connector (with cap)



Universal Cord/Lt Guide Tube

Connects to the control body; contains fiber optics, air/water/suction channels, some high pressure irrigation port



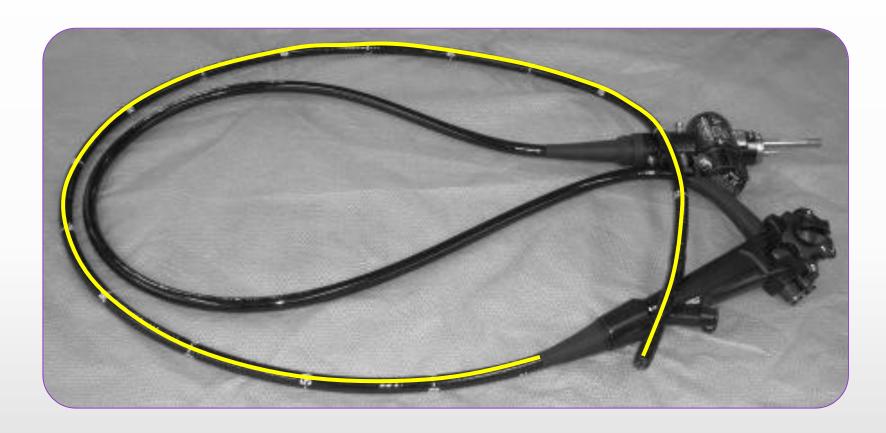
Control Body



Instrument Channel Port

Teflon

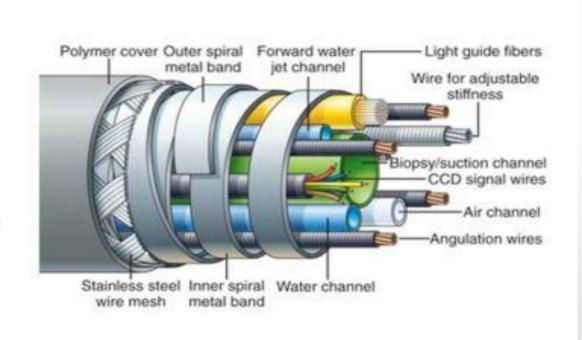
Company Confidential-Please Do Not Distribute



Insertion Tube

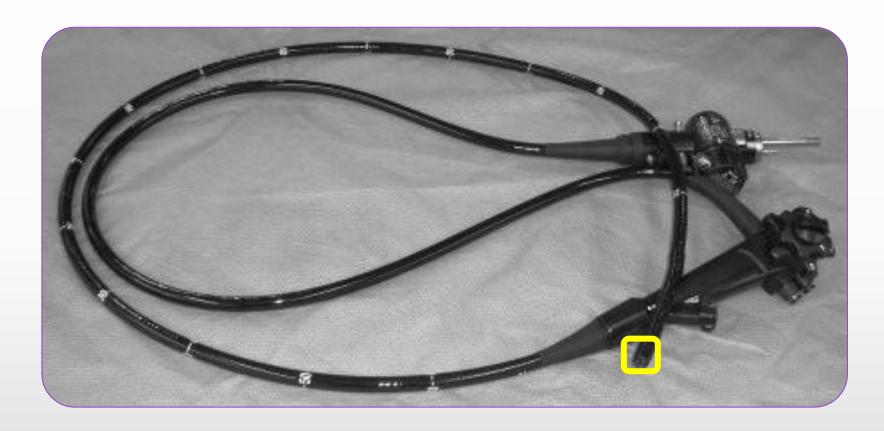
Insertion Tube

- Multiple components pass through densely packed channel
- No bigger in diameter than a heavy duty electrical extension cord
- Outer mesh stainless band surround inner components
- Two outer stainless bands surrounds stainless mesh band
- Thin durable polymer layer aids in insertion and prevents fluid invasion

