



# Ενδοσκόπια

Περιορίζοντας τον κίνδυνο Λοιμώξεων

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**ΕΚΠΑΙΔΕΥΤΙΚΟ  
ΠΡΟΓΡΑΜΜΑ IPC**  
(Infection Prevention & Control)

Ηράκλειο 29 Μαΐου 2026

# Nothing to Declare

Customs  
declaration forms

Please contact the customs  
duty manager if you have any  
customs related queries

CUSTOMS

Nothing to Declare





# Spaulding Classification of Medical Instruments



non-critical

Contact with intact skin

Low / Intermediate  
Level Disinfection

Reduces all organisms  
except spores



semi-critical

Contact with mucosa / body  
fluids

High Level Disinfection

Reduces all organisms  
and some spores



critical

Enters sterile site

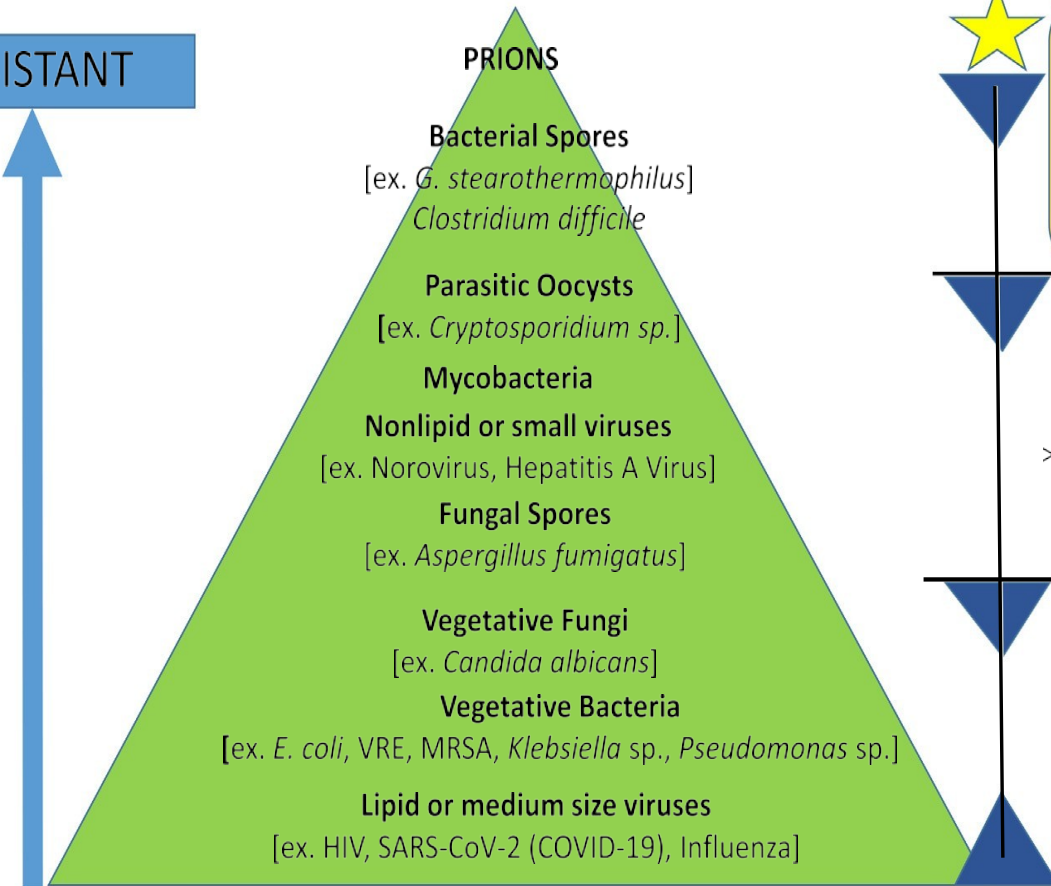
Sterilization

Reduces all organisms

# Spaulding Classification 1968 - 2023



RESISTANT



SUSCEPTIBLE

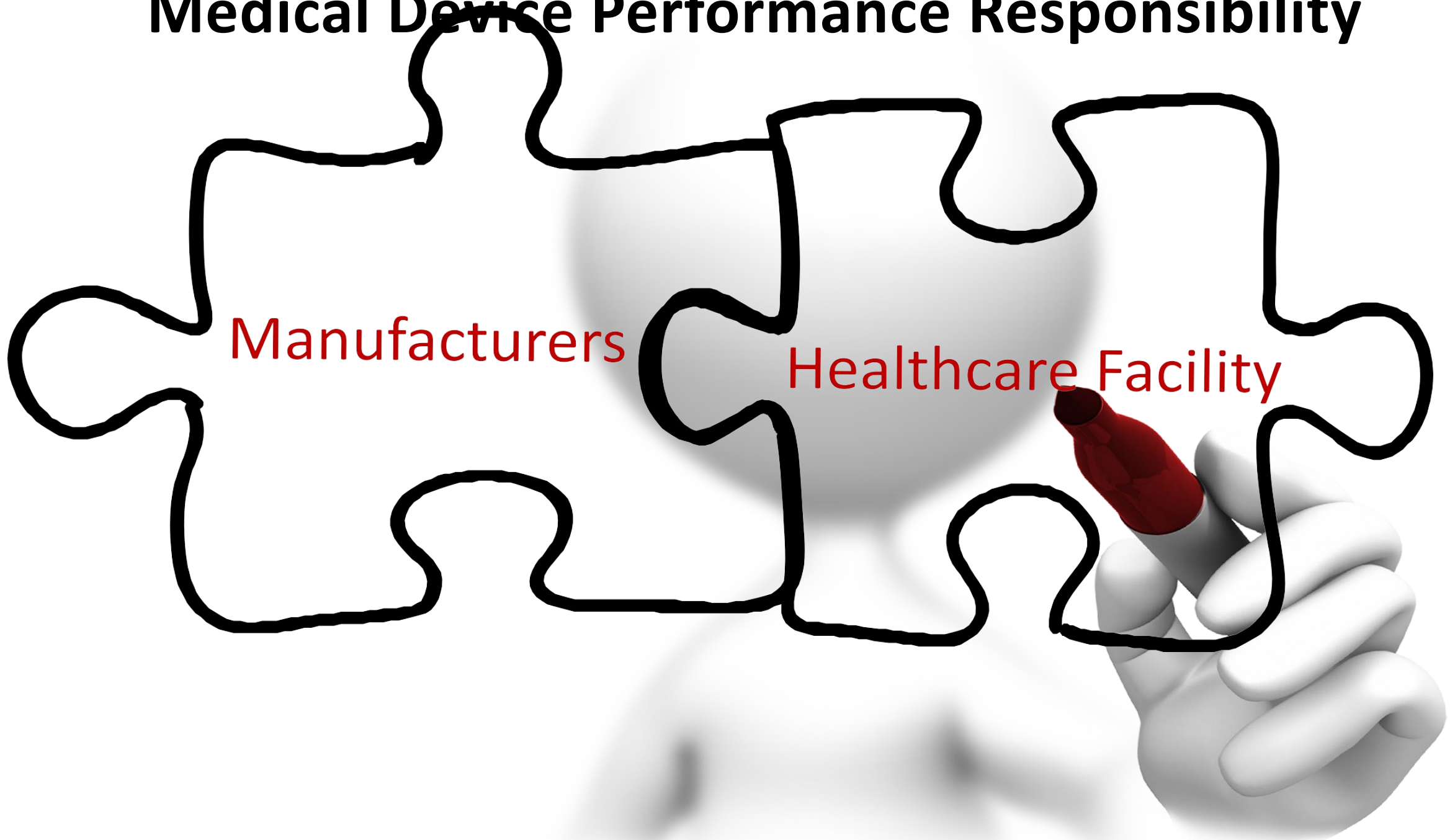
**Sterilization**  
 High temperature: Steam [40 min], dry heat [1 -6 hrs],  
 Low temperature: VH2O2 (~ 35 min), Ethylene oxide gas (15 h),  
 Chemical sterilants – 2% GTA (10 hrs , 20°C - 25°C),

**High Level Disinfection [HLD]**  
 Reduced concentrations and exposure times [For example  
 Chemical disinfectants:  
 >2% GTA , 0.55% OPA, peracetic acid, hydrogen peroxide;  
 Heat pasteurization; Ao=600]

**Low level Disinfection [LDL]**  
 Liquid disinfectants with no mycobacterial claim – chlorine-based products, 70%-90% alcohol, phenolics, H2O2  
 Short treatments (≥1 min). Heat pasteurization [Ao=60]

Pyramid of increasing microbial resistance to disinfectants and sterilants [Noting, this is a guide as the actual levels of resistance depend on the type of disinfection/ sterilization process]

# Medical Device Performance Responsibility



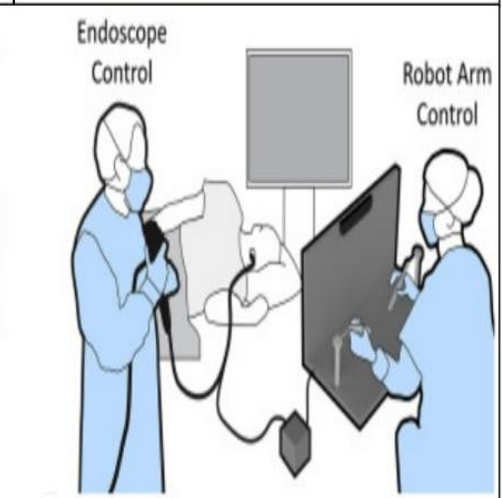
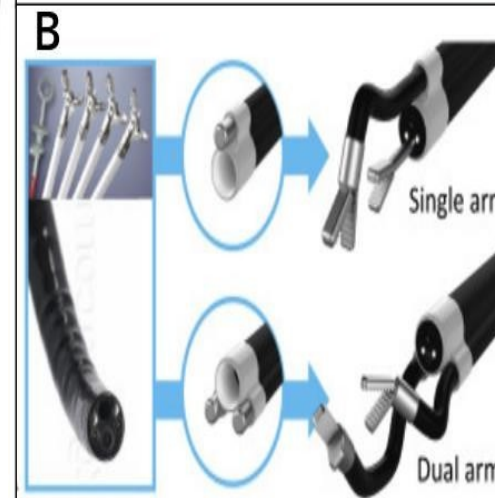
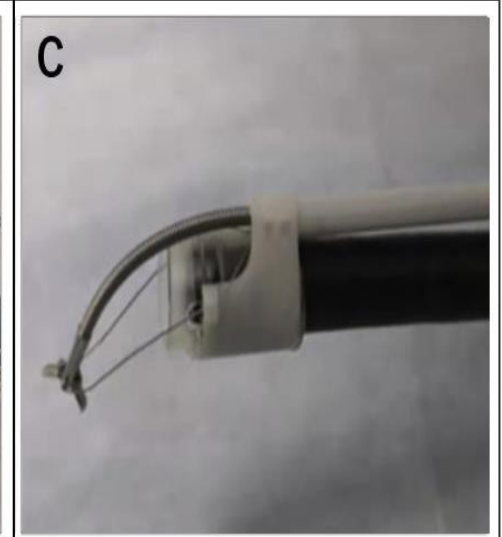
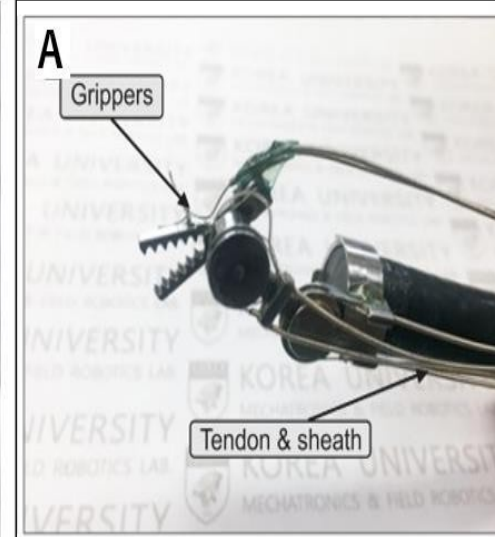
Manufacturers

Healthcare Facility

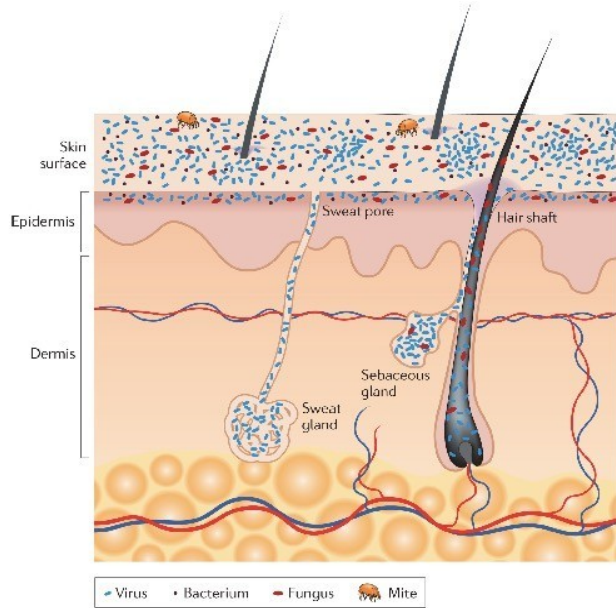
# What Most MDs Know About Device Reprocessing



