HOSPITAL DA LUZ
LEARNING HEALTH
TRAINING, RESEARCH & INNOVATION CENTER

ASP UNIVERSITY
CONTINUOUS MEDICAL EDUCATION

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WEBINAR SUMMARY

Endoscopic reprocessing: TOWARDS STERILIZATION?

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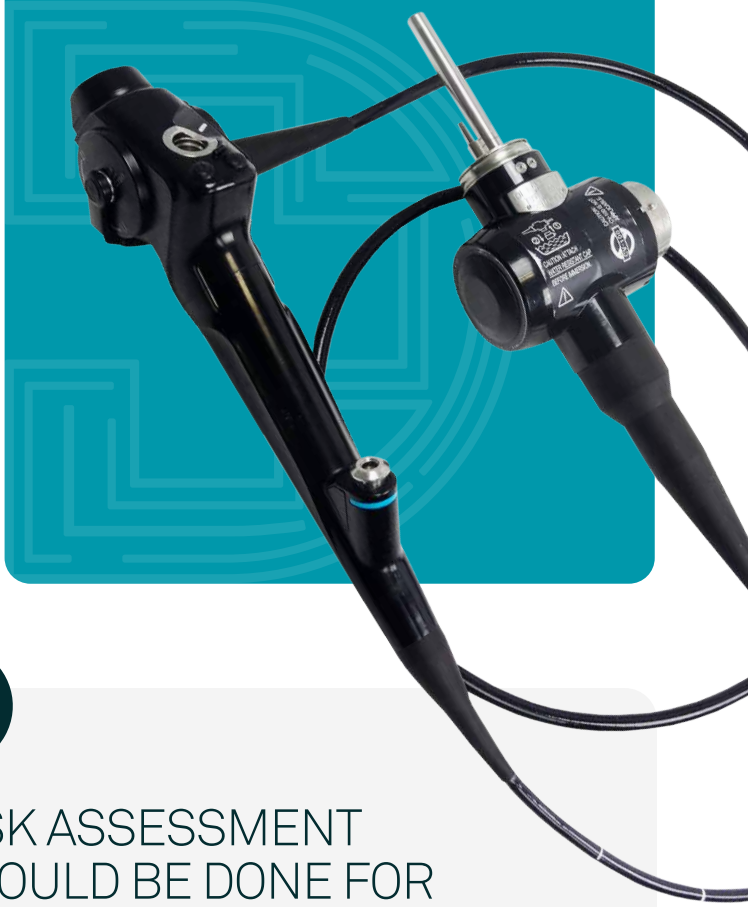
SPAULDING CLASSIFICATION IN MODERN ENDOSCOPY

As per CDC definition[1] Spaulding Classification is "a strategy for sterilization or disinfection of inanimate objects and surfaces based on the degree of risk involved in their use." There are three groupings of medical devices: lower risk non-critical medical devices which make contact with outer body surface, e.g. intact skin and require low to intermediate level disinfection for safe use; semi-critical devices, which make contact with broken skin and inner body surface, e.g. mucous membranes lining body cavities, these devices must be at least high level disinfected and preferably sterilized after each use; critical devices which make contact with blood, organs and sterile body tissues, these devices must be sterile for each use.



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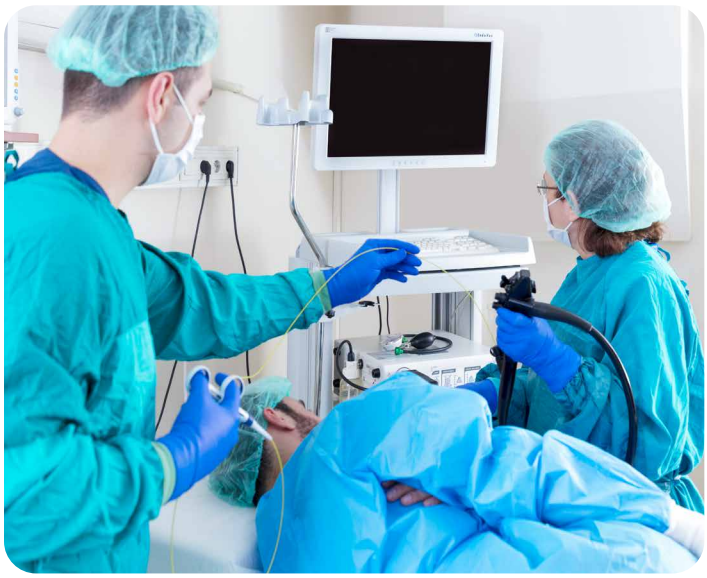
"Different procedures have varied levels of infection transmission risk."

RISK ASSESSMENT SHOULD BE DONE FOR ENDOSCOPIC PROCEDURES TO CHOOSE APPROPRIATE REPROCESSING STRATEGY.