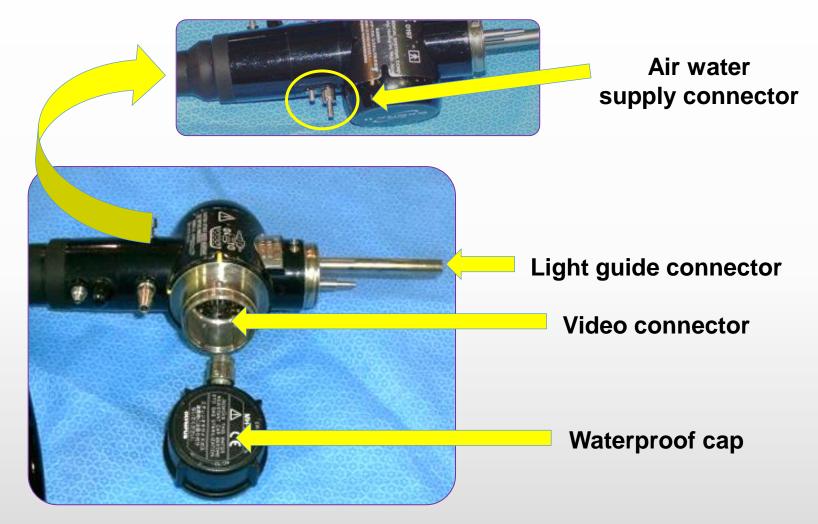




Bending Section



Distal Tip



Light & Video Connector

Company Confidential-Please Do Not Distribute

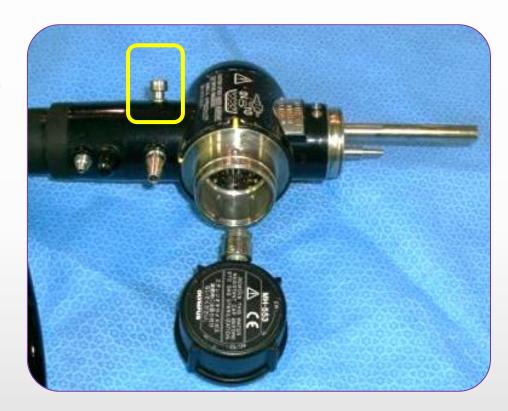
Connector-grounding port

Aux. water inlet

Suction connector

Video hub

Venting connector



Light & Video Connector

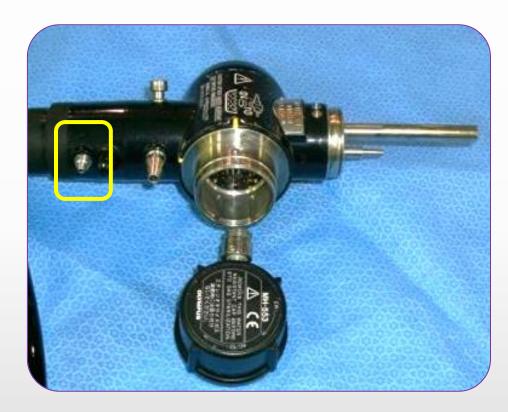
Connector-grounding port

Auxiliary/water inlet

Suction connector

Video hub

Venting connector



Light & Video Connector

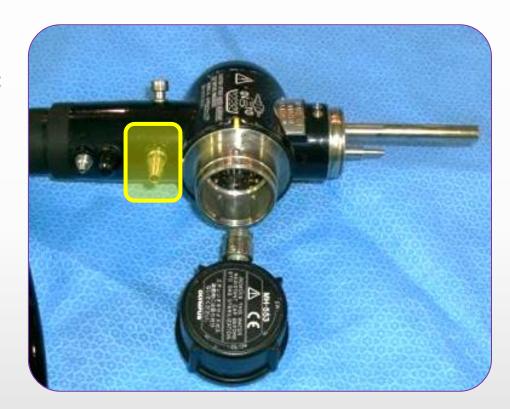
Connector-grounding port

Aux. water inlet

Suction connector

Video hub

Venting connector



Light & Video Connector

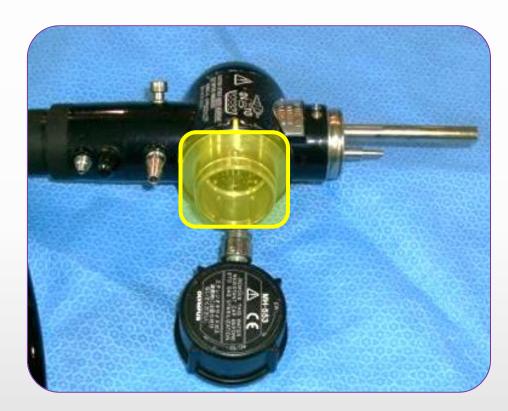
Connector-grounding port

Aux. water inlet

Suction connector

Video hub

Venting connector



Light & Video Connector

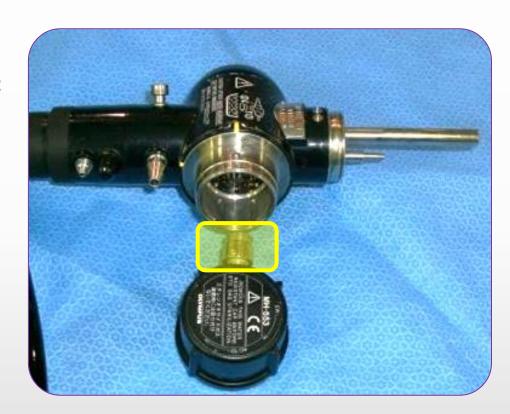
Connector-grounding port

Aux. water inlet

Suction connector

Video hub

Venting connector



Light & Video Connector

Connector-grounding port

Aux. water inlet

Suction connector

Video hub

Venting connector



Light & Video Connector

Connector-grounding port

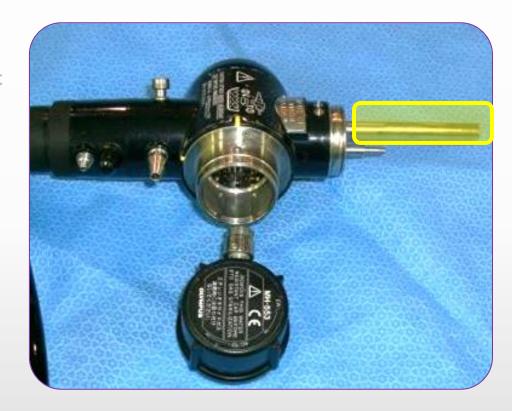
Aux. water inlet

Suction connector

Video hub

Venting connector

Waterproof cap



Light guide prong assembly

ight source to output socket

Light & Video Connector

Connector-grounding port

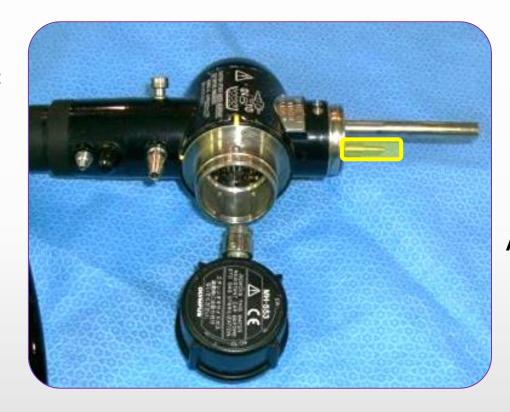
Aux. water inlet

Suction connector

Video hub

Venting connector

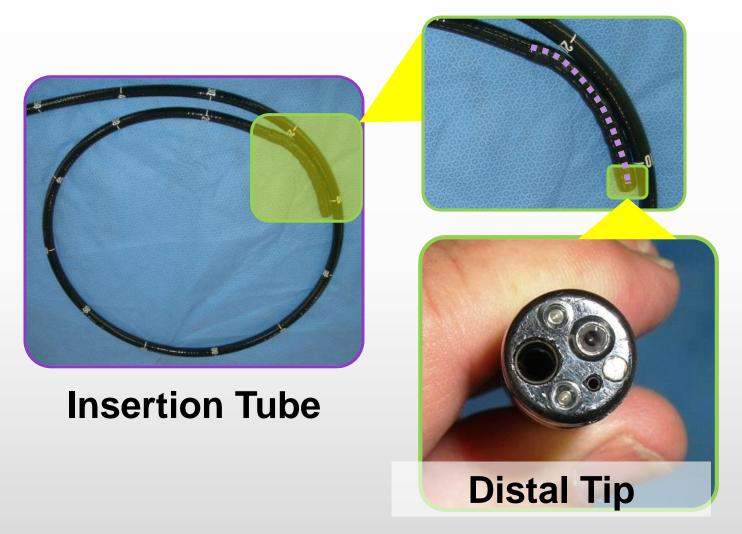
