AAMI | SUMMER LEARNING SERIES

Overcoming the Inherent Challenges to Extracting a Sample from a Clinically used Flexible Endoscope for Verification Testing

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Objectives

1- Endoscope clinical use and history
2- Reported issues with endoscopes
3- Scope design (angles, internal lumens)
4- A Look inside an endoscope
5- Physics of brushing
6- Current extraction methods
7- Turbulent Fluid Flow (TFF)
8- Verification testing

Disclosure

All opinions are those of the presenter.

This presentation reflects the techniques, approaches and opinions of the individual presenter. This sponsored presentation is not intended to be used as a training guide or promotion.

Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for the use of the device(s).

Healthmark's Policy

Healthmark’s Policy is to provide our customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost-effective manner.

This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence.

This presentation is part of that commitment, educating our customers.

Kaumudi and Jahan Bio sketch

Kaumudi Kulkarni is a microbiologist by training and has her Master's degree in Microbial cellular and molecular biology. She works as a Senior Manager of Research and Development at Healthmark Ind.

Kaumudi is a voting member of AAMI and ASTM and is also involved in the worldwide round robin testing of ISO protocols that impact cleaning of medical devices.

Kaumudi works with sterile processing professionals, medical device manufacturers and testing laboratories.

She is also involved in developing various simulated use test soils used in cleaning validations, along with developing new products that help improve patient care outcomes.

Jahan Azizi is a certified Biomedical Equipment Technologist with more than 33 years in healthcare settings investigating and reporting problems with medical devices, his focus has always been on fixing and correcting, then moving on to the next.

He also has spent several years on the issue of validating and optimizing surgical instrument reprocessing methods. He has worked in healthcare setting, device manufacturing and at Food and Drug Administration as well.

Jahan is a voting member of several AAMI standard committees and active in local and national societies.

Jahan will Discuss

Endoscope clinical use and history

Reported issues with endoscopes

What is an IFU?

Is a D.F.U and M.I.F.U. the same as an I.F.U.?

- **I**nstructions **f**or **U**se (IFU)
- **D**irections **f**or **U**se (DFU)
- **M**anufactures **I**nstruction **f**or **U**se (MIFU-Canada)
  - Yes, they are the same

ANSI /AAMI ST 79

- **2.55 instructions for use (IFU): Written** recommendations provided by the manufacturer that provide instructions for operation and safe and effective use of its device.

What is Endoscopy?

An endoscopy (looking inside) is a non-surgical procedure used to view the internal organs in a non-surgical way. These are often called "minimally invasive" procedures since they are less invasive ways to visualize and organs in some cases, apply treatment if it is already possible. It involves the use of an endoscope, a flexible tube with a camera attached to its end. The camera takes images of the inside of the digestive tract, allowing the diagnosing doctor to view the images on a TV monitor connected to the endoscope.
There are many types of endoscopy, each of which is designed for looking at a certain part of the body. Here we provide a brief overview of the most common types of endoscopy, including what they are used for and what to expect when you have them.

- Bronchoscopy
- Colonoscopy
- Cystoscopy
- Laparoscopy
- Laryngoscopy
- Mediastinoscopy
- Thoracoscopy
- Upper Endoscopy

The Facts- http://safeendoscopy.com/get-the-facts/

1. There are approximately 15,000,000 endoscopic procedures every year in the United States, which include Colonoscopy, Sigmoidoscopy and bronchoscopy.

2. Approximately 2.7% of all endoscopic procedures result in cross-contamination due to non-sterile endoscopes. These cross infections have been referred to as medicines dirtiest secret.

3. Common diseases transmitted through endoscopic cross-contamination are Hepatitis B and C, Tuberculosis, Salmonella, Human Papoloma Virus, Pseudomanus, Aeroginosa, Flu Viruses and other common bacteria. HIV, E. Coli and Kreuttzveld Jacobs Disease (Mad Cow Disease) can possibly be contacted through endoscopic procedures.

4. The current standard of care in the reprocessing of endoscopes is disinfection, which does not kill all microbial life. A sterilization standard would kill all microbial life.

1. Flexible endoscopes have valves and joints that are impossible to scrub, in which some channels are two to six feet long and just millimeters wide. With their intricate channels and valve systems, endoscopes are rife with joints, crevices and pores that regularly trap blood and tissue.

The Facts- http://safeendoscopy.com/get-the-facts/

6. Cross-contamination occurs because heavy encrustations of patient material, including dried blood, feces and mucous have been found inside the suction channels in flexible endoscopes which supposedly had been disinfected.

7. Flexible endoscopes are repaired every day- in service centers throughout the United States. Upon taking each piece apart from an endoscope that is supposedly disinfected, one can regularly observe mucous, blood and fecal matter dripping from endoscope valves.

8. Approximately 270,000 infections a year in the United States are a result of endoscopic cross-contamination. Furthermore, there are approximately 25,000 infections a year in New York due to endoscopic cross-contamination.

9. In 1992, the FDA and the Centers for Disease Control and Prevention adopted a sterilization standard for all reused dental devices entering a patient's mouth. However, for endoscopy, they retained the same disinfection standard deemed unsafe for dentistry.

