



PENTAX

PENTAX Medical Company
A Division of PENTAX of America, Inc.

Re: Decontamination of Returned Endoscopes

Dear Health Care Professional,

Endoscopes returned to a Pentax facility for any reason (repair, complaint investigation, etc.) **must** be decontaminated prior to shipment. Flexible endoscopes whose watertight integrity has been maintained (no "leaks") should be subjected to standard reprocessing procedures described in Pentax endoscope owner's manuals. Such reprocessing procedures would allow for subsequent safe handling by hospital staff, carrier and manufacturer/service personnel.

It is recognized that under certain circumstances (ex. "leak" found), standard reprocessing procedures could further harm a previously damaged or compromised instrument.

The following special decontamination procedures have been developed for Pentax flexible endoscopes that have "leaks" confirmed by a failed Pentax leakage test. Immersion of endoscopes with leaks into reprocessing solutions (detergent and/or liquid chemical germicides) may lead to further fluid invasion resulting in potentially significant instrument damage.

Important Notes

1. Always use a soaking cap, if applicable to a specific scope model, **PRIOR** to immersion in any fluid
2. Always perform a leakage test as per instructions supplied with the Pentax leak tester or Pentax endoscope owner's manual
3. Use only legally marketed liquid chemical germicides (high-level disinfectants/sterilants) identified by Pentax as being compatible with Pentax endoscopes

STEP ONE (A) PRE-CLEANING

Typically, standard pre-cleaning procedures should have already been performed in the examination room by the time a leak has been identified. If already pre-cleaned, proceed to **Step Two**.

STEP ONE (B) PRE-CLEANING

(Follow step 1(B), if pre-cleaning has NOT already been performed)

- Wipe off all gross debris from the endoscope insertion tube and control section.
- If **NO** leak was identified in the suction/instrument channel(s) system, aspirate enzymatic detergent solution through the channel(s) while **ONLY** the scope distal tip is submersed in solution. Then alternate aspiration of detergent and air several times to create agitation for better pre-cleaning.
- If a *leak has been detected* in the suction/instrument channel(s) system, proceed to **Step Three**.

STEP TWO CLEANING

Cleaning of clinically used instruments should be performed as thoroughly as possible under the unique circumstances (location and/or degree of leakage) for each device.

- Brush **ALL** areas of the suction/instrument channel(s) system (including within the insertion tube, channel inlet, control body, suction valve housing, light guide cable and suction port/connector) until visibly clean.
- Aspirate rinse water through **ALL** suction/instrument channels to flush out loosened and/or residual debris. Remove detachable components (air/water valve, suction valve, inlet seals, etc.) and soak them in an enzymatic detergent. Rinse and dry components.

STEP THREE Option 1 (Recommended)
ETHYLENE OXIDE GAS STERILIZATION

Following the ETO sterilization instructions and parameters described in Pentax owner's manuals, subject the previously cleaned endoscope to an Ethylene Oxide Gas Sterilization process.

Ideally, the instrument should be as dry as possible prior to ETO exposure. Therefore, an alcohol rinse through ALL channels with NO confirmed leaks, followed by forced air may be used to facilitate drying of surfaces.

STEP THREE Option 2
(LIQUID CHEMICAL GERMICIDE)

NOTE: For added protection from major fluid invasion, a leak tester should be used to maintain pressure within the endoscope whenever a leak has been found in any portion of the endoscope. Therefore, for all subsequent steps, maintain air pressure within the endoscope.

For those facilities where ETO gas is not available, the following special instructions for immersion in a liquid chemical germicide may be used.

NOTE: Confirming as accurately as possible the exact location of a leak may avoid unnecessary damage to the already compromised instrument.

3A. LEAK IN ENDOSCOPE SHEATH/COVER

If a leak has been found in the outer sheath/cover of the distal bending rubber, insertion tube, light guide cable and/or in a seam/crack in the control body cover/housing, cover the leak with electrical or other waterproof tape.

