

List of CDS Related Guidance

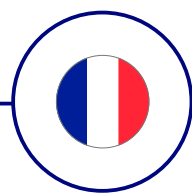
Processing Requirements for Thermolabile Flexible Endoscopes



CDS Related Guidance

Processing Requirements for Thermolabile Flexible Endoscopes

France



Procedure Room	Decontamination Area		
Precleaning	Manual Cleaning*	Manual Disinfection or EWD	Drying/Storage/Sterilization
Immediately after finishing patient's procedure By wiping the outer surface of the insertion tube and using standard medical-grade water (freshly prepared for every endoscope) to flush/rinse all channels Transport immediately into the processing area for further steps	“Double cleaning” (in the case of complete manual cleaning and disinfection) immediately following precleaning: first cleaning (freshly prepared detergent for every step and endoscope) incl. brushing for ≥10 minutes → rinsing with standard medical-grade water → second cleaning (freshly prepared detergent for every step and endoscope) incl. filling/flushing all channels for ≥5 minutes → rinsing with standard medical-grade water Use of alkaline cleaners (because of prions), where possible By regulation, cleaners must have disinfecting properties (mainly based on QAC, amine) Brushes must be single-use	Manually or EWD processing EWD having two cleaning cycles PAA-based disinfectants Spectrum of antimicrobial activity: bactericidal, tuberculocidal or mycobactericidal, fungicidal and virucidal, sporicidal (if necessary) Final rinse with · bacteriologically controlled water OR · packaged sterile water for irrigation of endoscopes used in sterile cavities, e.g. in transperietal choledochoscopy, urology	Drying: use of compressed medical-grade air Storage: use of drying and storage cabinets (EN 16442): maximum storage duration is seven days; upon removal, semicritical endoscopes can be used immediately, whereas critical endoscopes require HLD; by exceeding one week of storage time, a full reprocessing cycle is required (cleaning and disinfection) Conventional storage cabinets: endoscopes to be reused within 12 hours; by exceeding 12 hours, semicritical endoscopes must be disinfected and, regardless of the storage time, critical endoscopes require HLD before each use; by exceeding one week of storage time, a full reprocessing cycle is required (cleaning and disinfection) Sterilization: EtO sterilization is forbidden; installed base of other low-temperature sterilizers is very low (e.g. Sterrad)

Legend: EWD – endoscope washer-disinfector (chemo-thermal mechanical/automatic cleaning and disinfection) GDA – glutardialdehyde	PAA – peracetic acid 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
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* Mandatory, even in the case of EWD processing

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Remarks	Source
GI scopes incl. duodenoscopes classified as semicritical medical devices require cleaning and disinfection	Ministère de la Sante, de la famille, et des personnes handicapees; Nonnes pratiques de desinfection des dispositifs medicaux: guide pour l'utilisation des laveurs-disinfecteurs d'endoscopes (2003) https://sante.gouv.fr/IMG/pdf/ide_def241103.pdf
Endoscopes entering sterile body cavities classified as critical need to be sterile; in practice, for flexible URF, CYF, etc., cleaning and disinfection performed manually requiring HLD followed by final rinsing with sterile water	Ministère des affaires sociales et de la santé; INSTRUCTION N° DGOS/PF2/DGS/VSS1/2016/220 du 4 juillet 2016 relative au traitement des endoscopes souples thermosensibles à canaux au sein des lieux de soins (2016) https://solidarites-sante.gouv.fr/fichiers/bo/2016/16-08/ste_20160008_0000_0032.pdf
Delay procedure (EHEF): two–three times reprocessing followed by microbiological control (quarantine)	Liste des produits inactivants et format de dossier pour la revendication de performances d'inactivation (2021) https://ansm.sante.fr/vos-demarches/industriel/liste-des-produits-inactivants-et-format-de-dossier-pour-la-revendication-de-performances-dinactivation
Trend towards disposable endoscopes (e.g. URF, CYF, BF) → regulation 2016 defines situations for use of disposable endoscopes	

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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