Reprocessing Summary and Guide for Fujinon/Fujifilm Flexible GI Endoscopes

Flexible endoscopes are reusable medical devices which require special handling after each clinical use to render them safe for subsequent patient procedures. Endoscopic instruments should be subjected to appropriate reprocessing steps as described in detail in each endoscope Operation Manual/Instructions for Use (IFU). Reprocessing procedures are device-specific due to the fact that though seemingly similar in external appearance, their internal designs particularly lumens in indirect patient contact may vary significantly from one model to the next even within the same brand and/or endoscope type.

Individuals involved in the reprocessing of flexible endoscopes should be adequately trained on device-specific instrumentation and adhere to infection prevention and control standards. It is recommended that healthcare facilities should establish institutional quality assurance and safety programs addressing all endoscopy activities including endoscope preparation, reprocessing, maintenance, tracking, etc. Written standard operating procedures (SOPs) should be developed for endoscopy activities including documentation of comprehensive training and competency requirements for staff associated with endoscope use and preparation of instruments for subsequent patient procedures.

Reprocessing can be broken down into the following basic steps:

1) **Pre-Cleaning** (performed in the examination room)
2) **Leak Testing** (performed in a "cleaning room"/decontamination area)
3) **Cleaning/Rinsing** (performed in a "cleaning room"/decontamination area)
4) **High-Level Disinfection/Rinsing/Final Drying** (performed in a "cleaning room"/decontamination area)

This IFU Summary Guide has been prepared based upon Fujinon/Fujifilm manual reprocessing recommendations as described in Fujinon/Fujifilm Operation Manuals (IFUs). Unless noted otherwise all described steps are common with similarly designed Fujinon/Fujifilm "G5-type" flexible GI endoscopes having a single instrument channel and are 530-series, 450-series and/or 250-series models.

Since this information has been prepared as a summary to simplify the general understanding of Fujinon/Fujifilm's detailed instructions, it is important to check and confirm the latest device-specific operating and reprocessing (cleaning, disinfection and/or sterilization) recommendations described in Fujinon/Fujifilm instruction manuals which may identify additional steps for specialty scopes or instruments with special feature areas. This summary is not intended to replace or modify standard Fujinon/Fujifilm reprocessing recommendations described in the endoscope instruction manuals and provided with all newly purchased products.

Important Notes/Reminders

- Use personal protective equipment (impervious gloves, gowns, eye shield/face mask, etc.) during all reprocessing steps
- Identify all scope brands and models which are in inventory and intended to be reprocessed
- Prior to reprocessing, ensure that the reprocessing agents are compatible with the endoscope, AER, flushing aids, etc.
- Confirm that manufacturers' instruction manuals/IFUs are available for all relevant equipment (endoscope, AER, flushing aids, accessories, etc.)
- Have device-specific SOPs for reprocessing each instrument at-hand; ensure compliance with manufacturers' instructions and product claims
- Identify all channels, special feature areas and related scope components for each endoscope model; confirm each device's reprocessing requirements and check if any model, channel and/or scope component is contraindicated for reprocessing using any particular reprocessing method, process and/or chemical

- Depending upon specific product claims, various Automated Endoscope Reprocessors (AERs) are available for the automated cleaning and/or high-level disinfection of Fujinon flexible endoscopes. Each AER manufacturer must be consulted for their particular product claims, identification of compatible endoscope models which can be reprocessed in their AER and for device-specific reprocessing instructions for each endoscope.
- Although certain AER original equipment manufacturers (OEMs) may claim that their automated cleaning cycle can substitute for manual cleaning and channel brushing, Fujinon/Fujifilm recommends that endoscopes should be manually cleaned including channel cleaning by brush before attempting automated reprocessing.
- Flexible endoscopes should be inspected often – before, during and after use and reprocessing. Fujinon/Fujifilm recommends that any instruments whose suitability for use is questioned should be returned to the scope OEM for evaluation and service, as necessary.

Ensure that you have all appropriate equipment required for instrument reprocessing, including Personal Protective Equipment (PPE), compatible detergents and high-level disinfectants, 70% alcohol, soaking basins, flushing aids, leak testers, syringes, cleaning brushes, cleaning adapters, etc. Detergents should be fresh enzymatic or special formulations specifically intended to clean flexible endoscopes. Properly label and identify detergent solution in procedure room to avoid inadvertent use with patients. Regardless of whether clinically used or not in any given procedure, **all** internal channels/lumens within the endoscope must be reprocessed prior to next patient use.