- Attach the leakage tester and *while maintaining pressure* (continuous pumping of air) within the scope, the instrument may be immersed in a liquid chemical germicide (high-level disinfectant/sterilant). Providing NO leaks have been confirmed within the channels, they (the channels) should be completely filled with the germicide solution. The endoscope and channels should remain exposed to the germicide for the time period recommended by the germicide manufacturer.
- Keep the leak tester attached and maintain pressure within the endoscope while soaking or rinsing the scope and while flushing or rinsing its channels.

3B. LEAK IN INTERNAL CHANNELS

If a leak has been identified in a specific channel system (ex. air/water or suction/instrument), do NOT inject the liquid germicide into these areas. Germicide solution should ONLY be flushed into channels with NO LEAKS to prevent further fluid invasion.

- If leak tested properly and a leak has been identified within a channel inside the insertion tube only, the entire light guide cable (*excluding* control body) may be immersed in the liquid germicide. This applies to leaks indicated by escaping air bubbles out of the scope distal tip (channel exits/ports) only. If air bubbles escape from the (air/water, suction or forward water jet) valve housings in the control body or from the LG plug/PVE connector, do **NOT** immerse the control body or *ANY* portion of the LG cable.
- If NO leak has been found within *any* channels inside the insertion tube (as indicated by the absence of a trail of escaping air bubbles exiting the scope tip or valve housings in the control section during a leakage test), the entire insertion tube may be immersed in germicide solution.
- All channels with no leaks should be filled with germicide and the entire insertion tube up to but not including the control body may be soaked in the disinfectant/sterilant solution for the time & temperature recommended by the germicide manufacturer.

NOTE: If a leak has been identified but an exact location (insertion tube, control body, LG cable, LG plug/PVE connector, etc.) can not be confirmed, do NOT immerse the endoscope in fluid.

3C. LEAK AT THE SCOPE DISTAL TIP

NOTE: Due to the close proximity of the distal channel openings, nozzles, objective lens and LG cover glass (windows), etc. to each other, it may be difficult to discern the precise source of a distal leak. For example, a trail of air bubbles emanating from an air or water channel may appear as a leak from the "scope tip".

- For clarification purposes in this section, a leak at the scope distal tip refers to an actual crack in material or separation between joined surfaces and/or outright breakage in material/components composing the distal end (tip) of the endoscope. Typically, such compromises in the integrity of the scope are due to impact.
- If a true distal tip leak has been identified as the **SOLE** source of leakage, the rest of the endoscope may be soaked in a germicide solution and rinsed, providing the scope distal tip remains **OUT** of fluid. The internal channels can likewise be filled with & exposed to the germicide and rinsed as usual as long as the scope tip is kept **OUT** of solution.

3D. RINSE AND DRY

NOTE: Applies to all scopes decontaminated with liquid chemical germicides

- Rinse and then dry any areas that were exposed to the liquid chemical germicide.
- **ANY** cleaned portions of the endoscope that *have not* or *can not* be immersed in the germicide because of leakage should at least be wiped down with 70% alcohol.

IMPORTANT

NOTE: If one questions the adequacy of decontamination for any particular instrument, repeat Steps Two and Three.

ANY instruments that can **not** be decontaminated as per the special instructions in this document should be considered "CONTAMINATED" and treated as such.

All contaminated devices should be handled carefully as per OSHA guidelines and institutional protocol. Typically, contaminated medical equipment should be placed into an impermeable, 3 mil (thick) red plastic bag, labeled "Biohazard". This sealed plastic package if appropriately sized will allow the instrument to be placed within its carrying case for transportation to the manufacturer or service facility.

A Biohazard warning label should also be placed on the *outside* of the carrying case or carton for easy identification of its contents by personnel involved in shipping/receiving of product.

Lastly, the **condition** (contaminated or decontaminated and by what methods) of all returned instruments should be clearly stated on documentation (repair request form or other) supplied with each shipped product.