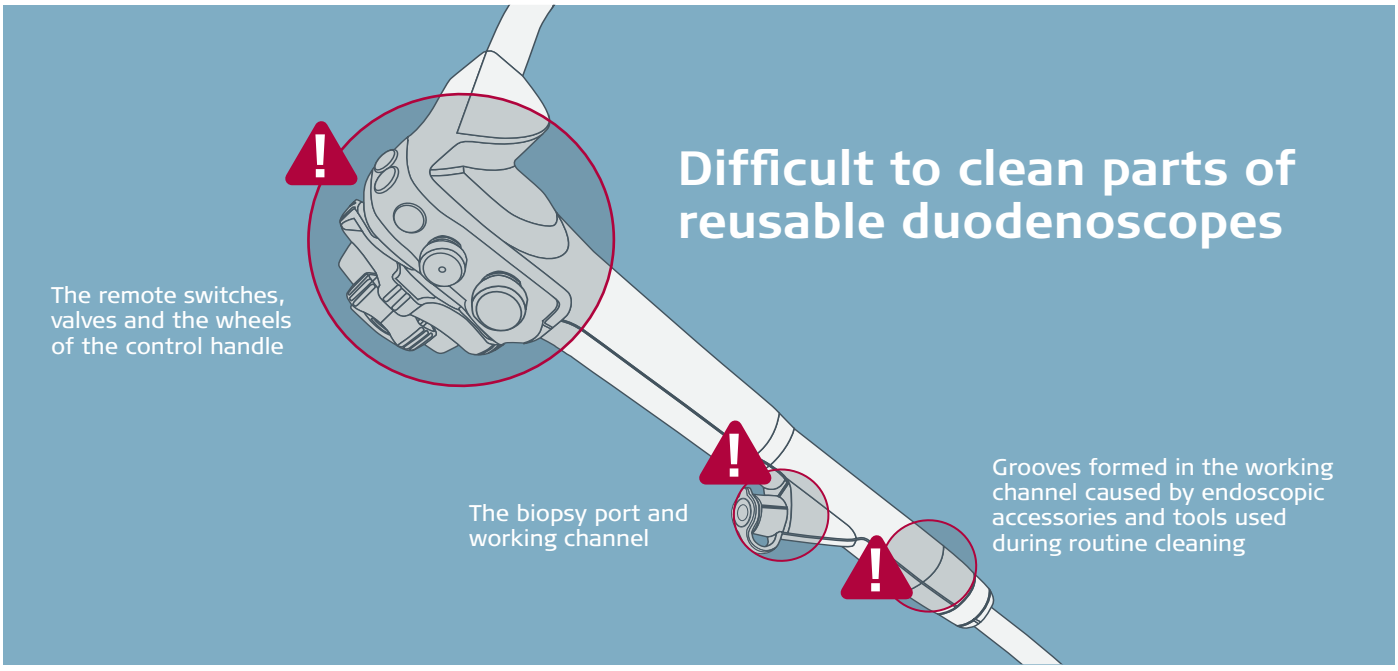
Safety risks related to reprocessing of reusable duodenoscopes

What you need to know

This document offers a quick overview of FDA communications around safety risks associated with reusable duodenoscopes used for ERCP procedures. It also includes key numbers from scientific studies indicating the rate and impact of contamination of reusable duodenoscopes.

The issue

Due to their complex design, duodenoscopes are difficult to clean properly. Multiple studies have shown that regardless of the reprocessing guidelines followed, no cleaning process effectively removes bacteria. Contaminated duodenoscopes have resulted in multiple outbreaks and deaths involving multi-drug-resistant organisms (MDROs) around the world.[1-4]



