

Boston Scientific receives FDA Clearance for Duodenoscope, EXALT™ Model D

16 December 2019 | News

The EXALT Model D Duodenoscope is the first and only FDA cleared single-use (disposable) duodenoscope on the market



Boston Scientific Corporation has announced U.S. Food and Drug Administration (FDA) 510(k) clearance of the EXALT™ Model D Single-Use Duodenoscope for use in endoscopic retrograde cholangiopancreatography (ERCP) procedures.

The EXALT Model D Duodenoscope is the first and only FDA cleared single-use (disposable) duodenoscope on the market and was granted Breakthrough Device Designation from the FDA to ensure patients and healthcare providers have timely access to this device.

This groundbreaking device has been developed as an alternative to reusable duodenoscopes, eliminating the need for duodenoscope reprocessing and repairs, and allowing physicians to use a new, sterile device for every procedure. The EXALT Model D Duodenoscope builds on the familiar design of standard reusable duodenoscopes so that physicians experience a minimal learning curve when adopting this technology.

Every year, more than 1.5 million ERCPs are performed worldwide using duodenoscopes to diagnose and treat various pancreatic and biliary conditions.

Reusable duodenoscopes are put through a rigorous disinfection process between uses in different patients and the vast majority of procedures with these devices are carried out safely and effectively; however, there have been a small number of cases in which infections have been transmitted between patients via contaminated devices, despite adherence to established protocols. As a result, the FDA has been working with duodenoscope manufacturers, medical societies, physicians and other stakeholders to address this concern. The FDA recently issued a recommendation that healthcare providers transition to duodenoscopes with disposable components or fully disposable devices, when they are available, and held an advisory committee meeting to discuss this process and other issues related to reducing infection transmission by reusable duodenoscopes.

Art Butcher, senior vice president and president, Endoscopy, Boston Scientific said, "The EXALT Model D Duodenoscope was developed to support clinicians in their mission to deliver the highest quality patient care. As a leading industry partner committed to advancing the care of pancreaticobiliary diseases for over 30 years, helping to ensure the integrity of ERCP is inherent in our mission to advance science for life and transform patient lives. This device, which was granted Breakthrough

Device Designation by the FDA, builds on our legacy of delivering meaningful innovation that improves clinical outcomes."

Boston Scientific voluntarily conducted a consecutive case series of the EXALT Model D Duodenoscope and found that expert endoscopists were able to complete ERCPs across a wide range of complexity using the single-use duodenoscope.