Waterproof cap



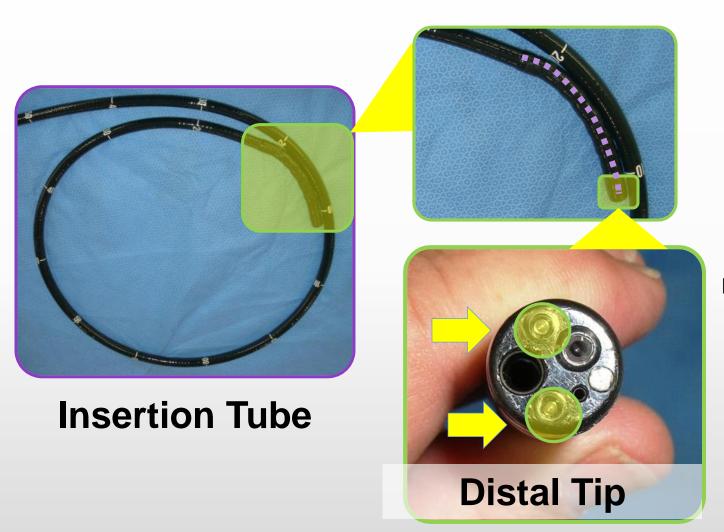
Light guide prong assembly

Air feed prong assembly

Light & Video Connector



Bending Section



Bending Section

Light guide lenses



Insertion Tube







Bending Section

Light guide lenses

Instrument channel



Insertion Tube



oe -

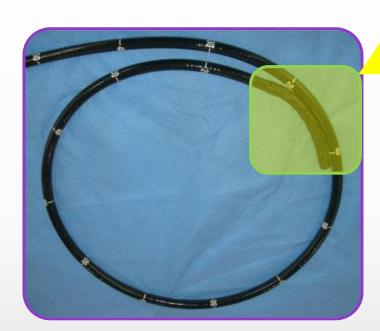


Bending Section

Light guide lenses

Instrument channel

Objective lens



Insertion Tube





Distal Tip

Bending Section

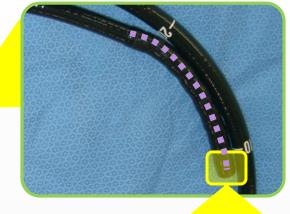
Light guide lenses

Instrument channel

Objective lens

Air/water channel





Insertion Tube



Bending Section

Light guide lenses

Instrument channel

Objective lens

Air/water channel

High pressure irrigation port



Instrument / Biopsy Channel



Right & Left angulation knob



Right & Left angulation lock



Up & Down angulation knob



Up & Down angulation lock



Air/water valve

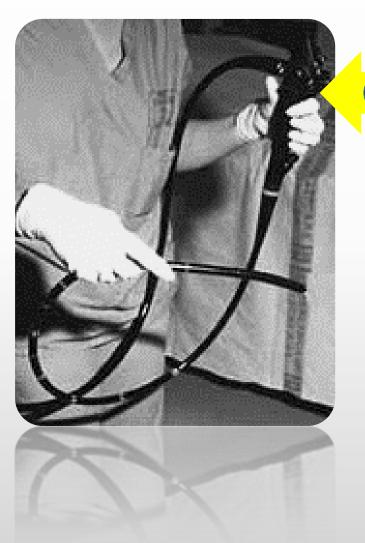


Suction valve



Camera capture / print buttons

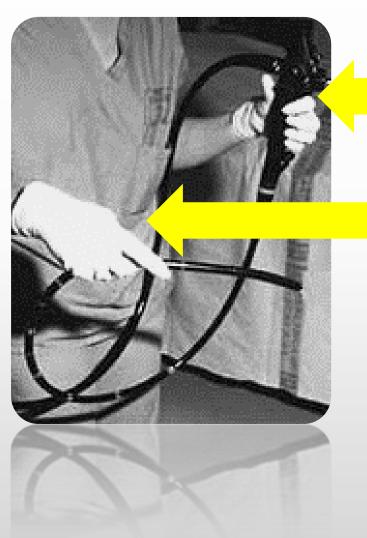
Control Body



When picking up an endoscope, we should always...

Start by lifting the *control body grip* with one hand.

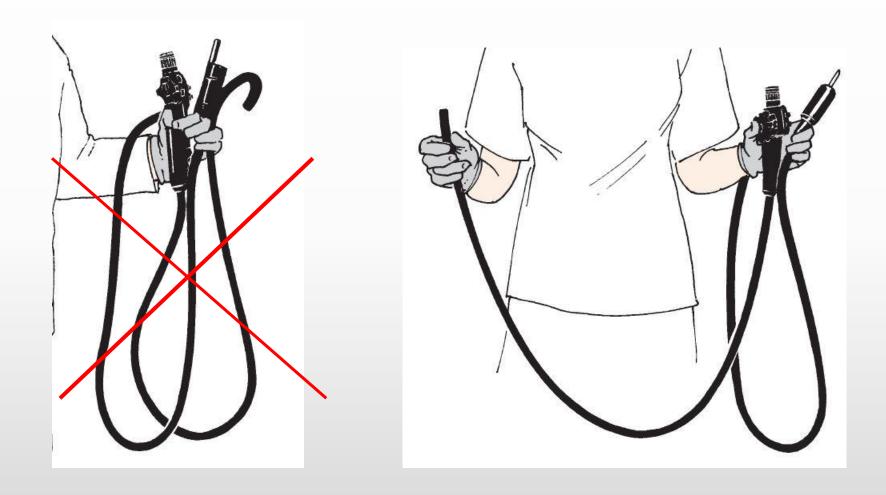
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When picking up an endoscope, you should always...

Start by lifting the *control body grip* with one hand.

Then, with the other hand, coil the *insertion tube* loosely, being careful not to crimp or kink.