10. The chemical used to disinfect endoscopes is Glutaraldehyde which if not thoroughly rinsed off can cause colitis.

https://www.endovision.org/history-of-endoscopy?lightbox=dataItem-ijcgi8ey

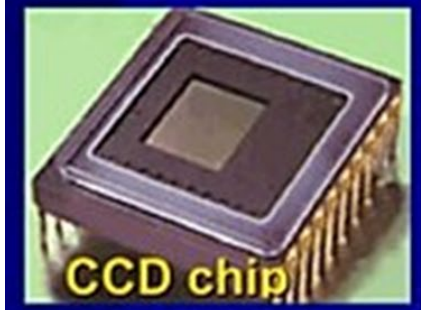
Wolf-Schindler semiflexible endoscope, 1932

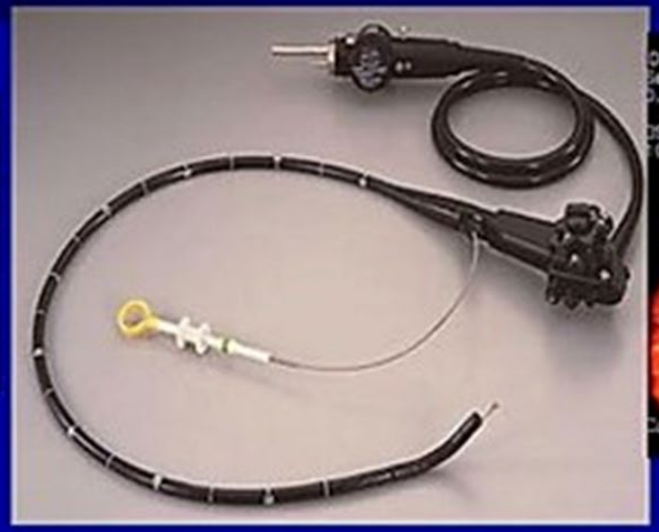
The transition from rigid to flexible endosccopy came half a century later with the incorporation of mirrors and prisms in a tube to create a semiflexible endoscope.

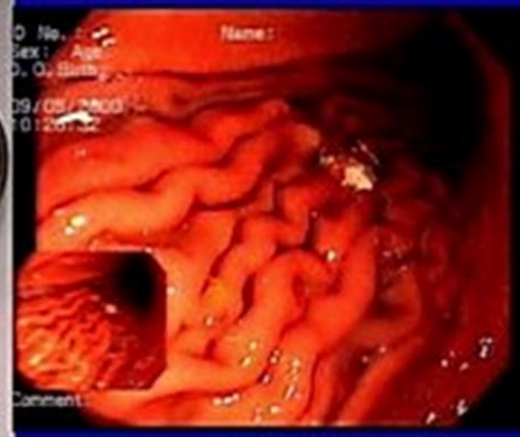
Hirschowitz fiberoptic endoscope, 1957

A fully flexible endoscope was made possible by the discovery of fiberoptics in the 1950s. Basil Hirschowitz is shown holding his creation

Video endoscope, 1984







A major optical "revolution" occurred in the 1980s with the invention of the silicon chip that captures light (photons) and converts photons to electronic signals.
The era of digital endoscopy was born.

California hospital says endoscope was not cleaned properly for 7 years*

An endoscope used to conduct colonoscopies at Queen of the Valley Medical Center in Napa, Calif., was not cleaned properly according to manufacturer's specifications over a seven-year period, putting roughly 5,000 patients at increased risk of infection, according to a *Napa Valley Register* report.

*http://www.beckershospitalreview.com/quality/california-hospital-says-endoscope-was-cleaned-improperly-for-7-years.html

*http://napavalleyregister.com/news/local/queen-of-the-valley-reports-errors-in-cleaning-commonly-used/article_96694e16-09ac-572d-bc4e-d130c3b48be9.html

Reported 10/19/15

"Jury orders Company to pay $6.6 million"

(L.A. Times, July 25, 2017)

- The decision follows an eight-week trial, the first in the U.S. related to gastrointestinal scopes causing outbreaks of drug-resistant infections.

- An investigation by federal, state and county officials concluded that *Virginia Mason followed the manufacturer's cleaning procedures and the scopes were still contaminated after reprocessing*.

- The jury said the company failed to provide adequate warnings about the scope or instructions for its cleaning after it was manufactured.

- An expert witness testified that "*The company would have realized its scopes were defective if it had sufficiently tested its cleaning and disinfection process before putting the devices on the market in 2010.*"

ECRI on Endoscope and surgical instruments Warnings

Over the last many years ECRI has warned us that scopes are an issue

- 2020 is # 3
- 2019 is # 5
- 2018 is # 2
- 2017 is # 2
- 2016 was # 1
- 2015 was # 4
- 2014 was # 6
- 2013 was # 8
- 2012 was # 4
- 2011 was # 3

Training and following the IFU is key to a clean, functional scope

Top 10 Health Technology Hazards for 2018

1. Ransomware and Cybersecurity Threats Can Endanger Patients
2. **Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk**
3. Mattresses and Covers May Be Infected by Body Fluids and Microbiological Contaminants
4. Missed Alarms May Result from Inappropriately Configured Secondary Notification Devices and Systems
5. Improper Cleaning May Cause Device Malfunctions, Equipment Failures, and Potential for Patient Injury
6. Unholstered Electrosurgical Active Electrodes Can Lead to Patient Burns
7. Inadequate Use of Digital Imaging Tools May Lead to Unnecessary Radiation Exposure
8. Workarounds Can Negate the Safety Advantages of Bar-Coded Medication Administration Systems
9. Flaws in Medical Device Networking Can Lead to Delayed or Inappropriate Care

