



Eastern North Carolina Society of Gastroenterology Nurses and Associates

New Bern, North Carolina





CarolinaEast Medical Center

Department of Gastroenterology

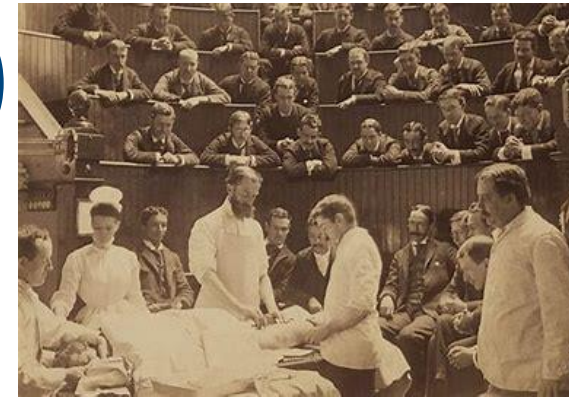
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Gastroenterologist
Advanced Therapeutic Endoscopist

Learning Objectives

1. Historical review and the bugs
2. FDA/Scopes
3. Learn about the factors that impact duodenoscope contamination and risk of endoscope-associated infections (EAIs)
4. Discuss the current data on the effectiveness of duodenoscope processing.
5. Describe new technologies designed to address the limitations of duodenoscope processing

Infection control

- Beginning of modern infection control 1847 (Semmelweis)
 - From autopsies to babies; hand washing, gloves
- Goodyear rubber company, gloves 1852 (Halsted)
- Hospital reform, 1858 (Florence Nightingale)
- Bad air 1864 (Lister)(Pasteur)
 - Microbes, antiseptics, fermentation and wounds
- International Medical Congress, Philadelphia 1876 (Keen)
 - Carpets, furniture, carbolic solution, soap & water, boiled instruments
- Sterile gowns, attire 1883 (Neuber)
- Heat Sterilization > Chemical, 1891 (Bergmann)



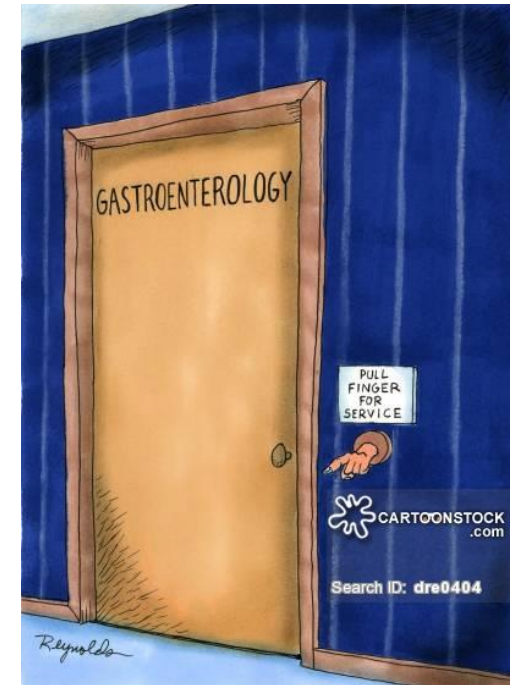
Infection control

- 1900's, 4,000 hospitals in US, infection rate was lower than the 1800's
 - Hospital mortality rate 25% -> 10%
 - TB, diphtheria, measles, typhoid, wound infections **(PCN)**
- Post-World War II, 1946 CDC
- Hospital employees were at significant risk
 - TB 50-100% Nurses, Medical students, converted skin test (+), 20% (+)
- World Health Organization, 1952 (Hepatitis)
 - No more chemical disinfectants for surgical instruments
- **First ever reported antibiotic resistant bacteria (MRSA), 1962***
- Joint Commission on Accreditation of Healthcare Organization
 - 1st Infection Control Program to receive accreditation, 1976



Infection control

- HIV/AIDS, Hep B/C (1980's)
 - Sharps, barriers, autoclaves
- Standard infection prevention
 - Instruments cleaning, decontamination, equipment, surfaces
 - Sterilization
 - Hygiene
 - Personal protective equipment (PPE)
 - Standards of equipment
- In the UK & England 2013
 - Single use instruments*** (Dentistry)
- Covid-19



The value of single use dental instruments

DENTAL REVIEW & NEWS

EDITOR; 03 June 2016



Summary

- **Use of high-quality single-use instruments can provide significant advantages to dentists in general dental practice. Advantages are sterility, convenience, reduced operating costs and efficiencies.**
- **The purchase costs of the single-use instrument option are less significant when the significant hidden costs of reusable instruments are considered, and their cost in use is typically significantly less than the reusable instrument option.**
- **Recent advances in the way that these instruments may be recycled have effectively addressed environmental concerns.**

Gastroenterology



Duodenoscope Contamination

- Which microbes are of concern?
- What is the risk of infection?
- How effective is HLD?
- Is there anything new?