# Disinfect This...

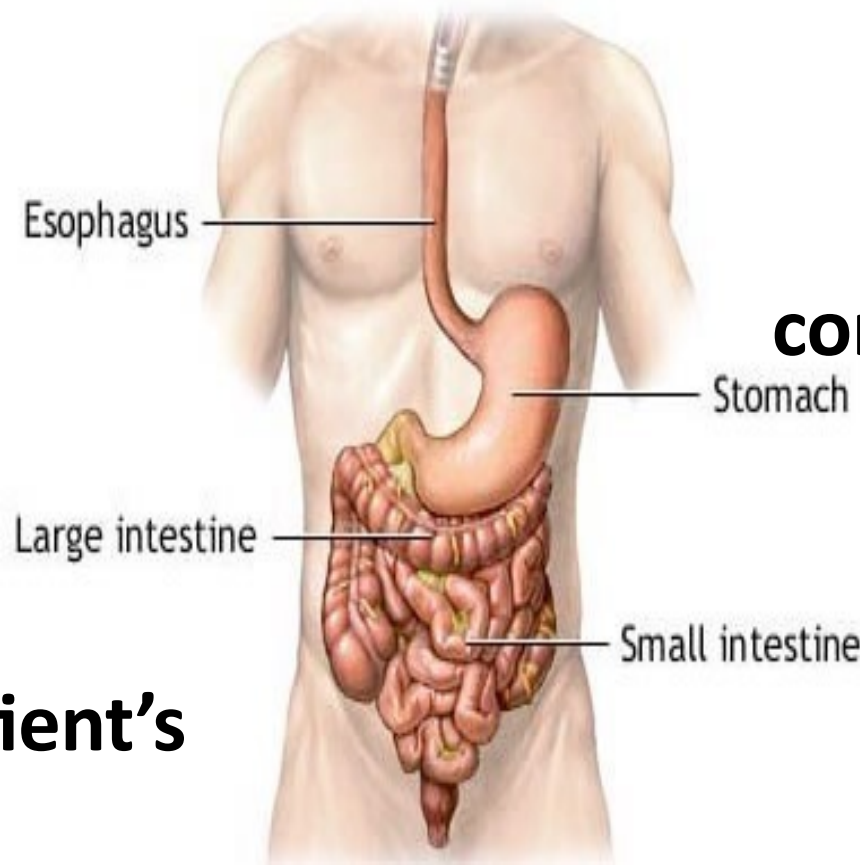


# Infections Related to Contaminated Medical Devices



**Endogenous:**  
Infections due to patient's own organisms

*Translocation of own flora*



**Exogenous:**  
Infection resulting from contaminated medical device

*Contaminated endoscopes with biomaterial from previous patients*

*Contamination by AER/Drying/Storage*

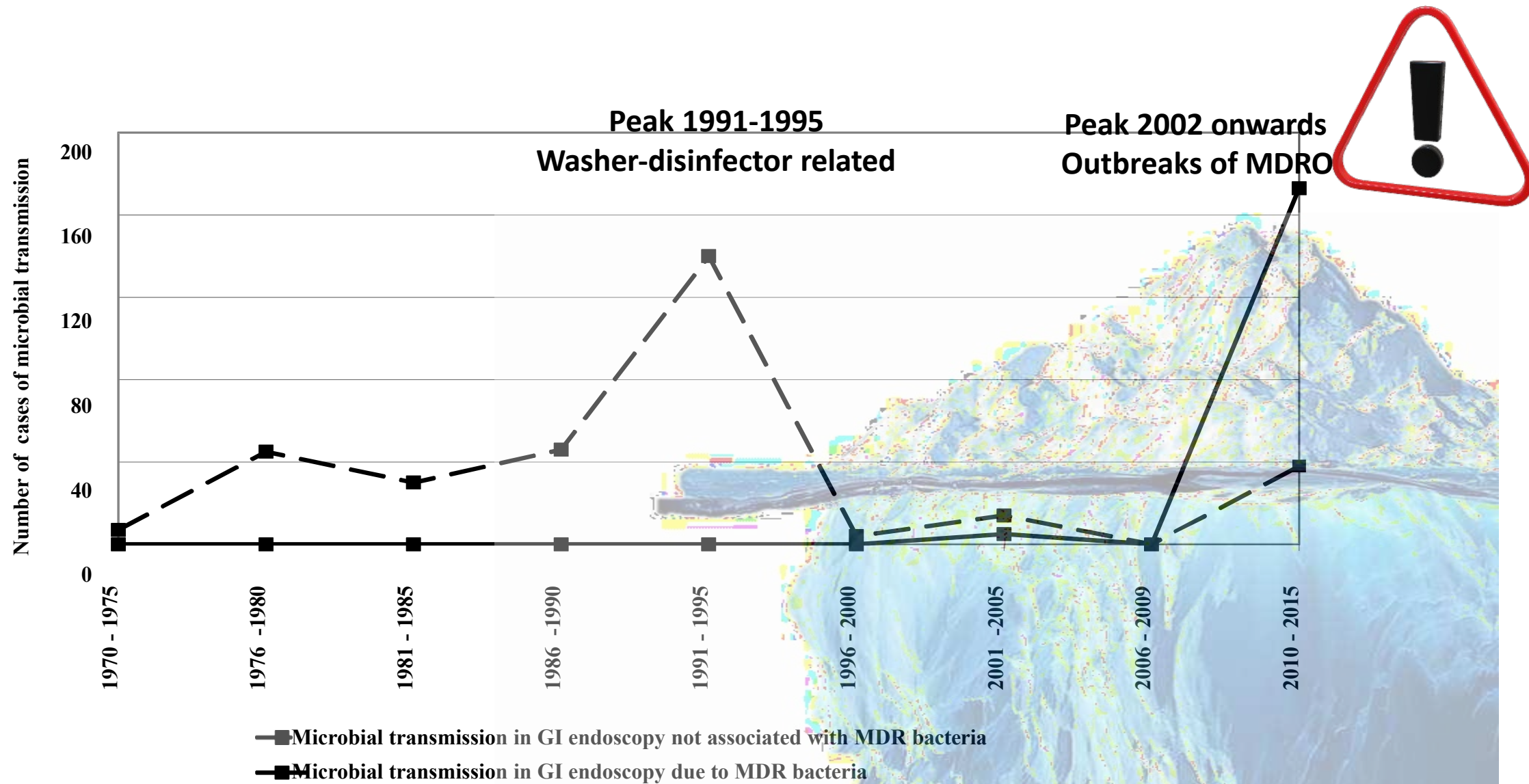


# Endoscope Immediately After Use



**10 Billion Particles**

# Outbreaks Related To Endoscopes: Tip Of The Iceberg



# A Killer on the Loose

Patients at UCLA were becoming death  
A superbug was spreading. Could doctors

## How a medical device maker kept U.S. hospitals in the dark about deadly infections

By CHAD TERHUNE AND MELODY PETERSEN  
DEC. 19, 2015



### Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication

[SHARE](#) [TWEET](#) [+](#) [EMAIL](#)

Date Issued: February 19, 2015

Updated: February 23, 2015

Updated: March 4, 2015

[Updated Information for Healthcare Providers Regarding Duodenoscopes](#)

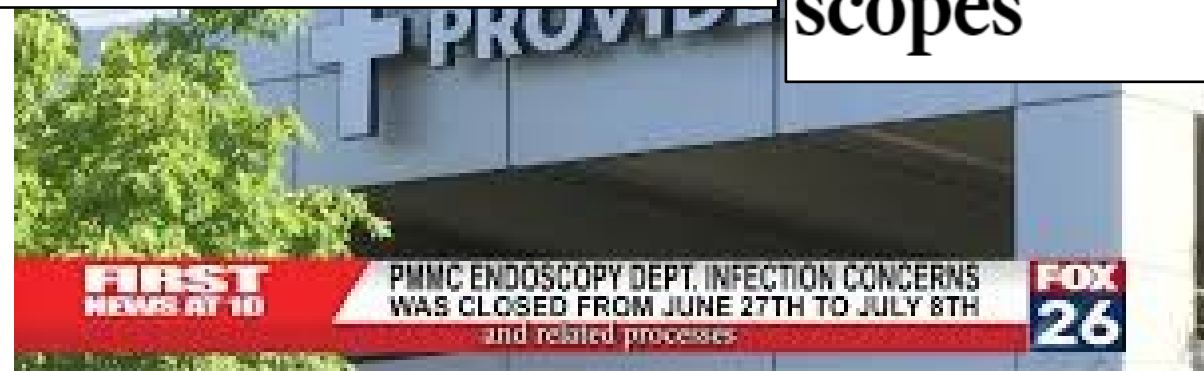
Los Angeles Times

## FDA reveals 142 cases of tainted scopes

KFF Health News

TRUMP 2.0 PUBLIC HEALTH RACE & HEALTH AUDIO INV

### Olympus Told U.S. Executives No Broad Scope Warning Needed Despite Superbug Outbreaks



# Gastrointestinal Endoscopy-Associated Infections: Update on an Emerging Issue

Digestive Diseases and Sciences (2022) 67:1718–1732

<https://doi.org/10.1007/s10620-022-07441-8>

INVITED REVIEW



## Gastrointestinal Endoscopy-Associated Infections: Update on an Emerging Issue

Anasua Deb<sup>1</sup> · Abhilash Periseti<sup>2</sup> · Hemant Goyal<sup>3</sup> · Mark M. Aloysius<sup>4,5</sup> · Sonali Sachdeva<sup>6</sup> · Dushyant Dahiya<sup>7</sup> · Neil Sharma<sup>8,9</sup> · Nirav Thosani<sup>10</sup>

**2011 – 2020 ERCP Related Reports:31**

**2011 – 2020 Upper GI Endoscopy (non-ERCP):21**

**1987 – 2018 Lower GI Endoscopy:5**

### Knowledge Gap

Although tremendous advancements have been made in GI endoscopy, **EAI**s persist as a lingering problem. With the evolution of **MDRO**, the challenges have attained new dimensions. **Reporting EAI incidence from developing countries is insufficient**; thus, the data are skewed for western Europe and North America. The **true incidence of EAI**, the microbiological profile of such infections, and its impact on healthcare expenditure in developing countries need to be studied.



• Upper GI endoscopy    • Duodenoscopy and ERCP    • Colonoscopy and sigmoidoscopy

Worldwide distribution of EAI from inception until 2020


# Under-Reporting

Digestive Diseases and Sciences (2019) 64:1409–1418  
<https://doi.org/10.1007/s10620-018-5431-7>

REVIEW



## Duodenoscope-Associated Infections: Update on an Emerging Problem

M. Rubayat Rahman<sup>1</sup> · Abhilash Periseti<sup>2</sup> · Roxana Coman<sup>3</sup> · Pardeep Bansal<sup>4,5</sup> · Rajiv Chhabra<sup>6</sup> · Hemant Goyal<sup>7</sup> 

1412

Digestive Diseases and Sciences (2019) 64:1409–1418

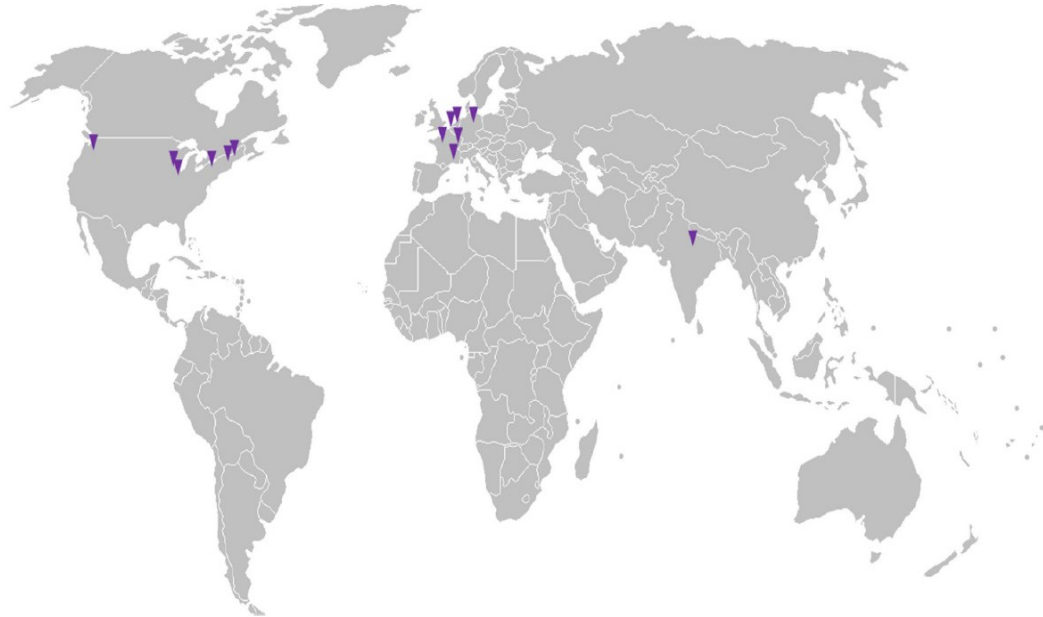


Fig. 1 Worldwide distribution of reported outbreaks of duodenoscopy-associated infections from 2000 to present

## Conclusion and Recommendations

Duodenoscope-associated infection, although **uncommon**, remains an important source of hospital-acquired infection. These infections are **considered rare events**, but it is important to note that **most of the endoscope reprocessing lapses are never reported or associated infections are not recognized**. Recent outbreaks of MDRO infections have highlighted the **limitations of current infection control guidelines** regarding ERCP. The inherently complex design of the duodenoscope, the ability of microbes to form difficult-to-remove biofilms, and the cost constraints associated with sterilization make cross-contamination difficult to eliminate. Automation of disinfection, novel sterilants, and technologies to prevent contamination are opening new horizons in the field of duodenoscope reprocessing.



