Reducing the Risk of Infection from Reprocessed Duodenoscopes

CDC/HICPAC

November 14, 2019

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How are duodenoscopes used?

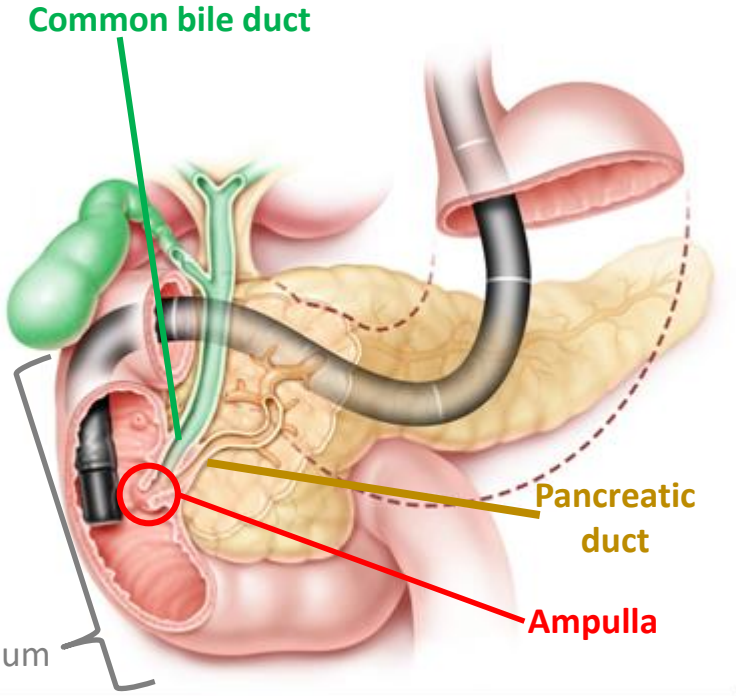
Endoscopic retrograde cholangio-pancreatography (ERCP)

- Procedure that combines upper gastrointestinal endoscopy and fluoroscopy to evaluate and treat problems of the bile and pancreatic ducts.

- ERCP is used when it is suspected that a person's bile or pancreatic duct may be narrowed or blocked due to tumors, gallstones, inflammation, infection, etc.

Endoscope inserted into mouth

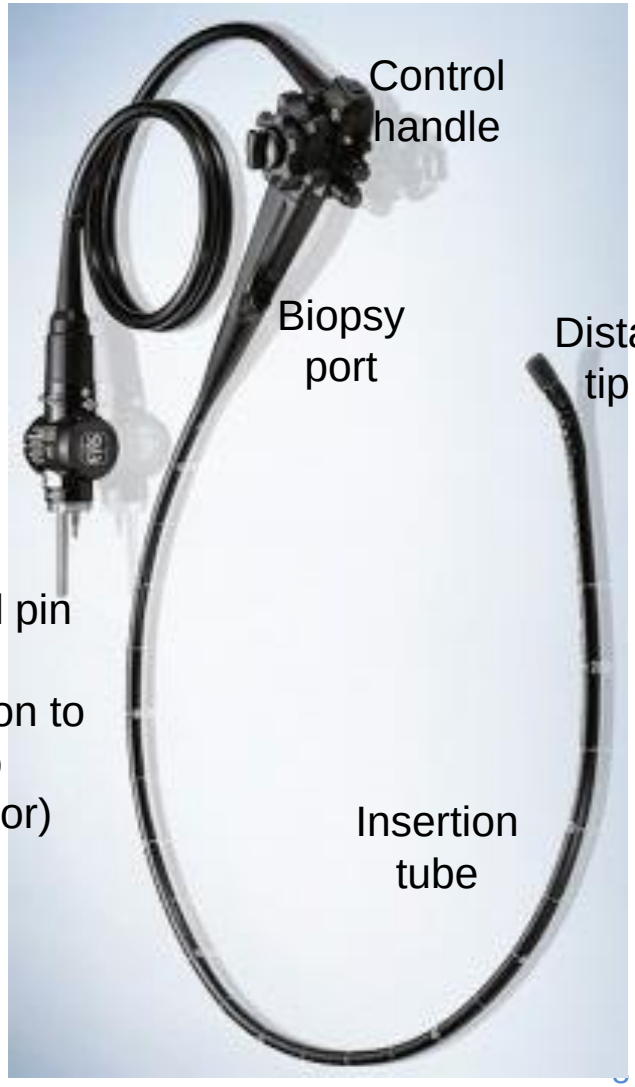
A.D.A.M.



https://medlineplus.gov/ency/presentations/100180_3.htm https://gi.org/topics/ercp-a-patients-guide/