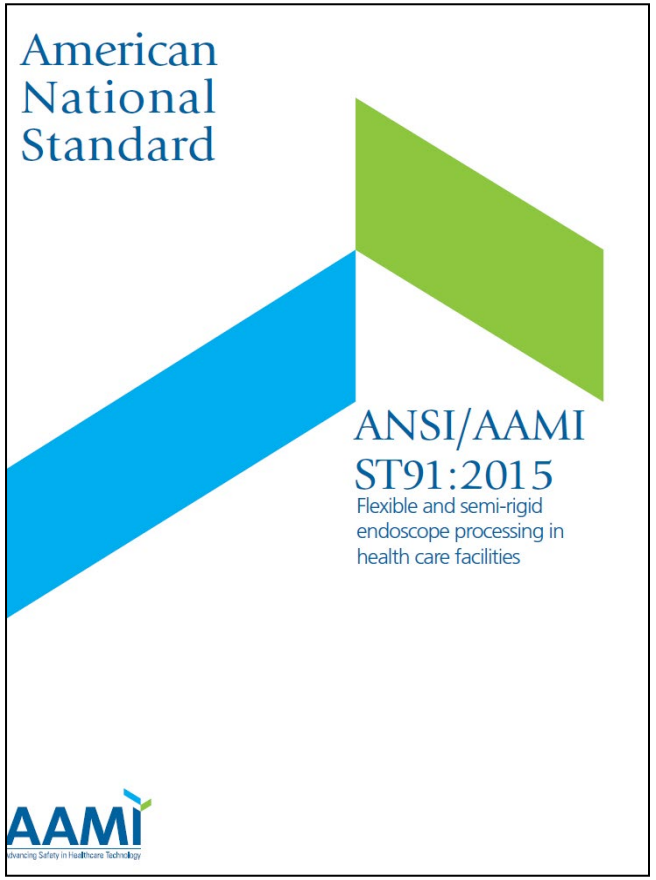
ECRI Endoscope Cleaning Recommendations

To achieve more reliable and effective endoscope reprocessing, ECRI Institute recommends that healthcare facilities:

1. Establish processes for assessing the **quality of the cleaning step**
   a. through magnification-aided visual inspections, and
   b. use of biochemical testing and
2. Implement measures to **dry** endoscope channels after reprocessing.

Reference ECRI 2018: https://www.ecri.org/Resources/Whitepapers_and_reports/Haz_18.pdf

What is ANSI/AAMI ST 91?



- Flexible and semi-rigid endoscope reprocessing in health care facilities
- Contains best practices for scope reprocessing in ANY setting
- Excludes TEE/ultrasound probes

http://www.aami.org/productspublications/ProductDetail.aspx?ItemNumber=2477

FDA's MAUDE - Manufacturer and User Facility Device Experience Database

MAUDE data represents reports of adverse events involving medical devices. The download data files consist of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.

Link to some of the Healthmark's quarterly Flexible Endoscope Incident Reports. These quarterly reports highlight reported incidents in MAUDE database.

http://www.healthmark.info/InstrumentCare/OpticalInspection/Flexible_Endoscope_Incident_Report_May__Volume_I.pdf
http://www.healthmark.info/InstrumentCare/OpticalInspection/Flexible_Endoscope_Incident_Report_October_Volume_II.pdf
http://www.healthmark.info/CleaningVerification/SamplingKit/Flexible_Endoscope_Incident_Report_October_Volume_II.pdf
http://www.healthmark.info/CleaningVerification/SamplingKit/Flexible_Endoscope_Incident_Report_May__Volume_I.pdf

What are the SGNA Guidelines?

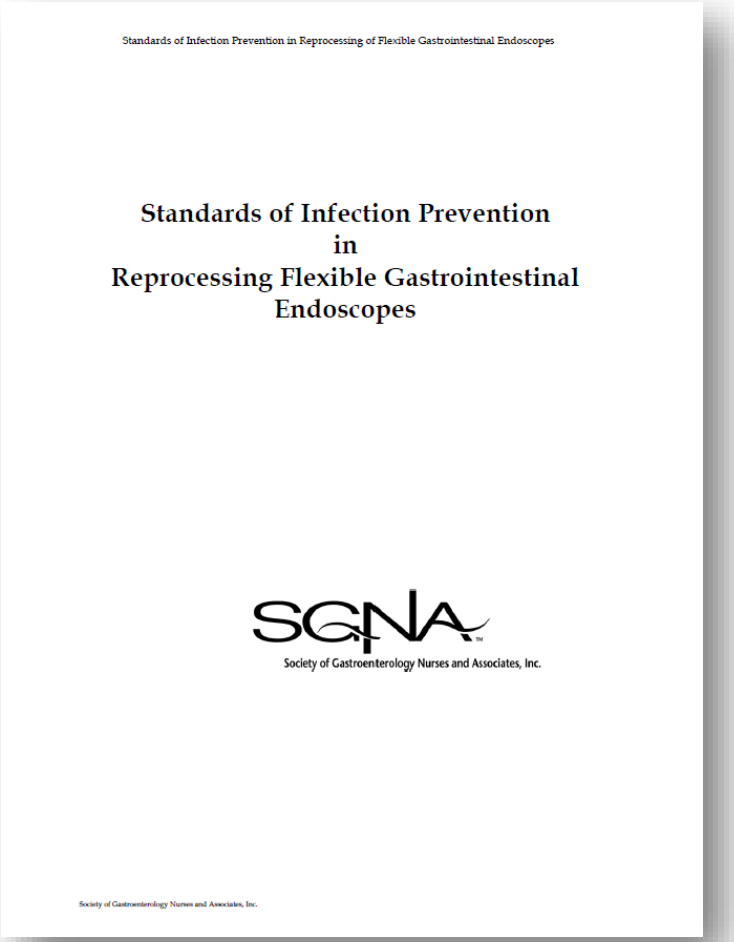
SGNA Standards and Practice Guidelines:

1. Guideline for Use of High-Level Disinfectants & Sterilants in the Gastroenterology Setting (2017)

2. Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes (2016)

