

Boston Scientific Comments on New England Journal of Medicine Article

NATICK, Mass., Jan. 23 [PRNewswire/](#) -- Boston Scientific (NYSE: BSX) today issued the following statement from Donald S. Baim, M.D., Chief Medical and Scientific Officer, on an article in the New England Journal of Medicine entitled "A Comparison of Bare-Metal and Drug-Eluting Stents for Off-Label Indications."

"The analysis from the National Heart, Lung and Blood Institute Dynamic Registry published in today's New England Journal of Medicine is the latest in a series of studies that have led the authors to conclude that drug-eluting stents are as safe or safer than their bare-metal counterparts, and significantly more effective at reducing re-narrowing within the stented segment (restenosis). This 6,551-patient registry of bare-metal and drug-eluting stents included a majority of patients who fell outside the current approved indications for drug-eluting stents, but who nonetheless showed no increase in either risk-adjusted mortality or heart attack, and a significantly lower rate of repeat procedures, through one-year follow-up. While the raw (unadjusted) mortality was higher in unapproved indications versus approved indications for both drug-eluting stents and bare-metal stents, it was significantly lower for drug-eluting stents than bare-metal stents in unapproved indications."

"These data are consistent with a series of other large registry analyses comparing drug-eluting and bare-metal stents that have emerged over the last year, and which have reasserted the underlying safety and efficacy of drug-eluting stents. This series includes the most recent data from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR), which reversed the findings from the SCAAR group's earlier analysis suggesting higher mortality with drug-eluting stents. The most recent SCAAR data showed no difference in mortality for drug-eluting stents compared to bare-metal stents. In addition, a number of other studies -- including the Western Denmark, New York State, Ontario and Massachusetts registries, as well as our own meta-analysis of all published mortality data containing nearly 150,000 patients -- have found that drug-eluting stents may actually reduce mortality by more than 20 percent compared to bare-metal stents, while also significantly reducing the need for repeat procedures to treat restenosis."

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: <http://www.bostonscientific.com/>.

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of 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 clinical trials, product performance and competitive offerings. 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 thereafter. 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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