- •All personnel should exercise **standard precautions** <u>at all times</u> when handling and processing endoscopes.
- •Full PPE is required throughout all steps.
- •All endoscopes should be inspected, tested, used and processed; according to the manufacturer's written instructions.

Flexible endoscopes **stored** in closed cases produce a humid, non-ventilated environment; and under these conditions may create an infection control risk.





Shipment Only

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Flexible endoscopes are *very fragile devices* and should be transported by themselves; (*one* scope *per* rigid covered container/marked as biohazard)

*No other items should be placed on top of the endoscope, or alongside during transportation, in decontamination areas, or while in the procedure room.



Small diameter scopes (Flex X2, DUR 8, URF-P6) are very fragile and unable to tolerate improper handling

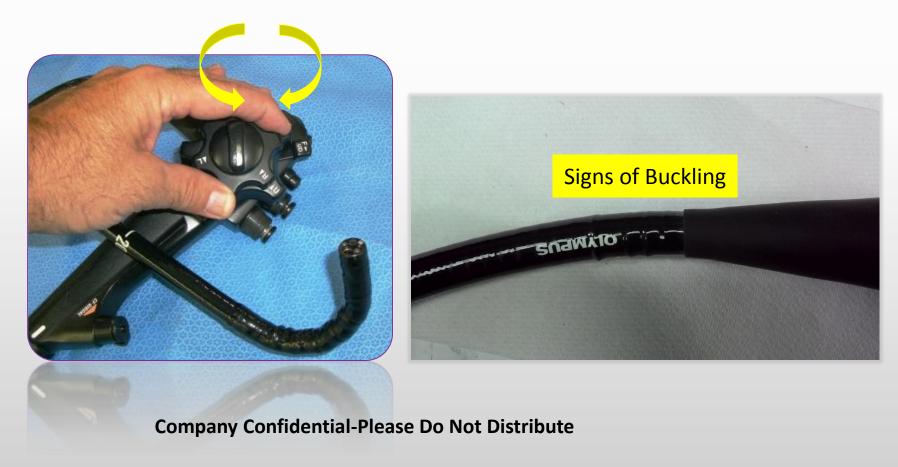




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Identifying Damage: Angulation

Movement or "play" in the angulation control knobs <u>usually</u> indicates an angulation adjustment is needed. This can result in angulation wires that are stretched or broken or an insertion tube that may be compressed due to buckling.



Identifying Damage at the Distal Tip

- Nozzles may become damaged, missing (potential adverse event) or misaligned
- Clogs in the air/water nozzle and/or instrument channel from a collapsed channel, foreign body blockage or severe bio burden buildup (potential patient infection)
- The video (CCD) chip is a delicate electronic component that will breakdown if/when exposed to corrosive fluids.
- Light guide lenses that are cracked will distort the light.
- C-Cover-excessive scratches, cracks or chips indicates poor care and handling (hitting on sinks, counters, OR beds)
- Check for any deterioration of adhesive around lenses

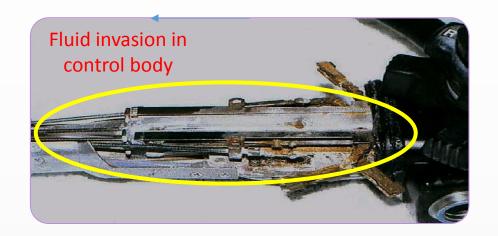




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☐ Fluid invasion can occur from puncture damage to the insertion tube, It guide tube, bsr, failed seals on the control knob, puncture in bx channel, failed placement of the water cap, etc.

Fluid Invasion





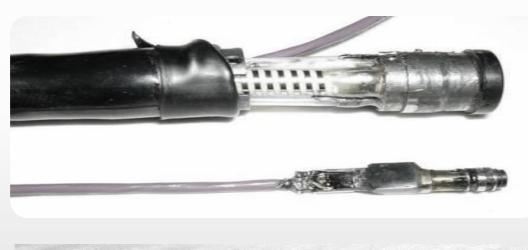
Ocular eyepiece removed, revealing extensive fluid damage (corrosion)

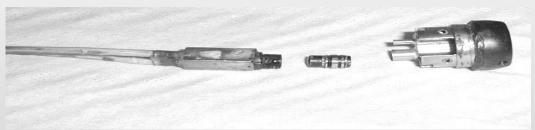


Identifying Damage-Fluid Invasion

The CCD (charged coupled device), aka known as the video chip, is located at the distal tip of the scope.

Fluid invasion-increases repair costs



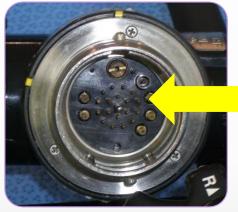




Fluid Invasion

The video image system has several integral components that are susceptible to damage from fluid invasion:







Video hub connector pins relay the electronic information from the CCD to the video connector and on to the video processor.

Never submerge video endoscopes without the water-resistant cap in place. Doing so can cause the entire scope to quickly fill with fluid.

Buckling





Some scopes have a variable stiffness control, which allows the user to control the rigidity and curvature of the flexible endoscope tube. Repeated manipulation over the boot area can initiate signs of buckling



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Buckling is observed by ripples/ridges on the endoscope; and commonly indicates internal structural damage.

What are some causes of buckling?

- Coiling the endoscope too tightly during transport-
- ✓ (coil loosely in appropriated size rigid container-hold endoscope safely with both hands)
- Bending, pressing down, over torqueing on the insertion tube during the procedure-
- √ (surgeon/resident is focused on the monitor/screen-may be repeatedly turning on boot area)
- Bending or pressing down on the insertion tube during manual cleaning-
- √ (holding scope incorrectly-against sinks or countertops)
- Users turning/ twisting the boot area-
- √ (may occur during procedure and upon aggressive washing-not once/but over time)
- Normal wear and tear depending upon age/and scope use-
- √ (scope inventory to match your facility scope procedure volume)

~A preventative maintenance program is important.

