Boston Scientific completes CE Mark for world's first Single-Use Duodenoscope, Exalt™ Model-D

Paris, France., (22 January, 2020)

Boston Scientific Corporation (NYSE: BSX) today announced it has completed CE Mark and initiated a limited market release of the EXALT™ Model D Single-Use (disposable) Duodenoscope for use in endoscopic retrograde cholangiopancreatography (ERCP) procedures.

The EXALT Model D Duodenoscope is the first and only CE Marked and FDA cleared single-use disposable duodenoscope on the market and was also granted Breakthrough Device Designation from the FDA to ensure patients and healthcare providers have timely access to this device. In Europe, the EXALT Model D Duodenoscope will be available to hospitals 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.

Every year, more than 500,000 ERCPs are performed in Europe, using duodenoscopes to facilitate diagnosis and treatment of various pancreatic and biliary conditions such as stones or blockages within the pancreatobiliary system.[1] 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.

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, according to a recent position statement from the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA), since the late 1970s there have been reports of nosocomial infections linked to endoscopic procedures[2] and the potential for infection, although extremely rare, is a public health concern. ESGE and ESGENA also recently called for crucial efforts to be taken to prevent such infections occurring, by implementing recommendations for optimal duodenoscope reprocessing.[3]

“Following on from the recent FDA clearance of the EXALT Model D Duodenoscope, I am delighted that we have completed CE Mark in Europe and that our physicians and hospitals will have access to the world’s first single use duodenoscope,” said Darragh Tolan, vice president, Endoscopy, Boston Scientific. “Patients and hospitals depend on us to protect life-saving ERCP procedures and avoid potential infections and we pride ourselves on offering them not just the highest quality devices, but our partnership and solutions. The EXALT Model D Duodenoscope is a prime example of our work not just in advancing the care of pancreaticobiliary diseases, but our commitment to being at the forefront of innovation and working together to improve patient outcomes.”

“With the EXALT Model D Duodenoscope, I can perform the same high-quality ERCP procedure with the added benefit of using a brand-new sterile device for each patient, thereby avoiding any cross-patient contamination and infection risk,” said Professor Marco Bruno, Professor of Gastroenterology & Hepatology, Head of the Department of Gastroenterology & Hepatology, Erasmus Medical Center, University Medical Center Rotterdam, The Netherlands. “I am excited by the launch of this device, which I see as a significant advancement in the evolution of endoscopy.”

The company now plans to commence a limited market release of EXALT Model D in Europe during the first quarter of 2020, beginning in Germany, France, Italy, UK and Sweden.

Please visit https://www.bostonscientific.com/en-EU/products/single-use-scopes/exalt-model-d.html for more information about the EXALT Model D Duodenoscope.

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 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.eu 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 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; the closing and integration of acquisitions; 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.

[1] BSC iDATA report

[1] https://www.esge.com/assets/downloads/pdfs/guidelines/2018_a_0759_1629.pdf

[1] https://mailchi.mp/db8ee87bd19b/esgena-e-news-august-600221?e=34bc4b4c88

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