3. Standard of Infection Prevention in the Gastroenterology Setting (2015)

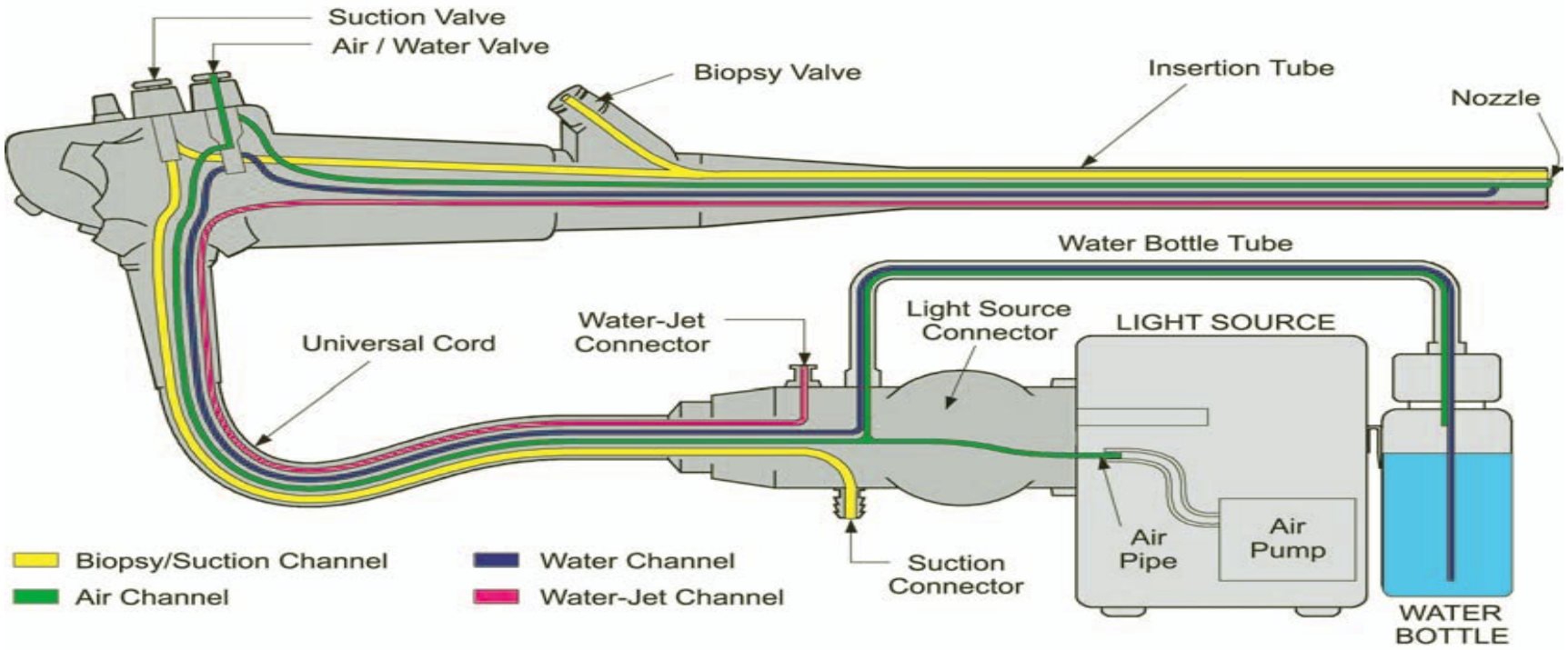
https://www.sgna.org/Practice/Standards-Practice-Guidelines



Kaumudi will Discuss

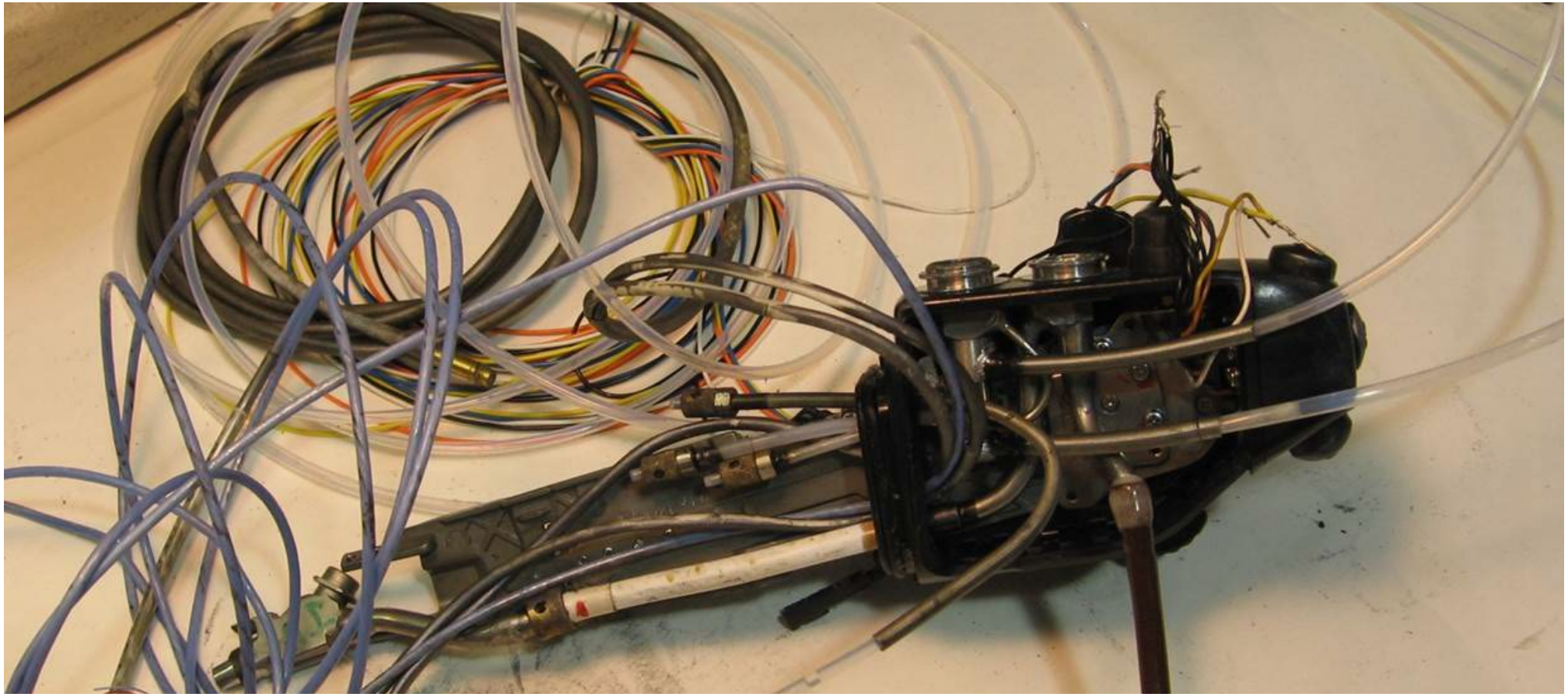
- Brief overview of the anatomy of a flexible endoscope
- Difference between cleaning verification and microbial surveillance of endoscopes
- Visual inspection using video borescopes
- Current sample extraction methods for endoscopes
- Turbulent Fluid Flow (TFF)