Dear Health Care Professional:

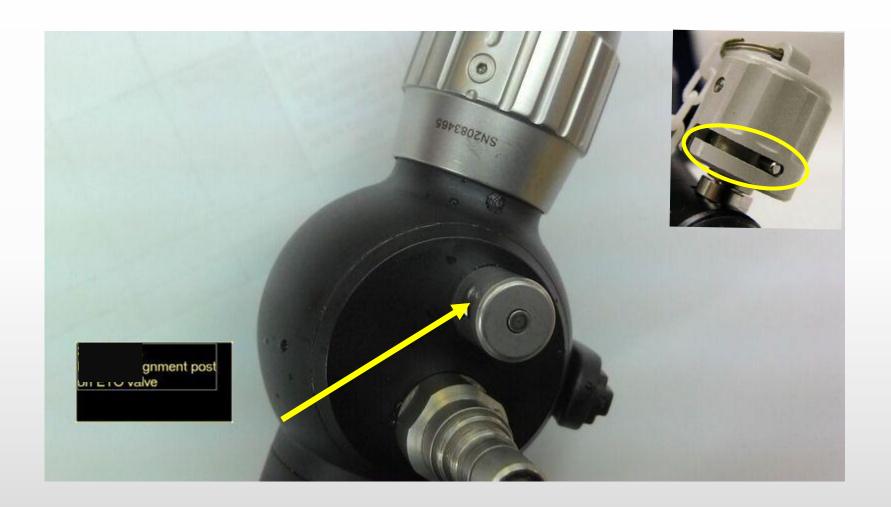
This notice is to inform customers that Olympus has received reports of inadvertent damage to Olympus fiberoptic/video endoscopes as a result of improper reprocessing in a STERRAD Sterilization System. Specifically, Olympus endoscopes were damaged as a result of failure to properly vent the endoscope by attaching the ETO cap to fiberoptic/video endoscopes, or removing the water resistant cap from video endoscopes prior to sterilization in a STERRAD Sterilization System. For proper reprocessing in a STERRAD Sterilization System, attach the ETO Cap to fiberoptic/video endoscopes (Fig. 1) or remove the Water Resistant Cap from video endoscopes (Fig. 2). If attaching an ETO cap to vent the endoscope, ensure that the ETO Cap is rotated completely (Fig. 3).

If the ETO cap is not placed on the scope during Sterrad or gas sterilization; pressure will build inside the scope and will cause the bending rubber to expand and depart from the scope.









The endoscope should be stored with valves and attachments *removed*, scopes *hung vertically in a well-ventilated cabinet or an approved* controlled storage area-safe from potential damage.





Dry the valves and attachments and store them unattached and along with the endoscope.

Improper Storage









Which 2 are NOT Care & Handling Related?

BUCKLING TO INSERTION TUBE AT STRESS BOOT

COMPRESSION DAMAGE TO INSERTION TUBE AT 42CM USES: 978

BROKEN IMAGE FIBERS

DETERIORATED C-COVER EPOXY -

IMPACT DAMAGE TO LIGHT GUIDE LENS SEALS IMPACT DAMAGE TO OBJECTIVE SEAL

OBSTRUCTED AIR/WATER NOZZLE

DETERIORATED BENDING RUBBER SEALS

Scope leaking from bending rubber.

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Tips For Protecting Your Investment

- ✓ Sufficient scope inventory
- ✓ Education
- ✓ More handlers increases likelihood of damage
- ✓ Proper inspection
- ✓ Proper leak testing
- ✓ Appropriate reprocessing chemicals
- ✓ Proper manual cleaning
- ✓ Proper HLD/Sterilization
- ✓ Proper transportation and storage methods





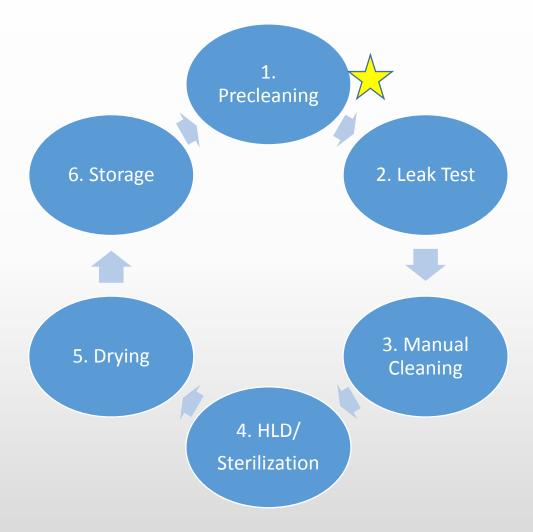
PENTAX IFU/Example

Care & Handling of Flexible Endoscopes

NOTE

All of the steps in the validated reprocessing protocol described in this manual are intended to be performed in rapid succession and as a single, continual procedure. There should be no breaks in between steps of the protocol that are of sufficient duration to permit the endoscope to dry to such an extent that dislodged debris and/or microbial contaminants would be permitted to dry onto any endoscope surface. In the event that drying of the endoscope occurs due to an excessive break in the reprocessing procedure, the procedure should be completely repeated, beginning with the first precleaning step.

AAMI ST_91, SGNA, Manuf IFU



Leak Testing Introduction

Flexible endoscopes *must* be leak tested after each and every use.

Leak testing will reveal any air leaks that may be present over the entire body of the flexible scope as the test is done while the scope is <u>completely immersed in water</u>.



Automated Leak Testing Units







- Pre-cleaning is an essential step to remove gross soil immediately after point of use.
- Improper or lack of; pre cleaning with endoscopes, may result in increased infections and cross contamination among multiple patients.
- When any biomaterial is not removed *immediately* after a procedure, it will dry and harden
- Hardened material acts as a barrier that prevents the penetration of disinfecting and sterilizing agents that kill microorganisms.
- The result is potentially infectious material still present on the endoscope or in the channels.

"When delays in pre-cleaning occur, additional reprocessing steps, which include an extended soak period, are required. Follow the manufacturer's instructions for delayed reprocessing of endoscopes".

Manufacturer IFU WARNING



• Proper care of the device after each procedure is extremely important. Immediately (within one hour) after the completion of a procedure, the endoscope, its removable components, and accessories should be both pre-cleaned and mechanically cleaned with detergent solution. Generally, if these endoscopes and accessories are not precleaned within 15 minutes and mechanically cleaned within one hour after the conclusion of the procedure, dried blood, mucus, or other patient debris may cause damage to the devices or interfere with the ability of the user to properly reprocess them.

