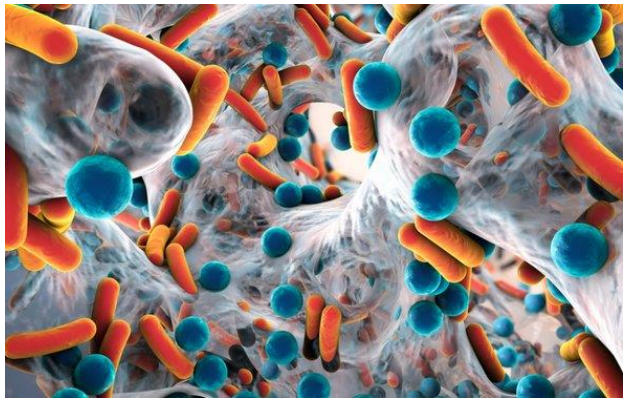
Endoscope reprocessing: Biofilm & Quality Systems



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Disclosures:

Consulting services: 3M, Olympus, ASP, Ofstead Associates, KARL STORZ, Novaflux, Kikkoman

Royalties: U of Manitoba: license to Healthmark

Sponsored Speaker: 3M, Ruhof, Ambu, Olympus

I do NOT represent any company and discussion of specific products is not meant as an endorsement.

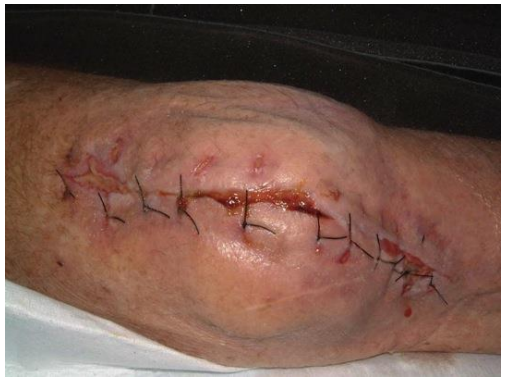
Objectives:

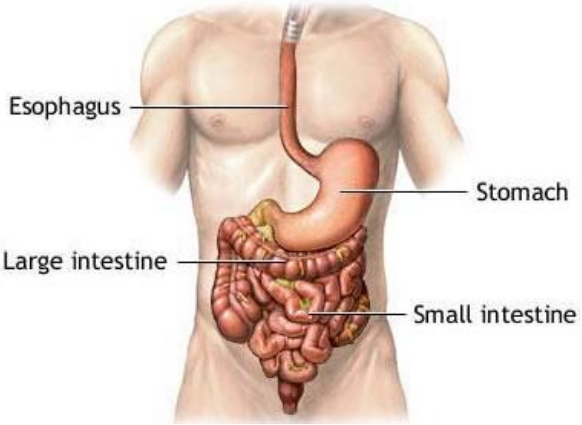
- ***Endoscope Contamination: Biofilm & Buildup Biofilm***
- ***Moisture during storage: Unrecognized***
- ***Adequate Drying of Channels***
- ***FDA Safety Communication***
- ***Summary: what to do?***

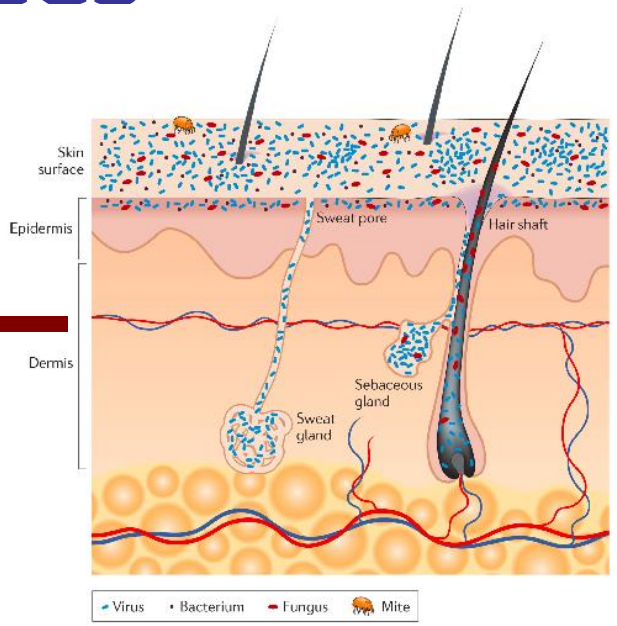
All Clipart Pictures in this presentation are from Free Google Images

Patient Infections related to Medical Devices

Endogenous: Infections due to patient's own organisms







Exogenous: Infection due to contaminated medical device

Current Published Data:

- Risk of Infection after endoscopy?
- Contamination of Patient-ready Endoscopes?

Infection Rates 7 days after Colonoscopy and OGD procedures in Ambulatory Surgery Centres in 2014

Type of Procedure	Number evaluated	Infections/1000 procedures
Screening colonoscopy	462,068	**1.13**
Non-screening colonoscopy	914,140	**1.57**
Osophagogastroduodenoscopy	873,138	**3.04**
Bronchoscopy	30,116	**16.54**
Cystoscopy	68,432	**4.42**
Screening mammogram	647,212	**0.61**

Wang P et al Rates of infection after colonoscopy and osophagogastroduodenoscopy in ambulatory surgery centres in the USA. Gut 2018. (http://dx.doi.org/10.1136/ gutjnl-2017-315308).

Types of Organisms causing infection

- Drug-resistant microorganisms
- *Escherichia coli*
- *Klebsiella pneumoni*ae
- *Clostridium difficile*
- *Pseudomonas spp.*
- *Staphylococcus spp.*
- *Streptococcus spp.*
- Gram-negative bacteria
- Anaerobes
- Human papillomavirus

Limitations:

1. *Doesn't differentiate endogenous vs exogenous infections*
2. *Doesn't identify* ***colonization*** *with multi-resistant organisms*

Wang P et al Rates of infection after colonoscopy and osophagogastroduodenoscopy in ambulatory surgery centres in the USA. Gut 2018. (http://dx.doi.org/10.1136/ gutjnl-2017-315308).

