Boston Scientific

Boston Scientific Receives FDA Clearance for EXALT™ Model B Single-Use Bronchoscope

MARLBOROUGH, Mass., Aug. 10, 2021 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced U.S. Food and Drug Administration (FDA) 510(k) clearance of the EXALT™ Model B Single-Use Bronchoscope, designed for use in bedside procedures within the intensive care unit (ICU) and operating room (OR).

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The EXALT Model B Bronchoscope can be used for a wide range of bronchoscopy procedures such as secretion management, airway intubation, percutaneous tracheostomy, double lumen endotracheal tube placement and biopsies. The device is offered in three sizes – slim, regular and large – each designed to deliver superior suction performance and direct, precise imaging.

"To effectively diagnose and treat disorders in the lungs and air passages, physicians require devices that provide high-quality imaging and visualization into a patient's anatomy," said Carla R. Lamb, MD, director, Interventional Pulmonary Medicine and director, Interventional Pulmonary Fellowship Program, Lahey Hospital & Medical Center[I]. "In my view, this device represents a scientific advancement in single-use bronchoscopes which could improve patient care."

Throughout the United States, more than 1.2 million bedside procedures involving a bronchoscope are performed in ICU and OR settings each year, and more than 3 million are performed worldwide.[II] While infrequent, there have been reports of patient infections linked to contamination of reprocessed flexible bronchoscopes, even when device cleaning and disinfection practices aligned with safety guidelines.[III] In situations where there is increased risk of spreading infection or when there is no support available for immediate reprocessing of a reusable bronchoscope, the FDA recommends health care providers consider using a single-use bronchoscope.[IV] Additionally, when treating patients with COVID-19, the American Association for Bronchology & Interventional Pulmonology recommends use of a single-use bronchoscope when possible.[V]

"To further increase patient safety and improve operational efficiencies within the hospital setting, many physicians have been making the transition to single-use scopes, which eliminate both the risk of infection associated with reusable devices, as well as time-intensive scope reprocessing," said Dave Pierce, executive vice president and president, MedSurg and president, Endoscopy, Boston Scientific. "Developed with physician needs and varying patient anatomies in mind, the EXALT Model B Bronchoscope was designed to bring a new level of suction and imaging performance to single-use scopes and offers a familiar design and feel to that of a reusable device."

For decades, Boston Scientific has worked closely with physicians to develop and introduce single-use technologies to advance patient care across various therapeutic areas. The EXALT Model B Bronchoscope is the latest device to join the company's single-use imaging portfolio alongside the EXALT™ Model D Single-Use Duodenoscope, LithoVue™ Digital Flexible Ureteroscope, SpyGlass™ DS Direct Visualization System and SpyGlass™ Discover Digital Catheter.

The company announced completion of CE Mark for the EXALT Model B Bronchoscope in May 2021.

Limited market release of the device in the U.S. will begin in the coming weeks.

For more information, please visit the EXALT Model B Single-Use Bronchoscope page on the Boston Scientific website.

About Boston Scientific
Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 40 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on Twitter and Facebook.

Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our business plans, clinical trials, product launches and product performance and impact. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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[I] Dr. Carla Lamb is a paid consultant for Boston Scientific Corporation. She has not been compensated for her quote within this press release.

[II] Data on file at Boston Scientific Corporation. Market research is as of 2019 and includes projections for 2020, incorporating estimates for the COVID-19 pandemic.

[III] Mehta A, Muscarella L. Bronchoscope-related "superbug" infections. CHEST Journal. 2019; 157(2). DOI: https://doi.org/10.1016/j.chest.2019.08.003

[IV] U.S. Food & Drug Administration. Flexible bronchoscopes and updated recommendations for reprocessing: FDA safety communication. June 25, 2021. https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication

[V] Wahidi, Momen M. MD, MBA; Lamb, Carla MD; Murgu, Septimiu MD; et al. American Association for Bronchology and Interventional Pulmonology (AABIP) Statement on the Use of Bronchoscopy and Respiratory Specimen Collection in Patients With Suspected or Confirmed COVID-19 Infection, Journal of Bronchology & Interventional Pulmonology: October 2020 - Volume 27 - Issue 4 - p e52-e54 doi: 10.1097/LBR.0000000000000681

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Additional assets available online: Video (1) Photos (2)

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