I. Pre-Cleaning (at Point of Use):

A. *Immediately* after completion of the procedure begin pre-cleaning in the examination room to remove patient material, reduce bioburden levels and to prevent residual debris from drying and hardening on instrument surfaces
B. Wipe the flexible portion (insertion tube) with lint-free cloth (ex. gauze) saturated with detergent solution
C. Alternate suctioning of detergent and air through the entire instrument/suction channel(s) system; repeat at least two more times and then aspirate air until the solution has been drained from the channel
D. Flush/purge the air and water channels; feed air into the air channel and water into the water channel, disconnect the water tank container and completely drain the A/W channels
E. Flush/purge all applicable special feature areas (water jet channel, exposed elevator channel, balloon channels, etc.); Inject detergent solution, followed by air through the water jet channel. (For applicable models leave Fujinon/Fujifilm JT-500 J Tube attached to scope)
F. Remove detachable scope components (AW valves, Suction valves, Forceps Valves, etc.); place reusable components in a container of detergent solution and begin soaking of smaller items.
G. Discard single-use components (ex. Forceps Valves, Balloons); check with the original equipment manufacturer (OEM) regarding conditions for acceptability of multiple patient use “disposable” 24 hour irrigation tubes/accessories
H. Carefully transport the “soiled” instrument in a covered container to a decontamination area - leave Fujinon/Fujifilm J Tube attached to applicable scope; avoid mishandling to prevent instrument damage – do not carry in a bag or allow portions of the scope to hit into each other which may create impact and/or scratches on delicate materials such as the distal bending section sheath

II. Leak Testing:

Regardless of reprocessing method, the endoscope should first be leak tested per manufacturer’s recommendations. Instruments should be fully immersed in a basin containing clean water during WET leak testing. Do not subject the endoscope to any impact or lay heavier portions of the scope on top of each other during placement in a sink or basin, as doing so can damage more delicate areas of the endoscope.

Fujinon/Fujifilm does not validate the effectiveness of non-Fujinon/Fujifilm leak testing devices including individual units and those built-into AER systems. Whether hand-operated, electro-mechanical, fully automated and/or featured in an AER, Fujinon/Fujifilm bears no responsibility for use of non-Fujinon/Fujifilm leak testers.

Customers should contact the OEM of their leak testers to confirm their product claims including compatibility with Fujinon/Fujifilm endoscopes and their ability to detect leaks under all recommended usage conditions.

A. Ensure that all removable scope components are detached from the endoscope PRIOR to leak testing
B. Attach a dry waterproof/soaking cap to the endoscope PRIOR to immersion in ANY fluid
C. Inspect the leak tester before use and connect it to the scope ***out of water*** – dry leak test scope BEFORE immersion; ensure leak tester has no fluid/moisture inside tubing, connector or bulb
D. Perform a DRY leak test by pressurizing the scope, letting stand for 30 seconds and checking if the indicator needle on the Fujinon/Fujifilm tester gauge drops ten gradations (or 5kPa).
E. Perform a WET leak test in clean water while manipulating the bending section and remote/video switches; confirm that no leak exists by looking for a continuous stream of air bubbles. If a leak is detected, contact Fujinon/Fujifilm for additional instructions.
F. If no leak has been detected and while the scope is out of water depressurize the scope, allow the distal bending sheath to return to its original pre-expanded condition and then disconnect the leak tester from the scope

III. Manual Cleaning:

Inspect all cleaning equipment (including cleaning brushes, channel adapters, etc.) and ensure their appropriateness for use. Discard reusable brushes with kinked/bent shafts and/or missing/deteriorated bristles. Do not reuse adapters which cannot be properly secured to a channel port and/or whose tubing may have a leak or otherwise be compromised. Use only those cleaning devices and accessories which have been validated for use with the respective endoscopes intended to be reprocessed.

Various products are intended to aid in and/or simplify the manual flushing of detergent solution and rinse water through endoscope channels. Deluxe units may offer additional features for entire scope cleaning including a large basin for complete instrument immersion and ample space to better accommodate channel brushing, dedicated ports for high pressure access to long, narrow scope channels, pre-measured detergent injections, sink overflow sensor, etc. Follow instructions of the original equipment manufacturers for these products and use only those channel adapters recommended by the OEMs.

- Do NOT assume that the same channel adapters used with a flushing aid or during manual cleaning can be used with an AER unless confirmed in writing by the AER OEM. Automated reprocessing instructions should be provided by each AER manufacturer based upon their own validated recommendations.