Evidence of GI Endoscope Contamination

Rauwers AW et al. Gut 2018 doi: 10.1136/gutjnl-2017-315082

Culture: Neutralizer & sample concentrated by filtration

Organism grown: GI flora	Number of Duodenoscopes	Quantity Range
Yeast	7	6 to 100 CFU
Klebsiella pneumoniae	4	100 to > 100 CFU
Enterobacter cloacae	3	100 to > 100 CFU
Escherichia coli	2	50 to 100 CFU
Klebsiella oxytoca	2	100 to > 100 CFU
Enterococcus faecium	1	1 CFU
Enterococcus faecalis	1	100 CFU
Pseudomonas aeruginosa	1	100 CFU
Staphylococcus aureus	1	> 100 CFU

- **Duodenoscopes: 15% of 155 tested were contaminated**
- **Current reprocessing & process control procedures not adequate**

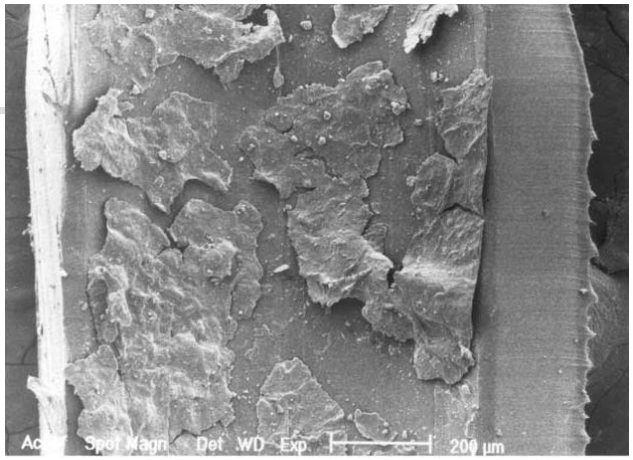
FDA Interim report on Duodenoscope Clinical Study April 2019 (Olympus, Pentax, Fujinon)

- High concern organisms: 5.6%
  (E. coli, P. aeruginosa, S. aureus etc)
- Moderate/Low concern organisms: 3.6%
  (*S. epidermidis, Bacillus spp, viridans Streptococci* etc)
- Duodenoscope reprocessing:
  NEEDS IMPROVEMENT

Statement from Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on continued efforts to assess duodenoscope contamination risk.(MedicalDevices/Safety/AlertsandNotices/ucm635828.htm)

Flexible Endoscopes: Biofilm

- **Expectation:**
  Biofilm SHOULD NOT form inside **dry** endoscope channels
- **Reality:**
  Build-up biofilm does form!



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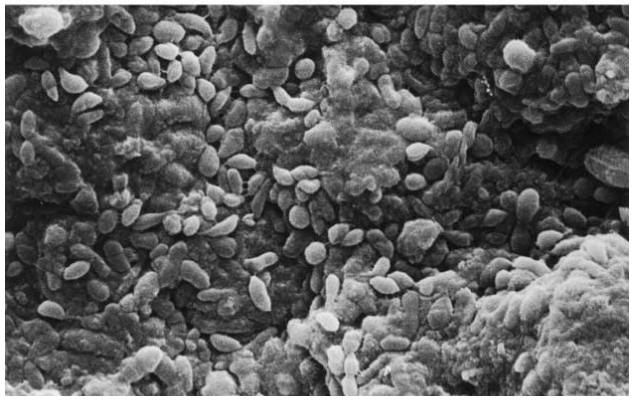
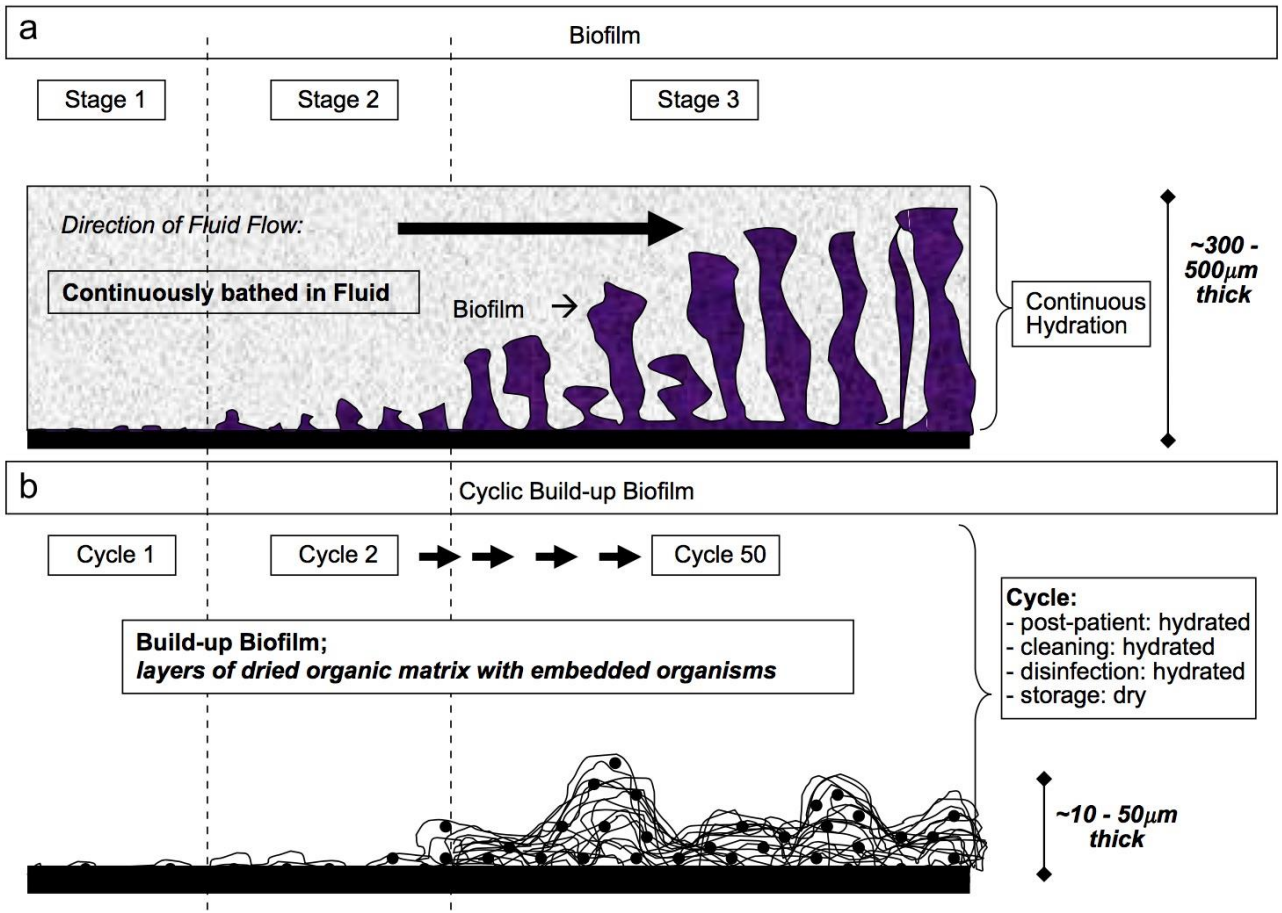
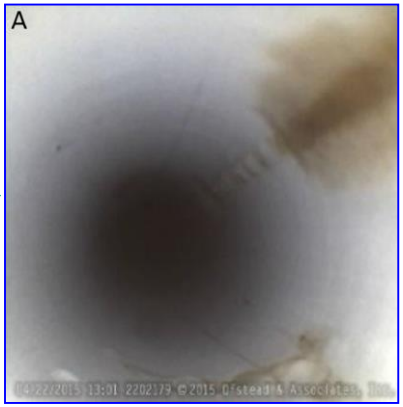