Contaminated duodenoscopes lead to EAIs

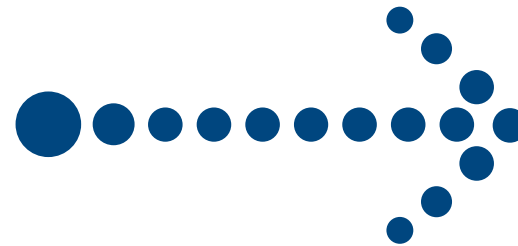
The Microbes



The Scope



Processing



**Increased
risk of EAIs**

The Microbes

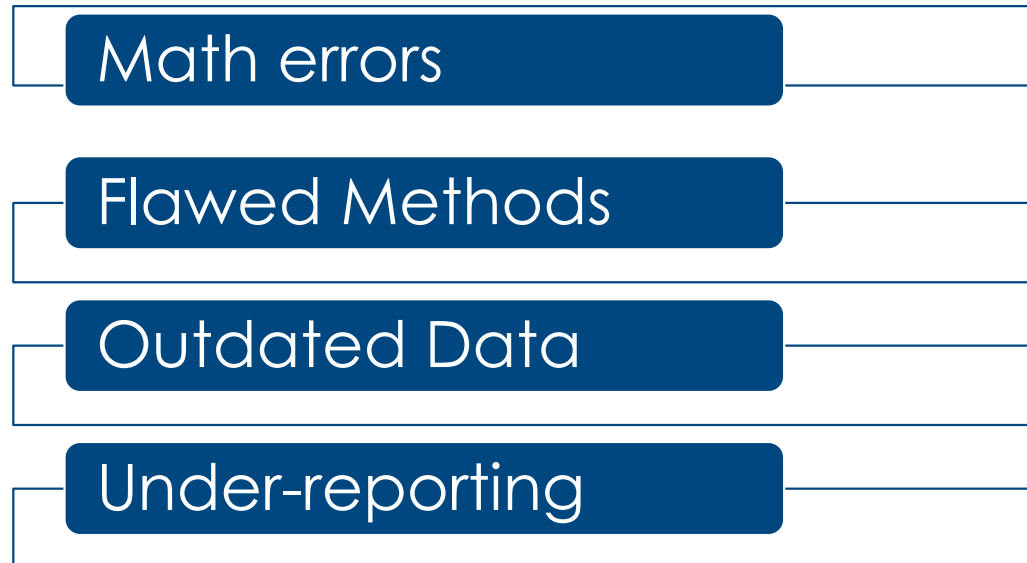


1. The current risk of EAls is still unknown
2. MDROs are difficult to detect which may result in silent spread

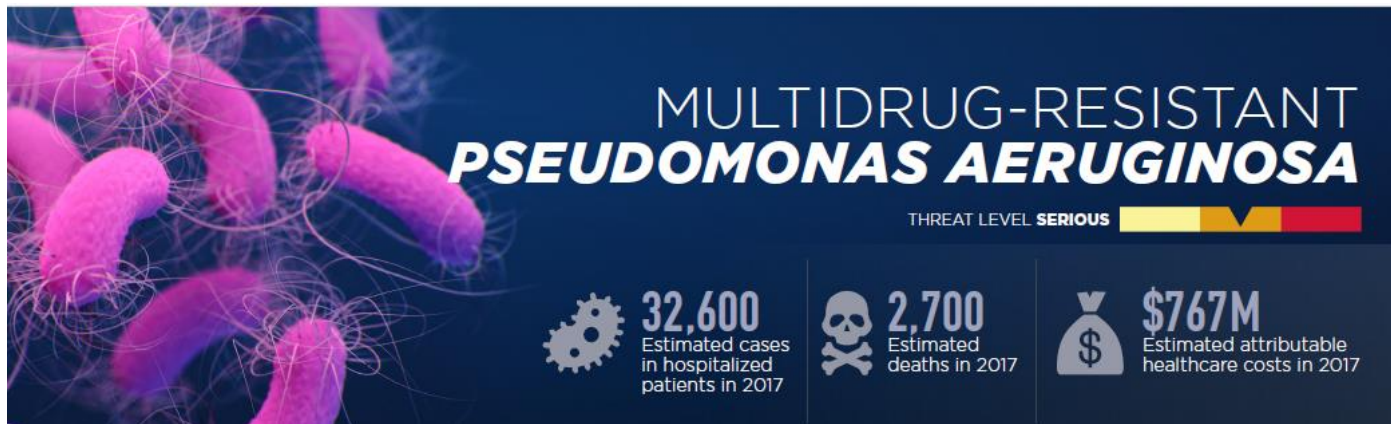
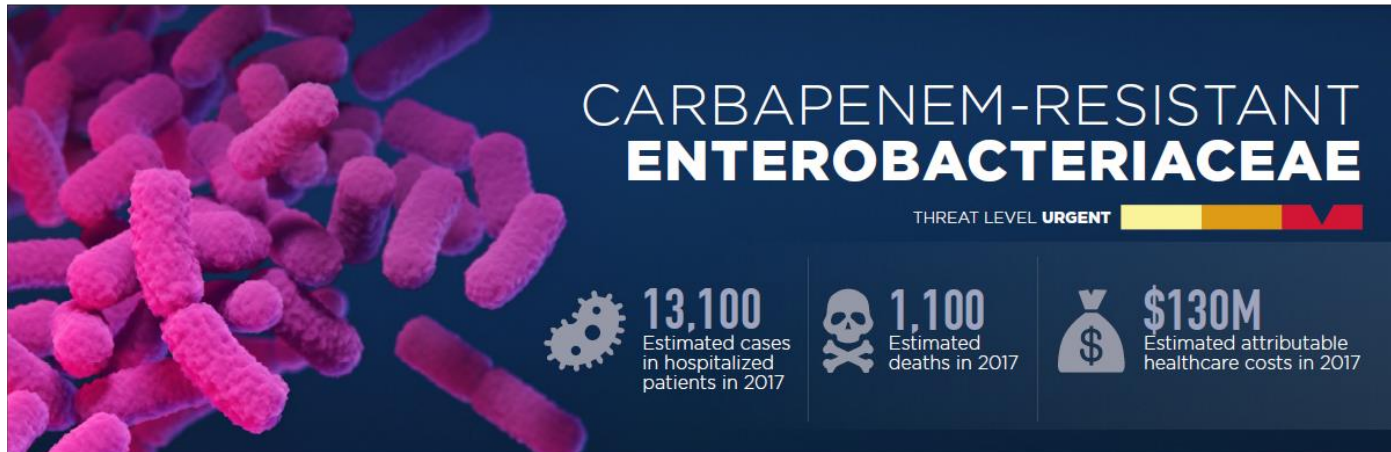
The Microbes: Risk of EAIs

Currently, there is no credible estimate of the true risk of an EAI from ERCP performed with a re-usable duodenoscope.

Previously cited risk estimates were re-evaluated and found to be incorrect.



The Microbes



Klebsiella pneumoniae
E. coli

The most common bacteria associated with EAls are also on the CDC's antibiotic resistance threat list

The Microbes – Detection can be difficult

Most facilities are ill-equipped to detect newly emerging MDROs

Reference	Outbreak Organism	Discovery of Outbreak
Wendorf et al. Seattle, WA	ESBL- <i>E.coli</i>	Washington State Surveillance Program
Epstein et al. Chicago, Ill	NDM- <i>E.coli</i>	Third party clinical lab, CDC
Potron et al. France	<i>E.coli</i> and <i>Kl. pneumoniae</i> _{OXA-204}	Reference Lab research project on OXA-204 resistance identifies regional, dual outbreak
Kim et al Los Angeles, CA	<i>Kl. pneumoniae bla</i> _{oxa-232}	OXA-232 identified via unrelated research project