Dry Leak Testing Equipment



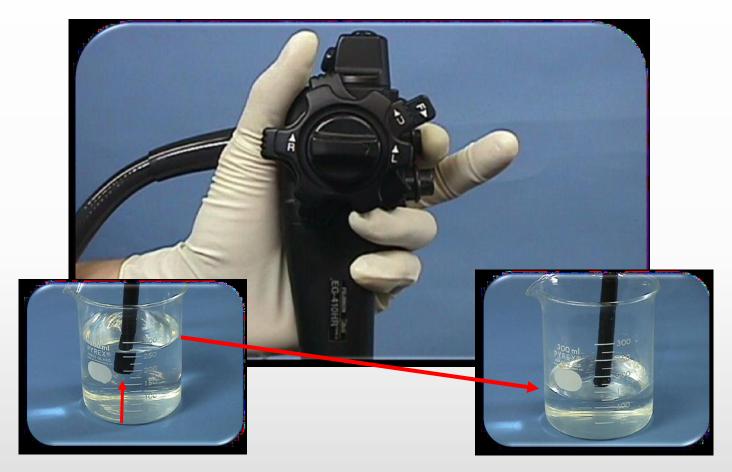
Biofilm-Video



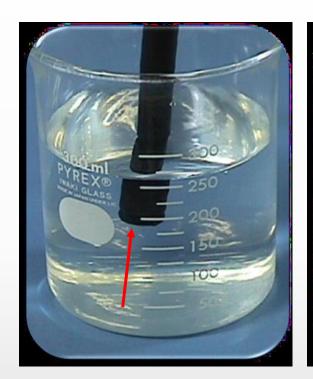
Pre-Cleaning



Wipe the outside of the insertion tube with a clean, lint free cloth soaked in enzymatic solution.



Press suction button to test suction





Alternate between enzymatic solution and air -aspirating until flow is <u>clear</u>.

Each
manufacturer
IFU will have
their own
specific
precleaning
protocol













- Transport one scope at a time separate from instrumentation or other accessories.
- loosely coiled with no sharp bends.



Per SGNA Standards:

Containers should be large enough to prevent damage to the endoscope

Transport the soiled endoscope to the reprocessing area in a closed container that prevents exposing staff, patients, or the environment to potentially infectious organisms.

The transport container must be labeled to indicate biohazardous contents

Leak Testing and Common Misconceptions

A leak is **NOT** always in the form of a steady stream of bubbles. We may also receive a leak "anywhere" on the scope (a leak is not always on the bending section or distal tip) A leaking scope can emit bubbles consistent with any one of the following types:

- Steady stream of bubbles
- Slow forming bubbles
- Periodically forming bubbles

If there are static bubbles present on the scope, wipe them away and ensure that the bubbles do not reform in the same spot.

A bubble that reforms indicates a possible leak.

Video

Care & Handling of Flexible Endoscopes











21 (33 of 70)





















AAMI ST_91 Guidelines

- c) Attach the leak tester.
- d) Turn the air compressor on and pressurize the endoscope.
- e) Establish pressurization by confirming that the bending rubber has expanded.
- Place the endoscope in a loose configuration in a large sink with a sufficient volume of clean water to completely immerse it.
- g) Completely flush all channels with water to remove trapped air.
- Gently rotate each directional knob and elevator control, looking for bubbles at the bending rubber as well as at the knobs.
- Massage video or remote switches in a circular manner to challenge the integrity of these components while looking for bubbles.
- j) Manipulate the insertion tube and light guide tube, if applicable, to uncover hidden leaks due to the position of the coiled endoscope.
- k) Perform a complete visual inspection of the endoscope for leaks. If static bubbles are attached to the endoscope, brush them away and inspect to ensure that bubbles do not return.
- Maintain pressure and inspection for a minimum of 30 seconds.
- m) Remove the entire endoscope from the test water.
- Stop pressurization by turning off the air supply.
- According to the manufacturer's written IFU, remove the leak tester from the air compressor and listen for the sound of evacuated air.
- If the endoscope is water tight, proceed with cleaning and disinfection processes.
- q) Document outcome of leak test.

Leak Testing Recommended Practices

1 Fill the

Fill the sink with clean, clear water



Is the sink marked?

Leak Testing Recommended

Fill the sink with clean, clear water



Remove all valves and biopsy cap from the endoscope



Leak Testing Recommended Practices

Fill the sink with clean, clear water



Remove all valves and biopsy cap from the endoscope



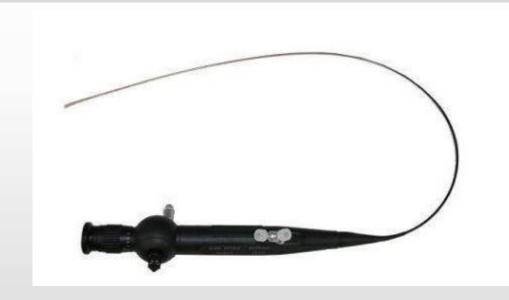
Connect endoscope to leakage tester and pressurize before submerging in water

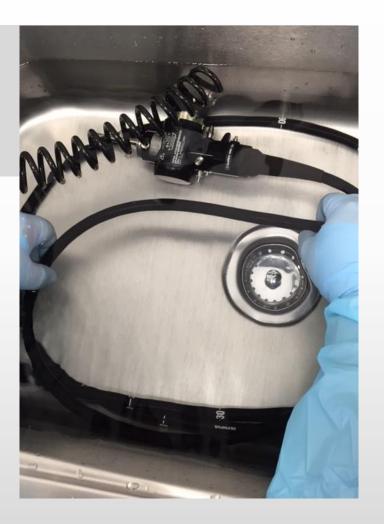


*How can we ensure the leak tester is working properly?

* Tubing dry?