2004: Air/Water channel of GI flexible endoscopes Pajkos et al J Hosp Infect 2004;58:224-9

2014: SEM showed biofilm in 54.6% of 66 Biopsy channels and 76.9% of 13 Air/water channels Ren-Pei W AJIC 2014; 42:1203-6

Comparison: Traditional to Buildup Biofilm





Zhong W, **Alfa M**, Howie R, Zelenitksy S.
Simulation of cyclic reprocessing buildup on reused medical devices. Comput Biol Med 2009 Jun; 39(6): 568-577.

Drying Endoscope channels for Storage

1. Endoscope manufacturer's instructions:

- Endoscopes MUST be dried prior to storage.
- ALL channels: alcohol flush & forced air drying

2. Automated Endoscope Reprocessors (AER)

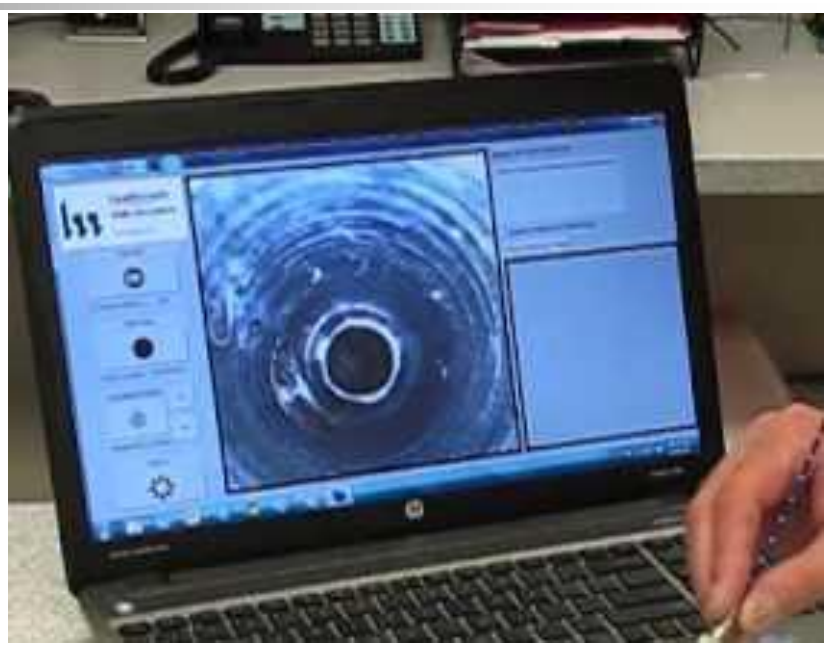
- many have alcohol flush and drying cycle
- they do NOT claim this dries sufficiently

3. Endoscopy clinic staff:

- Widespread believe that AER cycle adequately dries endoscopes for storage (AAMI ST91 states this)

Borescope:

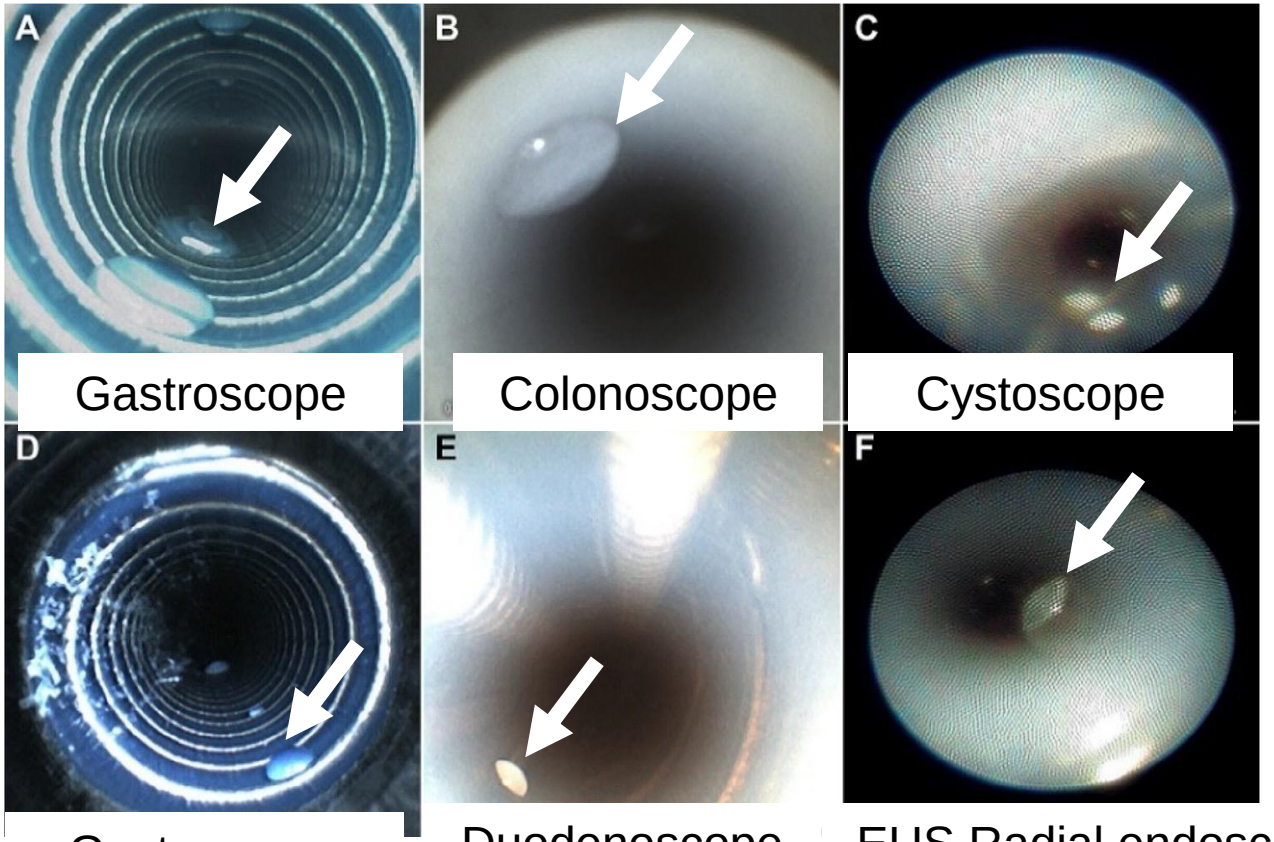
Inspect inner channel of endoscopes



Borescope use for endoscopes recommended by:
AAMI ST91 2015, AORN 2017, IAHCSSM 2017

After AER; alcohol flush, 6 min air flush & overnight storage

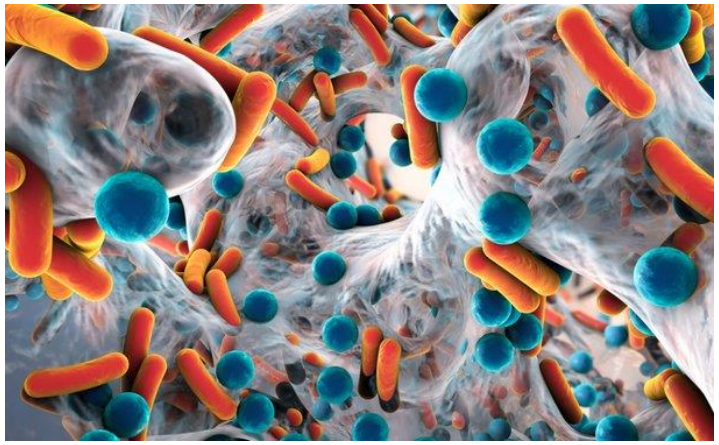
***Ambulatory Clinics*: Visible Fluid in 95% Channels**
[**Ofstead** et al AJIC 2017;45:e26-e33 doi.org/10.1016/j.ajic.2016.10.017]



Large healthcare systems: Visible fluid in 49% channels
[**Ofstead** et al AJIC 2018;45:e26-e33 doi.org/10.1016/j.ajic.2018.03.002]

Storage of endoscopes with moisture in Channels

- Much more extensive than recognized
- Leads to Build-up biofilm (BBF)
- Bacterial survival in BBF increases risk of infection transmission.



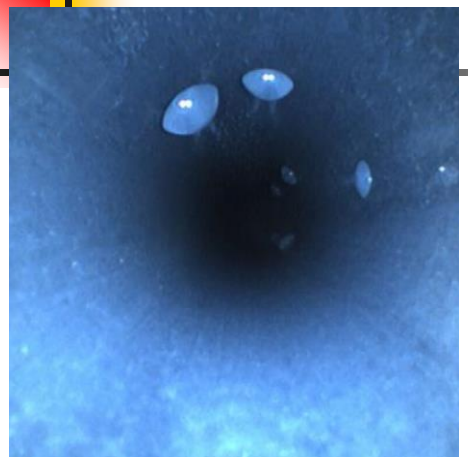
Olympus Statement Simethicone use

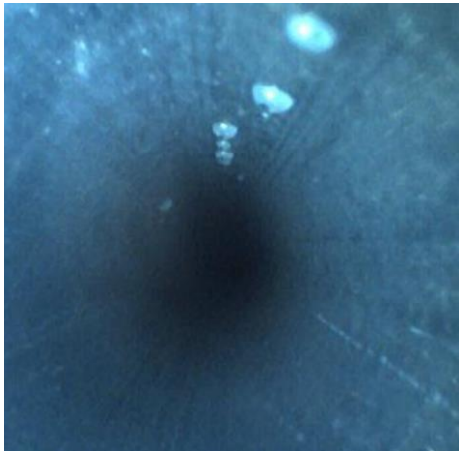
[June 29, 2018]:

- **Simethicone:** not easily removed by current reprocessing methods
- **Do Not use:** water insoluble lubricants such as Simethicone
- **Can use:** water soluble lubricants such as K/Y jelly, lidocaine jelly for insertion tube
- **If simethicone used** – administer in bowel prep or through Biopsy port

Simethicone retained despite reprocessing

Barak M. et al GIE 2018 10.1016/j.gie.2018.08.012





Simethicone tested at:

0.5%, 1%, 3% in water bottle as well as by biopsy port injection

Despite AER dry <u>PLUS</u> 10 min manual forced air dry:

Residual droplets & simethicone found in patient-used upper GI endoscopes even when used at lowest concentration 0.5%

Authors question clinical significance of simethicone residuals & suggested 2 x AER

Position Statements on Clinical Value of Simethicone

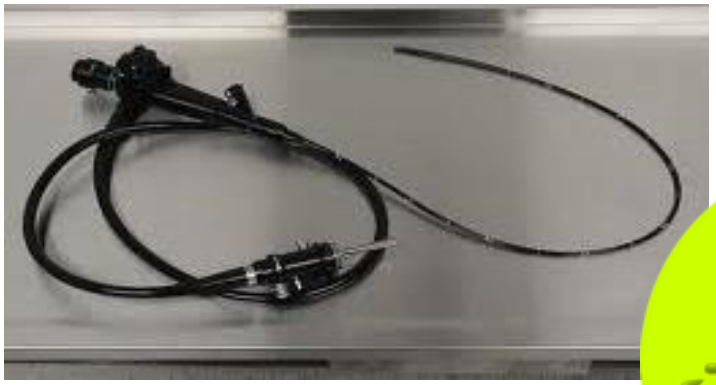
10% more polyps identified with simethicone in water bottle versus without.
Kutyla et al Influence of Simethicone Added to the Rinse Water during Colonoscopies on Polyp Detection Rates: Results of an Unintended Cohort Study.
Digestion 2018;98:217–221

