



Single-use duodenoscopes and duodenoscopes with disposable end caps

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Background and Aims: Multidrug-resistant infectious outbreaks associated with duodenoscopes have been documented internationally. Single-use duodenoscopes, disposable distal ends, or distal end cap sealants could eliminate or reduce exogenous patient-to-patient infection associated with ERCP.

Methods: This document reviews technologies that have been developed to help reduce or eliminate exogenous infections because of duodenoscopes.

Results: Four duodenoscopes with disposable end caps, 1 end sheath, and 2 disposable duodenoscopes are reviewed in this document. The evidence regarding their efficacy in procedural success rates, reduction of duodenoscope bacterial contamination, clinical outcomes associated with these devices, safety, and the financial considerations are discussed.

Conclusions: Several technologies discussed in this document are anticipated to eliminate or reduce exogenous infections during endoscopy requiring a duodenoscope. Although disposable duodenoscopes can eliminate exogenous ERCP-related risk of infection, data regarding effectiveness are needed outside of expert centers. Additionally, with more widespread adoption of these new technologies, more data regarding functionality, medical economics, and environmental impact will accrue. Disposable distal end caps facilitate duodenoscope reprocessing; postmarketing surveillance culture studies and real-life patient infection analyses are important areas of future research. (Gastrointest Endosc 2021;93:997-1005.)

The American Society for Gastrointestinal Endoscopy Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methods are used, with a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported adverse events of a given technology. Both are supplemented by accessing the “related articles” feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from tradi-

tional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. Reports on emerging technology are drafted by 1 or 2 members of the American Society for Gastrointestinal Endoscopy Technology Committee, reviewed and edited by the committee as a whole, and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through March 2020 for relevant articles by using the key words duodenoscope, carbapenem-resistant Enterobacteriaceae, single-use, disposable, infections, and reprocessing. Reports on emerging technologies are scientific reviews provided solely for educational and informational purposes.

Reports on emerging technologies are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment or payment for such treatment.

It is estimated that 500,000 to 660,000 ERCPs are performed annually in the United States.^{1,2} Recent duodenoscope-related, multidrug-resistant organism outbreaks have brought attention to the infection risk from these procedures, raising public health and governmental concerns.³ Before these multidrug-resistant organism outbreaks, procedures with duodenoscopes were considered safe and low risk for exogenous infection transmission if they were performed in strict accordance with manufacturer reprocessing instructions for use (MRIFU) and multi-society reprocessing guidelines. The most common infections after endoscopy are endogenous infections from the patient's own gut flora (eg, post-ERCP bacteremia in an incompletely drained bile duct).⁴ Contaminated endoscopes can cause exogenous infections transmitted indirectly from another patients' gut flora. Particularly concerning are reports of multidrug-resistant, duodenoscope-associated bacterial outbreaks of *Pseudomonas aeruginosa* infections⁵ and carbapenem-resistant Enterobacteriaceae, which include *Klebsiella pneumoniae*, *Enterobacter cloacae*, and *Escherichia coli*.

The distal tip of the duodenoscope contains a cable-actuated elevator mechanism that controls vertical deflection of devices passed through the accessory channel. This intricate design makes cleaning and reprocessing more challenging compared with conventional endoscopes.⁶ The inactivated elevator is contained in a recessed space that is difficult to clean, allowing for biofilm formation and persistence of bacteria after reprocessing.^{6,7} Other risk factors for exogenous duodenoscope transmission of bacteria include noncompliance with reprocessing guidelines, inadequate post-reprocessing endoscope drying and storage, endoscope wear and channel defects, and contaminated automated endoscope reprocessors and environments.^{4,8,9}