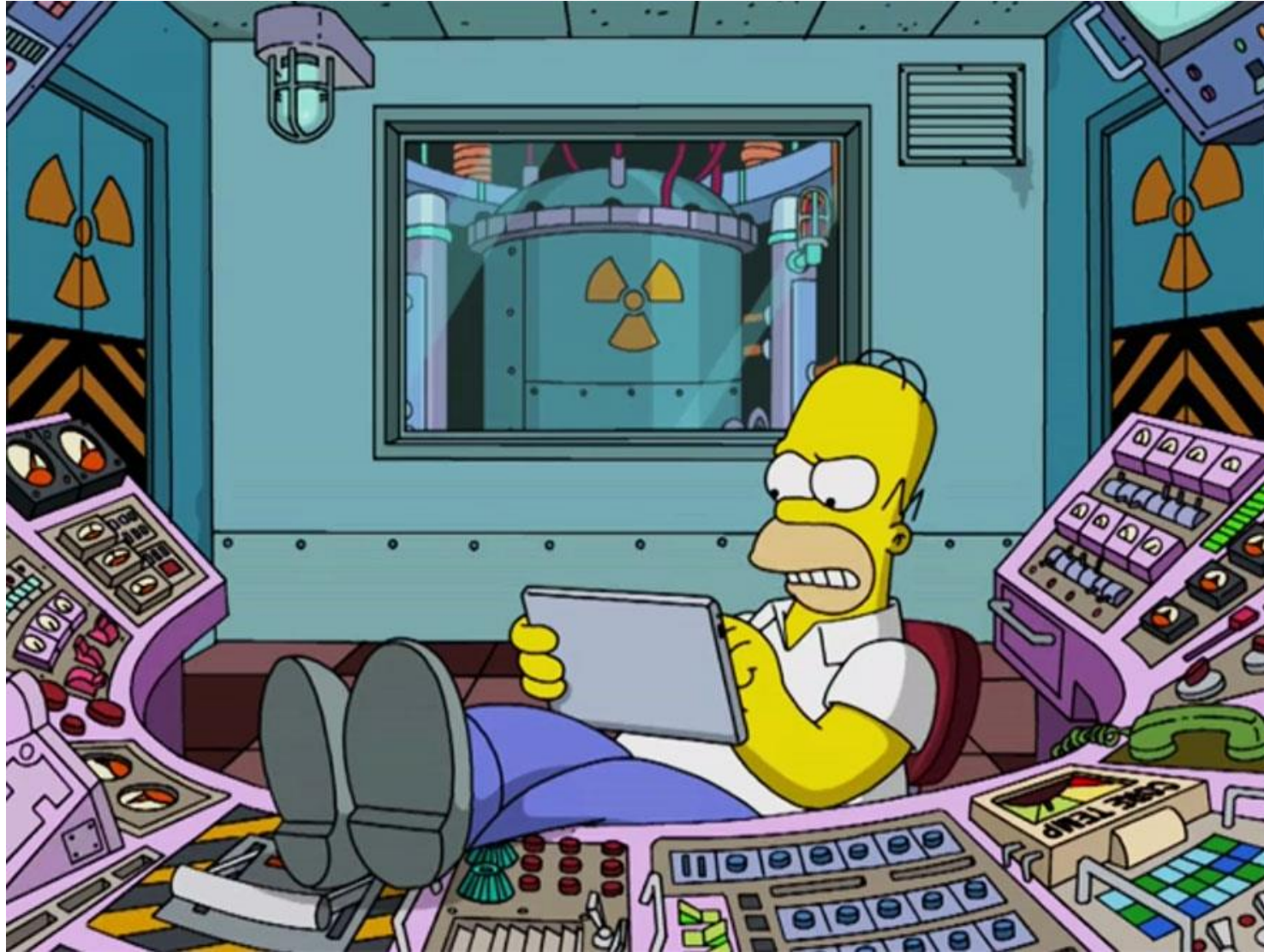
The Microbes: Why are EAIs hard to detect?

- Periprocedural Antibiotics Mask Transmissions
- Unremarkable profile of infectious agent
- Asymptomatic colonization & lack of screening
- Time between ERCP and symptoms: weeks, months, years
- Infection may present in sites unrelated to ERCP procedure
- MDROs may be difficult to detect

The Scopes?



Human error

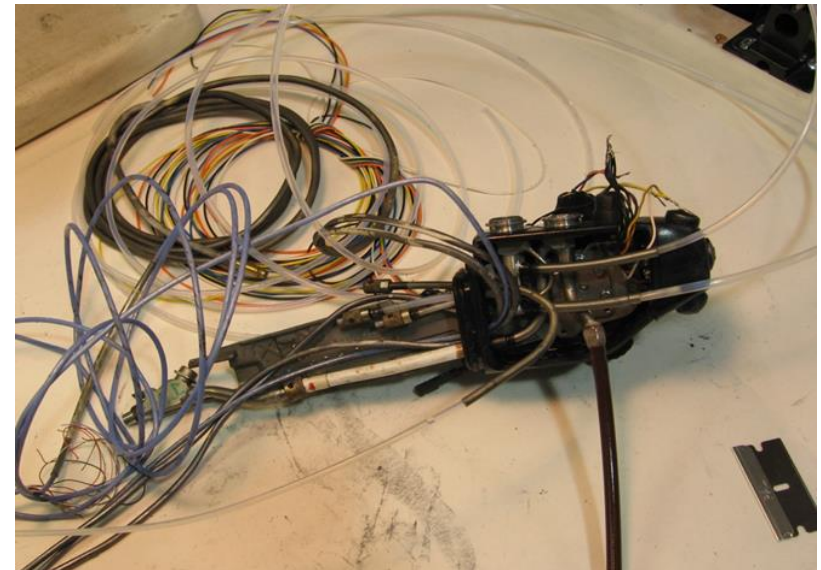
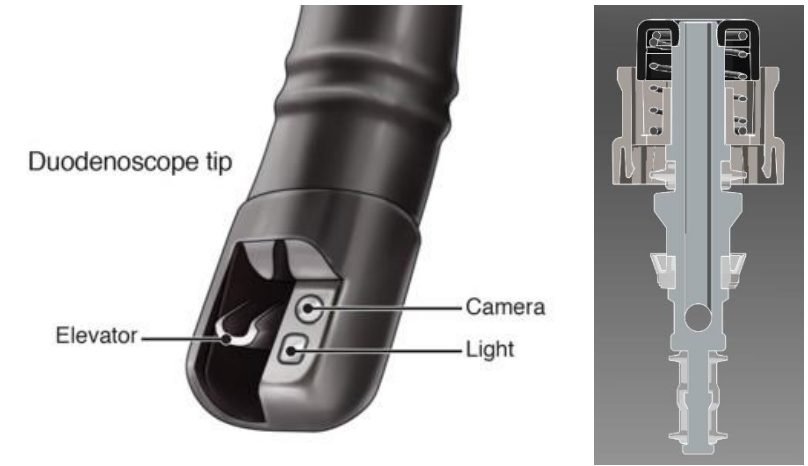
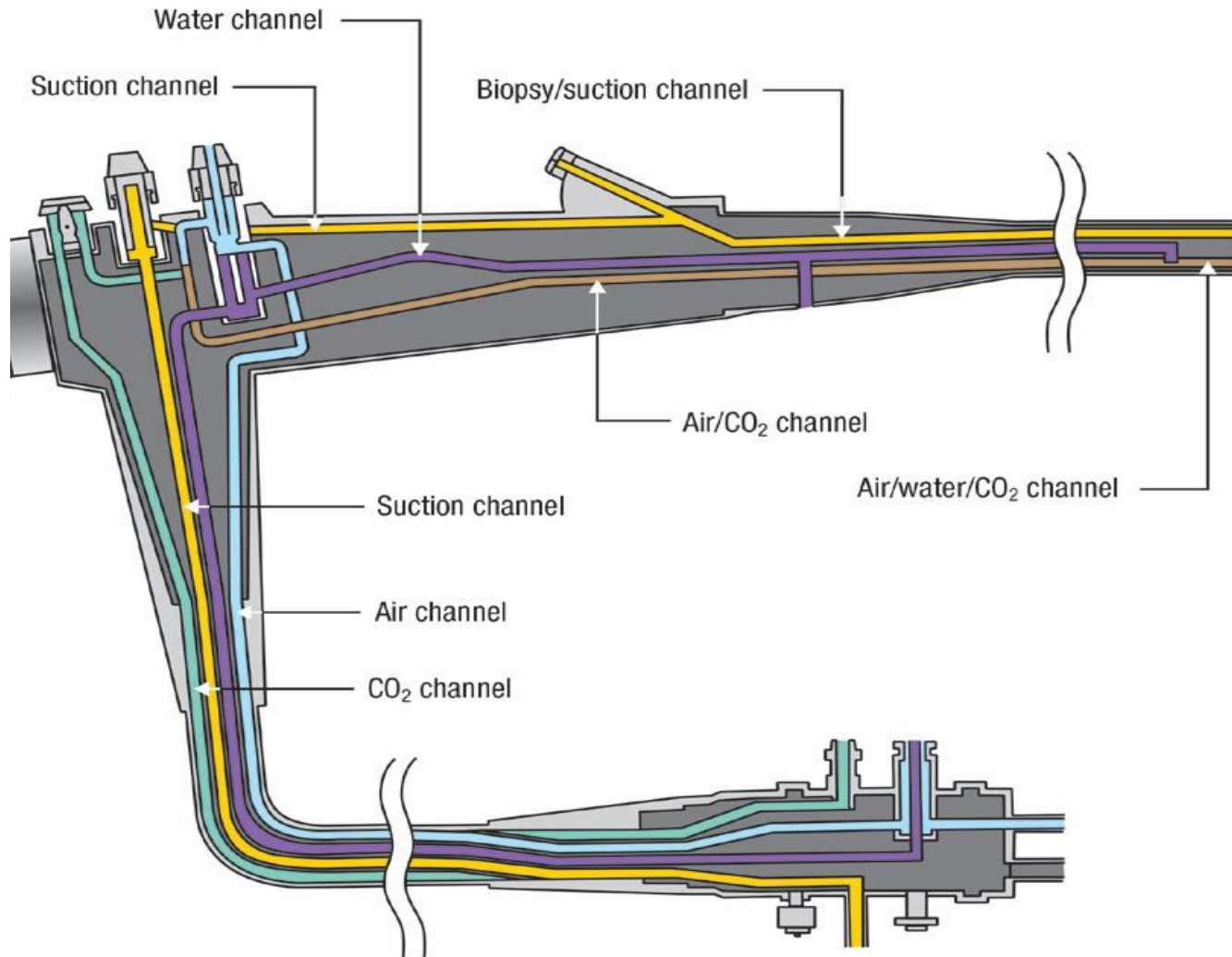