A look Inside the Common Olympus Flexible Endoscope



A. Flexible endoscopes are complex devices, many consisting of long narrow lumens with multiple bifurcations as shown above.
B. All channels of a scope must be reprocessed whether utilized during the procedure or not.
C. Due to the complexity of the channel structure of flexible endoscopes only the Automated Endoscope Reprocessor manufacturers connectors can be used with their systems.

Difficult to Clean due to Curves/Bends



How are Cleaning Verification and Microbial Surveillance Different?

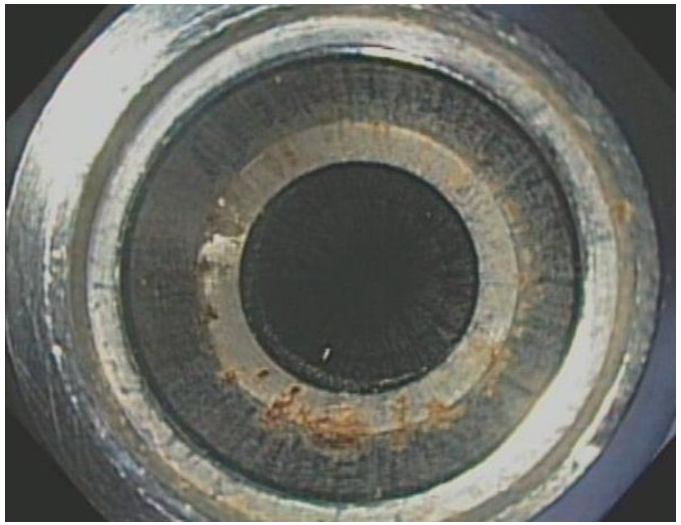
- Cleaning Verification: After the manual cleaning process.
- Microbial Surveillance: After AER / Storage. Not after manual cleaning.

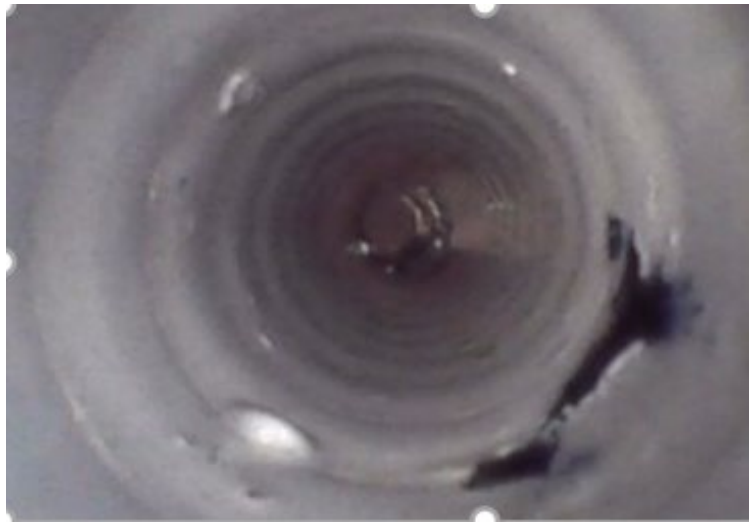
- Cleaning Verification tests are for residual analytes
  Protein, carbohydrates, hemoglobin, ATP
- Microbial Surveillance tests are for aerobic bacteria
  Culturing- For all types of bacteria
  Enzyme based rapid tests- Gram negative bacteria

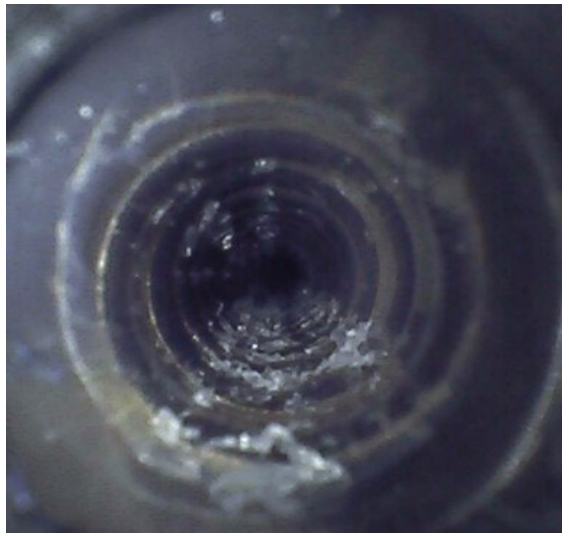
Borescope Inspection

- Tiny flexible scopes used to look inside the small areas of medical devices, especially to inspect the interiors of ports and lumen.
- Penetrate the channels and allow for direct inspection of the internal surfaces of a devices like arthroscopic shavers and flexible endoscopes, that otherwise cannot be viewed.