In 2015, the U.S. Food and Drug Administration (FDA) ordered each of the duodenoscope manufacturers (Fujifilm, Olympus, and Pentax) to conduct postmarket surveillance studies to evaluate the outcomes of device reprocessing in a real-world setting. This included an assessment of "human factors" contributing to reprocessing success or failure, in essence asking, "How well are endoscopy staff able to comply with MRIFUs?" The resulting data were unsettling because they demonstrated that despite the companies' published MRIFU and validated reprocessing guidelines, user compliance with guidelines was poor. For instance, Olympus' data revealed that 45 of 73 manual cleaning tasks were performed incorrectly by 27% of participants.¹⁰

Even in the setting of adequate reprocessing, there have been reports of duodenoscope-related infections.⁵

Evidence shows that duodenoscope reprocessing does not reliably eliminate bioburden, allowing potential bacterial pathogens to remain on endoscopes. Interim manufacturer postmarket sampling reports submitted to the FDA noted positive duodenoscope cultures for high-concern organisms in up to 5% of post-reprocessed ready-to-use duodenoscopes.¹¹ Furthermore, implementation of enhanced reprocessing procedures including the use of double high-level disinfection (HLD) (1 manual cleaning followed by 2 cycles of HLD without a second manual cleaning), culture and quarantine, and ethylene oxide sterilization did not eliminate duodenoscope contamination.¹²⁻¹⁶

In an effort to further reduce the risk of exogenous disease transmission, the FDA issued a statement in August 2019 encouraging endoscopy facilities to transition from fixed endcap duodenoscopes to those with newer design features that facilitate effective reprocessing or eliminate the need for reprocessing altogether.¹⁷ In this report we discuss the technologies available that address the FDA guidance, including single-use duodenoscopes and duodenoscopes with disposable end cap technology.

To date, the FDA has cleared 2 single-use duodenoscopes, 4 reusable duodenoscopes with removable/disposable end caps that facilitate reprocessing, and 1 end cap-sealing device:

- Duodenoscopes with disposable components:
 - Fujifilm Corporation, duodenoscope model ED-580XT (disposable end cap duodenoscope cleared under K181745)
 - Olympus Medical Systems, Evis Exera III duodenovideoscope Olympus TJF-Q190V (disposable end cap duodenoscope cleared under K193182)
 - Pentax Medical, duodenoscope model ED34-i10T (disposable end cap duodenoscope cleared under K163614 and K181522)
 - Pentax Medical, duodenoscope model ED34-i10T2 (disposable elevator duodenoscope cleared under K192245)
- End sheath device:
 - GI Scientific LLC, ScopeSeal (endoscopic contamination prevention sheath cleared under K183171)
- Single-use duodenoscope:
 - Boston Scientific Corporation, EXALT Model D single-use duodenoscope (fully disposable duodenoscope cleared under K193202)
 - Ambu Inc, Ambu aScope Duodeno (fully disposable duodenoscope cleared under K201098)

DUODENOSCOPES WITH DISPOSABLE END CAPS AND SHEATHS

Conventional duodenoscope end caps prevent tissue injury from the metal edges on the endoscopes, but when permanently affixed they also limit accessibility for cleaning of the elevator mechanism and other components

of the distal end. All 3 manufacturers of reusable duodenoscopes have designed endoscopes with removable and disposable end devices. The removable cap allows for easier access to the endoscope tip and around as well as behind the elevator mechanism during duodenoscope reprocessing. As a result, crevices around the elevator are less likely to serve as a potential nidus of persistent bacterial contamination and biofilm formation. One design eliminates the elevator as a nidus of infection by incorporating a single-use disposable distal tip that includes a disposable elevator mechanism. These instruments should theoretically reduce endoscope transmission of infections, but no study to date has confirmed this supposition. In addition, careful reprocessing of the duodenoscope according to MRIFU is still a critical step in minimizing contamination and potential exogenous downstream infections.