# ERCP-related Outbreak? Sequencing To The Rescue But You'll Have To Trash The Scope!



## Epidemiological investigations

Following the **detection of ESBL-producing *C. freundii* and *K. pneumoniae*** in patients who underwent **ERCP with duodenoscope 294**, the **scope was withdrawn**, and **ambi-directional epidemiological investigations** were started. This investigation included identification of all potential exposed patients (probable and proven cases) and **intensive investigation of the suspected duodenoscope**.

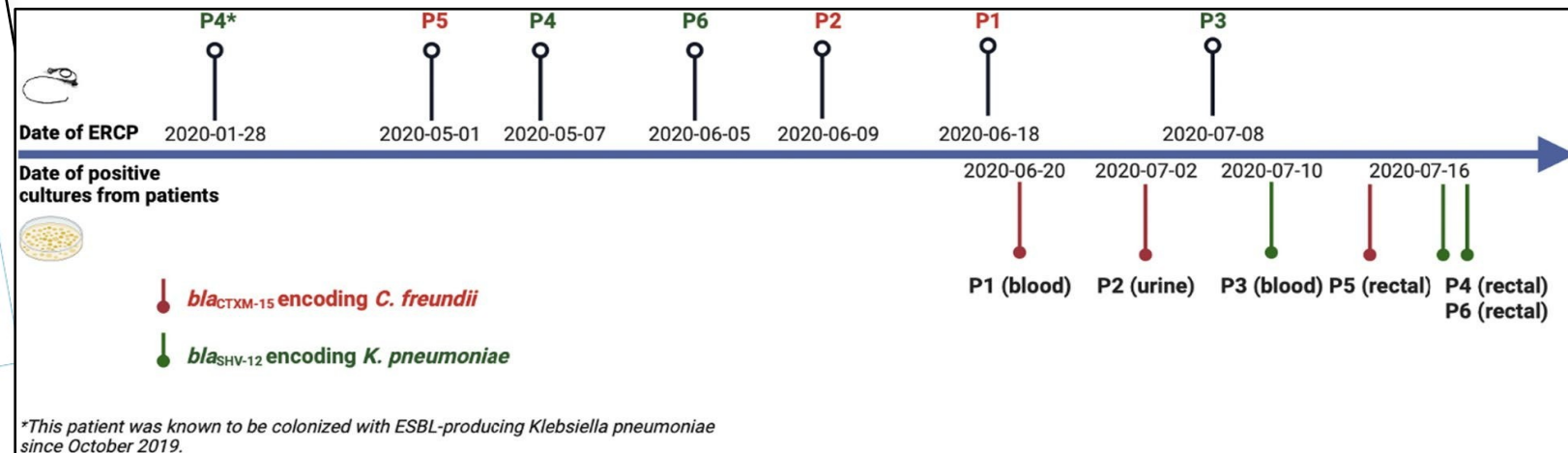
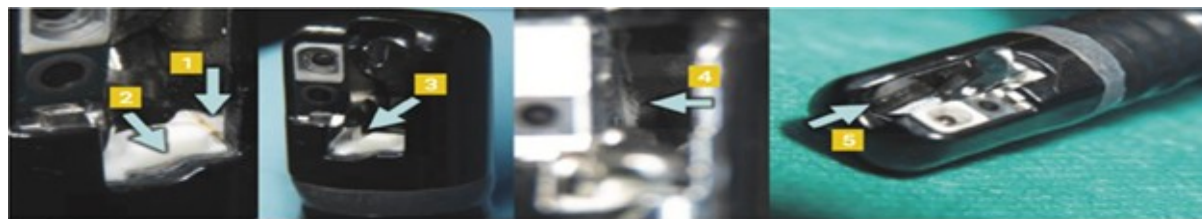


Fig. 1 Timeline of ERCP procedure and infection and colonization of patients. (\*This patient was known to be colonized with *bla*<sub>SHV-12</sub> *K. pneumoniae* since October 2019)

# ERCP-related Outbreak? Sequencing To The Rescue

## But You'll Have To Trash The Scope!

- University Medical Center Groningen (UMCG)
- Duodenoscope 294 (Introd. Mar 2019) Suspect Source
- Withdrawn July 2020 **Last surveillance culture Jan 2020 Neg(-)**
- **Culture samples (8) between Jul – Aug (National Sampling Method) Neg(-)**
- Dec 2020 team of experts:
  - ✓ Endoscope technician
  - ✓ Microbiologist from Olympus
  - ✓ IPier
- Thorough destructive investigation lead by external expert



a. distal end



b. bending section



c. trimming the tip cover



d. drive unit



e. O-ring and forceps elevator

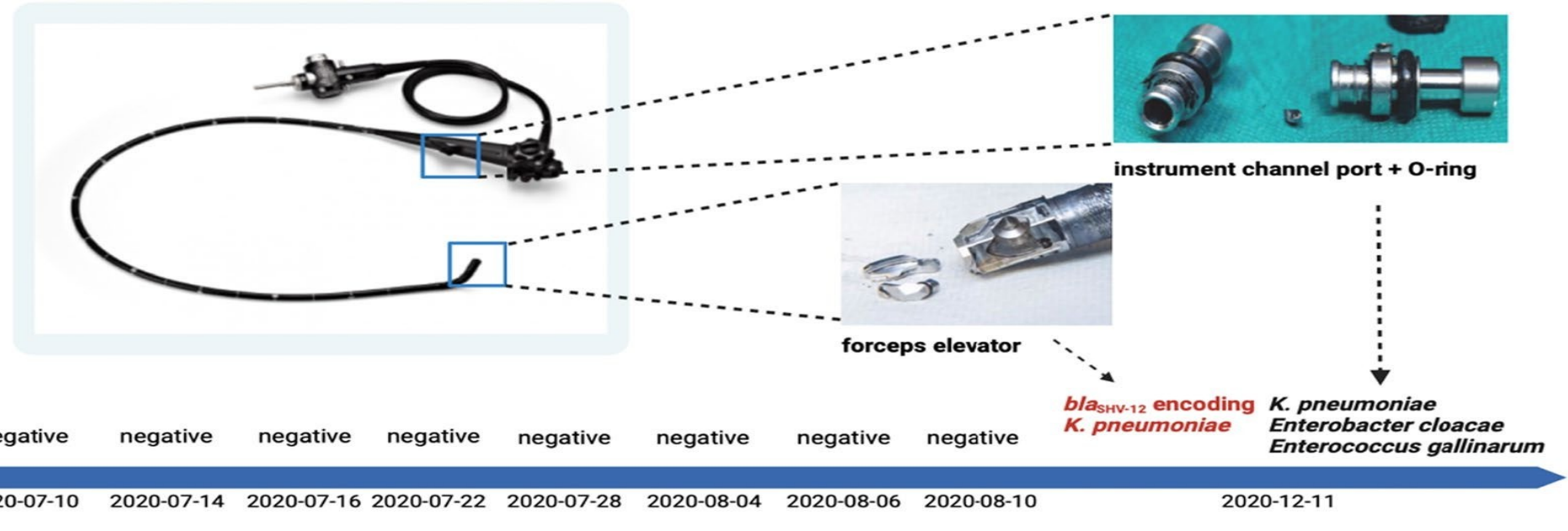


f. instrument channel port



g. instrument channel

# ERCP-related Outbreak? Sequencing To The Rescue But You'll Have To Trash The Scope!



## Duodenoscope investigation

8 cultures (standard and alternative methods) Neg(-)

Sampling forceps elevator (dismantled) Pos(+) *K.pneumoniae bla<sub>SHV-12</sub>*

Strain via NGS identical to Pts 3,4,6

Instrument channel port (incl. O ring) Pos(+) wild type *K. pneumoniae*, *Enterobacter cloacae*, & *Enterococcus gallinarum*

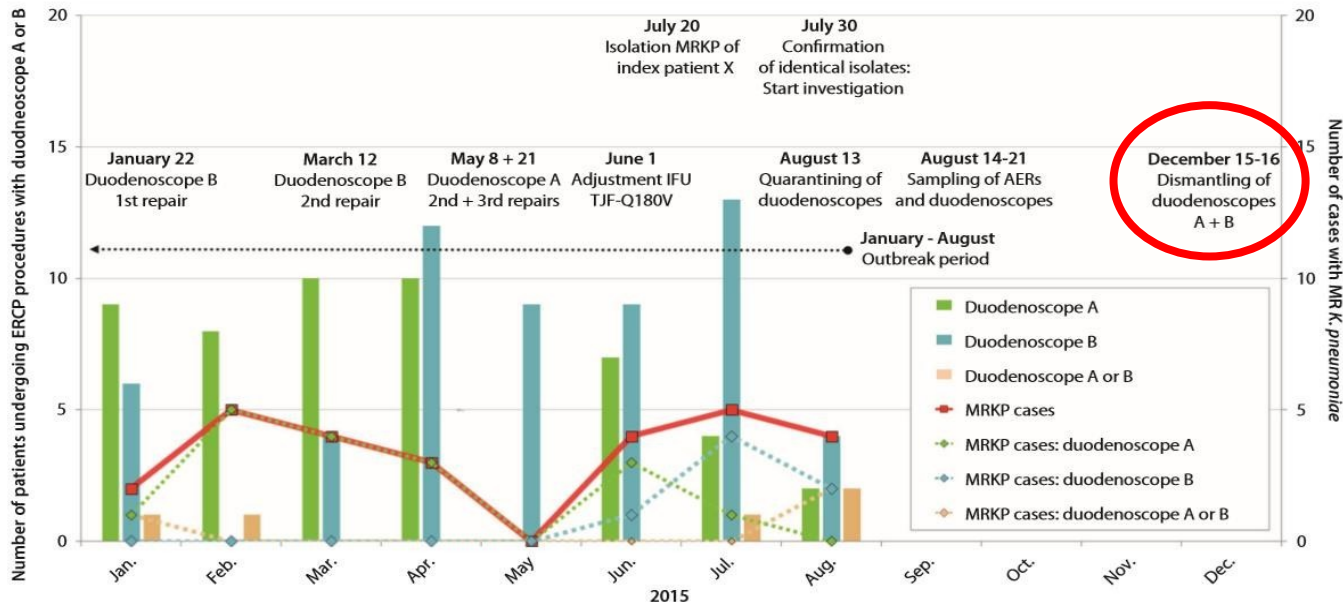
Instrument channel major damage and signs of biofilm formation (observed through the fiberscope)

Instrument channel brush samples Neg(-)

# The Dutch Love Trashing Their Scopes!

Contributing factors to an outbreak of multidrug-resistant *K pneumoniae*

Rauwers et al



**Figure 1.** Timeline of the outbreak. Green and blue bars, number of patients who have undergone an ERCP procedure with duodenoscope A or B, respectively. Follow-up procedures with the same duodenoscope were excluded; pink bar, number of patients who have undergone a procedure with duodenoscope A or B; solid red line, all MRKP cases retrospectively detected by clinical or screening cultures; dashed green line, all cases with MRKP treated with duodenoscope A; dashed blue line, all cases with MRKP treated with duodenoscope B; dashed pink line, all cases with MRKP treated with a TJF-Q180V duodenoscope, either A or B. The outbreak period was set from January to August 2015. MR, Multidrug-resistant; MRKP, multidrug-resistant *K pneumoniae*.