The Scope



1. One in 15 duodenoscopes are contaminated with pathogens despite adherence to IFUs and guidelines.
2. Transmission of pathogens occurs despite adherence to IFUs and guidelines.

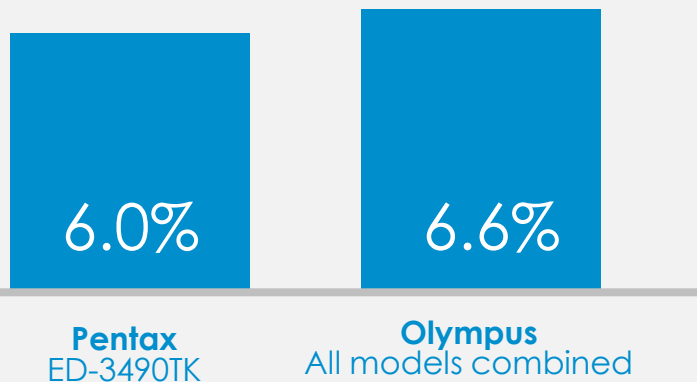
Duodenoscope complexity impedes effective processing



The Scope: Results from FDA 522 studies

High-Concern Organisms

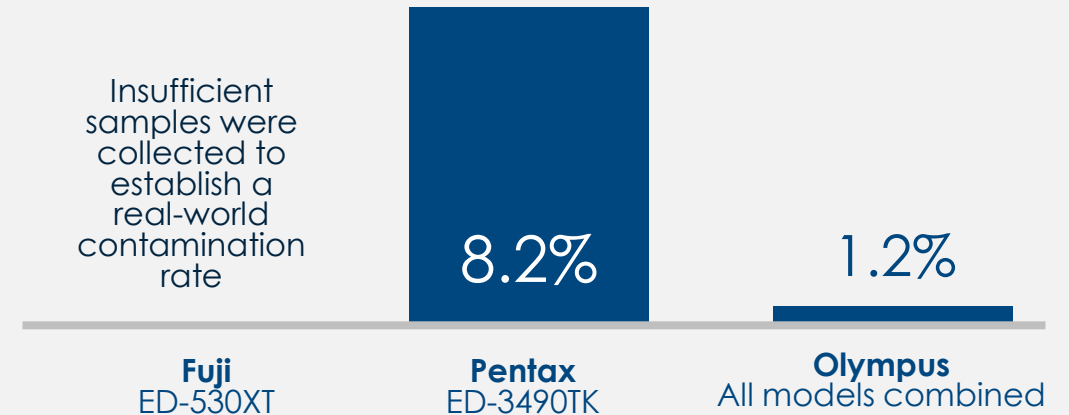
Insufficient samples were collected to establish a real-world contamination rate



Up to 6.6% of properly collected samples tested positive for high-concern organisms, **which cause diseases**

Low-Concern Organisms

Insufficient samples were collected to establish a real-world contamination rate



Up to 8.2% of properly collected samples tested positive for enough low-concern organisms to **indicate a processing failure**

The study was designed assuming less than a 0.4% contamination rate.



Olympus 522 site : https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=354&c_id=3726

Fujifim 522 site: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=353&c_id=3725

Pentax: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=355&c_id=3727

High-Concern & Low-Concern Organisms



High-Concern

- Pathogenic bacteria or fungi that cause disease
- Present in low numbers in environmental reservoirs
- Allowable limit = 0
- Examples: *E. coli*, *Klebsiella spp.*, *Pseudomonas aeruginosa*



Low-Concern

- Bacteria or fungi that may cause disease under certain circumstances
- “Environmentals”
- Often not-counted
- Allowable limit ≤ 100 colonies
- Examples: *Staphylococcus*, *Streptococcus*, *Bacillus*

Low Concern \neq No Concern

Only spore-formers should be present
(*Bacillus spp*)

> 100 CFU indicates HLD Failure

Indicates possible error in sampling

Act as the “canary in the coal-mine”



Appalachians Canary



The Scope: Outbreak Investigations

Duodenoscope-associated outbreaks where investigations showed no breach in processing protocols and/or negative culture results.

