

List of CDS Related Guidance

Processing Requirements for Thermolabile Flexible Endoscopes



CDS Related Guidance

Processing Requirements for Thermolabile Flexible Endoscopes

Belgium



Procedure Room	Decontamination Area			Remarks	Source
Precleaning	Manual Cleaning*	Manual Disinfection or EWD	Drying/Storage/Sterilization		
<p>Immediately after finishing patient's procedure</p> <p>By wiping the outer surface of the insertion tube and using (potable) water to flush/rinse all channels</p>	<p>Cleaning to be performed ASAP within a reasonable time frame in order to reduce biofilm formation, ideally within 30 minutes after use</p> <p>Cleaning solution freshly prepared for each endoscope</p> <p>pH-neutral enzymatic cleaners are preferred over pH-alkaline cleaners</p> <p>Manual leakage test in detergent solution</p> <p>Brushes must be single-use</p>	<p>EWD processing is state of the art</p> <p>PAA in preference to GDA</p> <p>Spectrum of antimicrobial activity: bactericidal, fungicidal, virucidal, mycobactericidal, and sporicidal (based on phase I and phase II EN standards)</p>	<p>After EWD processing (without active drying) the endoscope should be used within four hours</p> <p>Drying/storage cabinets (EN 16442) should preferably be used; also systems using ozone and PAA methods for horizontal storage exist</p> <p>LTSF sterilization is not recommended; critical devices (e.g. ureteroscopes) require H₂O₂ sterilization</p>	<p>Disinfection required of endoscopes without channel independently from usage of a protective sheath (e.g. UV-C disinfection, oxidative disinfectants)</p>	<p>Superior Health Council: Recommendations for the prevention of infections and management of heat-sensitive endocavitary medical devices and endoscopes (2020, SHC 9446)</p> <p>https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/18112020_shc-9446_endoscopes_vweb.pdf</p> <p>Good practices for the sterilization of medical devices (2017, SHC 9256)</p> <p>https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07022020_good_practices_for_the_sterilisation.pdf.pdf</p>

Legend:

EWD – endoscope washer-disinfector (chemo-thermal mechanical/automatic cleaning and disinfection)
 GDA – glutardialdehyde

PAA – peracetic acid
 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

*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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