Completely submerge endoscope



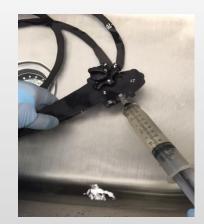




Completely submerge endoscope

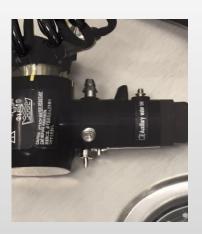


Flush all channel lumens with a syringe of clean water until all air is removed

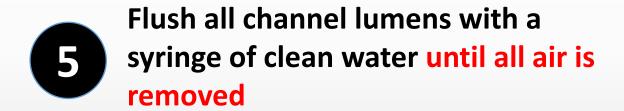




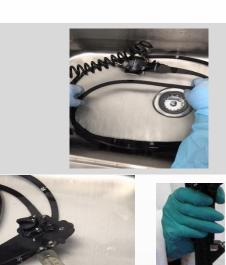




4 Completely submerge endoscope



6 Manipulate control knobs

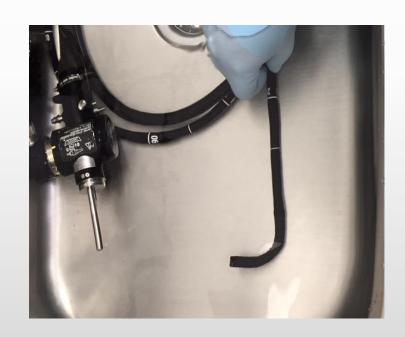








Carefully inspect articulating section and control knob area for bubbles



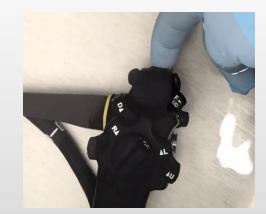


*A leak can occur *anywhere* on an endoscope

8 Carefully inspect articulating section and control knob area for bubbles



For video endoscopes: depress video switch pads and inspect for leaks or damage



Carefully inspect articulating section and control knob area for bubbles



For video endoscopes: depress video switch pads and inspect for leaks or damage



Gently manipulate the insertion tube and light guide tube and check for bubbles

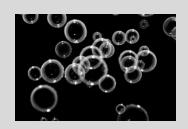








Perform a complete visual inspection of the endoscope checking for bubbles- for at least 30 seconds



If there are static bubbles present on the scope, wipe them away and ensure that the bubbles do not reform in the same spot. A bubble that reforms indicates a possible leak.

10

Perform a complete visual inspection of the endoscope checking for bubbles- for at least 30 seconds



11

If scope passes leak test, <u>remove</u> scope from water and depressurize

Perform complete visual inspection of endoscope for bubbles for at least 30 seconds



If scope passes leak test, <u>remove</u>

<u>scope from water</u> and depressurize

Disconnect scope from leak tester

13

If scope fails the leak test, keep the scope pressurized keeping connected to the leak tester

If scope fails the leak test, keep the scope pressurized and connected to the leak tester

Proceed with the following manual cleaning process





Add appropriate volume of detergent per gallon of clean water to a sink



Add appropriate volume of detergent per gallon of clean water to a sink



Completely submerge endoscope in detergent solution



Add appropriate volume of detergent per gallon of clean water to a sink



Completely submerge endoscope in detergent solution



Wash all external parts of the endoscope with a soft sponge or lint-free cloth

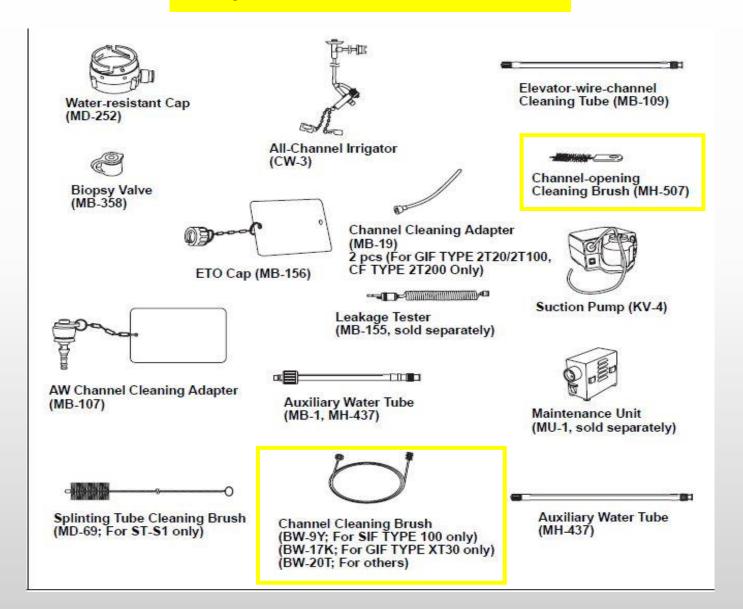




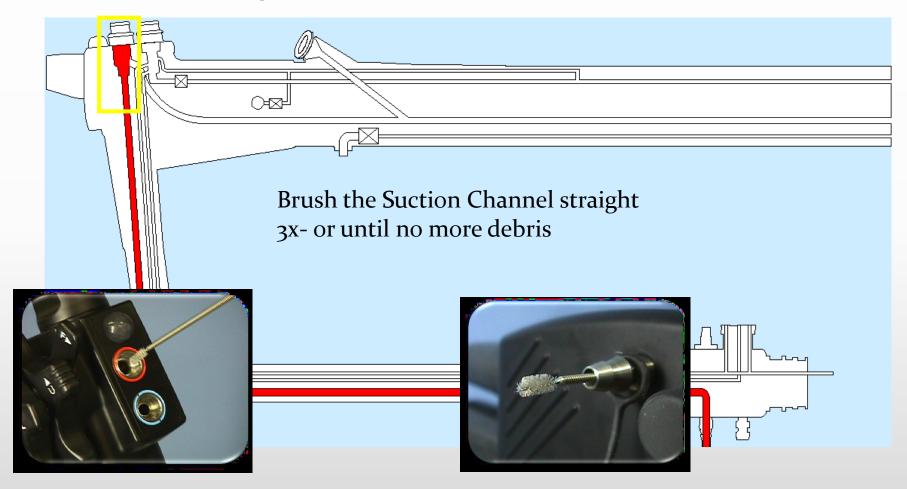
Brush all channel ports with appropriate sized, IFU approved cleaning brush