Location Reference	Culture Results	Errors in Processing?
Boston, MA Shenoy 2019	Negative	No
Cleveland, OH Fraser 2004	Negative	No
Los Angeles, CA Kim 2015	Negative	No
Park Ridge, Ill Epstein 2014	Negative	No
Milwaukee, WI Smith 2015	Negative	No
Los Angeles, CA US Senate Report, 2016	Not Reported	No
Pittsburgh, PA Marsh 2015	Negative	No
Seattle, WA Wendorf, 2015	Positive	No
New York, NY US Senate Report, 2016	Negative	Not Reported
Berlin, Germany Kola 2015	Negative	Not Reported
Claremont- Ferrand, France Aumeran 2010	Positive	No
Rotterdam, Netherlands Verfalle 2015	Positive	No

EAls



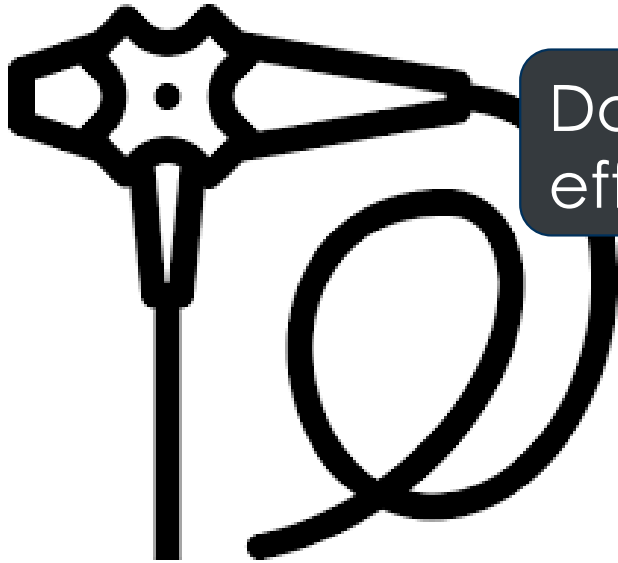
FDA/Single use duodenoscopes

- Roughly ½ million + ERCP's
- Highly intricate scopes
- Transmission of MDRO 1980's
- Multiple outbreaks across world
- 2019 FDA post-market surveillance, using HLD*
 - Voluntary standardization
 - Endoscope cultures
 - Innovation, new duodenoscopes
- Single use duodenoscopes 2019
- Single use endoscopes 2021
- Single use cystoscopes 2021
- Single use colonoscopes 2023



- *Since 2015 the FDA has released more safety communications than any other medical devices*

Processing



Do enhanced measures improve efficacy of processing?

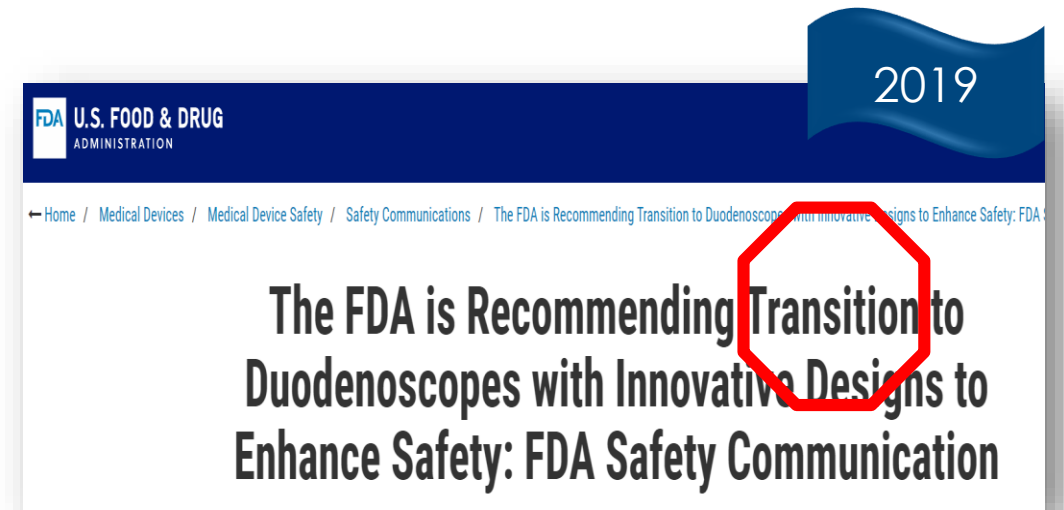
One of the biggest questions today is on the effectiveness of the FDA recommended enhanced measures.

Processing: FDA recommendations



A screenshot of the FDA website from 2015. The page title is "Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication". The date issued is August 4, 2015. The page includes a navigation menu with categories like Home, Food, Drugs, Medical Devices, etc. A blue ribbon in the bottom right corner indicates the year 2015.

- Repeat HLD (+/- manual)
- HLD + Terminal Sterilization (Ethylene oxide)
- HLD + Liquid Chemical Sterilization
- Microbiological Culture



A screenshot of the FDA website from 2019. The page title is "The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication". A red octagon highlights the word "Transition" in the title. A blue ribbon in the top right corner indicates the year 2019.

“The FDA believes the best solution to reducing the risk of disease transmission by duodenoscopes is through **innovative device designs that make reprocessing easier, more effective, or unnecessary.**”

FDA – Changed “transition” to “use”

Issued April 5,
2022

Use Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication

- **Why?** Concerns with cleaning and contamination data.
- **Options?** Fully disposable or designs that include disposable components

- Olympus TJF-180V recalled
- Pentax ED-3490TK/ED34-i10T – withdrawn
- Fujifilm ED-530XT - withdrawn



522 Studies for Duodenoscopes

Manufacturer	Final Results of 2015 522 Study		Interim Results of 2019 522 Study	
	Model	High Concern Organism Results	Model	High Concern Organism Results
Fujifilm	ED-530XT	Not completed, device withdrawn	ED-580XT	0.5% (2/417, 57% study completion)
Olympus	TJF-Q180V	4.1% (35/859)	TJF-Q190V	In progress
	TJF-160F/VF	6.6% (56/850)		
	JF-140F and PJF-160	Not completed, device withdrawn		
Pentax	ED-3490TK	6.0% (48/794)	ED34-i10T2	In progress
			ED32-i10	In progress
			ED34-i10T	Device withdrawn

- Very limited data
- High-concern organisms not the only issue
- Manufacturer's performing this testing introduces avoidable bias



FDA Safety Communication: 05Apr22

Quality Control program now **REQUIRED** for reusable duodenoscopes

“Institute a quality control program that includes sampling, microbiological culturing, and other monitoring methods.”

“Consider reprocessing with supplemental measures such as sterilization or use of liquid chemical sterilant processing system consistent with the device's labeling”

“Monitor your reprocessing procedures. Examples of monitoring are sampling and culturing...”

Processing: Enhanced Measures

Limited data indicate that Repeat HLD and Liquid Chemical Sterilization do not effectively eliminate duodenoscope contamination.

Reference	2X HLD			Liquid Chemical Sterilization		
	N	% Growth	% High Concern	N	% Growth	% High Concern
Gromski 2020	453	1.8% (8)	0.44% (2)	425	2.1% (9)	0.47% (2)
Rex 2017	Phase 1:627 Phase 2: 420 Phase 3:783	Phase 1: 9.4% (59) Phase 2: 4.8% (20) Phase 3: 4.9% (38)	Phase 1: 0.8% (5) Phase 2: 0.2 (1) Phase 3: 0.3 (2)	NA	NA	NA

Processing: Enhanced Measures

Limited data indicate that Repeat HLD and Ethylene Oxide Sterilization do not effectively eliminate duodenoscope contamination.

