



## Sterile disposable elevator cap in the reduction of cross-contamination

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Flexible duodenoscopes play a pivotal role in GI endoscopy, allowing various diagnostic and therapeutic procedures. The estimated number of ERCP procedures performed annually exceeds 450,000 in the United States.<sup>1</sup> However, flexible duodenoscopy is associated with the development of patient-to-patient cross-contamination and outbreaks of infection with multidrug-resistant organisms during ERCP procedures.<sup>2-4</sup> In a nationwide study, the standard duodenoscope disinfection process yields a persistent bacterial contamination rate of up to 20%.<sup>5</sup>

Comprehensive patient safety and infection control strategies to overcome uneventful cross-contamination and infections have been proposed, including validated, standardized reprocessing protocols; proper training of reprocessing personnel; provision of adequate resources to execute the overall reprocessing process; and surveillance culture and quarantine protocols for quality assurance.<sup>6</sup>

Several design-related challenges associated with flexible endoscopes have been suggested as potentially increasing the risk of cross-contamination, such as long, narrow, non-smooth interior channels; hinges; adjacent device surfaces between which debris can be forced or caught during use; and features that cannot be disassembled for optimal reprocessing.<sup>7,8</sup> Therefore, there is a particular interest in innovative engineering of the duodenoscope itself, aiming to reduce the

occurrence of adverse events through the development of new endoscopes designed with disposable components for the hardest-to-clean areas.

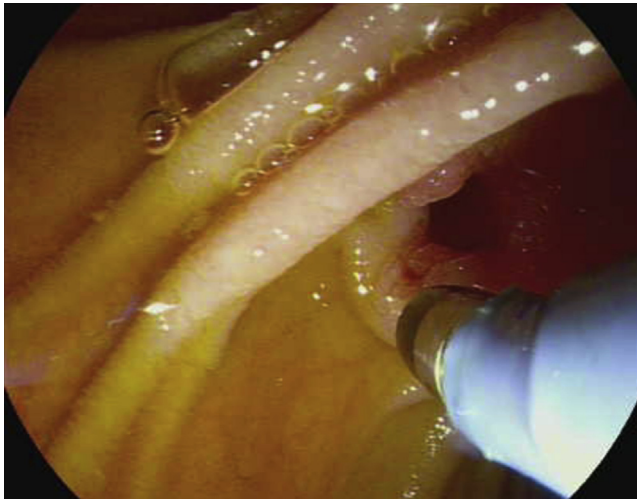
We present a novel video duodenoscope with a disposable cap (ED34-i10T2; Pentax Medical, Hoya Corp, Tokyo, Japan) as a tool for ERCP procedures. This high-definition duodenoscope (Figs. 1 and 2) has the advantage of having a disposable cap and elevator. This duodenoscope offers detailed visualization of the duodenum papilla for high precision in ERCP procedures. The disposable elevator cap simplifies the reprocessing process and increases the capacity for cleaning, reducing the risk of cross-contamination. In comparison to a standard duodenoscope, the DEC Video Duodenoscope ED34-i10T2 (Pentax Medical, Hoya Corp, Tokyo, Japan) (Video 1, available online at [www.VideoGIE.org](http://www.VideoGIE.org)) reduces the distal-end reprocessing surface by 35% as a result of improved access for clearing and disinfection as well as disposability of the elevator, which has a locking mechanism that prevents the cap from separating from the tip of the duodenoscope.<sup>9</sup> After easy removal of the disposable cap, the cleaning process is followed by a standardized reprocessing process before further ERCP procedures are performed with the duodenoscope and disposable caps. Currently, this duodenoscope with the disposable elevator cap is under



**Figure 1.** Sterile disposable duodenoscope cap with elevator before insertion over the tip of the reduced-surface video duodenoscope.



**Figure 2.** Disposable cap with elevator collocated over the tip of the video duodenoscope.



**Figure 3.** Endoscopic view of the duodenal papilla using the high-definition duodenoscope with the disposable cap.

evaluation in a randomized controlled trial assessing persistent bacterial contamination after disinfection, with an estimated persistent bacterial contamination rate of 3% (relative risk of reduction of 67%).<sup>10</sup>

High-definition image quality (Fig. 3) is a critical factor for endoscopic visualization of the duodenal papilla and affects endoscopist performance during ERCP procedures. Despite the changes in the duodenoscope design and the new disposable elevator, image quality is maintained with this equipment along with the improved efficiency and quality of the reprocessing process. In our institution, 700 ERCP procedures were performed with the new duodenoscope and disposable elevator cap from January 2018 to November 2019. The duodenoscope maintained an adequate technical success rate (biliary cannulation rate of 97.5%) and safety profile in comparison to previous duodenoscope models (post-ERCP pancreatitis rate of 4.14% and 1% rate of post-ERCP bleeding without reported cases of perforation or death). In addition, with this duodenoscope, 3 endoscopists performed 420 ERCPs with biliary stone removal, 280 ERCPs with biliary stent placement, and 100 ERCPs with digital single-operator cholangioscopy and maintained excellent maneuverability and performance during all procedures. However, proper studies must be conducted to guarantee the efficacy and safety of this new

equipment and verify its role in reducing the risk of device cross-contamination.

## DISCLOSURES

*Dr Robles-Medranda is a key opinion leader and consultant for Pentax Medical. All other authors disclose no financial relationships.*

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