

List of CDS Related Guidance

Processing Requirements for Thermolabile Flexible Endoscopes



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Processing Requirements for Thermolabile Flexible Endoscopes

USA



Procedure Room		Decontamination Area		
Precleaning	Manual Cleaning*	Manual Disinfection or EWD	Drying/Storage/ Sterilization	Source
Immediately following completion of the endoscope procedure At minimum, water used for reprocessing of endoscopes should meet the specifications that are recommended	Perform meticulous manual cleaning including brushing and flushing channels and ports before performing high-level disinfection (HLD) or sterilization	Manual or AER processing	Storage: After reprocessing is complete, store endoscopes and accessories in a manner that prevents recontamination, protects the equipment from damage and promotes drying	Centers for Disease Control and Prevention (CDC). Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee. (2017) https://www.cdc.gov/hicpac/pdf/flexible-endoscope-reprocessing.pdf

Legend:

EWD – endoscope washer-disinfector (chemo-thermal mechanical/automatic cleaning and disinfection)/AER – automated endoscope reprocessor

GDA – glutardialdehyde

PAA – peracetic acid

OPA – ortho-phthalaldehyde

ClO₂ – chlorine dioxide

LCS – liquid chemical sterilization

EtO – ethylene oxide

LTSF – low-temperature steam formaldehyde

H₂O₂ – 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

^{*}Mandatory, even in the case of EWD processing

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M00466EN-USA · 01/22 · OKM

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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