Reference	HLD			2X HLD			Ethylene Oxide Gas Sterilization		
	N	% Growth	% High Concern	N	% Growth	% High Concern	N	% Growth	% High Concern
Visrodia 2017	20	60% (12)	55% (11)	18	44.4% (8)	44.4% (8)	NA	NA	NA
Snyder 2017	174	16.1% (28)	NA	169	16.0% (27)	NA	173	22.5% (39)	NA
Bartles 2018	1399	7.3% (102)	0.4% (5)	1526	8.0% (122)	0.2% (3)	NA	NA	NA

New Technologies: Why are they needed?

Area of Opportunity	Description	Available Technology
Device Design Complexity	<ul style="list-style-type: none"> Endoscope design complexity impedes effective processing 	Single-use duodenoscope
Human Factors	<ul style="list-style-type: none"> Managing the capabilities and limitations of people to optimize processing performance and reliability. 	Single-use duodenoscope **Distal tip barrier** **Single-use end cap**
Endoscope Processing – Manual Cleaning	<ul style="list-style-type: none"> The most important step in processing High error rate Efficacy impeded by complex device design and human factors 	Distal tip barrier Single-use end cap
Endoscope Processing - Drying	<ul style="list-style-type: none"> Critical to prevent biofilm formation High error rate & Ineffective methods 	Single-use duodenoscope
Endoscope Processing Alternatives	<ul style="list-style-type: none"> Aimed at improving efficacy and consistency of endoscope processing 	Single-use duodenoscope Sterilization



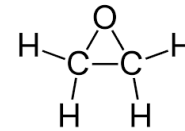
Sterilization

Sterilization: A process that eliminates all living organisms, including spores.

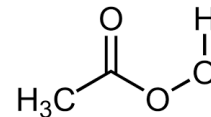
Low Temperature Sterilization:

- Ethylene oxide
- Hydrogen peroxide/Ozone
- Peracetic acid

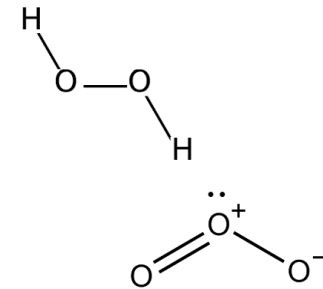
Ethylene oxide



Peracetic acid



Hydrogen peroxide/
Ozone



Duodenoscope Processing

Pros

- Theoretically failproof
- History of successful outbreak control

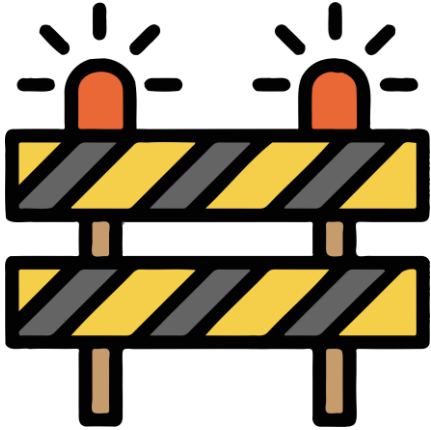
Cons

- Documented failures with all modalities
- May damage devices
- Efficacy dependent on meticulous manual cleaning & drying
- Validated for a finite number of cycles

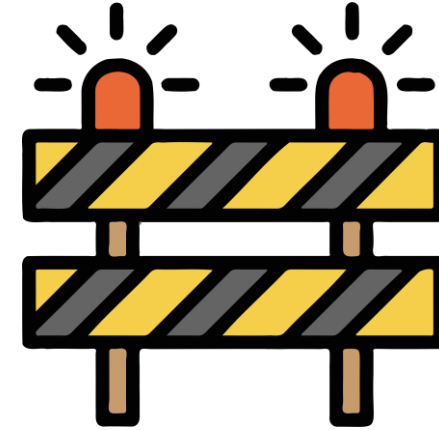
Factors Impacting Efficacy of Duodenoscope Processing

- Device design – Reduce Impact of Complexity
- Human Factors
- Endoscope Processing – Manual Cleaning
- Endoscope Processing - Drying
- Endoscope Processing Alternatives

Distal Tip Barriers



Single-use device that seals the elevator area to reduce contamination of the distal tip during ERCP procedures.



Duodenoscope Processing

Pros

- Single-use, sterile
- Instruments passed without contacting the elevator area
- Reduces soil level for hard to clean elevator mechanism

Cons

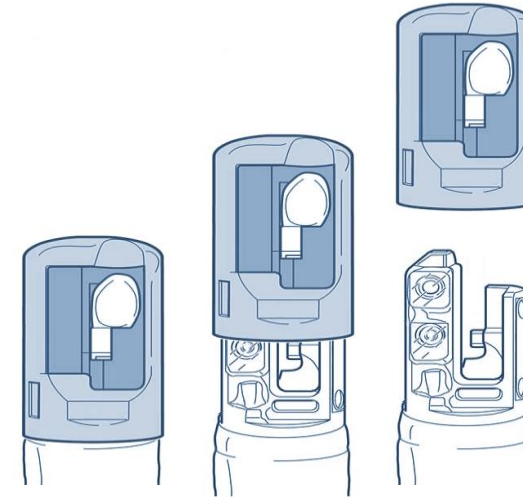
- Partial solution, full processing still required
- FDA cleared for limited models
- Complexities of manual cleaning not eliminated.
- Efficacy data is lacking

Factors Impacting Efficacy of Duodenoscope Processing

- Device design – Reduce Impact of Complexity
- Human Factors (?)
- Endoscope Processing – Manual Cleaning (?)
- Endoscope Processing - Drying
- Endoscope Processing Alternatives

Detachable Single-Use Distal Endcap

Removable, single-use distal cap that improves access to the elevator mechanism during duodenoscope processing.



Duodenoscope Processing

Pros

- Improves access to difficult to clean elevator mechanism during processing
- Single-use, sterile

Cons

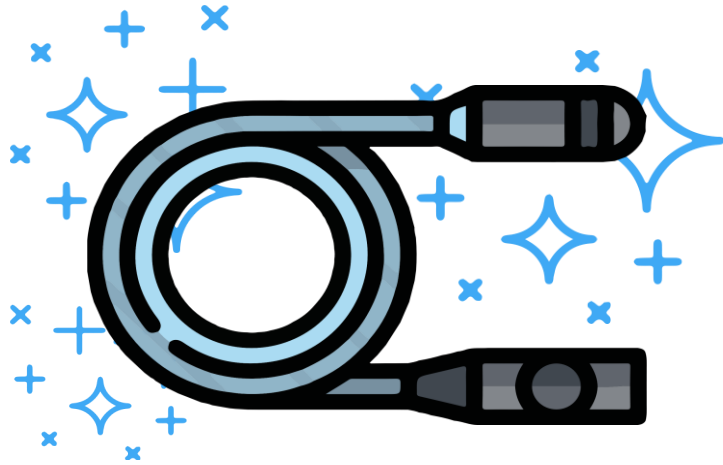
- Partial Solution, only addresses cleaning of distal tip, does not affect complexity
- Additional steps added to cleaning process

No efficacy data available, post-market studies in process

Factors Impacting Efficacy of Duodenoscope Processing

- Device design – Reduce Impact of Complexity
- Human Factors (?)
- Endoscope Processing – Manual Cleaning (?)
- Endoscope Processing - Drying
- Endoscope Processing Alternatives

Single-Use Duodenoscopes



Single-Use Duodenoscope that is discarded after use on one patient.