## *K. Pneumoniae* ESBL

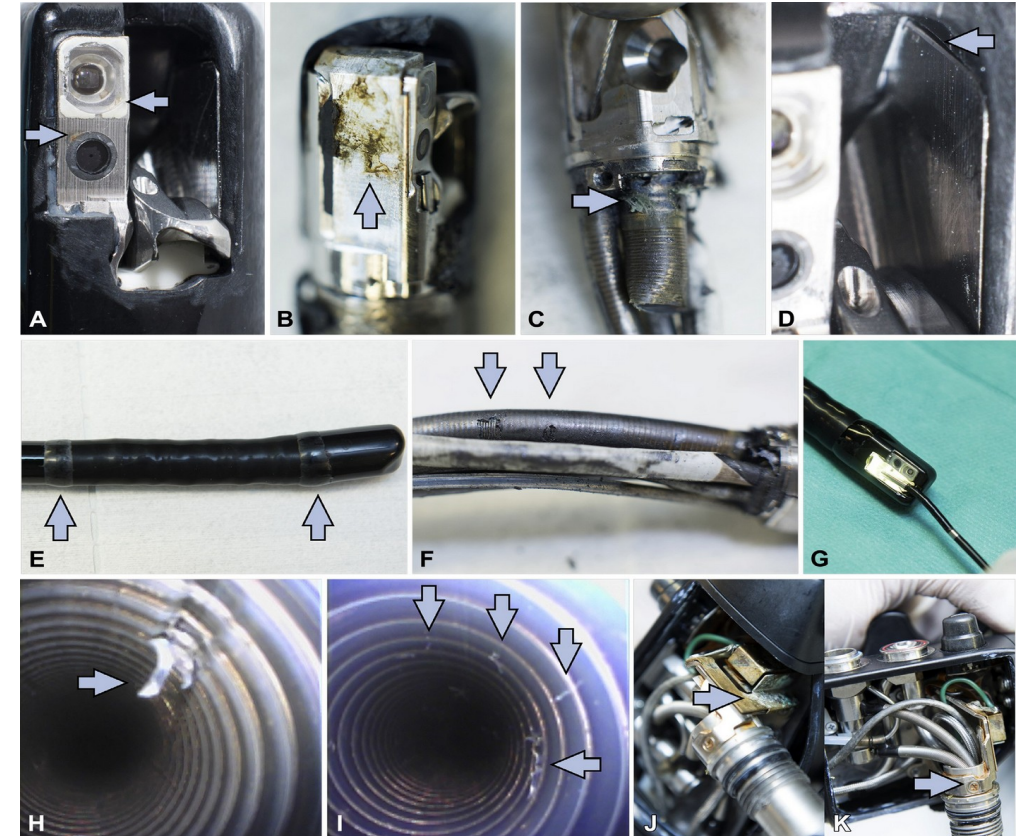
### Duodenoscope A;

- First contaminated endoscope
- **Attack rate 35%; (17/49 pts)**
- Flush suction & biopsy channel positive culture

### Duodenoscope B

- Second contaminated duodenoscope (6 months after A)
- **Attack rate 29% (7/24 pts)**
- Flush biopsy channel positive culture

**Patients: 15 by clinical samples, 11 by contact screening 10 infections (9 sepsis, 1 cholangitis)**



Endoscope related outbreaks investigations may include **Dismantling** and use of PCR and NGS

# GI Endoscopes: Shift from Disinfection to Sterilization

EDITORIAL

Editorials represent the opinions of the authors and *JAMA* and not those of the American Medical Association.

## Gastrointestinal Endoscopes A Need to Shift From Disinfection to Sterilization?

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

**More than 10 million** gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.<sup>1</sup> Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.<sup>1</sup>

In this issue of *JAMA*, Epstein and colleagues<sup>2</sup> report findings from their investigation of a cluster of New Delhi metallo- $\beta$ -lactamase (NDM)-producing *Escherichia coli* associated with gastrointestinal endoscopy that occurred from March 2013 to

July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 pa-

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection.<sup>3,4</sup> High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.<sup>3</sup> However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)-cleared for gastrointestinal endoscopes such as duodenoscopes.

Second, more health care-associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device.<sup>3,5</sup> However, until now,



Related article page 1447

# Shift From Disinfection to Sterilization

## ANSI/AAMI ST91

It is **ADVISED** that flexible and semi-rigid endoscopes be **USED IN SEMI-CRITICAL** applications and be **STERILIZED** prior to use (xiii).

Effective cleaning followed by **ROUTINE STERILIZATION** of flexible endoscopes is **PREFERRED** because of the significant public health risk (xiv).

**STERILIZATION** of endoscopes can reduce this risk because of the **GREATER MARGIN OF SAFETY** in the overkill process (xiv).

## AORN

Sterilize reusable, flexible endoscopes that are manufacturer-validated for **STERILIZATION WHEN POSSIBLE** (2.1)

Correctly sterilized and handled items are **RARELY ASSOCIATED WITH PATIENT INFECTION** (2.1)

The use of low-temperature sterilization and **LCS METHODS HAVE BEEN VALIDATED AS EFFECTIVE FOR DUODENOSCOPES** (2.2)



## Low Temp Sterilization

- ETO
- $vH_2O_2 \pm O_3$
- PAA

The **margin-of-safety** with **HLD** is very slim, in part because it **eliminates fewer microbes** than sterilization ( **$6 \log_{10}$  vs  $12 \log_{10}$** ). **Suboptimal practices** can **detract** from processing effectiveness, and breaches are common\*

Rutala & Weber. *AJIC*, 2023

Simard et al. *AJIC*, 2019

\*Ofstead et al. *AJIC*, 2025

# Society Guidelines and Recommendations



- ✓ Manual Cleaning
- ✓ Automated Endoscope Reprocessor



- ✓ Additional HLD Cycle
- ✓ Duodenoscope Culturing
- ✓ Duodenoscope Sterilization

U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

- ✓ ATP Testing



- ✓ Storage Time Prior to Reprocessing
- ✓ Loupe Magnification or Borescope
- ✓ Reprocessing Staff



- ✓ Disposable Duodenoscope Components



European Society of Gastrointestinal Endoscopy  
*Working together in endoscopy to achieve optimal patient care.*



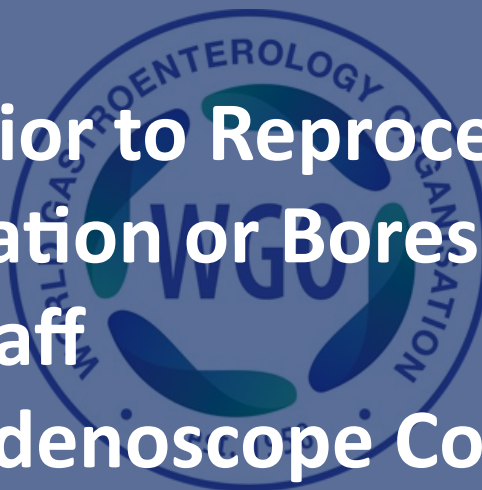
WEO

World Endoscopy Organization



BRITISH SOCIETY OF GASTROENTEROLOGY

中华医学会消化内镜学分会  
Chinese Society Of Digestive Endoscopy



GESA

Gastroenterological Society of Australia



## MULTISOCIETY TASK FORCE ARTICLE



# Multisociety guideline on reprocessing flexible GI endoscopes and accessories



**Lukejohn W. Day, MD,<sup>1</sup> V. Raman Muthusamy, MD, MAS,<sup>2</sup> James Collins, BS, RN, CNOR,<sup>3</sup>  
Vladimir M. Kushnir, MD,<sup>4</sup> Mandeep S. Sawhney, MD, MS,<sup>5</sup> Nirav C. Thosani, MD,<sup>6</sup> Sachin Wani, MD<sup>7</sup>**

This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy.

## Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position Statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) – Update 2018



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### Bibliography

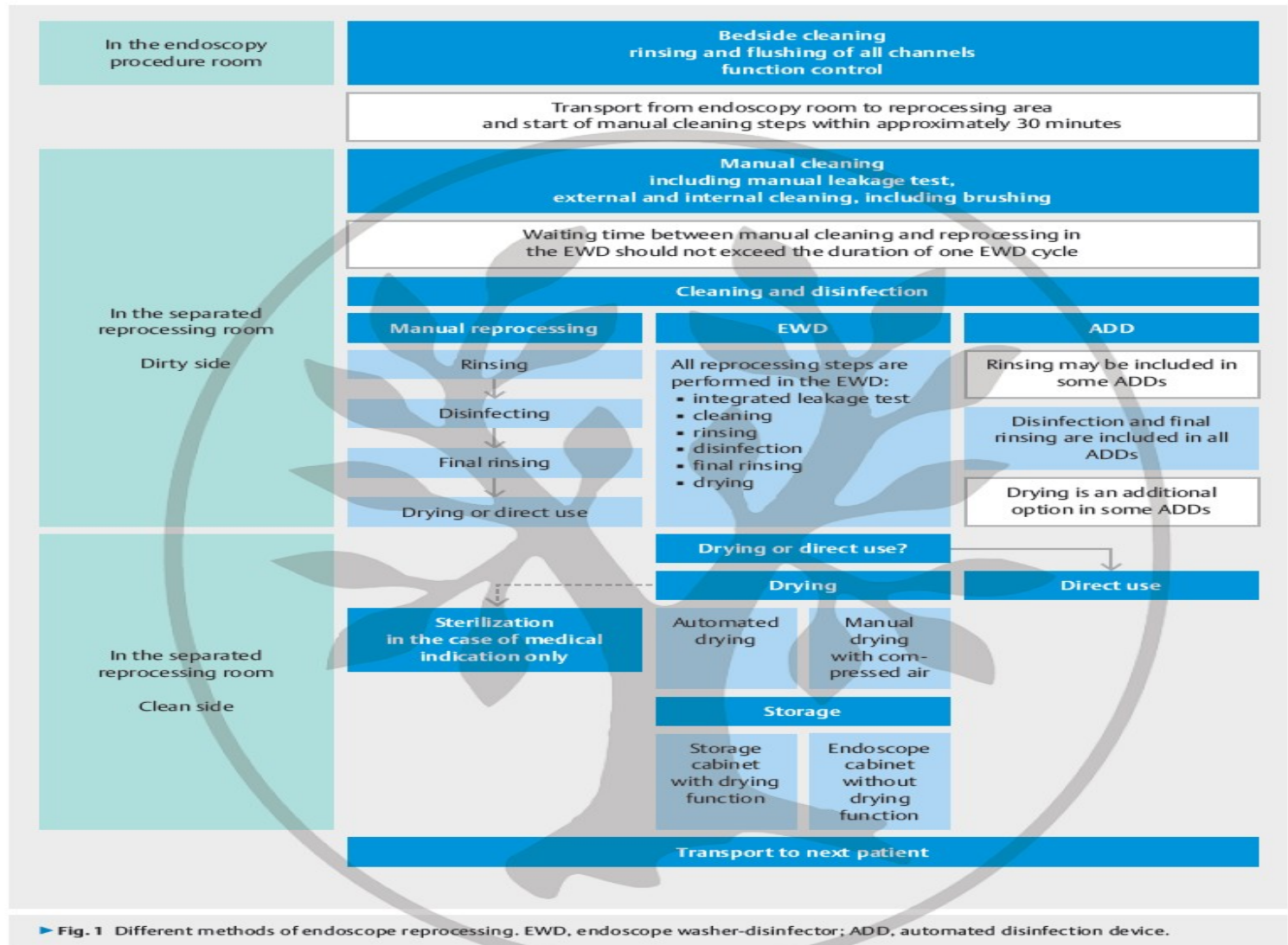
DOI <https://doi.org/10.1055/a-0759-1629>  
 Published online: 20.11.2018 | Endoscopy 2018; 50: 1205–1234  
 © Georg Thieme Verlag KG Stuttgart · New York  
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### ABSTRACT

