

Statement of Kenneth Stein, M.D., Chief Medical Officer, Cardiac Rhythm Management, Boston Scientific on JAMA Article

NATICK, Mass., Jan. 4, 2011 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) today issued the following statement from Kenneth Stein, M.D., Chief Medical Officer, Cardiac Rhythm Management, on an article that was published online today by the *Journal of the American Medical Association*. The article reported on a study that found that about 20 percent of patients who received an implantable cardioverter defibrillator (ICD) did not meet evidence-based guidelines for receipt of one.

"Guidelines represent consensus from the scientific community that a given procedure or treatment is beneficial, useful and effective. Boston Scientific is proud to have sponsored many of the clinical trials that provided the scientific foundation for the guidelines referenced in the *JAMA* article.

"However, it is important to place these results in their appropriate clinical context. Sudden cardiac arrest (SCA) is the most common cause of death in the U.S. About 460,000 Americans die each year from SCA; that is more than lung cancer, breast cancer and HIV-related diseases combined. Currently, more than a million patients are eligible for an ICD, but only a small percentage of patients actually receive the life-saving device. In fact, previous studies show that ICDs are used in only 20-40 percent of indicated patients in the U.S.

"Dr. Sana Al-Khatib has made important contributions to addressing the under-utilization of device therapies for the prevention of SCA. She played a key role in organizing the Sudden Cardiac Arrest Thought Leadership Alliance, a think tank on the issue that met in December 2009. That meeting led to a recent publication on the issue: *"Addressing disparities in sudden cardiac arrest care and the under-utilization of effective therapies."* Its major conclusion was: "Despite overwhelming clinical trial evidence, expert opinion, national guidelines, and a vast array of educational conferences, evidence-based, life-prolonging drug and device therapies continue to be under-utilized, with significant disparities in SCA care and use of ICDs in vulnerable populations, including blacks, women and the elderly."

"It is interesting to note that three of four cases cited in the *JAMA* article were outside the guidelines solely on the basis of timing, and that many of these patients would have qualified within a matter of weeks or months.

"ICD and cardiac resynchronization therapy defibrillator (CRT-D) therapies have been shown to be cost effective in the MADIT II, COMPANION and SCD-HeFT clinical trial patient populations. In addition, long-term data from the MADIT II study showed that the life-saving benefits of ICD therapy were sustained at eight years (34 percent relative reduction in the risk of death). In that trial, one life was saved for every eight patients who received an ICD.

"While ICDs are at times used outside the guidelines, the more fundamental problem is that on the whole, this life-saving therapy is under-utilized, rather than over-utilized."

About Boston Scientific

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: www.bostonscientific.com.

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