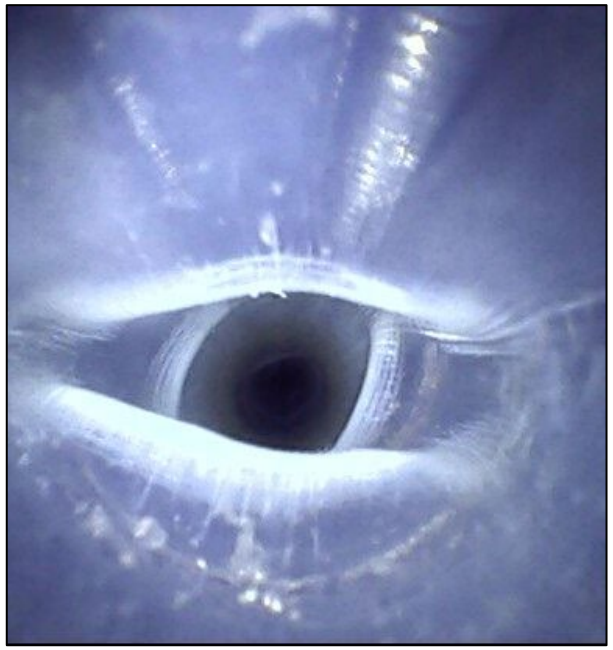
Borescope Inspection
Staining, Moisture, Tearing observed inside Endoscopes







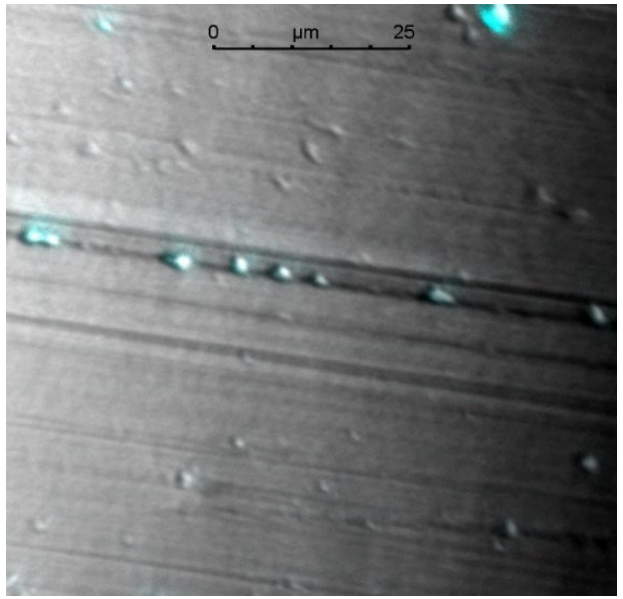
Borescope Inspection
Pinching Observed in the Channels