A. Do NOT reprocess the endoscope together with any sharp-edged objects including forceps, needles, etc.
B. Prepare **fresh** enzymatic detergent solution as per detergent manufacturer's recommendations
C. Immerse entire endoscope and all scope components in fresh detergent solution; keep scope fully submerged during subsequent steps; clean all exterior surfaces of the scope using a lint-free cloth, sponge and/or brush
D. Avoid tight coiling of the flexible portions - insertion tube and umbilical cable; larger coiling of the scope will allow easier channel brushing (less frictional resistance) compared to tighter coiling of the tubes
E. Using OEM-provided cleaning brushes intended for specific channel sizes mechanically clean accessible channels, ports, valves, scope tip, around nozzles, elevator mechanism, etc.; typically, non-OEM brushes have not been validated by the scope OEM as being effective. Check with the brush supplier to confirm their effectiveness for cleaning device-specific endoscope channels.
F. Brush the suction tube within the LG/umbilical cable – insert brush from the suction cylinder through the LG cable until the brush exits the suction connector; wipe debris off bristles before withdrawing brush back into channels
G. Brush the suction/instrument channel(s) within the insertion tube starting from suction valve cylinder down to scope distal end – also pass brush from forceps inlet (biopsy port) to scope distal tip and from the suction cylinder to the forceps inlet; again, wipe debris off bristles before withdrawing or re-introducing brush into channels
H. Brush instrument channel inlet ports, valve cylinders, recessed areas, etc. until all surfaces are visibly clean
I. Brush all other accessible channels or lumens (in applicable scopes)

J. Using the Fujinon/Fujifilm-supplied channel cleaning adapters, flush detergent into EACH channel, IF featured in scope including:
    a) Suction/instrument channels (primary and secondary channels on two-channel scopes)
    b) Air and water channels
    c) Water jet channels
        - ensure removal of rubber check-valve (ex. AJ-500) BEFORE flushing - use Fujinon/Fujifilm recommended tubes (ex. JT-500) or adapters (ex. CJ-500)
    d) Exposed elevator wire/channels on older instruments (also inject detergent onto/around elevator mechanism to ensure complete contact with distal tip surfaces)
    e) Balloon channels in ultrasound scopes and/or certain enteroscopes
    - Automated or electro-mechanical channel flushing devices may be substituted for the manual flushing of detergent via syringes described in the previous steps; follow the validated instructions developed by the OEM of the flushing aid for specific channel connections, flushing requirements and flow verification
K. During the flushing process, visually confirm that detergent flows out from each channel opening until no air bubbles exit – this will ensure that the channels are filled with cleaning solution
L. Using brush, sponge and/or lint-free cloth mechanically clean, then flush all channel openings/ports and scope components with detergent; manipulate valves during cleaning to allow better perfusion of cleaning solution and exposure to component surfaces
M. Components with residual debris may be cleaned via an ultrasonic cleaner; ultrasonic cleaning is recommended for components which will subsequently be steam sterilized. Check with Fujifilm instruction (CDS) manuals to confirm which items can be ultrasonically cleaned and steam sterilized
N. Ensure the entire scope including all channel surfaces remains in contact with detergent solution (as per detergent OEM recommendations for time and temperature)
O. After purging all channels with air, remove the endoscope and components from detergent solution; discard used detergent
P. Rinse scope, all internal channels and components with water to remove residual detergent and debris
Q. Visually inspect all items; repeat cleaning process if necessary to ensure removal of residual patient material/debris
R. Dry scope exterior, internal channels and scope components prior to subsequent high-level disinfection procedures

IV. High-Level Disinfection:

Manual High-Level Disinfection

Flexible GI endoscopes (and bronchoscopes) which normally come into contact with mucous membranes are considered semi-critical medical devices that require at least high-level disinfection. Use only those liquid chemical germicides which have been FDA-cleared as high-level disinfectants and are recognized as compatible for the specific instruments intended to be reprocessed.

It should be noted that channel flushing aids are not labeled for use as disinfecting devices or as disinfectors; these products are intended to assist in the flushing of detergent solution, water and/or air during manual cleaning – they are not intended for endoscope disinfection. Check all product claims and IFUs with the OEM.