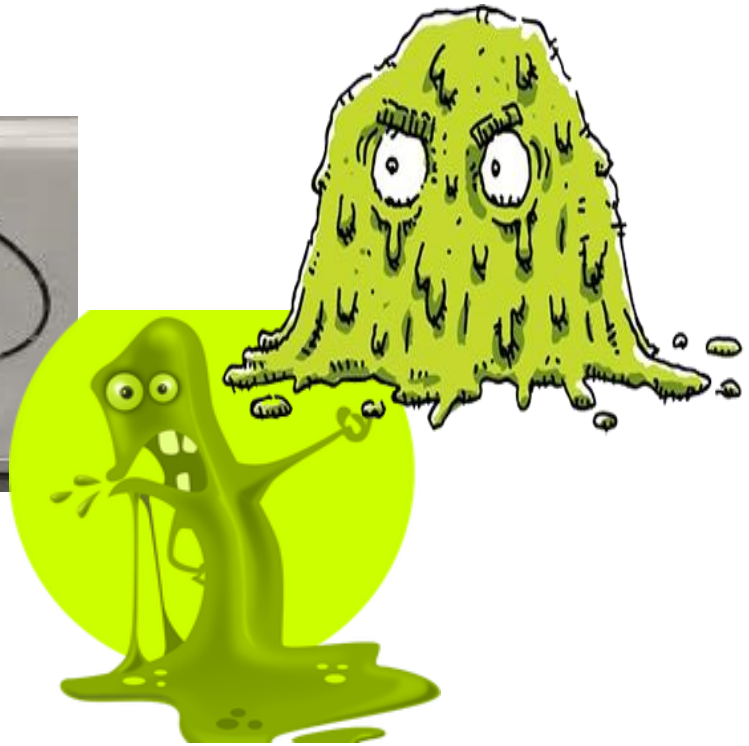
ECRI report 2018 Aug 17, 2018:
Each site needs to decide whether to ban simethicone in endoscopes or not

Australia position statement 2019: OK to use simethicone in any channel.

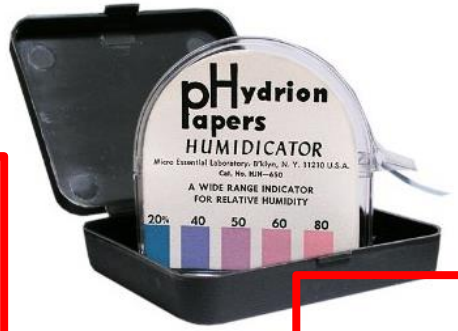
Simethicone Use

“Stuck between a rock and a hard place!!”



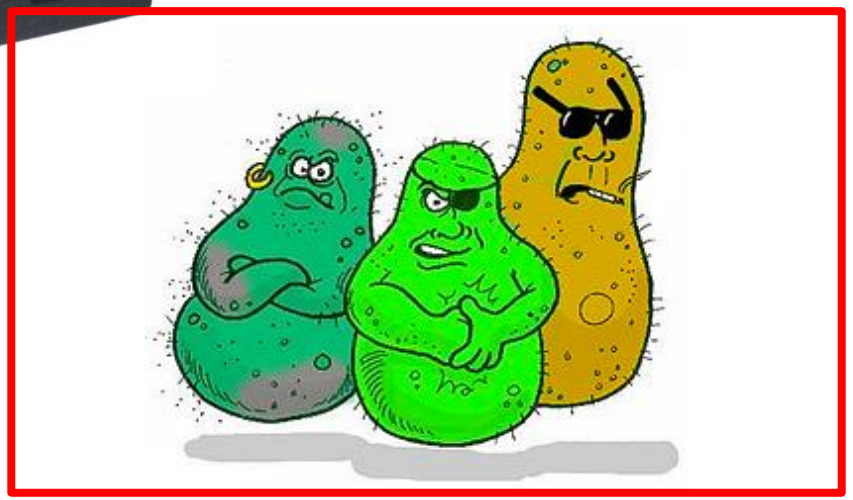


Take Home Message:
DRY.....DRY.....DRY....!!!



Ofstead 2017:
Humidicator strips correlate with borescope test for residual fluid

<u>Dry channels</u>:
NO bacterial replication



<u>Moisture in channels</u>:
Bacterial replication → BIOFILM

Perumpail RB, et al. Endoscope reprocessing: Comparison of drying effectiveness and microbial levels with an automated drying and storage cabinet with forced filtered air and a standard storage cabinet. Am J Infect Control 2019 https://doi.org/10.1016/j.ajic/2019.02.016