The first FDA-cleared duodenoscope with a disposable end cap (OE-A62) was the Clarity Access Performance HD duodenoscope (ED34-i10T; Pentax Medical, Montvale, NJ, USA). This duodenoscope incorporates a detachable, single-use distal end cap to help reduce the risk of cross-contamination and increase access to critical components of the distal end for cleaning. The latest version of the Pentax duodenoscope with disposable end cap is redesigned to include a disposable elevator (DEC video duodenoscope, ED34-i10T2; Pentax Medical) that has also been cleared by the FDA. It contains a sterile, single-use, 13.6-mm distal end cap (KUMOE-A63; Pentax Medical) made of polycarbonate with an integrated disposable elevator made of polyether ether ketone (Fig. 1). Duodenoscope dimensions, optics, and tip characteristics are discussed in Table 1. The duodenoscope is compatible with the Pentax EPK-i5110 and EPK-i7010 video processors. After each use, the endoscope is reprocessed per manufacturer guidelines.

The newest FDA-cleared Olympus duodenoscope (TJF-Q190V; Olympus America, Center Valley, Pa, USA) contains a sterile, single-use, distal end cap (MAJ-2315; Olympus America). The polyethylene cap is clear (to enable improved visibility) (Fig. 2) and measures 13.5 mm in diameter and 20.65 mm in length. The cap must be torn along a seam to remove it from the endoscope, thus preventing reuse. The TJF-Q190V duodenoscope dimensions, optics, and tip characteristics are presented in Table 1. After each use the endoscope is reprocessed per manufacturer guidelines. A distal-end flushing adapter (MAJ-2319; Olympus America) is used during manual cleaning to make flushing steps more automated and reproducible.

Fujifilm's newest duodenoscope, the ED-580XT model (Fujifilm Corporation, Tokyo Japan), received 510(K) clearance in March 2019. The ED-580XT maintains a similar overall structure relative to prior iterations of the Fujifilm duodenoscope (Fig. 3). The tip of this endoscope has a single-use end cap (DC-O7D; Fujifilm Corporation) that results in a slightly wider endoscope tip (14.9 mm) than prior



Figure 1. ED34-i10T2 duodenoscope head with the single-use distal end cap (KUMOE-A63). Note the elevator is part of the cap and is disposable. (Figure courtesy of and used with permission from Pentax Medical.)

iterations but otherwise creates minimal changes to the end dimensions of the endoscope and elevator mechanism. The endoscope dimensions, optics, and tip characteristics are presented in Table 1. The ED-580XT is compatible with Fujifilm processors VP-7000, VP-4450HD, and VP-4440HD.

Data on the effectiveness of distal end caps are emerging. The Fujifilm ED-580XT and single-use end cap (DC-O7D) were examined in a randomized prospective study evaluating contamination rates after endoscope MRIFU-guided reprocessing with the distal cap detached before reprocessing compared with reprocessing with the removable cap still attached.¹⁸ In this study, 108 duodenoscopes were randomized after use for conventional ERCP indications in a 1:1 fashion to the 2 reprocessing protocols and adenosine triphosphate (ATP) testing, and bacterial culture was performed after a single cycle of HLD. The average ATP level was significantly lower in the end cap-detached group compared with the end cap-attached group (45.2 RLU vs 141.0 RLU; $P < .001$). It should be noted that testing for ATP may not correlate to endoscope cultures after HLD but is a marker of bioburden because it is present in microorganisms as well as human cells.¹⁵ There were no positive cultures in the end cap-detached group regardless of ATP level. Among the end cap-attached reprocessing group, there were 41 ATP levels >40 RLU and a single positive culture for a nonpathogenic bacterium (coagulase-negative *Staphylococcus*) from within the (+) ATP group. Studies comparing duodenoscopes with the end cap removed versus standard fixed cap instruments have not been published.