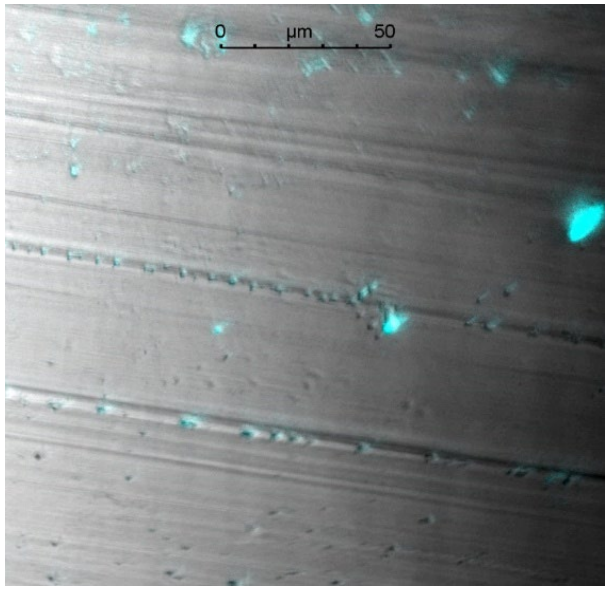


Debris Underneath Damaged Lens – Inaccessible to Cleaning and Disinfection

Bacteria Grooving in the Gouges

Microscopy Images Source: US FDA OSEL

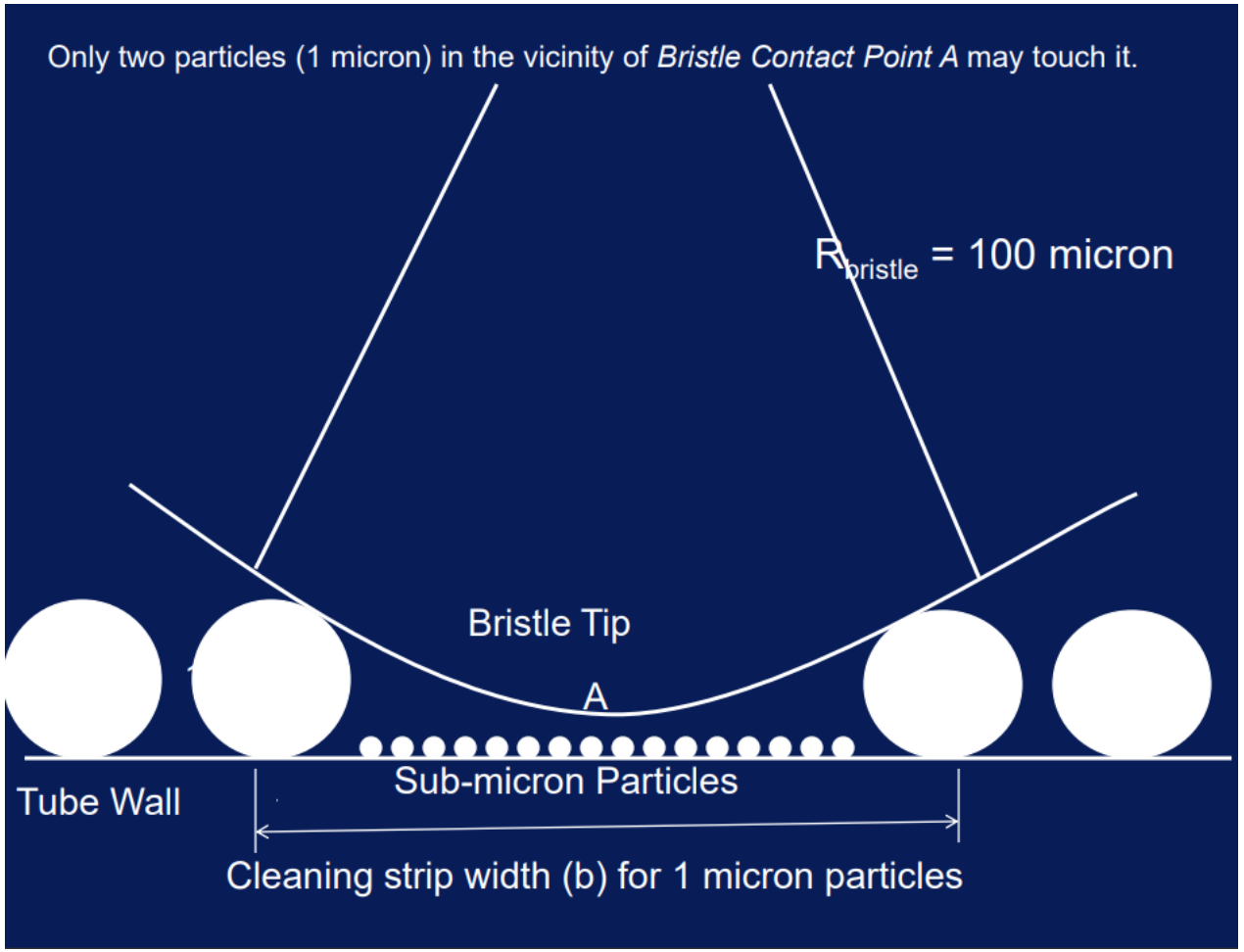




Fluorescence imaging of clinically used endoscope accessory channel stained using the DAPI protocol.

Mechanism of Brushing

Courtesy: Dr. Mohamed E. Labib, NovaFlux



Current Endoscope Channel Extraction Methods

Current methods for obtaining samples from endoscope channels:

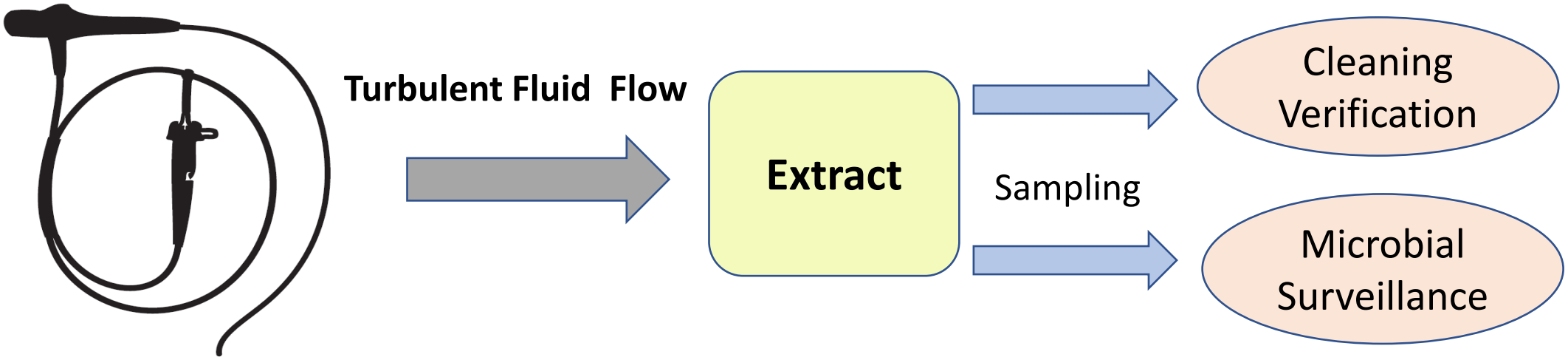
- **Flush- Brush- Flush method**: Sterile water is flushed through the channel, then the channel is brushed with a channel bristle brush or a pull-through channel cleaner, and then flushed again with sterile water. Sample collected into a sample container.
- **Flush method:** Sterile water is flushed through the channel and the sample is collected, after an air purge with a syringe.

The extracted samples can be tested for:

- Protein, hemoglobin, carbohydrate, adenosine triphosphate (ATP) post cleaning
- Aerobic bacteria post HLD/sterilization

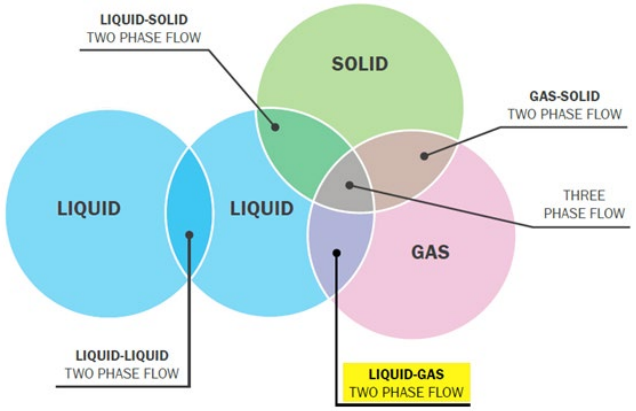
Novel Turbulent Fluid Flow Technology for Sample Extraction

This novel technology will be useful for effective sample extraction of lumened medical devices like endoscopes for the purpose of cleaning verification and microbial surveillance.



Creating Turbulent Fluid Flow (TFF) using Two Phases

- A **single-phase flow** involves flow of a single phase: Solid, Liquid or Gas.
- A **multi-phase flow** involves a simultaneous flow of two or more phases.
- Turbulent Fluid Flow Technology is the simplest case of a multiphase flow.



