

Boston Scientific Completes CE Mark for EXALT™ Model B Single-Use Bronchoscope

Company to begin limited market release in Europe in June

MARLBOROUGH, Mass., May 25 2021 -- Boston Scientific Corporation (NYSE: BSX) today announced it has completed CE Mark for the EXALT™ Model B Single-Use Bronchoscope, a single-use device designed for bedside procedures in the intensive care unit, operating room and bronchoscopy suite. Limited market release of the device is expected to commence in Europe in the coming weeks.

The EXALT Model B Bronchoscope will be offered in three sizes – slim, regular and large – to allow for use in a wide variety of bronchoscopy procedures such as secretion management, airway intubation, percutaneous tracheostomy, double lumen endotracheal tube placement and biopsies.

“As single-use bronchoscopes are relatively new, continued innovation is necessary to ensure physicians can achieve direct and precise visualization into a patient’s lungs and air passages,” said Prof. Dr. Kaid Darwiche, head of the Department of Interventional Pneumology at Ruhrländklinik in Germany. “The EXALT Model B Bronchoscope provides clear, crisp imaging and high-powered suction – both of which are critical to successfully identify any abnormalities in the patient’s airway.”

Throughout Europe, more than 1.5 million procedures involving a bronchoscope are performed each year.ⁱ While the potential for infection due to reprocessing of reusable scopes is low, there have been reports of scope-associated contaminations and post-procedure infections.ⁱⁱ To combat this risk, a recent position statement from the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology Nurses and Associates (ESGENA) strongly recommended the use of single-use endoscopic accessories whenever possible.ⁱⁱⁱ

“Single-use scopes are emerging as the preference for many physicians due to their ability to eliminate the risk of scope-related infection that may result from ineffective reprocessing while also increasing operational efficiencies in the hospital setting,” said Dave Pierce, executive vice president and president of MedSurg and president of Endoscopy, Boston Scientific. “Innovation is central to our mission, and the EXALT Model B Bronchoscope is designed to provide physicians with the high-quality functionality and feel of a reusable scope, while addressing heightened patient safety needs and improving efficiency.”

The EXALT Model B Bronchoscope is the latest device in the Boston Scientific single-use imaging portfolio. For decades, the company has worked closely with physicians to continuously innovate and develop single-use technologies within the gastrointestinal, pancreaticobiliary, surgical, urological and airway spaces to advance patient care, including the [EXALT™ Model D Single-Use Duodenoscope](#), [LithoVue™ Digital Flexible Ureterscope](#), [SpyGlass™ DS Direct Visualization System](#) and [SpyGlass™ Discover Digital Catheter](#).

Please visit www.bostonscientific.eu/EXALT-B for more information about the EXALT Model B Bronchoscope.

The EXALT Model B Bronchoscope is not available for use or sale in the United States.

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 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.

ⁱⁱ Mehta A, Muscarella L. Bronchoscope-related “superbug” infections. CHEST Journal. 2019; 157(2).
DOI:<https://doi.org/10.1016/j.chest.2019.08.003>

ⁱⁱⁱ Beilenhoff Ulrike et al. Reprocessing in GI endoscopy: ESGE–ESGENA Position Statement – Update 2018, Endoscopy 2018; 50