

List of CDS Related Guidance

Processing Requirements for Thermolabile Flexible Endoscopes



CDS Related Guidance

Processing Requirements for Thermolabile Flexible Endoscopes

American Society for Gastrointestinal Endoscopy Standards (ASGE)

Procedure Room	Decontamination Area			
Precleaning	Manual Cleaning*	Manual Disinfection or EWD	Drying/Storage/Sterilization	Source
<p>Immediately after a procedure is completed</p> <p>Wipe the exterior of the endoscope with a detergent solution. Aspirate detergent through all channels (e.g., air/water and instrument/suction channels) until the aspirant is clear. Perform precleaning/point of use treatment of specific areas of duodenoscopes (e.g., elevator channel, recess) and specialty care endoscopes (e.g., balloon attachment groove in endoscopic ultrasound endoscopes)</p>	<p>Clean the entire endoscope, including valves, channels, connectors and all detachable parts, using only model-specific cleaning devices (such as brushes) designed for the endoscope model being cleaned</p> <p>Manual cleaning occurs within the manufacturers' recommended time frame, usually within 60 minutes after the endoscope is released from the procedure. When cleaning is delayed beyond this interval, the manufacturers' IFU for delayed processing are followed</p>	<p>HLD preferred in an AER</p>	<p>Drying: Endoscopes should undergo drying after the completion of all reprocessing steps</p> <p>Storage: Endoscopes should be stored in secure cabinets</p> <p>Endoscopes can be placed either in a vertical or horizontal position depending on the validated design of the endoscope cabinet</p> <p>Sterilization: Recommend EtO when necessary</p>	<p>American Society for Gastrointestinal Endoscopy. Multisociety guideline on reprocessing flexible GI endoscopes and accessories. (2021)</p> <p>https://www.giejournal.org/article/S0016-5107(20)34851-3/pdf</p>

Legend: EWD – endoscope washer-disinfector (chemo-thermal mechanical/automatic cleaning and disinfection)/AER – automated endoscope reprocessor GDA – glutardialdehyde PAA – peracetic acid OPA – ortho-phthalaldehyde ClO ₂ – chlorine dioxide	LCS – liquid chemical sterilization EtO – ethylene oxide LTSF – low-temperature steam formaldehyde H ₂ O ₂ – hydrogen peroxide OR – operating room EHEF – European Hygiene Experts Forum HLD – high-level disinfection	TGA – Therapeutic Goods Administration Sterilant – chemical (high-level disinfectant) that has been cleared as capable of destroying all viable microorganisms, including bacterial spores (mainly relevant for Americas) Process chemical use life Process chemical shelf life
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*Mandatory, even in the case of EWD processing

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As medical knowledge is constantly growing, technical modifications or changes of the product design, product specifications, accessories and service offerings may be required. This quick reference guide is a mere summary of some important procedure steps and/or product information. It is not meant to replace the instructions for use. Any user of this product must at all times observe all mandatory information for the product, found, in particular, on the labels and the instructions for use.

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