Boston Scientific

New Societal Guidelines Recommend Subcutaneous Implantable Cardioverter-Defibrillator for Patients with Ventricular Arrhythmias at Risk of Sudden Cardiac Death

American Heart Association, American College of Cardiology and Heart Rhythm Society Issue Updated Guidelines Underscoring Benefits of the S-ICD System

MARLBOROUGH, Mass., Nov. 8, 2017 /PRNewswire/ -- Updated guidelines issued by the American Heart Association (AHA), the American College of Cardiology (ACC) and the Heart Rhythm Society (HRS) now formally recommend the use of a subcutaneous implantable cardioverter-defibrillator (S-ICD) for the treatment of patients with ventricular arrhythmias and the prevention of sudden cardiac death.[1] The Boston Scientific (NYSE: BSX) EMBLEM™ MRI S-ICD System is the only S-ICD on the market, and the only implantable defibrillator available that provides protection for patients at risk of sudden cardiac death without touching the heart.

Co-published in *Circulation,* the *Journal of the American College of Cardiology (JACC)* and the *Heart Rhythm Journal (HRJ),* the "2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death" supports the use of an S-ICD device with a Class IIa recommendation for all patients who meet the criteria for an implantable cardioverter-defibrillator (ICD) without a need for pacing. The guidelines also strongly recommend the use of an S-ICD device as the standard of care with a Class I recommendation for the subset of these patients who have inadequate vascular access or are at high risk for infection, including those with diabetes mellitus.

Patients at high risk for infection often have limited venous access which can result in a prolonged or failed implantation of a transvenous ICD (TV-ICD). Per a recent analysis of more than 6,400 patients, those implanted with TV-ICD were at an eight-fold higher rate of lead complications than patients who received an S-ICD device.[2]

"The addition of the S-ICD System to these clinical guidelines reinforces the value this device can bring to a broad ICD-indicated patient population, through avoidance of transvenous lead-specific complications," said Kenneth Stein, M.D., senior vice president and chief medical officer, Rhythm Management and Global Health Policy, Boston Scientific. "The clinical significance of the updated guidelines provides a call to action for physicians to include the S-ICD System in shared decision making with their ICD-indicated patients."

Earlier this year, the HRS recommended private health insurance companies update any limited or unavailable coverage to ensure all patients with appropriate clinical rationale have access to therapy with the S-ICD device. Positive coverage policies for the S-ICD System have been established by the Centers for Medicare and Medicaid Services and private payers representing more than 90% of insured individuals in the U.S.

The S-ICD System is included in the European Society of Cardiology guidelines, published in 2015, for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death.

For more information on the EMBLEM MRI S-ICD System, visit www.bostonscientific.com/sicd.

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 35 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 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.

CONTACTS:
Laura Aumann
Media Relations
(651) 582-4251 (office)
Laura.Aumann@bsci.com

Susie Lisa, CFA
Investor Relations
(508) 683-5565 (office)
investor_relations@bsci.com

[1] Al-Khatib SM, Stevenson WG, Ackerman MJ, Bryant WJ, Callans DJ, Curtis AB, Deal BJ, Dickfeld T, Field ME, Fonarow GC, Gillis AM, Hlatky MA, Granger CB, Hammill SC, Joglar JA, Kay GN, Matlock DD, Myerburg RJ, Page RL, 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death, *Heart Rhythm* (2017), doi: 10.1016/j.hrthm.2017.10.036.

[2] Indranill Basu-Ray, et al. Subcutaneous Versus Transvenous Implantable Defibrillator Therapy. JACC: Clinical Electrophysiology. Sep 2017, 496; DOI: 10.1016/j.jacep.2017.07.017

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