1. Rauwers AW, Voor in 't holt AF, Buijs JG, de Groot W, Erler NS, Bruno MJ, Vos MC, Nationwide risk analysis of duodenoscope and linear echoendoscope contamination, Gastrointestinal Endoscopy (2020), doi: doi.org/10.1016/j.gie.2020.05.030
2. Rex DK, Sieber M, Lehman GA, et al. A double-reprocessing high-level disinfection protocol does not eliminate positive cultures from the elevators of duodenoscopes. Endoscopy. 2018;50(6): 588-596. doi:10.1055/s-0043-122378.
3. Naryzhny I, Silas D, Chi K. Impact of ethylene oxide gas sterilization of duodenoscopes after a carbapenem-resistant Enterobacteriaceae outbreak. Gastrointestinal Endoscopy (2016), doi: dx.doi.org/10.1016/j.gie.2016.01.055
4. Snyder GM, Wright SB, Smithey A, et al. Randomized Comparison of 3 High-Level Disinfection and Sterilization Procedures for Duodenoscopes. Gastroenterology. 2017;153(4):1018-1025. doi:10.1053/j.gastro.2017.06.05 2.

Response from FDA

Increasing focus on improving reusable duodenoscope safety

In recent years, FDA has continually posted safety communications regarding the risks of post-endoscopic infections caused by contaminated reusable duodenoscopes.[5]

From 2015 - 2019
20% of FDA's Safety Communications are related to contaminated endoscopes, mainly reusable duodenoscopes

August 29, 2019
FDA recommends transition to innovative device designs that make reprocessing easier, more effective, or unnecessary

July 1, 2020
CMS issues HCPCS C code for single-use endoscopes used in performing ERCP

July 17, 2020
aScope Duodeno receives 510(k) clearance and is ready for launch

July 24, 2020
FDA reiterates their recommendation to shift to duodenoscopes with innovative designs, including the single-use aScope Duodeno

Since 2015, one in five FDA Medical Device Safety Communications were endoscope-related

> *"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"*[6]

5. https://www.fda.gov/medical-devices/medical-device-safety/safety-communications
6. https://www.fda.gov/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication

Results of meta-analysis published in EClinicalMedicine – The Lancet

Conclusion: A 15.25% contamination rate for "patient-ready" reusable duodenoscopes.

The meta-analysis examined 15 studies constituting a total sample size of 13,112 duodenoscopes considered patient-ready.[7]

9.20%
Contamination rate after using double high-level disinfection (dHLD) or sterilization (EtO)

15.25%
Total contamination rate of reprocessed duodenoscopes

16.14%
Contamination rate after using high level disinfection (HLD) only

The meta-analysis demonstrated that neither double HLD nor sterilization (EtO) had eliminated the risk of contamination.

A review by Rubin et al.

> *"Identified 32 outbreaks involving almost 400 patients that occurred between January 2000 and December 2017[8]"*

7. S. Larsen et al., Rate and impact of duodenoscope contamination: A systematic review and meta-analysis, July 14, 2020, https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30195-4/fulltext#seccesectitle0001

8. Rubin ZA, Kim S, Thaker AM, Muthusamy VR. Safely reprocessing duodenoscopes: current evidence and future directions. Lancet Gastroenterol Hepatol. 2018;3(7):499-508. doi:10.1016/2468-1253(18)30122-5

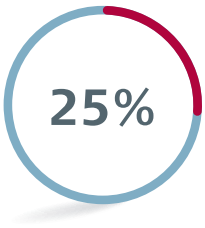
How to increase awareness

A recent survey[9] of 297 ERCP physicians in the EU, US and Japan suggests that they show an awareness of the risk of contamination with reusable duodenoscopes. At the same time, however, the survey also shows that ERCP physicians may not have insight into the reprocessing methods used at their facilities or the potential benefits of alternatives, such as single-use duodenoscopes. That is why we believe it is important for infection preventionists and ERCP physicians to communicate and share knowledge.

Survey of ERCP physicians

Responses from 175 physicians surveyed in Germany, Italy, Spain, France and UK indicate an awareness of contamination risks, but little insight into reprocessing practices.

The average contamination rate estimated by physicians for their facilities



The average number of physicians who were unaware of the reprocessing setup at their facility

The average percentage of ERCP procedures the physicians would like to convert to single-use

For more information about GI infection control, please visit: **ambu.com/GI-infection-control**

9. Internal Ambu survey.