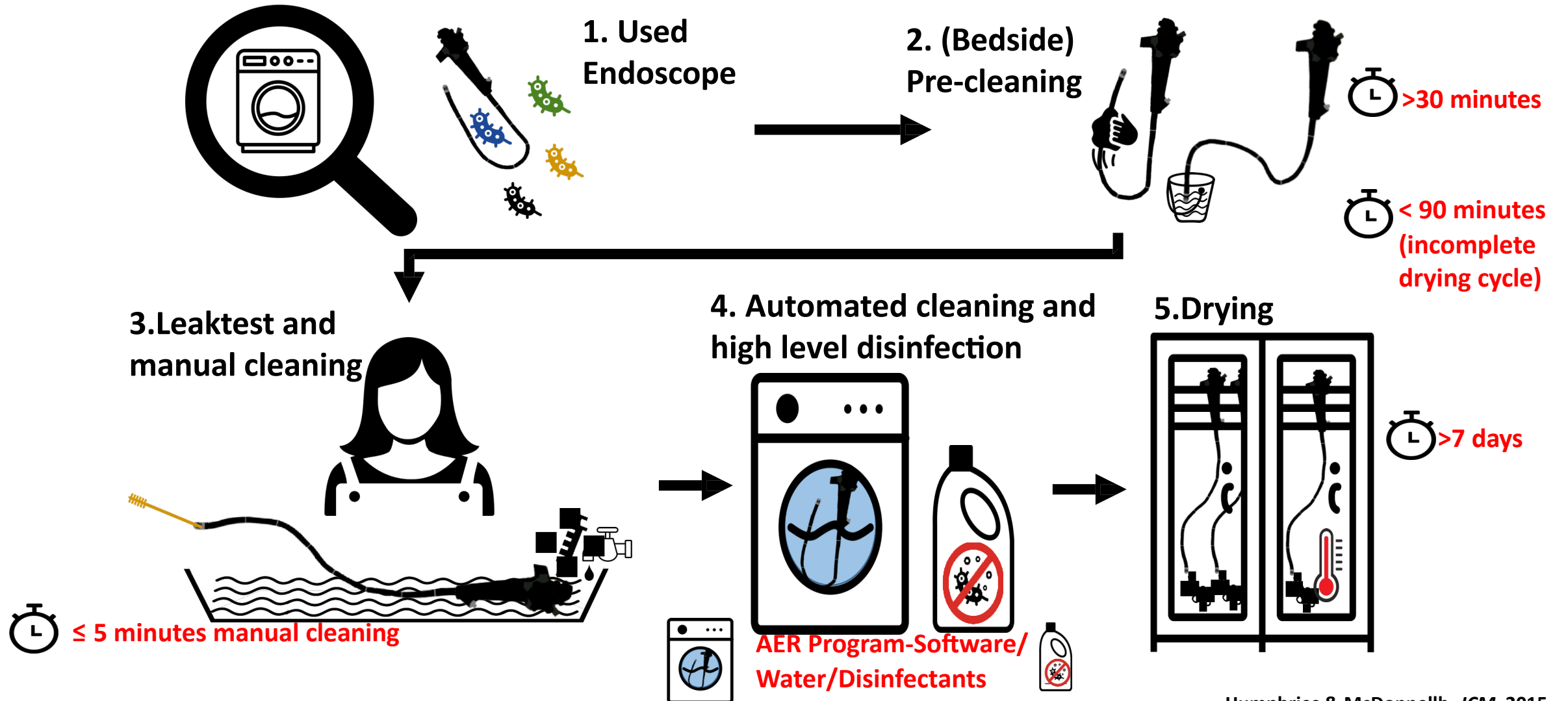
This Position Statement from the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology Nurses and Associates (ESGENA) sets standards for the reprocessing of flexible endoscopes and endoscopic devices used in gastroenterology. An expert working group of gastroenterologists, endoscopy nurses, chemists, microbiologists, and industry representatives provides updated recommendations on all aspects of reprocessing in order to maintain hygiene and infection control.



The insertion tube and critical components (e.g. the distal end of duodenoscopes and echoendoscopes) should be wiped externally with cleaning solution, using a soft, disposable cloth/sponge, and checked for any macroscopic damage.

Typically, air/water channels should be flushed with water from the water bottle. It is important to consider the use of cleaning valves for the air/water channel, according to the manufacturer's IFU.

# Standard Workflow For Endoscope Reprocessing And Commonly Identified Lapses



# Endoscope Anatomy

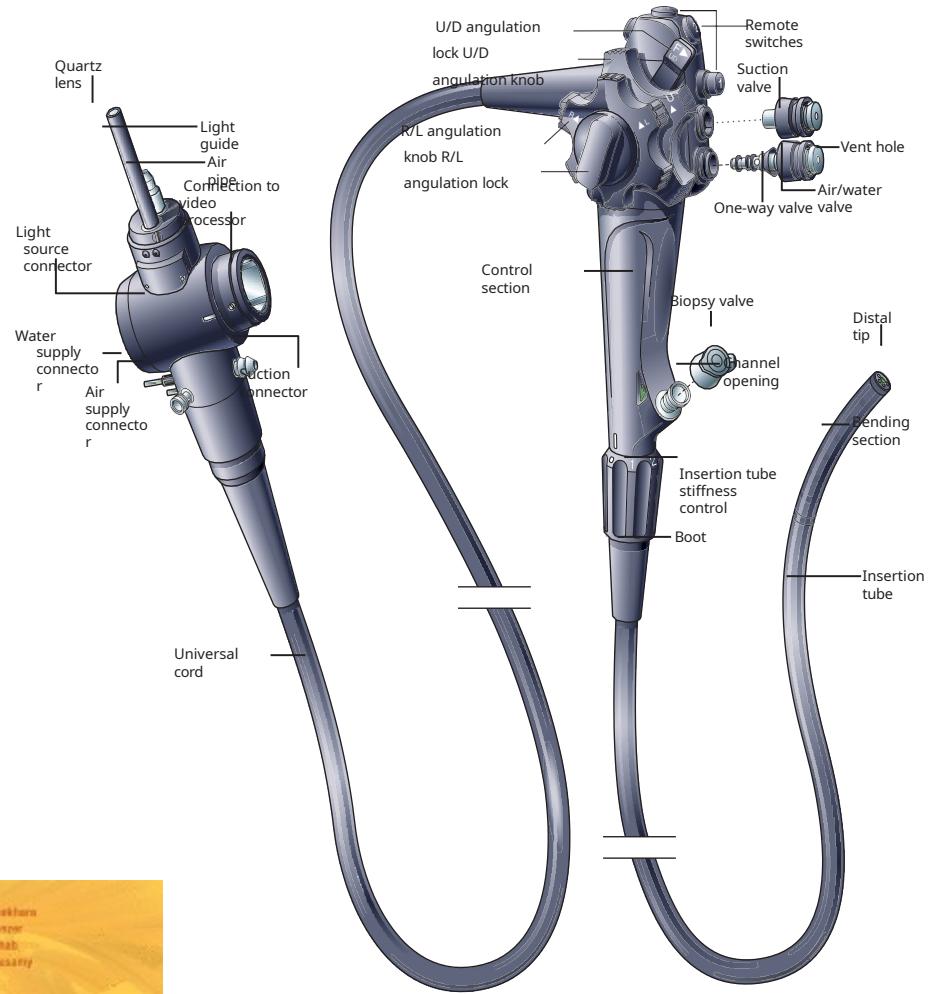


FIG 3.1 Components of the endoscope. *D*, down; *L*, left; *R*, right; *U*, up.

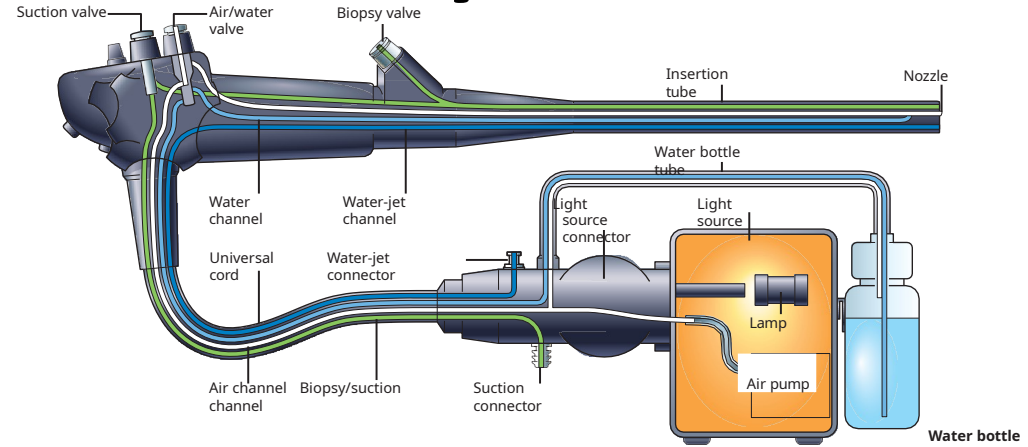
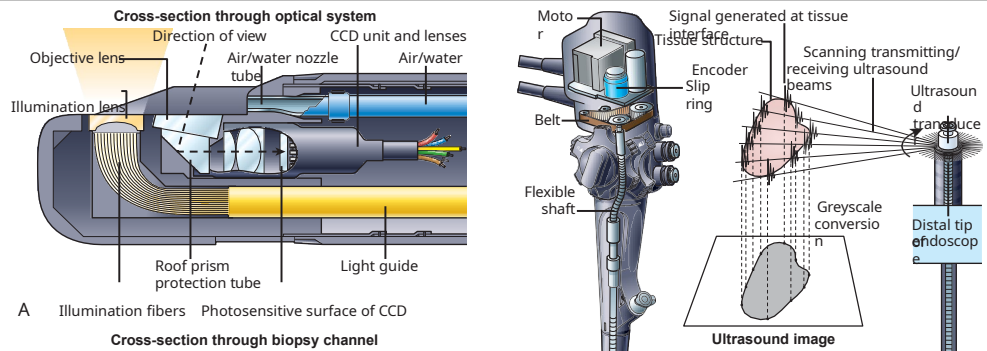
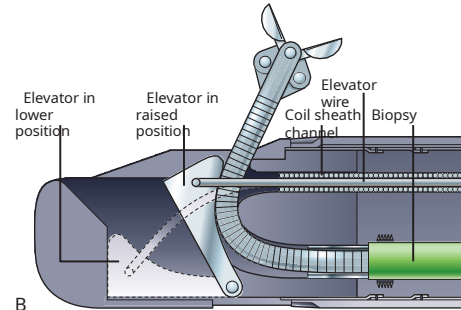


FIG 3.6 Configuration of the air, water, light, and suction systems in the endoscope.



A Illumination fibers Photosensitive surface of CCD

Cross-section through biopsy channel



B

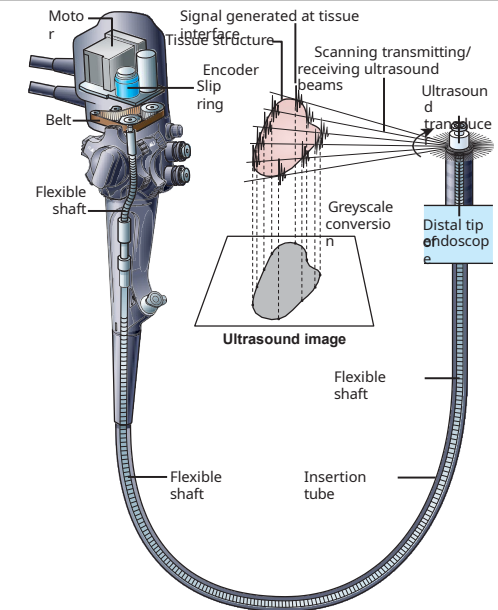
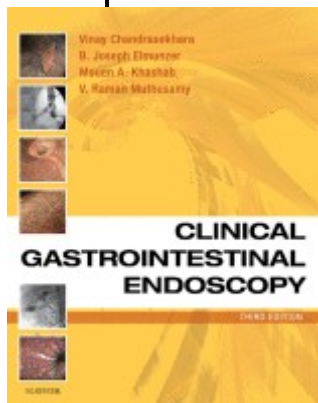


FIG 3.9 Echoendoscope.

FIG 3.8 Cross-sectional view of the side-viewing endoscope showing A, the direction of view, as well as B, use of elevator when using endoscopic accessories. *CCD*, Charge-coupled device.



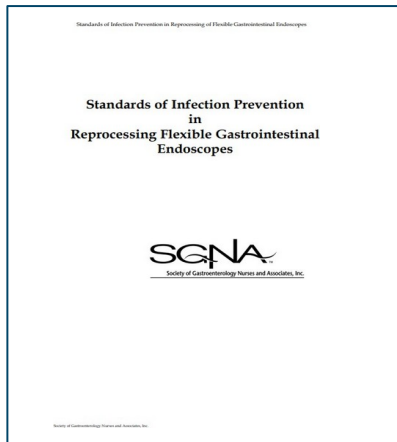
# Manual Cleaning Is Today's Gold Standard



**“Thorough attention to cleaning is crucial for overall processing effectiveness and patient safety. Failure to perform effective cleaning can result in disinfection failure.”<sup>1</sup>**



**“Meticulous cleaning must precede any sterilization or high-level disinfection of these instruments...Failure to perform good cleaning can result in sterilization or disinfection failure, and outbreaks of infection can occur.”<sup>2</sup>**



**“Manual cleaning of endoscopes is necessary prior to automated/manual HLD or sterilization...This is the most critical step in removing the microbial burden from an endoscope.”<sup>3</sup>**



**“Manual cleaning is a crucial part of the reprocessing pathway, and when precleaning and manual cleaning are followed, the number of pathogens detected on endoscopes can be decreased by 99.9%.”<sup>4</sup>**

- 1.American National Standards Institute. ANSI/AAMI ST91:2021; Flexible and semi-rigid endoscope processing in health care facilities. (2021) doi:10.2345/9781570208300.c
- 2.Rutala, W. A., Weber, D. J. & Healthcare Infection Control Practices Advisory Committee. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (2019).
- 3.Loyola, M. *et al.* Standards of infection prevention in reprocessing flexible gastrointestinal endoscopes. *Gastroenterol Nurs* 43, E142–E158 (2020).
- 4.ASGE Quality Assurance in Endoscopy Committee *et al.* GI endoscope reprocessing: a comparative review of organizational guidelines and guide for endoscopy units and regulatory agencies. *Gastrointest Endosc* 95, 1048-1059.e2 (2022).