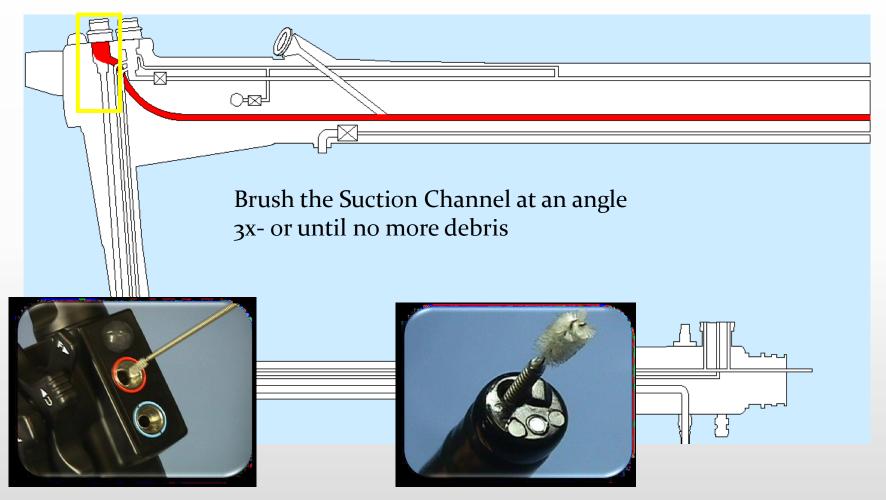
Olympus Gastroscope IFU Example-ITEMS NEEDED

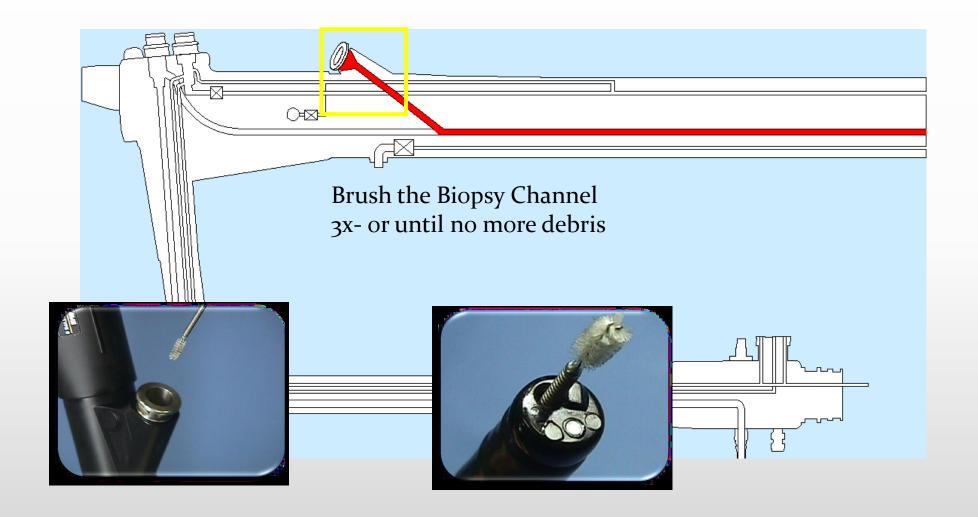


Brushing Suction Channel



Brushing Suction Channel





4

Brush all channel ports with appropriate sized, IFU approved cleaning brush



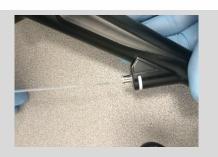
5

(for duodenoscopes) clean-brush & flush elevator arm and distal end assembly with the appropriate sized IFU approved cleaning brush









(for duodenoscopes) clean elevator arm and distal end assembly with the appropriate cleaning brush



Brush all appropriate channel lumens





Ensure that the brush tip passes completely through each channel lumen



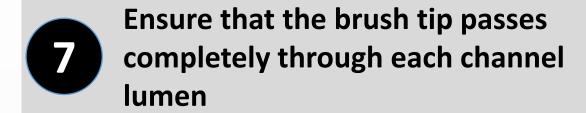


Ensure that the brush tip passes completely through each channel lumen



Wipe brush tip free of debris before withdrawing back through the channel







In order to avoid damage to the endoscope distal end, never attempt to insert a cleaning brush into endoscope

distal tip.

Wipe brush tip free of debris before withdrawing back through the channel



Repeat a minimum of three times or until no debris is visible on cleaning brush





IMPORTANT:

What is wrong in these images?



When performing the manual cleaning of flexible endoscopes; users should place the scope fully submerged in the detergent solution—"detergent contact time" is very important for removing debris and the prevention of biofilm on the endoscope and within the channels.

*Per AAMI ST_91 Section 5.5-"Place the endoscope in the solution, keeping it below the fluid's surface level at all times"

PATIENT SAFETY



Company Confidential-Please Do Not Distribute

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Dispose of single use brush <u>or</u> reprocess the multi-use brush according to manufacturer's recommendations



Dispose of single use brush <u>or</u>
process multi-use brush according to manufacturer's recommendations



Connect flushing adaptor to endoscope and thoroughly flush channels



Dispose of single use brush <u>or</u>
process multi-use brush according to manufacturer's recommendations



Connect flushing adaptor to endoscope and thoroughly flush channels



(For automated flushing devices) follow manufacturer's guidelines for use



13

Drain sink and remove enzymatic cleaner residue

Drain sink and remove enzymatic cleaner residue

(In a separate sink) Thoroughly rinse external endoscope under <u>free</u> <u>flowing</u> clean water

Drain sink and remove enzymatic cleaner residue

(In a separate sink) Thoroughly rinse external endoscope under free flowing clean water

Thoroughly flush all lumens with clean water

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(For automated flushing devices) follow manufacturer's guidelines for use



16

(For automated flushing devices) follow manufacturer's guidelines for use



17

Remove scope from sink

(For automated flushing devices) follow manufacturer's guidelines for use



17 Remove scope from sink

Dry endoscope w lint free cloth, flush channels with 70% isopropyl alcohol followed by instrument air

If Sterrad or ETO
sterilizationFlush with 70%
Isopropyl alcohol
through all
channel lumens

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Drain and clean sink

Drain and clean sink

Process endoscope according to manufacturer's instructions (Manual HLD, AER or Sterilization)



Thank You