Contamination and Infections Associated with Reprocessed Duodenoscopes

- In September 2013, CDC alerted FDA of association of multi-drug resistant organism infections and duodenoscopes
- 522 Studies indicate contamination rates with high concern organisms, ranged from 4 to 6%
- Reports of infections and outbreaks continue to occur



http://www.medtechtrade.com/en/equipment/duodenoscope-2

U.S. FOOD & DRUG ADMINISTRATION

Meeting of the General Hospital and Personal Use Devices Advisory Committee

Reducing the Risk of Infection from Reprocessed Duodenoscopes

November 7, 2019

Panel Deliberation Questions and Recommendations

FDA CDRH General Hospital and Personal Use Devices Panel

Advisory Committee Meeting

November 6 – 7, 2019

Agenda Day 2 - Reducing the Risk of Infections from Reprocessed Duodenoscopes

12:30 pm **FDA Presentation** Shani Haugen, PhD

1:20 pm Open Public Hearing

- **Nursing Professional Societies** – Association of perioperative Registered Nurses (AORN); Society of Gastroenterology Nurses and Associates (SGNA) Erin Kyle, DNP, RN, CNOR, NEA-BC and Catherine Bauer, MSN, MBA, RN, CGRN, CFER
- **Healthmark Industries-** Jahan Azizi, Mary Ann Drosnock, and John Whelan, BSN, RN
- **Providence St. Joseph Health System-** Rebecca Bartles, MPH, CIC, FAPIC and Jack Brandabur, MD
- **The Joint Commission-** Sylvia Garcia-Houchins, MBA, RN, CIC

1:50 pm **Guest Speaker Presentations**

- **Endoscopes: Reprocessing Challenges and Quality Assurance Michelle Alfa, PhD, FCCM**
- **Human Factors and Quality Assurance Cori L. Ofstead, MSPH**

2:40 pm Perspectives from Stakeholder Professional Societies

- **Physician Gastrointestinal Professional Societies** – American College of Gastroenterology (ACG); American Gastroenterological Association (AGA); American Society for Gastrointestinal Endoscopy (ASGE); Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)- Michael L. Kochman, MD, and Bret T. Petersen, MD
- **International Association of Healthcare Central Service Material Management** (IAHSCMM)- Susan Klacik
- **Infection Management Professional Societies** – Association for Professionals in Infection Control and Epidemiology (APIC); Infectious Diseases Society of America (IDSA); Society for Healthcare Epidemiology of America (SHEA)- Michael Anne Preas, MS, RN, CIC, FAPIC

3:10 pm Perspectives from Device Manufacturers

- **FUJIFILM Medical Systems** U.S.A., Inc. Randy Vader
- **Olympus Corporation of the Americas** Ross Segan, MD, MBA, FACS
- **PENTAX Me**dical J. Hudson Garrett Jr., PhD, MSN, MPH, FNAP
- **Ambu In**c. Patrick Hurley, PhD
- **Boston Scientific Corporation** Brian J. Dunkin, MD

1. Considering the currently available MDR data and postmarket surveillance data, as well as the challenges with implementation of new reprocessing methods and adoption of new technologies, does the panel recommend
   - continued incremental improvements (e.g., disposable endcap duodenoscopes, release of newly validated reprocessing instructions) to improve the safety of reprocessed duodenoscopes versus
   - more substantial changes to duodenoscopes and reprocessing methods?

Panel recommendations:

Focus on training and oversight of reprocessing. Collaborate with manufacturers, accrediting organizations, and other stakeholders to promote correct reprocessing of duodenoscopes in healthcare settings.

Avoid mandates on strategies to reduce risk. Carefully consider next steps and make deliberate decisions.

2. Does the panel have comments on FDA's proposal to standardize duodenoscope durability testing to include 250 cycles of simulated use, cleaning, high level disinfection, and terminal sterilization?

Panel recommendations:
Standardize durability testing. Damage to the duodenoscopes was not often recognized by healthcare personnel
Collaborate with industry on details of durability testing

3a. The panel is asked to comment on the potential for new designs to reduce the observed contamination rate with reprocessed duodenoscopes, and the urgency with which the transition to new duodenoscopes should be made.

Panel recommendations:

Insufficient data on reduction in contamination due to new duodenoscope designs

Consider additional modifications to the device design and reprocessing instructions, education, and practices

3b. For technologies that are intended to reduce contamination rates for duodenoscopes, what is the appropriate balance between demonstrating the effectiveness of the technology prior to marketing, versus the benefit of having the technology available for use?

Panel recommendations:

Need to demonstrate effectiveness of designs intended to reduce the risk of contamination prior to those devices being available for use

Noted challenges associated with generating such data prior to marketing

4. Does high-level disinfection provide an adequate margin of safety? Considering the challenges and benefits of sterilization for routine duodenoscope reprocessing, is a transition towards sterilization warranted, and if so, how can the inherent challenges with sterilization be addressed?

Panel recommendations:

Cleaning is the most important step

In properly cleaned duodenoscopes, high level disinfection is appropriate

- Reports indicate that duodenoscopes are not properly cleaned

Challenges in implementation of sterilization

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Summary of Feedback

1. Focus on reprocessing training and oversight
2. Standardize durability testing

3a. Improve development of reprocessing techniques

3b. Use both premarket and postmarket data

4. HLD sufficient if done properly; challenges with implementation of sterilization


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