# Borescope: Look through the hole



## Use:

- Inspecting channels during training and competency testing
- Routine QA
- Repairs

## Recommended by:

AAMI ST91

AORN

IAHCSSM

SGNE

ASGE Multi Society Guideline: Day et al. *Gastr Endo*, 2021

# Three Hospitals Residual Moisture after AER, Alcohol Flush, Forced Air Drying & Overnight Storage



Fig 2. Residues observed on external surfaces of endoscopes. (A) Oily residue near biopsy port of pediatric colonoscope A-10; (B) dried “water spots” on control handle of cystoscope B-17; and (C) whitish-blue, powdery residue under control handle knobs of gastroscope B-5.



Fig 4. Visible defects observed during visual inspections. (A) Non-intact channel lining in gastroscope B-2; (B) damaged distal end with exposed metal mesh fibers protruding from gastroscope C-1; and (C) white debris protruding from the water jet outlet on the distal end of gastroscope C-3.

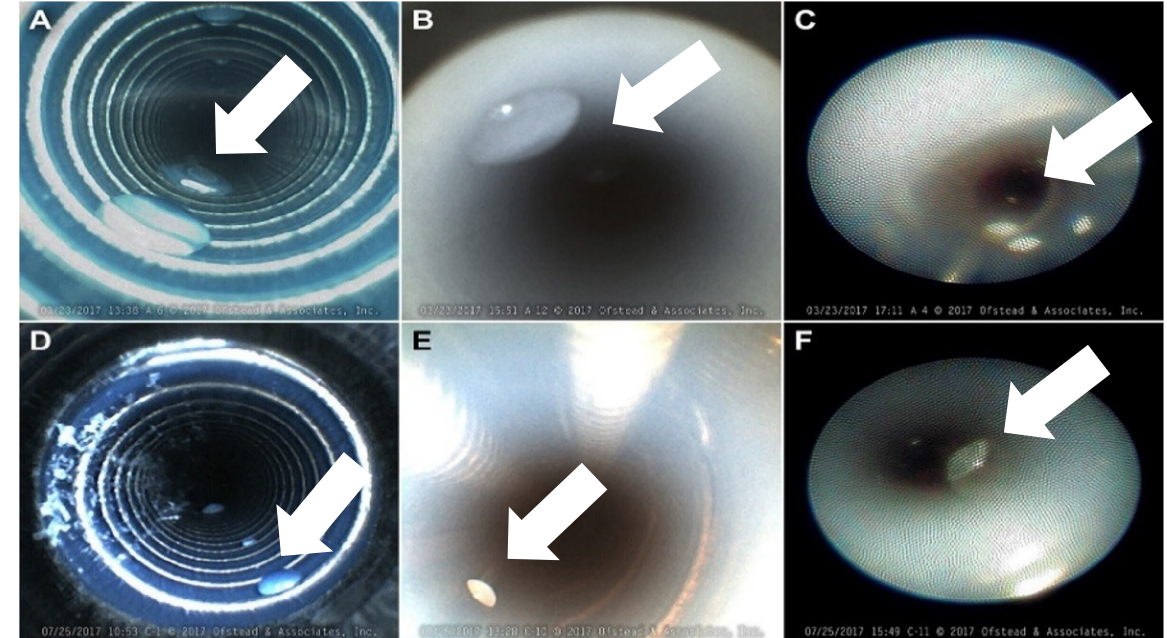


Fig 1. Retained fluid droplets found inside endoscope channels. (A) Gastroscope A-6; (B) Colonoscope A-12; (C) Cystoscope A-4; (D) Gastroscope C-1; (E) Duodenoscope C-10; and (F) EUS Radial Endoscope C-11.

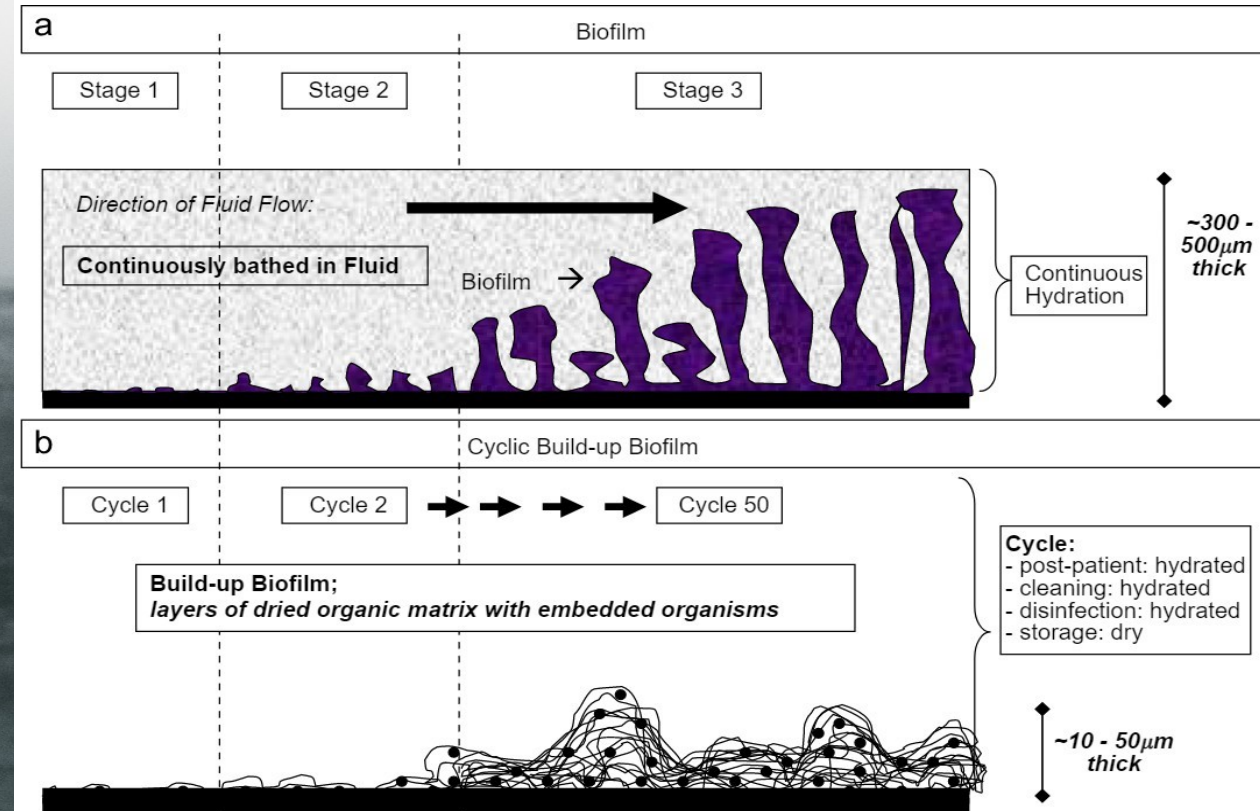
**Inadequate reprocessing** and **insufficient drying** contributed to retained fluid and contamination found during this **multisite study**. More effective methods of endoscope reprocessing, drying, and maintenance are needed to prevent the retention of fluid, organic material, and bioburden that could cause patient illness or injury.

# Biofilms...The “Dirt” of Endoscopes



# Biofilm Many Faces...WBs, DSBs, BBFs

THIS IS THE WET BIOFILM  
THIS IS THE DRY SURFACE BIOFILM  
AND THIS ONE IS THE BUILD UP BIOFILM



Traditional biofilm model versus cyclic buildup biofilm model

Michele Alfa has introduced the term cyclic buildup biofilm (CBB or BBF) and published several papers on cyclic buildup biofilm (CBB) replicating biofilm formation in endoscopes

# Cyclic Build Up Biofilms Evidence

## The effect of multiple cycles of contamination, detergent washing, and disinfection on the development of biofilm in endoscope tubing

Karen Vickery, BVSc, MVSc, PhD,<sup>a</sup> Quan-D. Ngo, MB BS,<sup>b</sup> Jean Zou, BM, MM, PhD,<sup>b</sup> and Yvonne E. Cossart, M (Med), FRCPA<sup>b</sup>  
 Sydney, Australia

*Am J Infect Control*, 2009

INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY

ORIGINAL ARTICLE

## Simulated-Use Polytetrafluoroethylene Biofilm Model: Repeated Rounds of Complete Reprocessing Lead to Accumulation of Debris and Viable Bacteria

Michelle J. Alfa, PhD,<sup>1,2</sup> Harminder Singh, MD,<sup>3</sup> Zoann Nugent, PhD,<sup>3</sup> Donald D. Olson, MD,<sup>1</sup> Nancy Olson, BSc,<sup>1</sup> Pat DeGagne, RT,<sup>1</sup> and Harminder Singh, MD,<sup>3</sup>

Winnipeg, Manitoba, Canada; Belo Horizonte, Goiás, Brazil

Removal of visible soil

## A novel polytetrafluoroethylene-channel model, which simulates low level of culturable bacteria in buildup biofilm after repeated endoscope reprocessing

Michelle J. Alfa, PhD,<sup>1,2</sup> Maira M. Ribeiro, PhD,<sup>3</sup> Cristiana da Costa Luciano, PhD,<sup>4</sup> Rodrigo Franca, PhD,<sup>5</sup> Nancy Olson, BSc,<sup>1</sup> Pat DeGagne, RT,<sup>1</sup> Harminder Singh, MD<sup>6</sup>

Winnipeg, Manitoba, Canada; Belo Horizonte, Goiás, Brazil

*Gastrointest Endosc*, 2017

*Infection, Disease & Health* (2018) 23, 189–196



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Available online at [www.sciencedirect.com](http://www.sciencedirect.com)

ScienceDirect

4. High-level disinfection

5. Storage  
 Protection in a dry, sterile environment

3. Manual cleaning

Friction & Enzymatic Detergent<sup>1</sup>  
 Most important step for reprocessing success

Research paper

Determination of bacterial species present in biofilm contaminating the channels of clinical endoscopes

K. Johani<sup>a,b</sup>, H. Hu<sup>a</sup>, L. Santos<sup>a,c</sup>, S. Schiller<sup>a</sup>, A.K. P. Almatroudi<sup>a,e</sup>, K. Vickery<sup>d</sup>

*Infection Control & Hospital Epidemiology* (2021), 1–7

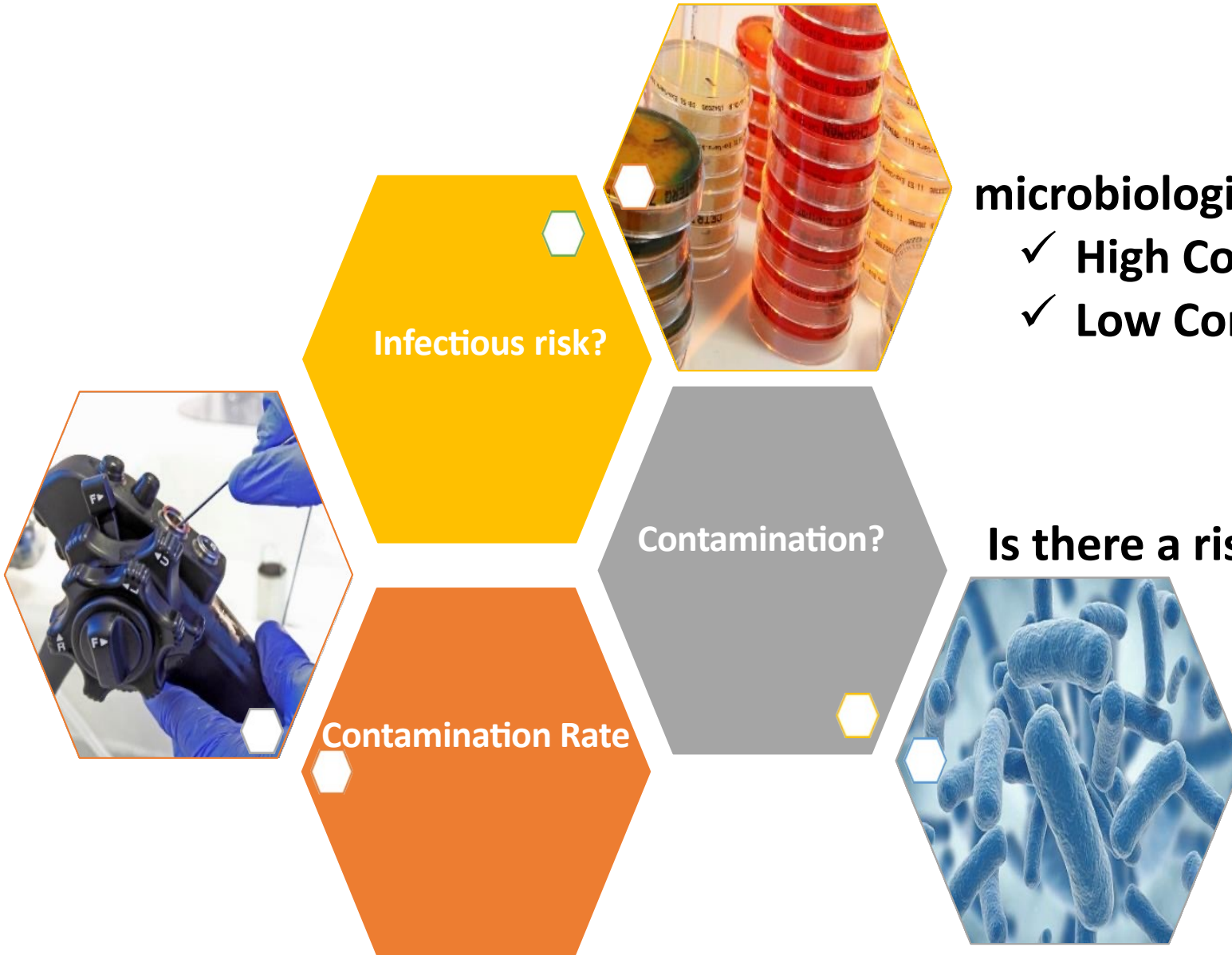
Original Article  
 Success

## Biofilm accumulation in new flexible gastroscop channels clinical use

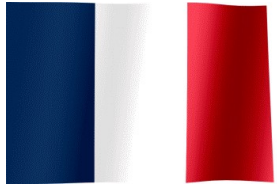
Luísa Gomes Borges Primo PhD<sup>1</sup>, Anaclara Ferreira Veiga Tipple PhD<sup>2</sup>, Dayane de Melo Costa PhD<sup>2</sup>,  
 Luísa Vieira Toledo Guadagnin PhD<sup>1</sup>, Adriana Silva Azevedo MPH<sup>1</sup>,  
 and Stefânia Netto de Oliveira Leão-Vasconcelos PhD<sup>3</sup>, Michelle Alfa PhD<sup>4</sup> and Karen Vickery PhD<sup>5</sup>



# Microbiological Assessment



# Endoscope Sampling And Culturing Methods



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.