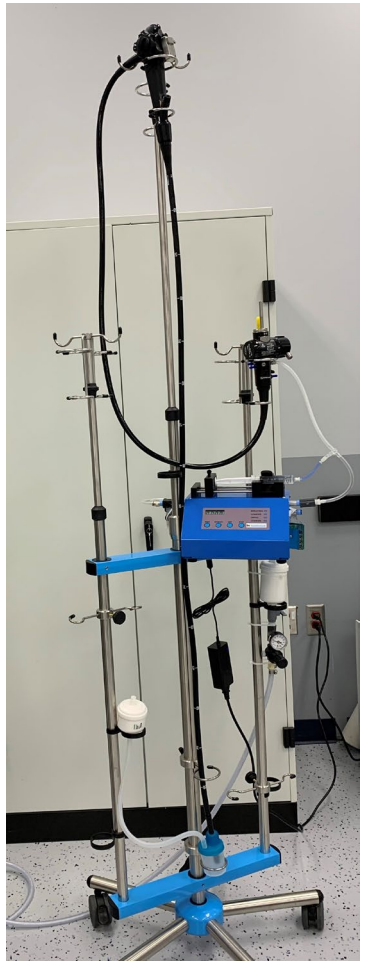
- Turbulent Fluid Flow technology utilizes the Liquid- Gas two phase flow for efficient sample extraction.

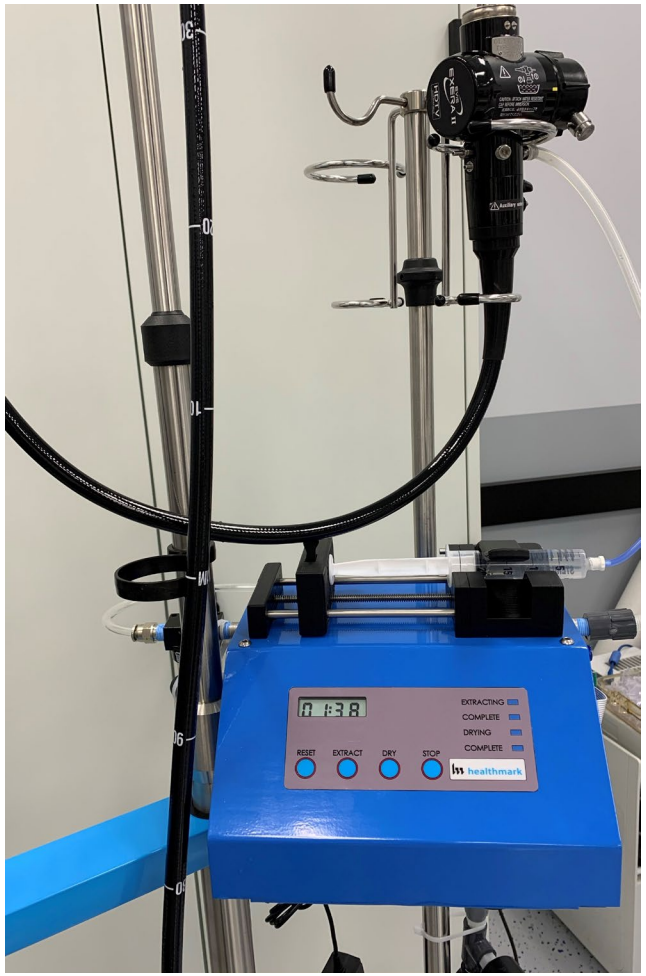
Overview of the Turbulent Fluid Flow Technology

- Novel technology for endoscope channel sample extraction.
- Utilizes a two-phase mixture of gas under pressure and sterile water.
- This mixture is passed through the channels at a predetermined flow rate.
- The water droplets under increased velocity impact the inner surface of the channels, thereby removing the adhered contaminants effectively.

Generating the TFF Extraction

- Turbulent Fluid Flow is generated by an apparatus that mixes the incoming regulated compressed air and sterile water.
- This mixing generates a turbulent mixture (air and water) at a predetermined flow rate suitable for an endoscope channel.
- The TFF channel extraction apparatus is hooked to an endoscope to extract the inner channels.





TFF Microbial Sampling Results

Source: "*Turbulent fluid flow is a novel closed-system sample extraction method for flexible endoscope channels of various inner diameters*". *Sohn, Alfa, Lai, Tabani, Labib Journal of Microbiological Methods, 2020*

Parameter	Suction Biopsy Channel	Air/ Water Channel	Auxiliary Channel
With TFF	% Extraction Efficiency based on CFU/cm^2		
E. faecalis Average	98.44	99.09	99.96
P. aeruginosa Average	98.66	99.21	99.98
C. albicans Average	99.39	99.60	99.97
Flush Brush Flush or Flush Alone (No TFF)	% Extraction Efficiency based on CFU/cm^2		
E. faecalis Average	83.68	89.95	95.76
P. aeruginosa Average	85.38	89.03	85.39
C. albicans Average	86.68	88.73	97.54

Conclusion

- Endoscopes are important tools that doctors use to detect and treat certain conditions without major surgery. They are used to treat conditions like non-cancerous polyps, Barrett's esophagus, bile duct stones, and gastric cancer few examples.
- The endoscope complex design and intricate mechanisms create challenges for cleaning and disinfections. The endoscopes pose a risk of disease transmission.
- Cleaning verification and microbial surveillance are important and reliable tools for effective endoscope reprocessing.
- Borescopes are a valuable tool in detecting damage, residual soil, moisture and retained foreign objects in flexible endoscopes.

Conclusion- continued

- The Turbulent Fluid Flow system is a novel technology used for effective sample extraction from lumened medical devices like endoscopes.
- The technology is robust and effectively removes the organic contaminants and bacteria in the long narrow channels of endoscopes.
- The closed loop system reduces the cross contamination from environment and technicians.
- Both these technologies offer useful tools for the quality assurance process of endoscope reprocessing.

Questions?

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