Duodenoscope Processing

Pros

- Eliminates the need for device processing.
- Eliminates risk of cross-contamination due to ineffective processing.

Cons

Learning Curve

Factors Impacting Efficacy of Duodenoscope Processing

- Device design – Reduce Impact of Complexity
- Human Factors
- Endoscope Processing – Manual Cleaning
- Endoscope Processing - Drying
- Endoscope Processing Alternatives

Considerations

1. ERCP volume?
2. How many providers perform ERCP's
3. Is there provider consensus on use
4. What level (ASGE grade) of ERCP is performed at your center
5. What are hospital/local/regional CRE & MDRO
6. Annual costs repairs?
7. Annual costs reprocessing?
8. Annual cost of service contract?
9. Has there been any infections?
10. What is the frequency of after-hours ERCP's?

ERCP grading scale

June 13, 2020 [ERCP](#)

The ASGE ERCP (Endoscopic retrograde cholangiopancreatography) grading scale indicates the procedure complexity and predicts the chance of complications.

The ERCP grading scale:

Grade 1

- Deep cannulation of duct of interest, main papilla, sampling
- Biliary stent removal/exchange

Grade 2

- Biliary stone extraction < 10 mm
- Treat biliary leaks
- Treat extrahepatic benign and malignant strictures
- Place prophylactic pancreatic stents

Grade 3

- Biliary stone extraction > 10 mm
- Minor papilla cannulation in divisum, and therapy
- Removal of internally migrated biliary stents
- Intraductal imaging, biopsy, FNA
- Management of acute or recurrent pancreatitis
- Treat pancreatic strictures
- Remove pancreatic stones mobile and < 5 mm
- Treat hilar tumors
- Treat benign biliary strictures, hilum, and above
- Manage suspected sphincter of Oddi dysfunction (with or without manometry)

Grade 4

- Remove internally migrated pancreatic stents
- Intraductal image-guided therapy
- Pancreatic stones impacted and/or > 5 mm
- Intrahepatic stones
- Pseudocyst drainage, necrosectomy
- Papillectomy
- ERCP after Whipple or Roux-en-Y bariatric surgery

FDA/Scopes

- Infection control
- Regulatory environment
- Workflow
- Repair costs
- Water usage
- Solid waste
- Patient preference



Duodenscopes

- ***SINGLE USE***

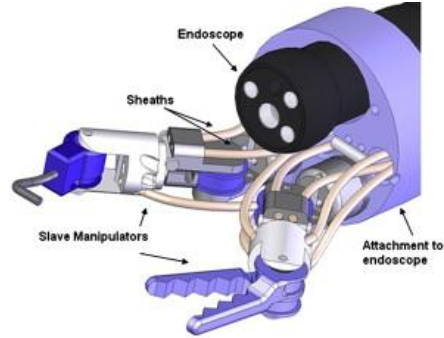
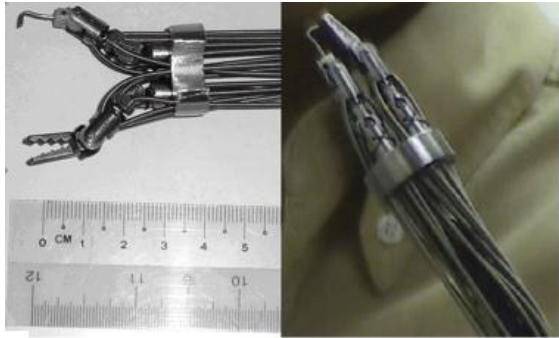
- Performance
- Infection control
- Operational costs
- Budget/cost variability
- Environmental
- Staff/Safety

- ***McGarr's USE***

- Platform
- Modularity
- Adaptability
- Storage
- Consistency
- Product support

NOTES

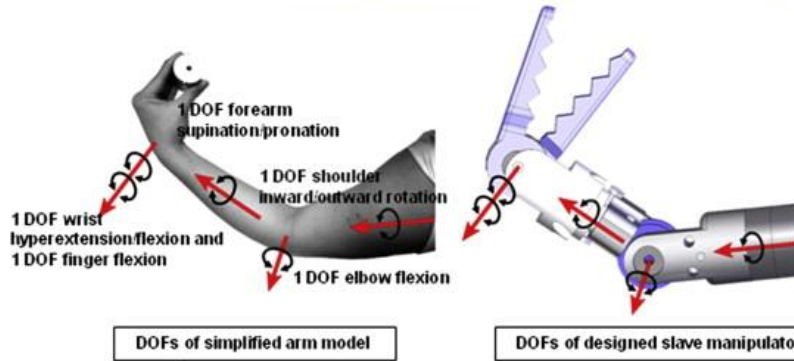
Natural Orifice Transluminal Endoscopic Surgery