Channel-purge Storage cabinets

- HEPA filtered or medical grade air flushed through all channels

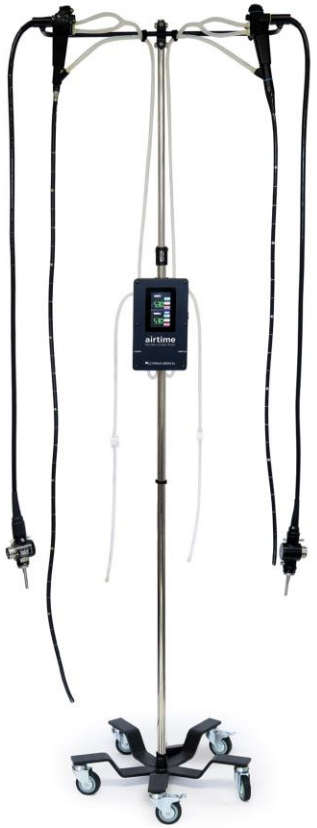
- many manufacturers

Wassenburg Medical

ARC Healthcare Solutions

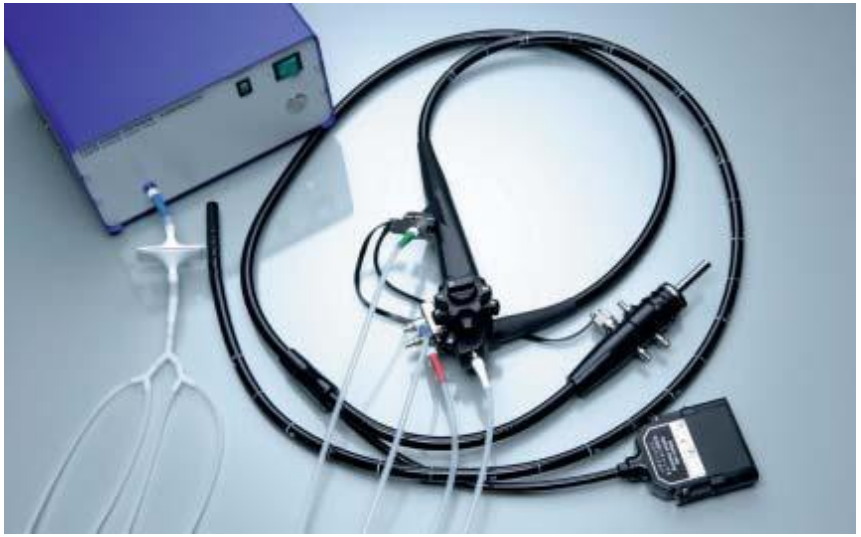
Commonly used in Europe but <u>NOT</u> commonly used in North America

Small air-flushing pumps: facilitate drying before storage



Air-Time Channel dryer

Tri-Core Systems Inc

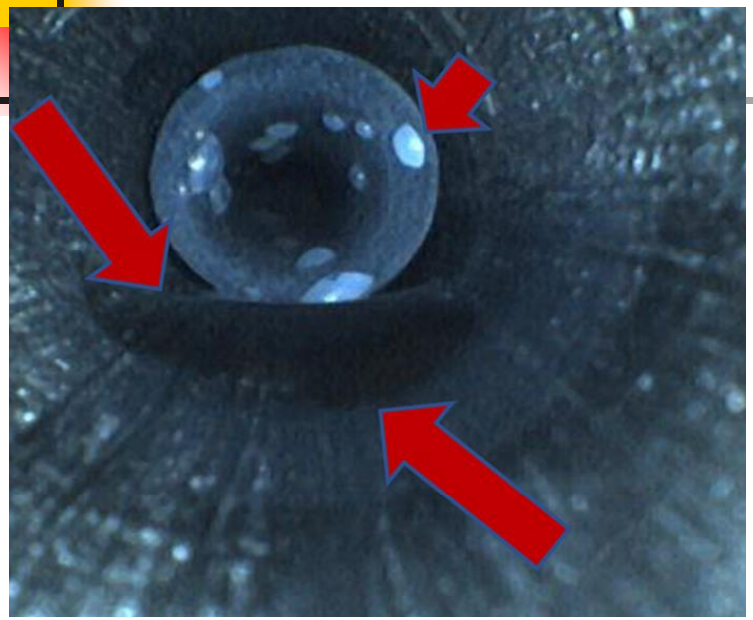


Fujinon

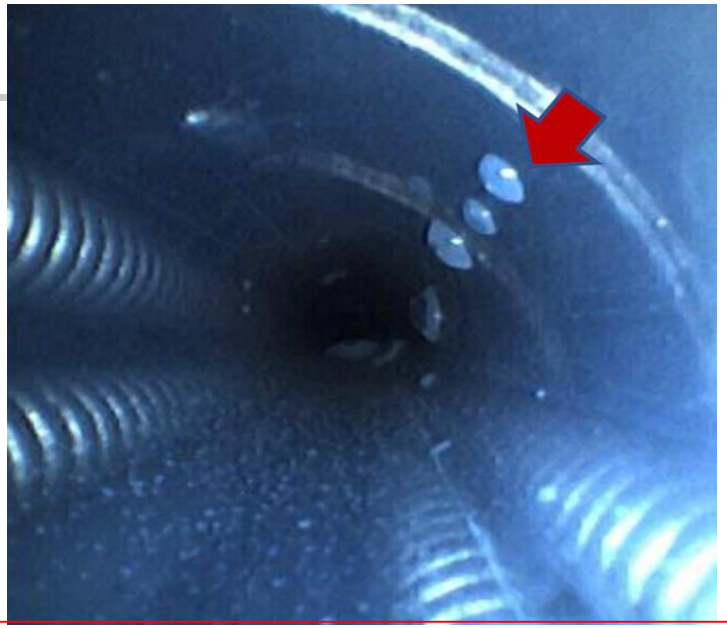
Images from Manufacturer's website

Automated vs Manual Drying:

Barakat et al GIE 2018, doi: 10.1016/j.gie.2018.08.033

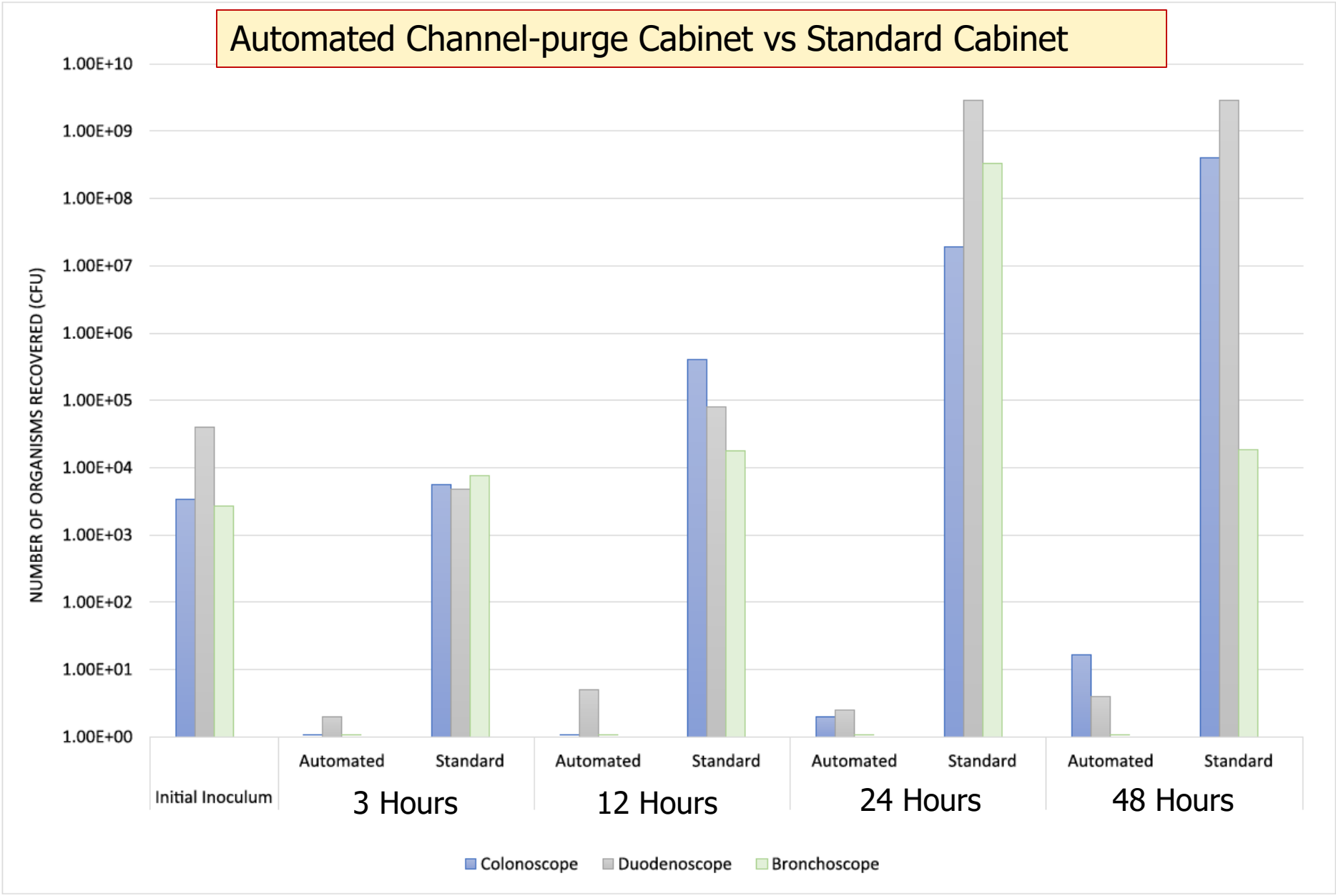


After AER alcohol flush and 1 min air dry



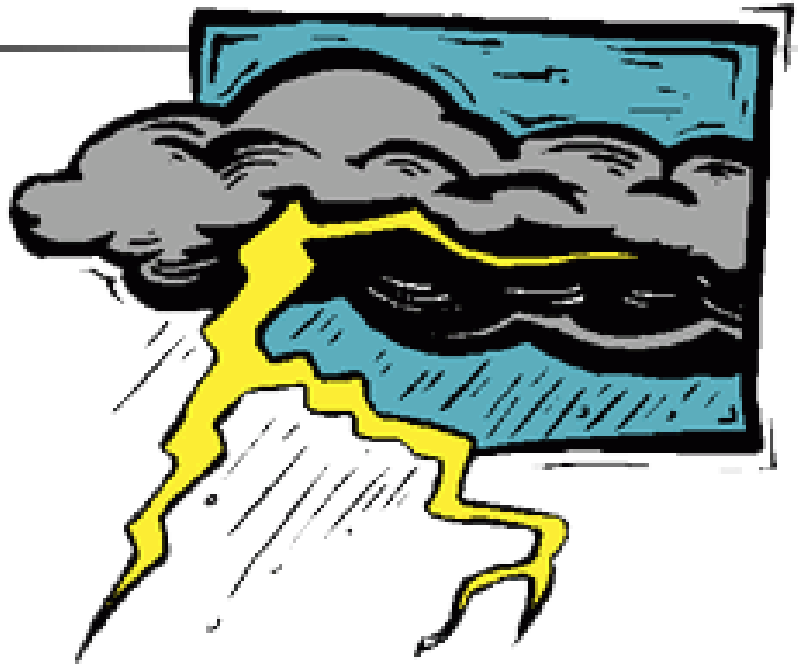
After AER alcohol flush and 1 min air dry and; ***10 min manual dry*** with forced air

Virtually no retained fluid after automated 10 minutes of air pump drying



R.B. Perumpail et al. American Journal of Infection Control 2019

What more can happen…..?



- FDA Safety Communication Aug 29, 2019

FDA Safety Notification: Aug 29, 2019

- **The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety**
  - Move away from fixed endcap to design the facilitates or eliminates need for reprocessing
  - Meticulously follow reprocessing instructions
  - Quality Control: Sampling & culture plus other monitoring
  - Consider sterilization: low temperature or Liquid chemical
  - Routine inspection and periodic maintenance

NEW FDA CLEARANCES:

To date, the FDA has cleared two duodenoscopes with disposable endcaps that facilitate reprocessing:

- **Fujifilm Corporation**, Duodenoscope model ED-580XT (cleared under K181745 (https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181745.pdf))
- **Pentax Medical,** Duodenoscope model ED34-i10T (cleared under K163614 (https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163614.pdf) and K181522 (https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181522.pdf))

Culture of Endoscopes:

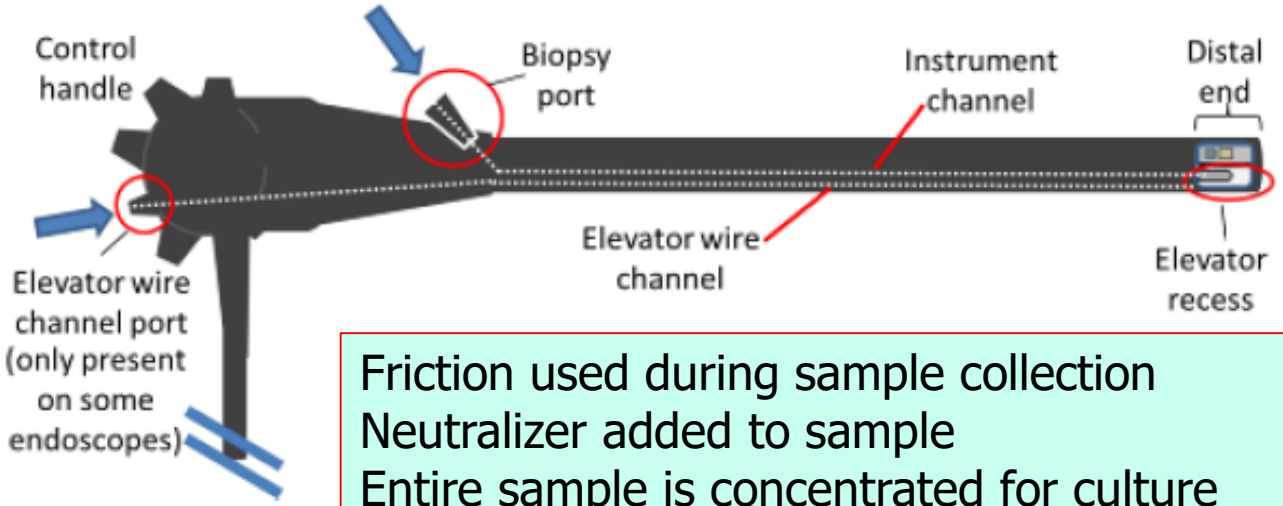
Feb 2018: FDA/CDC/ASM Duodenoscope surveillance sampling and culturing: Reducing the risk of infection