Additional innovative approaches have been developed to protect the distal end of the duodenoscope. One such product, ScopeSeal (GI Scientific LLC, Arlington, Va, USA), received FDA clearance in October 2019 for use with the Olympus TJF-Q180V duodenoscope. It is a sterile, single-use, disposable endoscopic shield for protecting the distal end of a duodenoscope from contamination during ERCP procedures and for the after-use precleaning step (Fig. 4). This single-use product consists of a lens that fits over the endoscope lens (while preserving duodenoscope optics), a port that seals the irrigation/insufflation channel openings, and a plastic sheath (ScopeSeal's proprietary working channel extension) that fits into the biopsy

TABLE 1. Comparison of disposable end cap duodenoscopes and disposable duodenoscopes

	Disposable distal end caps				Disposable duodenoscopes	
	Olympus TJF-Q190V	Pentax Clarity Access Performance HD	Pentax DEC	Fujifilm ED-580XT	Boston Exalt	Ambu aScope Duodeno
Field of view, degree	100	100	100	100	108	130
Observation range/depth of field, mm	5-60	4-60	4-60	4-60	5-60	
Distal end diameter, mm	13.5	13	13	13.1	15.1	13.7
Insertion tube diameter, mm	11.3	11.6	11.6	11.3	11.3	11.3
Maximum diameter of insertion portion (end cap attached), mm	13.5	13.8	13.6	14.9	15.1	13.7
Minimum diameter of instrument channel, mm	4.2	4.2	4.2	4.2	4.2	4.2
Bending capability (up/down), degree	120/90	120/90	120/90	120/90	120/90	120/90
Bending capability (left/right), degree	110/90	105/90	105/90	90/110	90/110	90/110
Working length, mm	1240	1250	1250	1250	1240	1240



Figure 2. TJF-Q190V duodenoscope head with the single-use distal end cap (MAJ-2315) and flushing adapter (MAJ-2319). (Figure courtesy of and used with permission from Olympus America.)

channel, thus isolating the instruments passed through the channel from the elevator mechanism. The plastic sheath permits passage of devices up to 10.7F in size. The device is a proprietary combination of medical-grade optical materials and elastic polymers, with select, encapsulated medical-grade wire reinforcement of articulating areas. The distal end dimension is 14 mm and overall length 29 mm.

Benchtop testing using ScopeSeal during 30-minute simulated procedures demonstrated no evidence of contamination of the duodenoscope from outside bacteria and similarly no contamination to the outside environment from a contaminated duodenoscope.¹⁹ In vivo clinical trials have not been published.

DISPOSABLE DUODENOSCOPES

Disposable sterile duodenoscopes eliminate transmission of exogenous infections because they are single use, and thus patient-to-patient transmission via the endoscope is not possible. The single-use functionality eliminates the need for reprocessing. Currently, 2 disposable duodenoscopes have been cleared by the FDA. The endoscope operating characteristics (up/down and right/left angulation) are similar to the reusable duodenoscopes (Table 1).

The first FDA-cleared, single-use disposable duodenoscope was the EXALT Model D (Fig. 5) (Boston Scientific Corporation, Marlborough, Mass, USA). It is intended for use with the EXALT Controller/Processor for endoscopy



Figure 3. Fujifilm ED-580XT duodenoscope head with single-use distal end cap (DC-O7D). (Figure courtesy of and used with permission from Fujifilm Corporation.)

and endoscopic surgery within the duodenum. The elevator is designed to have guidewire-locking capabilities. The EXALT Model D insertion tube is constructed of a urethane polymer coating over a metal braided and coiled composite. The EXALT Model D is recyclable. After the duodenoscope is used, it is placed in a separate receptacle and transported to a third-party destination for medical-grade recycling. This is coordinated by the third-party company and is not the responsibility of the hospital. The metal and plastic components are separated and processed separately by the third party. Repurposed material from the duodenoscope is not used in other medical devices or for future duodenoscopes.

A second single-use disposable duodenoscope, the aScope Duodeno (Fig. 6) (Ambu Inc, Columbia, Md, USA), is also commercially available in the United States, having received 510k clearance in July 2020. This single-use, flexible, 700-g videoendoscope uses the Ambu aBox duodenovideoprocessor. This instrument is also recyclable through a third party in similar fashion to that described above. Repurposed material from the duodenoscope is not used in other medical devices or for future duodenoscopes.