A. Check Minimum Effective Concentration (MEC) of the high-level disinfectant per manufacturer's labeling
B. Immerse the entire endoscope and scope components in a high-level disinfectant prepared per germicide manufacturer's recommendations
C. Attach the supplied Fujinon/Fujifilm channel disinfecting adapters to the endoscope
D. Avoid introduction of air bubbles during the subsequent flushing process
E. Flush the disinfectant into EACH channel (regardless of whether used clinically or not); ensure contact of disinfectant with all channel surfaces including:
    a) Suction/instrument channel (primary and secondary channels on two-channel scopes)
    b) Air and water channels
    c) Water jet channel

- ensure removal of rubber check-valve (ex. AJ-500) BEFORE flushing - use Fujinon/Fujifilm recommended tubes (ex. JT-500) or adapters (ex. CJ-500)

d) Exposed elevator wire/channel on older instruments (also inject disinfectant onto/around elevator mechanism to ensure complete contact at scope distal tip)
e) Balloon channels in ultrasound scopes and/or enteroscopes

F. During the flushing process, visually confirm that disinfectant flows out from each channel opening until no air bubbles exit – this will ensure that the channels are filled with disinfectant solution
G. Provided all channels are filled with solution and while the instrument remains fully immersed, disconnect all channel disinfecting adapters and syringes to ensure exposure of disinfecting solution to previously mated surfaces (between adapters and channel/cylinder ports)
H. Follow germicide manufacturer's recommendations for exposure time, temperature, etc.
I. Flush disinfectant solution into/through each scope component; manipulate valves while flushing and ensure contact of disinfectant with all component surfaces
J. After exposure to the disinfectant, purge all scope channels with air using the provided disinfecting adapter
K. Air purge all removable scope components
L. Immerse the entire scope and all components in sterile or filtered water
M. Rinse the scope, all channels and components with sterile water - **Note:** most germicides require a triple water rinse; follow disinfectant manufacturer's recommendations
N. Air purge all previously rinsed channels and components
O. Perform a final alcohol rinse/flush through all internal channels to aid in the evaporation of moisture; use 70% alcohol from a sealed container
P. Follow the alcohol rinse with forced air to thoroughly dry all surfaces
Q. Wipe and dry all external surfaces of scope using a lint-free cloth
R. Many removable components (ex. valve mechanisms) may be pre-vacuum steam sterilized in lieu of high-level disinfection; check with scope OEM for compatibility of specific items with steam sterilization

"Automated" Reprocessing by an Automated Endoscope Reprocessor (AER)

Prior to AER use, all endoscope OEM recommendations for pre-cleaning, leak testing and manual cleaning as summarized in the preceding steps should have been performed. Unless the particular AER has channel monitoring capability, ***before*** **"automated" reprocessing the end user should first confirm that all internal channels are intact, unblocked and free of restrictions/obstructions** that could otherwise limit or impede the ability of reprocessing agents to flow through tubing/adapters and contact all channel surfaces. It should be recognized that regardless of AER if the internal channels of an endoscope are blocked/obstructed, reprocessing solutions may not make contact with all channel surfaces, and therefore portions of the endoscope may remain contaminated.

Use only those AERs and high-level disinfectants which are legally marketed and are recognized as compatible with the specific devices intended to be reprocessed. Make sure that all AER OEM care and maintenance recommendations including periodic replacement of water filters are followed.

It should be noted that some AERs may use elevated temperatures during automated reprocessing. It is recommended that prior to handling and/or removal from the AER, Fujinon/Fujifilm flexible endoscopes which have been heated during reprocessing should be allowed to cool down and return to room temperature to minimize the potential for instrument damage.

A. Review AER manufacturer's device-specific instructions for reprocessing each endoscope, internal channel and scope component
B. Confirm each AER product claims for reprocessing specific model instruments and components intended to be reprocessed
C. Check if the AER manufacturer has identified any limitations for use with respect to a specific endoscope model, internal channel, special feature area and/or component/accessory;
Certain AERs may
    - not be able to reprocess all scope types (ex. ultrasound, two-channel)

- may have limited reprocessing claims depending upon scope condition or patient procedure (ex. if endoscope is used during "emergency procedures", not reprocessed within one hour after use)
- may make no claims for special feature areas (ex. exposed elevator wire channels) and/or endoscope component (ex. suction valve) or accessory (ex. irrigation tube)