- Friction during sample collection
- Neutralizer to protect damaged bacteria and stimulate them to grow
- Concentration of entire sample (e.g. filtration)

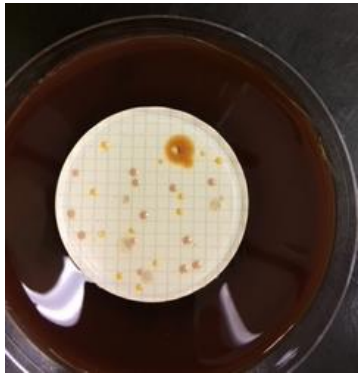
https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/UCM597949.pdf

FDA/CDC/ASM Protocol

- **One combined sample collected from:**
  - Elevator recess (flush-brush-flush)
  - Instrument channel (flush-brush-flush)
  - Elevator wire channel (if unsealed)



Friction used during sample collection
Neutralizer added to sample
Entire sample is concentrated for culture



Validated by Olympus, Pentax, Fujinon; 65% - 100% extraction efficacy

New Low Temperature Sterilization: Sterizone VP4

Turn-around-time ~ 1 Hr

- *H_2O_2 + Ozone*
- *Mixed loads*

FDA cleared for many endoscope lumen dimensions (duodenoscopes?). Limited published data

Vanessa Molloy-Simard et al *Elevating the standard of endoscope processing: Terminal sterilization of duodenoscopes using a hydrogen peroxide–ozone sterilizer. AJIC 2019;47:243-250*]

Upcoming FDA Actions:

- Including Real-World Contamination Rates in the Labeling
- Exploring the Expansion of Available Validated Methods
- Exploring the Potential for Monitoring Reprocessing Effectiveness
- Planning an FDA Advisory Committee Meeting to Discuss Duodenoscope Reprocessing Nov 2019

Key Take Home Messages:

- Endoscope contamination: 9% to 15%
- MIFU issues:
  - HLD & Sterilization failure if Biofilm & BBF present
  - Simethicone – not reliably removed by current MIFU
- Wet Storage is widespread → biofilm
- Shift to sterilization: limited options
- Quality Systems approach

WHAT TO DO…???

Key HICPAC Audit Tools: *Reprocessing Flexible endoscopes*

- HICPAC: Gap analysis and risk assessment Tools
- HICPAC: Endoscope Reprocessing Audit Tool
- HICPAC Competency Verification Tool

2017 CDC-HICPAC Essential elements of a reprocessing program for flexible endoscopes

Sample Gap Analysis Tool: Reprocessing Flexible Endoscopes

Essential Steps for Flexible Endoscope Reprocessing

Completed by: _____ Date completed: _____

Essential Elements of Endoscope Reprocessing	Practice Meets Element (Y/N)	Facility Practice & Supporting Documentation (if any)	Deficiency Identified? (Y/N)	Barriers to Implementing Essential Element
Pre-cleaning				
Is pre-cleaning performed at point-of-use, immediately following completion of the endoscope procedure?				
Are flexible endoscopes and reusable accessories pre-cleaned following the device manufacturer's instructions for use (IFU)?				
Are the pre-cleaned endoscopes placed in rigid container labeled as BIOHAZARD for transport to the reprocessing area?				
Leak Testing (for endoscopes that require leak testing)				
Is the leak test performed using manufacturer's IFU after each use and prior to manual cleaning?				
Manual Cleaning				
Is meticulous manual cleaning performed according to manufacturer's IFU before performing high-level disinfection (HLD) or sterilization?				
Does manual cleaning include brushing and flushing channels and ports consistent with the manufacturer's IFU?				
Is manual cleaning performed within the timeframe specified in the manufacturer's IFU?				
Visual Inspection				
Are the endoscope and its accessories visually inspected after manual cleaning?				
Disinfection or Sterilization				
Is HLD or sterilization performed in accordance with the manufacturer's IFU following cleaning and visual inspection?				

ENDOSCOPE REPROCESSING: *NEW PARADIGM*

- ***What is the situation in your facility??***
  You don't know what you don't know!
- **Specific Audit with Data**
  - **Test:** efficacy of manual cleaning *(rapid organic tests or ATP test)*
  - **Test:** Dry overnight Storage *(borescope or humidicator strips)*
  - **Test:** Culture of endoscopes *(FDA/CDC/ASM culture protocol)*

Audit

Endoscope Reprocessing: Paradigm Shift!

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4. FDA orders duodenoscope manufacturers to conduct postmarket surveillance studies in health care facilities. Oct 5, 2015 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM465639
5. FDA Statement; Statement from Jeff Shuren, MD, Director of the Center for Devices and Radiological Health, on continued efforts to assess duodenoscope contamination risk. April 12, 2019. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm)
6. The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication Aug 29, 2019 https://www.fda.gov/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication
7. Barakat MT, Girotra M, Huang RJ, et al. Scoping the scope: endoscopic evaluation of endoscope working channels with a new high-resolution inspection endoscope (with video). Gastrointest Endosc. 2018 Oct;88(4):601-611.e1. doi: 10.1016/j.gie.2018.01.018.
8. Barakat MT, Huang RJ, Banerjee S, Comparison of automated and manual drying in the eliminating residual endoscope working channel fluid after reprocessing (with video), Gastrointestinal Endoscopy (2018), doi: 10.1016/j.gie.2018.08.033
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13. Perumpail RB, Marya NB, McGinty BL, Mathusamy VR. Endoscope reprocessing: Comparison of drying effectiveness and microbial levels with an automated drying and storage cabinet with forced filtered air and a standard storage cabinet. Am J Infect Control 2019 https://doi.org/10.1016/j.ajic/2019.02.016