A comparative nonblinded benchtop study was conducted comparing the EXALT Model D with 3 different reusable duodenoscopes: Olympus Corporation model Q180V, Pentax Corporation model ED-3470, and Fujifilm Holdings Corporation(model ED-530XT.²⁰ The benchtop model was constructed to simulate the human digestive tract from mouth to duodenum with a papilla and bile duct. Four ERCP tasks were evaluated: guidewire locking, plastic stent placement and removal, metal stent placement and removal, and basket sweeping. Outcomes measured were completion of tasks, procedure time, subjective ratings of performance,



Figure 4. ScopeSeal. (Figure courtesy of and used with permission from GI Scientific, LLC.)

navigation/pushability, tip control, and image quality on a scale of 1 (worst) to 10 (best). All 4 tasks were completed by 6 expert endoscopists from tertiary care centers using all 4 duodenoscopes. Overall completion times per task and overall ratings were similar between all 4 duodenoscopes. Navigation and pushability ratings were lower for the single-use duodenoscope compared with the reusable scopes. Tip control ratings were similar for all 4 duodenoscopes. Image quality ratings (scale 1-10, with 10 being the best rating) were similar between the EXALT Model D and 2 reusable duodenoscopes (ED-530XT and Q180V; all 3 with a median rating of 9.0) and superior to 1 reusable duodenoscope (ED-3470TK; 9.0 vs 8.0, $P < .01$). Regarding the tasks performed, the disposable duodenoscope functioned similarly for guidewire locking compared with the only reusable instrument with an elevator locking mechanism. All duodenoscopes fared the same for the 3 other ERCP tasks in this unblinded study.

The EXALT Model D single-use duodenoscope has been evaluated in a single-arm human case series and randomized human study comparing its performance with a reusable duodenoscope.²¹ The multicenter, prospective, single-arm study was performed by 7 expert endoscopists at 6 academic medical centers (NCT03701958). The authors did report financial relationships (consulting and research support) with the manufacturer. Sixty patients without surgically altered anatomy were enrolled with a wide spectrum of ERCP complexity including 11.7% grade 1 (least complex), 43.3% grade 2, 43.3% grade 3, and 1.7% grade 4 (most complex). Forty-four patients (73%) underwent prior ERCP with 48.3% having undergone a prior biliary sphincterotomy, 3.6% a prior pancreatic sphincterotomy, and 12.3% both biliary and pancreatic sphincterotomies. The most common indications for ERCP were placement, removal, or exchange of a biliary stent ($n = 33$, 55%), evaluation of a biliary stricture ($n = 16$, 26.7%), and removal of biliary stones ($n = 11$, 18.3%).



Figure 5. EXALT Model D single-use duodenoscope and the EXALT Controller. (Figure courtesy of and used with permission from Boston Scientific Corporation.)



Figure 6. Ambu single-use duodenoscope and the Ambu Controller. (Figure courtesy of and used with permission from Ambu.)

Fifty-eight ERCPs (96.7%) were completed using the single-use duodenoscope only, and both ERCP failures (3.3%) were completed after crossing over from the single-use duodenoscope to a reusable duodenoscope. One crossover patient had a tight intrahepatic stricture complicating primary sclerosing cholangitis. The disposable endoscope was difficult to torque and maneuver. The second patient failed attempted pancreatic duct cannulation. Three patients developed post-ERCP pancreatitis, 1 had postsphincterotomy bleeding, and 1 had a pre-existing infection from walled-off pancreatic necrosis that worsened postprocedure. No reported adverse events were related to the single-use duodenoscope.