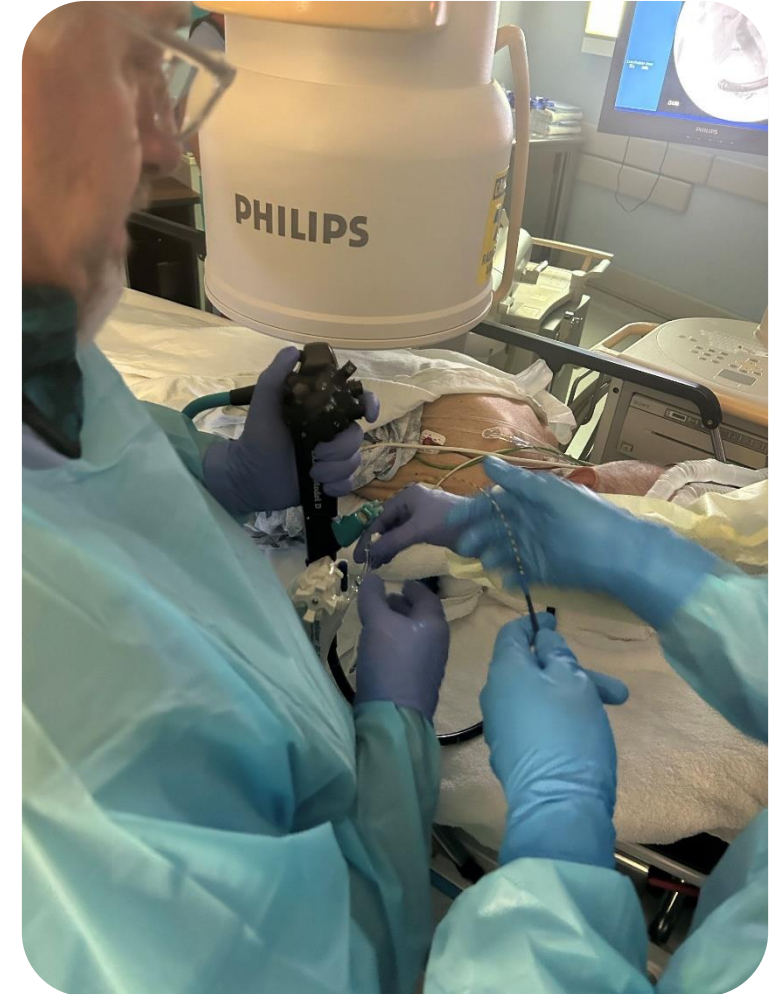
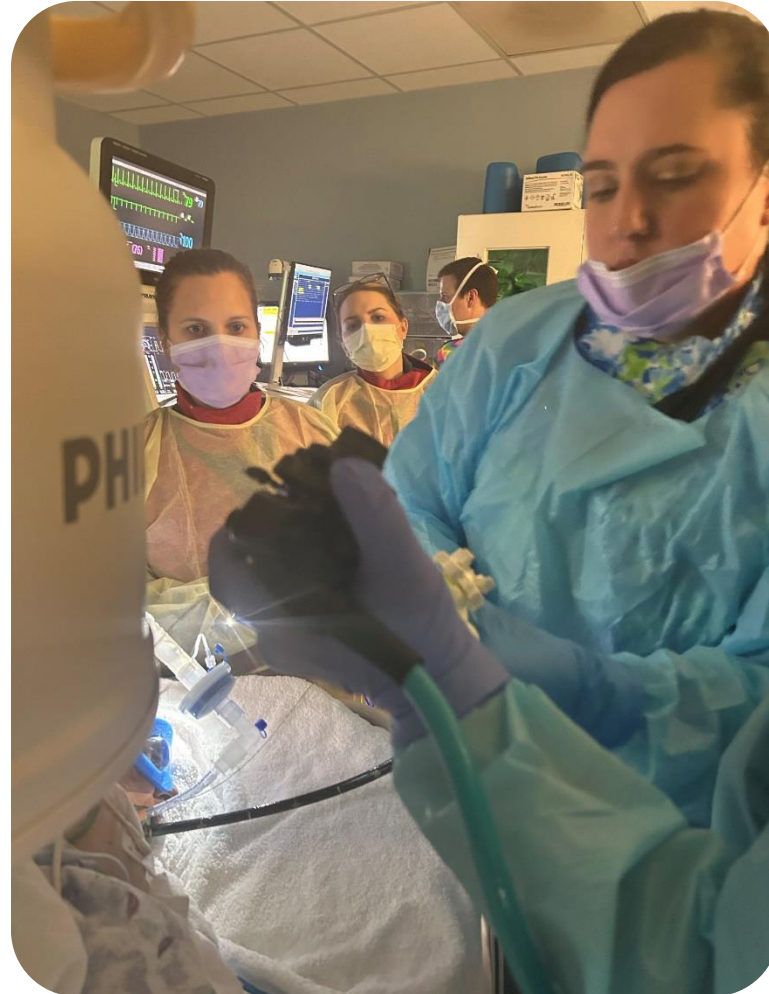
NOTES: INSTRUMENTS

Triangulation principle used in laproscopic surgeries

The Cobra triangulating scope [USGI Medical, San Juan Capistrano, California].

A slide titled "NOTES: INSTRUMENTS" containing a diagram of the triangulation principle, a photograph of the Cobra triangulating scope, and its manufacturer information.

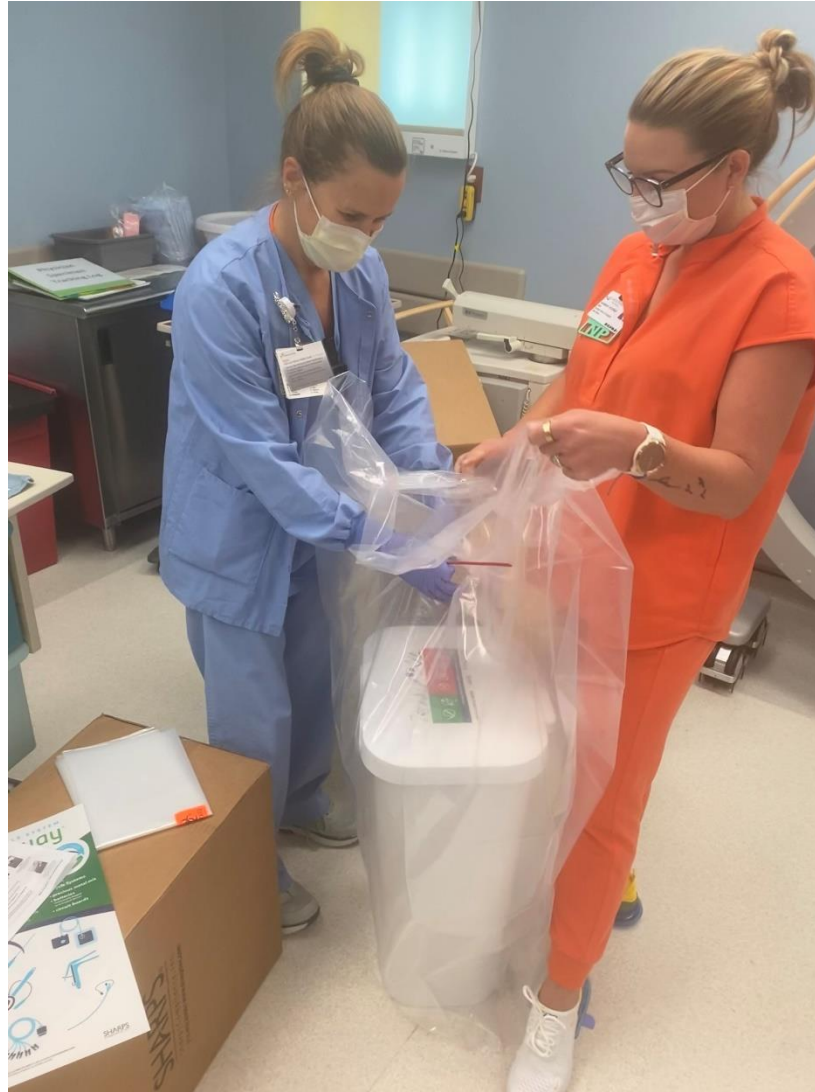
Platform



Modularity



Recycle



Summary



There is no credible estimate of infection risk from reusable duodenoscopes



MDRO transmission is difficult to detect resulting in “silent spread”



Persistent contamination poses an increased risk of pathogen transmission



Current processing technologies do not consistently eliminate contamination



New Technology developments designed to address contamination issues need real-world efficacy data

THE END

