EXALT™ Model D Single-Use Duodenoscope
Key Messages and Q&A

Core Messages

- Boston Scientific received Food and Drug Administration (FDA) 510(k) clearance for the EXALT™ Model D Single-Use Duodenoscope in the United States in December 2019, followed by CE Mark in Europe in January 2020.

- The EXALT Model D Duodenoscope was the world's first commercially available single-use duodenoscope. The duodenoscope has been developed as an alternative to reusable duodenoscopes and to deliver a familiar design in a single-use platform. A single-use scope eliminates the need for reprocessing and repairs and allows physicians to use a new, sterile device for every procedure.
    - Every year, more than 1.5 million ERCPs are performed worldwide using duodenoscopes to diagnose and treat various pancreatic and biliary conditions.[1,2]

- The EXALT™ Model D Duodenoscope was granted Breakthrough Device Designation from the FDA. This program was implemented to expedite the development and review process for medical devices that are novel or offer new technology for patients with life-threatening or irreversibly debilitating conditions. The Breakthrough Device Program is designed to ensure patients and healthcare providers have timely access to important technologies.

- In June 2020, Boston Scientific announced that the Centers for Medicare & Medicaid Services (CMS) approved its application for a transitional pass-through (TPT) payment category to describe single-use endoscopes, including the EXALT™ Model D Single-Use Duodenoscope, under the Medicare hospital outpatient prospective payment system (OPPS). The intent of TPT payment is to facilitate Medicare beneficiary access to the advantages of new and innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure Ambulatory Payment Classifications (APC) rate.

- 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. There have been a small number of cases in which infections have been transmitted between patients via contaminated devices, despite adherence to established protocols. With the EXALT Model D Duodenoscope, physicians have a brand-new device for each patient as a way to address the potential issue associated with improperly reprocessed duodenoscopes.

Supplemental Messages

- The FDA has been working with device manufacturers, medical societies, physicians and other stakeholders to encourage improved processes and technologies to address duodenoscope reprocessing and maintenance. 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 a November 2019 advisory committee panel to discuss this process and other issues related to reducing infection transmission by duodenoscopes.[3]

- The EXALT Model D Duodenoscope is well positioned to address FDA's guidance, and may also address some economic and operational challenges hospitals face when adjusting equipment, procedures and policies for new guidelines.

- Boston Scientific voluntarily conducted a consecutive case series of the device and found that expert endoscopists were able to complete ERCPs with a wide range of complexity using a single-use duodenoscope. The median overall satisfaction rate with the single-use duodenoscope was rated 9 out of 10.

Physician Spokesperson Talking Points

- The healthcare industry is shifting toward using single-use devices to reduce capital footprints, increase efficiencies by limiting post-procedure maintenance and lower risks of healthcare-associated infections (HAIs) while still delivering the same quality of results for patients.

- With the EXALT Model D Duodenoscope, a physician can perform the same high-quality procedure while knowing they are using a brand-new sterile device for each patient. Also, the EXALT Model D Duodenoscope builds upon the familiar design of the reusable duodenoscope so that physicians experience a minimal learning curve when adopting this technology.

Frequently Asked Questions

EXALT Model D Duodenoscope

What is a duodenoscope?
Duodenoscopes are flexible, lighted tubes that are threaded through the mouth, throat, and stomach into the top of the small intestine (duodenum). They are used during endoscopic retrograde cholangiopancreatography (ERCP).[1]

What is an ERCP?
Endoscopic retrograde cholangiopancreatography (ERCP) is a potentially life-saving procedure to diagnose and treat problems in the pancreas and bile ducts. In the United States, duodenoscopes are used in more than 500,000 ERCP procedures each year.[2]

Why do patients need an ERCP?
Doctors perform ERCP to find and treat problems in the pancreatic duct and bile duct. For example, patients may have ERCP if their doctor suspects a disease of the pancreas or liver or a problem in the bile ducts. ERCP may also be conducted to find the cause of abnormal results from a blood test, ultrasound, or CT scan or to fix a problem that was identified on one of these tests. Finally, ERCP can help doctors decide if a patient needs surgery and if so, which surgery is best.[4]

Who may benefit from the EXALT Model D Duodenoscope?
Given its single-use design, which reduces potential issues associated with improper reprocessing, patients undergoing ERCP may benefit from the device due to its improved safety.

Further, single-use devices benefit physicians who perform ECRP, as the EXALT Model D Duodenoscope eliminates the need for reprocessing and repairs while maintaining the high functionality of traditional devices.

Why is the EXALT Model D Single-Use Duodenoscope an important option?
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 a November 2019 advisory committee panel to discuss this process and other issues related to reducing

infection transmission by duodenoscopes.[3]

With the EXALT Model D Single-Use Duodenoscope, physicians have a brand-new device for each patient as a way to address the potential issue associated with ineffectively reprocessed duodenoscopes.