CRITICAL ENDOSCOPIC PROCEDURES

Rigid endoscopes are used in laparoscopic and arthroscopic surgical procedures and are classified in the same critical risk category as invasive surgical instruments. Semi-flexible and flexible endoscopes are routinely used for interventional invasive medical procedures such as biopsies, polypectomies, injection etc. accessing sterile body tissues and circulatory systems by breaching mucous membranes. Single use sterile tools such as snares, brushes, needles, and others are passed through endoscope biopsy channels before coming in contact with sterile body tissues.

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“Invasive procedures can be performed by accessing sterile body tissues through mucous membranes.”

ENDOSCOPES ARE ROUTINELY USED FOR CRITICAL INVASIVE PROCEDURES.

DIFFERENCES BETWEEN THE HLD AND STERILIZATION

Scopes can carry as much as 10^7-10^{10} bacteria after the procedure[2]. Depending on risk classification endoscopes must be high level disinfected or sterilized for each use. High-level disinfection complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores. The CDC defines high-level disinfectant as a sterilant used for a shorter contact time to achieve a 6-$\log_{10}$ kill of an appropriate Mycobacterium species[3]. Sterilization – killing of all viable pathogens. The chance of a single viable pathogen surviving sterilisation process is less than one in a million, e.g. the Sterility Assurance Level is 10^{-6}

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“High-level disinfection significantly reduces endoscope contamination but there can be surviving microorganisms post disinfection including bacterial spores.”

STERILIZATION IS VALIDATED TO **KILL ALL PATHOGENS** ON AN INSTRUMENT.

THE BEST PRACTICE FOR PATIENT SAFETY

There are numerous studies proving survival of pathogenic microorganisms on endoscopes after high level disinfection. These disinfection survivors have cause numerous outbreaks of healthcare associated infections and led to procedure complications including fatalities[4,5,6]. Meticulous cleaning followed by sterilization or use of sterile single use endoscopes can substantially reduce risk of infection transmission and improve patient safety.

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"Including sterilization as part of endoscope reprocessing where possible can eliminate residual contamination and make endoscopic procedures safer for patients."

BEST PRACTICE MAY MEAN TO GO ABOVE THE LOWEST ACCEPTABLE DECONTAMINATION LEVEL.

Take home messages:

- ENDOSCOPES ARE ROUTINELY USED FOR INTERVENTIONAL INVASIVE MEDICAL PROCEDURES BRINGING THEM IN CRITICAL HIGH-RISK CATEGORY.
- BACTERIA CAN SURVIVE IN ENDOSCOPES AND CAUSE INFECTION OUTBREAKS DESPITE CAREFUL REPROCESSING OF INSTRUMENTS IN ACCORDANCE WITH MANUFACTURER'S GUIDELINES.
- HIGH-LEVEL DISINFECTION SIGNIFICANTLY REDUCES ENDOSCOPE CONTAMINATION BUT THERE CAN BE SURVIVING MICROORGANISMS POST DISINFECTION INCLUDING BACTERIAL SPORES.
- EVEN THOUGH HIGH-LEVEL DISINFECTION MAY BE ACCEPTABLE METHOD OF ENDOSCOPE REPROCESSING STERILIZATION WHERE POSSIBLE CAN ELIMINATE RESIDUAL CONTAMINATION AND MAKE ENDOSCOPIC PROCEDURES SAFER FOR PATIENTS.

Bronchoscope image: https://www.olympus-europa.com/medical/en/Products-and-Solutions/Products/Product/BF-XT190.html

References: **1.** https://www.cdc.gov/infectioncontrol/guidelines/disinfection/rational-approach.html **2.** Rutala WA, Weber DJ, 2016. Outbreaks of carbapenem resistant Enterobacteriaceae infections associated with duodenoscopes: what can we do to prevent infections?. Am J Infect Control. 2016 May 2;44(5 Suppl):e47-51. doi: 10.1016/j.ajic.2015.10.037. **3.** https://www.cdc.gov/infectioncontrol/pdf/-guidelines/disinfection-guidelines-H.pdf **4.** Epstein L, Hunter JC, Arwady MA, Tsai V, Stein L, Gribogiannis M, Frias M, Guh AY, Laufer AS, Black S, Pacilli M, Moulton-Meissner H, Rasheed JK, Avillan JJ, Kitchel B, Limbago BM, MacCannell D, Lonsway D, Noble-Wang J, Conway J, Conover C, Vernon M, Kallen AJ. New Delhi metallo-β-lactamase-producing carbapenem-resistant Escherichia coli associated with exposure to duodenoscopes. JAMA. 2014 Oct 8;312(14):1447-55. doi: 10.1001/jama.2014.12720. PMID: 25291580. **5.** Ofstead CL, Quick MR, Wetzler HP, Eiland JE, Heymann OL, Sonetti DA, Ferguson JS.Effectiveness of Reprocessing for Flexible Bronchoscopes and Endobronchial Ultrasound Bronchoscopes. Chest. 2018 Nov;154(5):1024-1034. doi: 10.1016/j.chest.2018.04.045.Epub 2018 May 31. PMID: 29859183. **6.** https://www.fda.gov/medical-devices/letters-health-care-providers/infections-associated-reprocessed-urological-endoscopes-letter-health-care-providers.

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