D. Depending upon AER it may be necessary to confirm that programming of the AER satisfies the parameters for use of the disinfectant/germicide, detergent, etc. Also, check the MEC of the disinfectant as recommended in its labeling
E. Confirm that AER OEM-recommended adapters/tubes are available on site for reprocessing each endoscope model and/or component
F. Ensure that the endoscope is properly positioned within the reprocessing chamber as per AER manufacturer's instructions, so that the lid will not damage the scope, channel adapter tubes will not kink and the scope and/or channel adapter tubes will not interfere with the AER rotating spray arm, if available
G. Ensure that all adapters/tubes are properly connected between the endoscope/channels and machine/ports as per AER manufacturer's recommendations
H. Confirm that any scope check-valves (ex. within water jet system and/or irrigation tubes) are removed before reprocessing as per manufacturer's instructions
I. Confirm precise placement of scope components, accessories, etc. in the designated location within the reprocessing chamber of the AER (and adapter connections, if recommended)
J. Automated reprocessing should be performed while ensuring:
    - the entire scope and components remain immersed in the disinfectant per OEM recommendations for the appropriate exposure time and temperature
    - all channel adapters/tubes remain connected during the entire process
    - there are no kinks/restrictions within channel adapter tubing that may impede flow of solution
    - reprocessing solutions travel through and exit each individual channel
    - the alcohol and air cycles have dried all internal scope channels and fluid doesn't drip out of the scope after reprocessing
K. After automated reprocessing and cool down period (if necessary), the endoscope should be removed from the AER without delay
L. Any reprocessing steps (ex. alcohol flush) which are **not** performed by the AER for each channel or component, *should be performed* ***manually*** as per the endoscope OEM's recommendations
M. It is imperative that all internal channels are thoroughly dried via an alcohol flush and final air purge even if these steps must be performed manually
N. Retain AER printout to document decontamination of all instruments; maintain log of all instruments and patient data
O. Document and follow AER manufacturer's routine periodic maintenance schedules

Post-Disinfection:

Storage:

A. Confirm that all internal channels and scope surfaces were exposed to alcohol and then dried
B. Ensure that all removable scope components including waterproof caps are detached to promote better aeration of channels/ports and connectors during storage
C. Disengage any angulation locks and ensure locks are in free position
D. A continuous channel purging/forced air drying feature in a storage cabinet is advantageous to maintain properly dried instruments
E. Instruments should be well protected from contamination while in storage; hang scopes in a well ventilated, dust-free cabinet with flexible portions (insertion tube and umbilical cable) in a vertical position
F. Ensure that any scope rack, storage cabinet and/or doors contain no sharp-edged surfaces, screws, hinges, etc. that could scratch/damage the scope
G. Establish processes to easily and clearly distinguish patient ready instruments from those not yet reprocessed
H. Follow facility SOPs for reprocessing stored instruments

Re-use:

A. **BEFORE** use, inspect endoscope and all scope functions as described in OEM instruction manuals
   - Use only sterile water for any preparation for use inspection of the endoscope involving water

B. Ensure that the distal objective lens is clean, the endoscopic image is clear, air/water/suction/water jet systems function properly, etc. Prime irrigation tubing and water delivery channels before patient use.

C. Prior to clinical use ensure all one-way check-valve mechanisms are properly attached in water jet and/or irrigation systems as per OEM recommendations

Ancillary Endoscopic Devices:

- Always adhere to national reprocessing guidelines and to manufacturers' recommendations on preparation, use, care and maintenance, etc. of all endoscopic equipment
- Sterile water should be used during endoscopic irrigation or distal lens cleaning; water tanks/bottles should be high-level disinfected or sterilized at least on a daily basis consistent with OEM recommendations
- Single-use devices should be discarded after use
- Simethicone-based anti-gas substances including Mylicon should not be added to water delivery sources as they may be difficult to remove from bottle, tubing and/or scope surfaces and residues may prevent successful reprocessing
- Confirm the multiple patient use claims of 24 hour "disposable" tubing sets, accessories and single dose sterile water sources for endoscopic irrigation
- Critical items (ex. biopsy forceps, FNA needles, papillotomes, etc.) require sterilization (or disposal) after each use

Fujinon/Fujifilm recommendations described in this summary and provided in detail in endoscope instruction manuals may not be valid for instruments repaired by unauthorized service providers. Standard Fujinon/Fujifilm reprocessing instructions have not been validated for devices repaired by unauthorized service personnel and/or utilizing non-Fujinon/Fujifilm service parts and materials. Material compatibility with recognized reprocessing agents/methods cannot be assured if non-OEM parts and materials are utilized in the servicing of Fujinon/Fujifilm instruments. Users should consult their service provider to identify compatible reprocessing agents and to obtain validated reprocessing recommendations for specific instruments repaired utilizing non-OEM parts and materials and/or whose original device specifications may have been altered.

Representative Fujinon/Fujifilm GI Endoscope (G5 type) with Water Jet

(Depending upon scope model, WJ channel port may be relocated to LG connector)