What does it mean for your facility?
A single-use scope eliminates the need for reprocessing and repairs and allows physicians to use a new, sterile device for every procedure. Having access to the EXALT Model D Single-Use Duodenoscope allows your facility to reduce our capital footprint, increase efficiencies by limiting post-procedure maintenance and lower risks of healthcare-associated infections (HAIs) while still delivering the same quality of results for patients.

What does it mean for your patients?
Patients may now receive the same high quality treatment as a reusable duodenoscope with the added peace of mind knowing that this medical device has never been used on another patient.

What is the EXALT Model D Duodenoscope?
The EXALT Model D Duodenoscope has been developed as an alternative to reusable duodenoscopes and to deliver a familiar design in a single-use platform, eliminating the need for reprocessing and repairs, and providing physicians with confidence that the device is sterile right out of the package. With the EXALT Model D Duodenoscope, physicians have a brand-new device for each patient as a way to address any concerns associated with improperly reprocessed duodenoscopes. It builds upon the familiar design of the reusable duodenoscope so that physicians experience a minimal learning curve when adopting this technology.

The EXALT Model D Duodenoscope, which was granted Breakthrough Device Designation by the FDA, builds on the Boston Scientific legacy of delivering innovative solutions that improve clinical outcomes and was developed to support clinicians in delivering the highest quality of patient care.

What is the EXALT Model D Duodenoscope used for?
The EXALT Model D Duodenoscope us intended for use in endoscopy and endoscopic surgery within the duodenum. Duodenoscopes are used in endoscopic retrograde cholangiopancreatography (ERCP) procedures, enabling physicians to diagnose and treat various pancreatic and biliary conditions.

How common are procedures that require the use of a duodenoscope?
Every year, more than 1.5 million ERCPs are performed worldwide. More than 500,000 of these are in the U.S. [1,2]

FDA recognized the need for a device such as the EXALT Model D Duodenoscope and granted it a Breakthrough Device Designation, which was the first commercially-available single-use duodenoscope in the world. With this device, physicians have a brand-new device for each patient, as a way to address any concerns associated with improperly reprocessed duodenoscopes. Further, the device builds upon the familiar design of the reusable duodenoscope so that physicians experience a minimal learning curve when adopting this technology.

The EXALT Model D has been called the world's first single-use duodenoscope. Is that really true?
Yes, the Exalt Model D Duodenoscope is the world's first single-use duodenoscope cleared by a regulatory body.

What problem(s) does the EXALT Model D Duodenoscope help solve? What is the significance of having a single use device?
Reusable duodenoscopes are put through a rigorous disinfection process between uses and the vast majority of procedures with these devices are carried out safely and effectively. 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 device manufacturers, medical societies, physicians and other stakeholders to encourage improved processes and technologies to address this issue. The agency 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 panel to discuss this process and other issues related to reducing infection transmission by duodenoscopes.[3]

The EXALT Model D Duodenoscope is built to be disposable so that physicians have a brand-new device for each patient as a way to address any concerns associated with improperly reprocessed duodenoscopes. The scope has been developed as an alternative to reusable duodenoscopes and to deliver a familiar design in a single-use platform, eliminating the need for reprocessing and repairs, and providing physicians with confidence that the device is sterile out of the package.

What is the environmental impact of a disposable duodenoscope?
We offer a sustainability program for our U.S. customers who choose to adopt the EXALT Model D Duodenoscope and work closely with medical grade recyclers and waste management experts to potentially eliminate any incremental landfill impact associated with single use endoscopes.

Duodenoscope Issues and Safety
Can you tell me about the issues with reusable duodenoscopes?
Every year, more than 1.5 million ERCPs are performed worldwide using duodenoscopes.[1, 2] These devices are critical to examining the pancreatic and bile ducts in order to diagnose and treat severe, often life-threatening conditions. While the vast majority of procedures with these devices are carried out safely and effectively, 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 device manufacturers, medical societies, physicians and other stakeholders to encourage improved processes and technologies to address this issue. The agency 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 panel to discuss this process and other issues related to reducing infection transmission by duodenoscopes.[3]

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[1] United States Food and Drug Administration website: "Infections Associated with Reprocessed Duodenoscopes" August 29, 2019.
[2] Boston Scientific Internal Estimate
[3] United States Food and Drug Administration website: " The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication" April 10, 2020
[4] Society of American Gastrointestinal and Endoscopic Surgeons: “ERCP (Endoscopic Retrograde Cholangio-Pancreatography) Patient Information From Sages” April 1, 2020