A recent randomized controlled trial aimed to compare the performance of the EXALT Model D single-use duodenoscope with a standard reusable duodenoscope (model TJF-180; Olympus America) for native papilla low-complexity ERCP performed in an expert tertiary care referral center for advanced endoscopy.²² All authors did report financial relationships (consulting) with both Boston Scientific and Olympus America. Ninety-eight patients were randomized to 48 procedures with the disposable endoscope and 50 to the reusable endoscope. The number of attempts at successful cannulation was lower in the disposable endoscope group (2 vs 5, $P = .013$). However, ease of passage of the endoscope to the stomach, image quality, image stability, and air-water button functionality were all statistically worse. There was no statistical difference in rate of cannulation, adverse event rate, need for advanced cannulation techniques, or need for crossover.

The authors concluded that the single-use duodenoscope was an alternative to reusable endoscopes for low-complexity ERCP, given the similar technical and safety profile.

Direct clinical comparisons of the aScope Duodeno with conventional duodenoscopes and/or other disposable alternative options are not currently available. A multi-center, single-arm, prospective, observational cohort study is underway (NCT 4628949).

SAFETY

In general, relatively limited safety concerns have been raised with the currently available products. However, reports have been submitted to the FDA regarding loosening of the single-use end cap during procedures that has resulted in spontaneous cap dislodgement from the endoscope into the patient's oropharynx or GI tract.²²

FINANCIAL CONSIDERATIONS

The retail prices for the disposable caps and duodenoscopes are listed in [Table 2](#). Note these prices are list prices and can vary depending on institutional contracts with vendors.

The medical economics of disposable duodenoscopes may provide challenges. It is unclear how institutions could afford a disposable duodenoscope with current reimbursement. Bang et al⁷ highlighted this challenge utilizing an activity-based costing and financial model to further

TABLE 2. List prices of single-use duodenoscopes and duodenoscopes with disposable end caps

Product	Manufacturer	List price (U.S.\$)
ED34-i1023 duodenoscope	Pentax Medical	54,485
KUMOE-A63 cap		55
TJF-Q190V duodenoscope	Olympus	63,500
MAJ-2315 cap		8.50
Flushing adapter (MAJ-2319).		241 (1 is included with purchase of the scope)
The EXALT Model D single-use duodenoscope	Boston Scientific	4400
The EXALT processor		79,000
aScope Duodeno	Ambu	1995
aBox Duodeno videoprocessor		14,995

Note these are list prices, and each institution may negotiate prices based on volume purchased and so on. ScopeSeal is preparing for an initial commercial introduction of the technology. The company has not released the commercial pricing for the technology.

understand the medical economics of disposable duodenoscopes. A per-procedure cost of ERCP was estimated to assess the break-even costs for transitioning to disposable duodenoscopes. This was based on the reusable cost of the duodenoscope, annual repairs, cost of the endoscope washer inclusive of maintenance, endoscope cleaning supplies, cleaning-related labor costs, and fixed costs of investment in capital equipment. This analysis did not take into account the capital cost of prior investment for nondisposable duodenoscopes when transitioning to disposable duodenoscopes. The per-procedure cost can vary from \$797 to \$1547 for centers performing in the 75th percentile of ERCP volume and \$1318 to \$2068 for centers performing at the 25th percentile of ERCP based on infection rates of .4% to 1%, respectively. The break-even cost for a disposable duodenoscope for a low-volume center (<50 ERCPs a year) was \$1300. The break-even cost for a disposable duodenoscope for a large-volume center (>150 ERCPs a year) was \$800.

Additional payments may be possible for the use of disposable duodenoscopes, which would partially offset the cost of the endoscope. The Centers for Medicare & Medicaid Services approved an application for a transitional pass-through payment category to describe single-use endoscopes under the Medicare hospital outpatient prospective payment system. The new device transitional pass-through code (C1748) that started July 1, 2020 applies to billing for the disposable duodenoscopes when they are used in treatment of Medicare beneficiaries in the hospital outpatient setting. The transitional pass-through code is a payment system designed to allow hospitals to bill for the incremental costs of the duodenoscope in addition to the Current Procedural Terminology (CPT) code for out-

patients with Medicare. Medicare does not set a specific amount for pass-through codes. It is based on the initial CPT code charged for the procedure, the cost of the device for the hospital, how much the hospital charges Medicare (every hospital has their own charging formula), and the cost-to-charge ratio that Medicare applies to every charge. The payment for C1748 therefore varies by institution according to their cost-to-charge data submitted to Centers for Medicare & Medicaid Services. It is important to note this payment does not apply to inpatient procedures or commercial insurance. An example of the payment formula for a hospital is as follows:

- A. Cost of disposable duodenoscope \times a mark-up factor
- B. Cost-to-charge ratio
- C. $A \times B$ = Medicare's calculated cost for the hospital
- D. Medicare offset amounts for CPT4 code billed
- E. Total amount received by the hospital is $C - D$

The offset amounts (amounts subtracted from payments for use of the disposable endoscope) can be found at <https://www.cms.gov/files/document/r10166cp.pdf> (see their Table 9). A few commonly used codes and offset amounts are as follows: ERCP with sphincterotomy (CPT 43262) is \$376.68, ERCP with stone removal (CPT43262) is \$376.38, ERCP with stent placement (CPT 43274) is \$1287.96, and ERCP with stent exchange (CPT 43276) is \$1392.66.

AREAS OF FUTURE RESEARCH

Many devices discussed have been fast tracked and approved by the FDA for clinical use. The FDA has provided clear guidance to manufacturers requesting further research on the issue of contamination and clinically significant infection rates.¹⁷ Thus, postmarketing clinical studies examining positive surveillance culture rates and infection rates will be important, particularly for duodenoscopes with disposable caps to confirm the adequate prevention of development of biofilm and persistent contamination around the elevator and within the accessory channel. Future research might also clarify best practices for reprocessing the duodenoscopes with distal end cap attachments (sterilization vs double HLD vs evolving technologies). Additional data regarding the clinical effectiveness of disposable duodenoscopes are desirable, including use in a larger number of patients who are ERCP naive, with greater diversity of endoscopist experience and expertise, and in wide-ranging clinical settings, including community hospitals. In addition, it will be important to verify that adverse events, quality, and safety are comparable with older generation duodenoscopes. Finally, cost-effectiveness studies will further clarify the economics of using these new types of duodenoscopes.

Innovations in endoscope reprocessing tools and techniques are an important parallel avenue of future research.

Emerging and novel approaches such as advancements in disinfection technologies, video-auditing of endoscope reprocessing,⁸ biomarker utilization, and innovative post-reprocessing endoscope inspection techniques²³ will need to be considered and integrated into comparisons with the emerging data for disposable duodenoscopes and distal attachments.

Future research should evaluate the environmental impact of fully reusable duodenoscopes, reusable endoscopes with disposable attachments, and single-use duodenoscopes as well as novel ways to repurpose or recycle these medical devices. Related research among disposable bronchoscopes has suggested that the environmental footprint may be comparable with reusable endoscopes when considering the chemicals used and personal protective equipment required for endoscope reprocessing.²⁴

CONCLUSIONS

In response to reported cases of multidrug-resistant infections resulting from cross-contamination through the use of reusable duodenoscopes, the FDA has advised manufacturers and endoscopy practices transition from fixed end cap duodenoscopes to those with newer design features that facilitate or eliminate the need for reprocessing. The options now include 6 duodenoscopes with disposable components, including 4 with single-use distal ends that facilitate reprocessing and 2 that are fully disposable single-use instruments. Although disposable distal ends facilitate duodenoscope reprocessing, future data from postmarketing surveillance culture studies and real-life patient infection analyses are anticipated to validate the efficacy in reducing post-reprocessing contamination. Fully disposable duodenoscopes eliminate the risk of exogenous patient-to-patient transmission of infection, and future studies will clarify further aspects of functionality, medical economics, and environmental impact.

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Abbreviations: ATP, adenosine triphosphate; CPT, Current Procedural Terminology; FDA, U.S. Food and Drug Administration; HLD, high-level disinfection; MRIFU, manufacturer reprocessing instructions for use

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