GESA - Gastroenterological Society of Australia. Infection control in endoscopy 2nd Edition. 2003

Gillespie E, Despina Kotsanas D, Stuart RL. Microbiological monitoring of endoscopes: 5-year review. J Gastroenterol Hepatol 2008; 23:1069–1074



Rauwers AW, Voor In't Holt AF, Buijs JG et al. High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study. Gut 2018; 67: 1637–1645








FDA/CDC/ASM. Duodenoscope Surveillance Sampling and Culturing Protocols. 2018



Hygiene Requirements for the Reprocessing of Medical Devices. Bundesgesundheitsbl 2012 · 55:1244–1310.

# Sampling methods

COUNTRY:		 FRA	 AUST	 NL	 USA	 GER
Sample sites	Instrument channel	Y (FSF <sup>a</sup> ) [2]	Y (FB <sup>c</sup> ) [1]	Y (FSBF <sup>e</sup> ) [2]	Y (FBF <sup>b</sup> ) [2]	Y (F) [2]
	Suction/instrument channel	Y (FSF) [3]	Y (F <sup>d</sup> ) [3]	Y (FSBF) [3]	N	Y (F) [3]
	Air/water channel	Y (FSF) [4]	Y (F <sup>d</sup> ) [2]	Y (FSF) [4]	N	Y (F) [4]
	Elevator recess (distal end) with brush or swab	Y [1]	N	Y [1]	Y (1)	Y [1]
Sampling solution		NDP + thio	<b>Sterile water</b>	NaCl 0.9%	<b>Sterile water</b>	NaCl 0.9%
Addition of neutralizer to extracted sample		No (NDP + thio used for sampling)	<b>No</b>	<b>No</b>	Y (NDP + thio)	Y (NDP + thio) two time concentrated
Sample volume ( sampling solution + neutralizer)		100 mL (distal end) + 130 mL (channels)	30 mL	60 mL	82 mL	3 x 50 mL
Friction for instrument channel (bristle brush)		<b>N</b>	Y	Y	Y	<b>N</b>
Number of samples		2 (all channels pooled & distal end)	1 (all channels pooled)	2 (all channels pooled & distal end)	1 (Instrument channel & distal end pooled)	4 (All channels separately & distal end)

(a) FSF: Flush-Suction-Flush, (b): FBF: Flush-Brush-Flush, (c): FB: Flush-Brush, (d) F: Flush, (e): FSBF: Flush-Suction-Brush-Flush. Y: Yes, N: No, NDP + thio: Neutralizing Pharmacopeia Diluent plus thiosulfate. [x]: figures in square brackets define the chronology in which channels/sites were sampled.

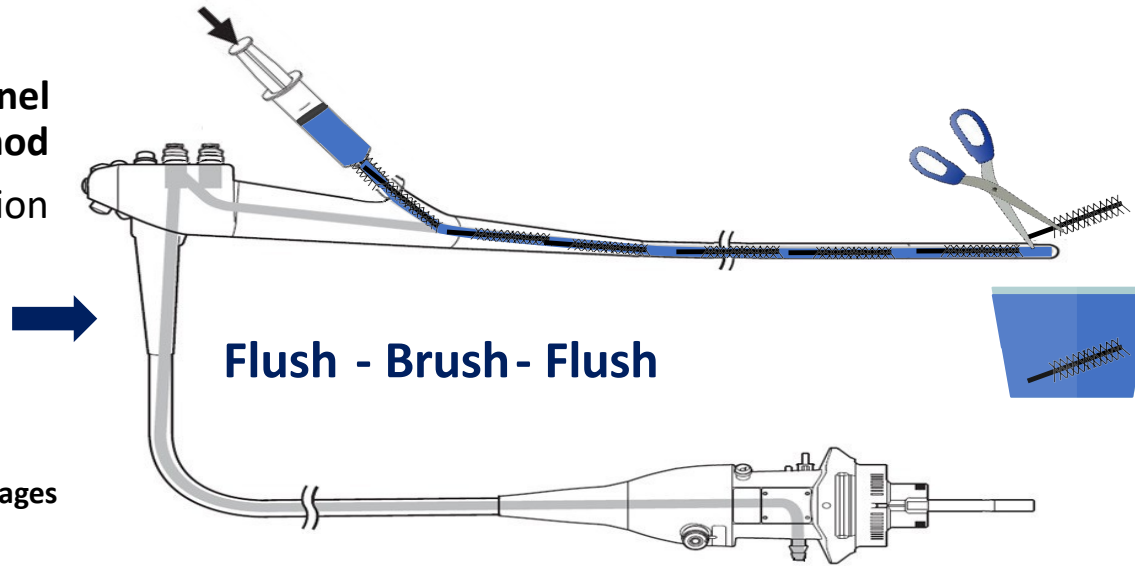
# Sample Collection




## Sampling of the instrument channel using the flush-brush-flush method

- Injection of the sampling solution in the instrument channel followed by an air purge,
- Brushing of the channel,
- New injection of sampling solution and air purge.

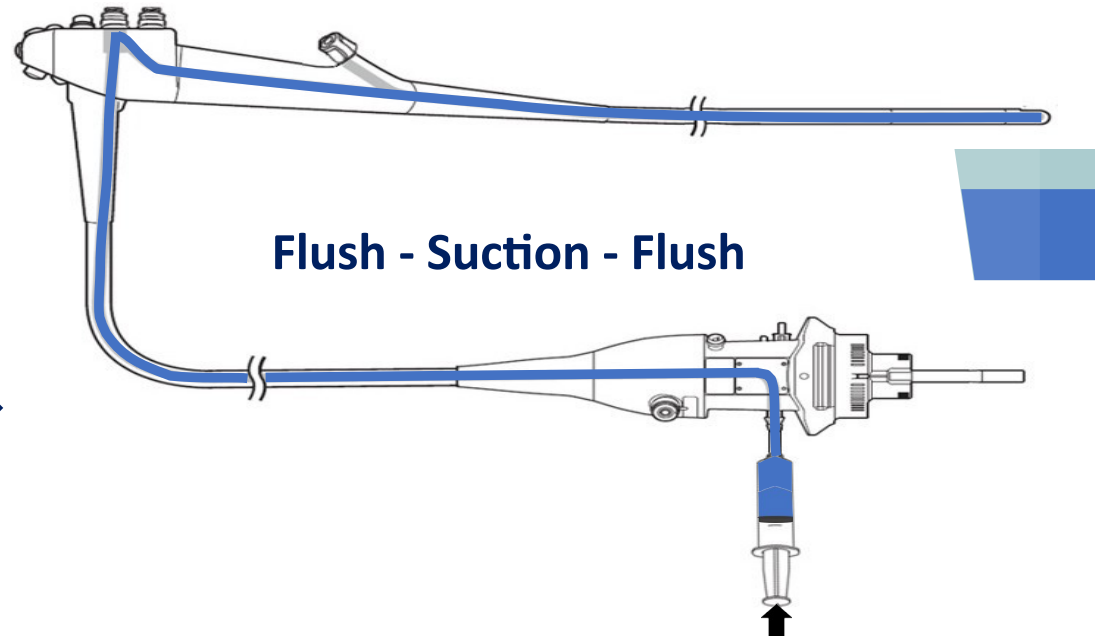
Note: for Australian method repeat all stages on suction and suction/instrument channel.



## Sampling of the suction/instrument channel using the flush-suction-flush method

Injection of the sampling solution from the suction connector(A) while the valve cylinders were closed with the MH-944 connector (B) (Flush). 

The plunger of the syringe was pulled up (Suction) and down (Flush) and the channel was purged with air.



## Sampling of the duodenoscope distal end



1. Swabbing along the seam between the distal cap and the distal end
2. Elevator recess flush – elevator down and up
3. Elevator brush (large brush)
4. Elevator brush (small brush)

# Cultures...Low PPV

Sampling and culturing methods differ in their **sensitivity** to detect contamination

**Not Detected ≠ Not Detectable**

- ✓ Sampling method
- ✓ VBNC State
- ✓ Biofilm
- ✓ Culture Medium
- ✓ Microorganisms & Microbial Load
- ✓ Centrifuge/Filtration
- ✓ Molecular Method
- ✓ Incubation Temp/Duration

ORIGINAL ARTICLE: Clinical Endoscopy

Contaminated duodenoscopes in ERCP: sensitivity of detection and risk of underdetection



Koen van der Ploeg, MD, MSc,<sup>1,2</sup> Juliette A. Severin, MD, PhD,<sup>2</sup> Corné H. W. Klaassen, PhD,<sup>2</sup> Margreet C. Vos, MD, PhD,<sup>2</sup> Marco J. Bruno, MD, PhD,<sup>1,\*</sup> Bibi C. G. C. Mason-Slingerland, MD, PhD<sup>2,\*</sup>

Rotterdam, The Netherlands

Journal of Hospital Infection 149 (2024) 36–45

Available online at [www.sciencedirect.com](http://www.sciencedirect.com)



Journal of Hospital Infection



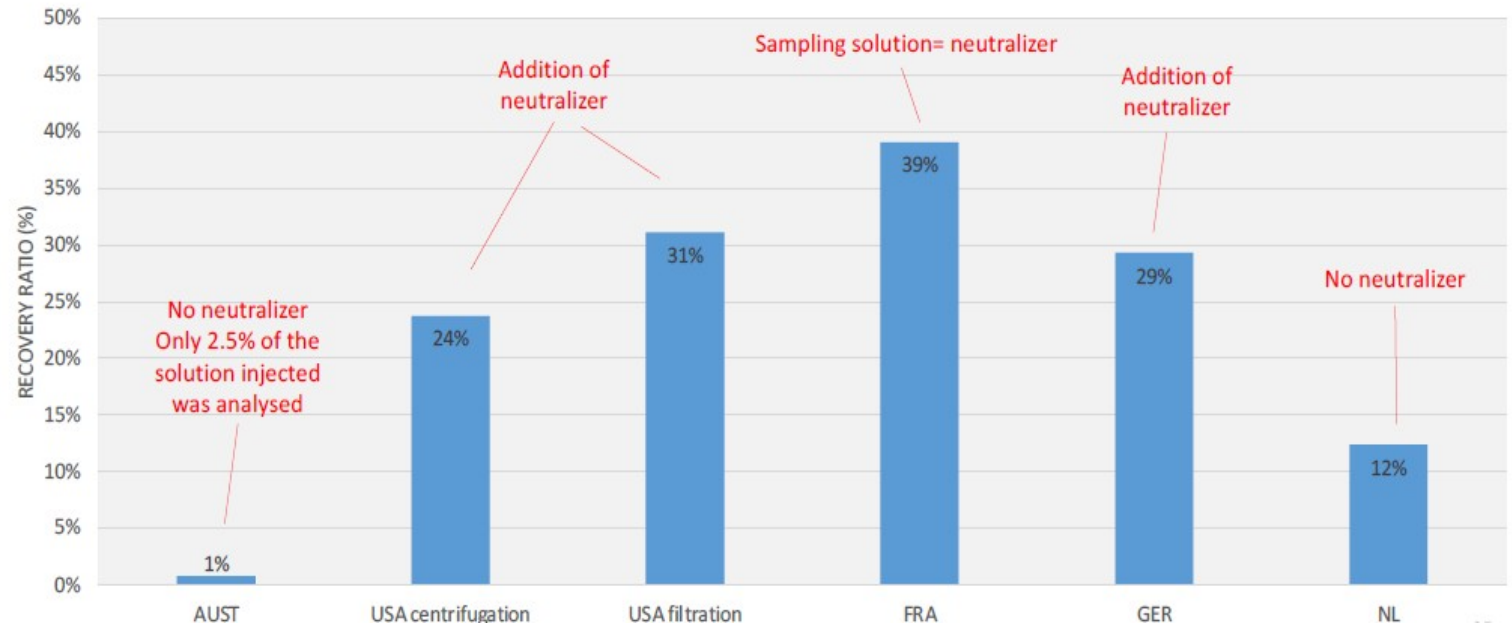
journal homepage: [www.elsevier.com/locate/jhin](http://www.elsevier.com/locate/jhin)

Endoscope sampling and culturing methods

L. Pineau<sup>a,\*</sup>, M. Alfa<sup>b</sup>, C. Radix<sup>a</sup>

<sup>a</sup> Medical Device Testing, Eurofins Biotech Germande, Aix-en-Provence, France

<sup>b</sup> AlfaMed Consulting Inc., Winnipeg, Manitoba, Canada



Van der Ploeg et al. *Gastrointest Endosc.* 2025

Pineau et al. *JHI*, 2024

# Cleaning Verification



## Organic Residue Detection

Color change, visual interpretation  
Single or multiple organic markers

- Protein
- Hemoglobin
- Carbohydrates

✓ *Quantifiable kits:*

<6.4  $\mu\text{g}/\text{mL}$  or 3-6.4  $\mu\text{g}/\text{cm}^2$   
*Cutoff\**



## ATP Bioluminescence Assays

Level of ATP hand-held detector,  
Quantifiable

- RLU Cut-off varies by test kit used
- RLUs **DO NOT** indicate level of microbes (microbes can be present even if RLU < cutoff)
- ATP Assay may detect, patient secretions, food
- Role of ATP in endoscopes **not resolved** yet

## Single-use duodenoscopes and duodenoscopes with disposable end caps



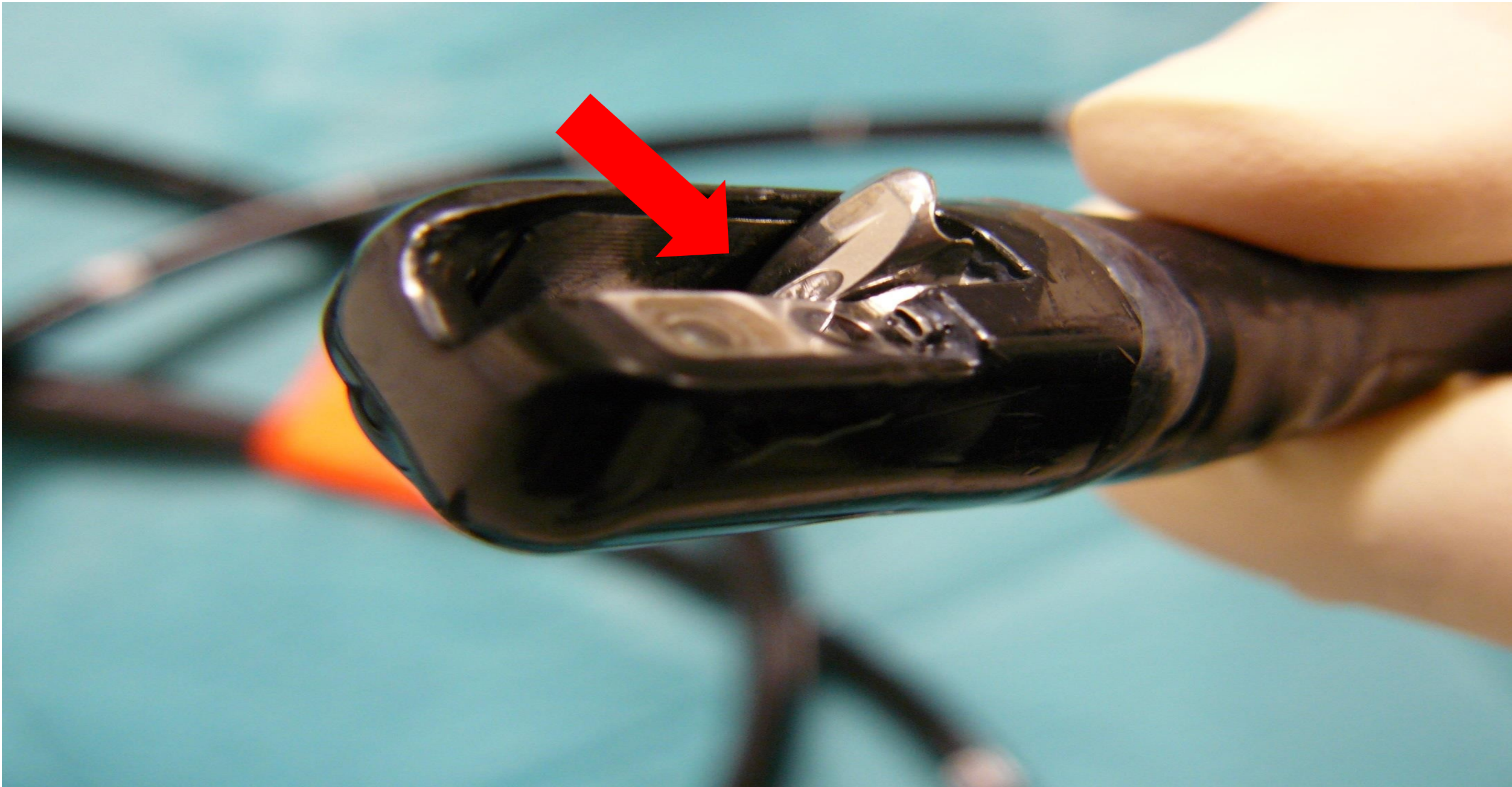
Prepared by: ASGE TECHNOLOGY COMMITTEE

Arvind J. Trindade, MD,<sup>1,\*</sup> Andrew Copland, MD,<sup>2,\*</sup> Amit Bhatt, MD,<sup>3</sup> Juan Carlos Bucobo, MD, FASGE,<sup>4</sup> Vinay Chandrasekhara, MD, FASGE,<sup>5</sup> Kumar Krishnan, MD,<sup>6</sup> Mansour A. Parsi, MD, MPH, FASGE,<sup>7</sup> Nikhil Kumta, MD, MS,<sup>8</sup> Ryan Law, DO,<sup>9</sup> Rahul Pannala, MD, MPH, FASGE,<sup>10</sup> Erik F. Rahimi, MD,<sup>11</sup> Monica Saumoy, MD, MS,<sup>12</sup> Guru Trikudanathan, MBBS,<sup>13</sup> Julie Yang, MD, FASGE,<sup>14</sup> David R. Lichtenstein, MD, FASGE, (Chair, Technology Committee)<sup>15</sup>

FDA has advised manufacturers and endoscopy practices transition to **newer design** features that facilitate or eliminate the need for reprocessing.

- ✓ Single-use distal ends that facilitate reprocessing
- ✓ Fully disposable single-use instruments
- ✓ Fully disposable duodenoscopes

# Duodenoscopes: Single-use Or Disposable End Caps





*\*Take  
home message*

# Συμπεράσματα

## Πρόβλημα

- ✓ Οι ενδοσκοπήσεις (γαστρ/κο, αναπν/κο) αποτελούν συχνό αίτιο συρροών Ν.Λ. συνδεδεμένες με Ιατροτεχνολογικές Συσκευές (Medical Device)
  - Αγνοούμε το πραγματικό μέγεθος του προβλήματος
  - Κορυφή του παγόβουνου MDROs
- ✓ Οι συρροές Ν.Λ. εμφανίζονται αν και οι Κ.Ο. & IFUs έχουν τηρηθεί
  - Μήπως έχουμε πολλούς κανόνες και η διαδικασία είναι εξαιρετικά πολύπλοκη?
  - Μήπως βασιζόμαστε υπερβολικά στην HLD? Μήπως χρειάζεται αποστείρωση?
- ✓ Έχουμε Κ.Ο. & Οδηγίες αλλά δεν υπάρχει απόλυτη συμφωνία (μέθοδος επεξεργασίας, στέγνωμα, αποθήκευση, επιτήρηση κοκ)
- ✓ Η πρόληψη απαιτεί αυστηρή τήρηση των Κ.Ο. & IFUs (Αλλά τα IFUs ΔΕΝ είναι το «Ευαγγέλιο»...Ας είμαστε σκεπτικοί...)

## Λύσεις

- ✓ Εκπαίδευση (πιστοποίηση) προσωπικού
- ✓ Επιτήρηση Διαδικασιών Απολύμανσης
- ✓ Μικροβιολογική Επιτήρηση
  - Καλλιέργειες ± PCR ± NGS
  - Χρήση συσκευών ATP
  - Έλεγχος πρωτεϊνικού υπολείμματος
- ✓ Σχέδιο για ανίχνευση & περιορισμό συρροών
  - Επιτήρηση & Διασύνδεση Ενδοσκ/κό Τμ. – ΕΝΛ
  - Contact Tracing for outbreaks
  - Monitor Outcomes
- ✓ Νέα τεχνολογία/σχεδιασμός
  - Disposable End Caps Duodenoscopes
  - Ενδοσκόπια Μιας Χρήσεως
  - HLD x2 ή ΑΠΟΣΤΕΙΡΩΣΗ
  - Επανασχεδιασμός (κατασκευαστές)

# Ενδοσκόπια & Μικροβιακή Επιμόλυνση

Να Ανησυχούμε ... **ΝΑΙ!**

Να το Αγνοήσουμε ... **ΟΧΙ!**

Να Κάνουμε Κάτι ... **ΝΑΙ!**



Στο τέλος της ημέρας...

Το ενδοσκόπιο θυμάται τα πάντα

Το ενδοσκόπιο ΔΕΝ ξεχνά:

- ✓ τον προηγούμενο ασθενή
- ✓ τα μικρόβια
- ✓ τα μικρά λάθη στη διαδικασία

# Death by PowerPoint

Endoscopes. Clean Process. Safe Patients.  
Good IPC Saves Lives.

-   
**CLEAN SCOPE**
-   
**FOLLOW THE PROCESS**
-   
**USE THE RIGHT DISINFECTANT**
-   
**PROTECT YOURSELF**
-   
**STOP INFECTIONS**

Ευχαριστώ!   
Ερωτήσεις.



I'm clean and ready to go!



## ENDOSCOPE REPROCESSING & IPC — EVERYTHING. ALL AT ONCE. ⚠️ SO MUCH TO KNOW!

### Why It Matters

- Prevents infections
- Protects patients and staff
- Ensures compliance & safety
- Extends scopelife span
- Reduces costs

### Risk of Transmission

Pathogen	Survives in Azule
Bacteria	Hours - Days
Mycobacteria	Days - Weeks
Mycotic	Weeks - Months
Fungi	Weeks - Months
Spores	Months - Years

### Outbreaks Happen

- 2015 - ERCP - CREP - CRE
- 2016 - EGD - MNDO
- 2018 - Bronchoscopy - GI cluster
- 2020 - Hospital-wide GI cluster

The process works. When we follow it.

### Environmental Cleaning

- High-touch surfaces
- Floors and walls
- Focus daily
- Don't forget
- Disinfectants

### REPROCESSING STEPS (High-Level - Follow Every Step, Every Time)



Key Success - Right Time - Right Place - Right Staff - Test - Track - Store - Stay Sharp

### Disinfectants & Coagents

Agent	Concentration
Gluconolide	2,0 Tm
Opresolase	0,15 Tm
Peracetic Acid	0,2 Tm
Hydrogen Peroxide	7,5 Tm
Always follow IFU	7,5 Tm

### Contact Times to the Gear

- Check tssed
- Immerse hung
- No air pockets
- Exact time
- Rinse well

### Monitoring Every day, Every load.

- Tested
- Multi-parameter
- Done
- Documentation
- Out of range

### Standards & Guidance

- ANSES/ISH - reprocessing
- AORN/SQRA - cleaning guidelines
- CDC - TOCC - reprocessing recommendations
- Manufacturer IFU - the common flag

### Environment Matters



### IPC Chain



IF IN DOUBT, CLEAN IT OUT! 😊

### Key Reminders

- The scope is sterile - clean!
- The process is not optional.
- No shortcuts!
- No shortcuts - everything is going
- Every time, every time, every time
- Ask questions
- Speak up
- Stay & assist
- Speak up
- Our patients rely on us every last line
- We fear the defense
- We save lives
- Zero risk

Άλλες 2,347 διαφάνειες ακόμη!



IPC TODAY  
SAFETY  
TOMORROW



EVERY SCOPE. EVERY TIME. EVERY PATIENT.

Together, we make a difference.

