

Boston Scientific Welcomes New Guidance on the use of Cardiac Technologies for Patients With Arrhythmia or Heart Failure

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Boston Scientific welcomes the National Institute for Health and Care Excellence (NICE) guidance on the use of implantable cardioverter defibrillators (ICDs) and cardiac resynchronisation therapy (CRT) for arrhythmias and heart failure. In the updated Technology Appraisal announced today, people with ventricular arrhythmias (an irregular heart beat in the ventricles) are eligible for an ICD, which can help prevent cardiac arrest in those who have previously survived a life-threatening arrhythmia.[i] In people with heart failure, CRT can improve life expectancy and quality of life. Boston Scientific looks forward to working with the National Health Service (NHS) to implement this guidance.

Nearly 75,000 people develop heart failure each year and a further 1 million people are affected by cardiac arrhythmia in the UK and with an ageing population the numbers are expected to rise. Heart failure constitutes one of the biggest hospitalisation costs facing the NHS in the UK with over 5% of emergency admissions and 2% of all NHS inpatient bed days.[ii]

"We are extremely pleased that the updated NICE guidance has now been published," said Pierre Chauvineau, vice president, Rhythm Management Europe, Boston Scientific. "As patients live longer, we believe that increased device battery longevity is vital and can translate to fewer replacement procedures and a lower risk of complications. We believe that reducing re-intervention can also have an important impact on the UK health system, offering substantial savings to commissioners and increased efficiency for cardiac services able to treat more new patients. Boston Scientific ICDs and CRT-D devices have demonstrated unsurpassed longevity performance,[iii],[iv] which is backed by an industry leading warranty."

NICE recommends ICDs as a treatment option for people with previous serious ventricular arrhythmia, people with familial cardiac conditions with a high risk of sudden death and people who have undergone surgery to repair congenital heart disease. Furthermore, NICE expands its recommendations on ICDs and CRT (CRT-P with pacing or CRT-D with pacing and defibrillation) for people with heart failure who have left ventricular dysfunction with an LVEF (left ventricular ejection fraction) of 35% or less.[i]

"As clinicians, we are always looking to provide our patients with the most appropriate treatment specific to individual health care needs, and having a choice of devices is important. Now that we have the guidelines, we need to ensure they are put into practice so that patients eligible for ICD and CRT receive these devices, improving their standard of care," commented Dr Jay Wright, Consultant Cardiologist, Liverpool Heart and Chest Hospital.

This guidance has been long awaited by patient groups with arrhythmias and heart failure. The guidance is also welcomed by clinicians treating these patients, as the increased patient eligibility for ICD and CRT therapies will improve access and help better manage these serious and life threatening conditions. In 2013, 8,151 patients were implanted with their first device.[v]

"Today's NICE announcement has been a long time coming from the last guidance issued in 2006 - 2007, and we are very pleased by the recommendations, as many more patients are indicated for device therapies. Arrhythmia and heart failure are both serious and life threatening conditions that can have a significant impact on patients and their families," said Trudie Lobban MBE, founder and CEO, Arrhythmia Alliance.

As a global medical technology leader, Boston Scientific's current product portfolio features the world's longest-lasting ICDs and CRT-Ds, with real-world longevity projections of nine to 13 years,[vi] and the world's smallest and thinnest ICDs. Boston Scientific's commitment to quality and innovative engineering excellence is further demonstrated by an advanced battery and improved warranty of up to 10 years for some models, which can help reduce healthcare costs through fewer replacement surgeries due to lower incidence of battery depletion. [vi]The benefits of Boston Scientific's ICDs and CRT-Ds extend to patients which over time could mean fewer re-implant surgeries, a lower risk of implant complications and better patient overall outcomes.

For high resolution images and the latest updates on Boston Scientific technologies, visit: news.bostonscientific.co.uk

For more information on the guidance go to: <http://guidance.nice.org.uk/index.jsp?action=byId&o=14580>

About Boston Scientific

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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 markets for our products, battery longevity and impact, 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.

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References

i. NICE FAD on ICD and CRT June 25, 2014

ii. <http://www.nhs.uk/Livewell/Healthyhearts/Pages/Arrhythmias.aspx>

iii. Alam M, Munir B, Rattan R, Flanigan S, Adelstein E, Jan S, Saba S. Battery Longevity in Cardiac Resynchronization Therapy Defibrillators. 2013; Europace (2013) doi: 10.1093/europace/eut301. First published online: October 6, 2013. Battery Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators is an independent, single-center, retrospective observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from January 1, 2008 to December 31, 2010 at University of Pittsburgh Medical Center hospitals. The initial study population included 746 patients: 94 were excluded at the onset because they were lost to follow-up within a month of implant, 6 others were excluded because they had a Biotronik CRT-D and that number of devices precludes meaningful comparison. The four-year survival rate was 67% for Medtronic, 94% for Boston Scientific and 92% for St. Jude Medical. Medtronic = 416 patients, Boston Scientific = 173 patients, St. Jude = 57 patients. Survival rate calculated using device replacements for battery depletion as indicated by ERI.

iv. Haarbo J, Hjortshøj S, Johansen J, Jorgensen O, Nielsen J, Petersen H. Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers: Data from the Danish ICD Registry. Presented at HRS 2014. <http://ondemand.hrsonline.org/common/presentation-detail.aspx/15/35/1241/9000> Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers was an independent, retrospective observational study comparing battery

longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from January 1, 2007, to October 31, 2013, in all clinical settings in Denmark. The initial study population included 2,793 patients: battery depletion or device failure was identified in 43 Medtronic, 4 Biotronik, 1 Boston Scientific and 33 St. Jude devices. The four-year survival rate was 81.1% for Medtronic, 95.8% for Biotronik, 95.7% for Boston Scientific and 93.6% for St. Jude Medical. Medtronic = 651 patients, Boston Scientific = 136 patients, St. Jude = 1,587 patients, Biotronik = 369. Time to exchange of the device because of battery depletion or device failure recorded in the Danish ICD Registry was the endpoint.

v. Hospital Episode Statistics 2012/13 published by the NHS (OPCS codes for ICD, CRT-P and CRT-D).

vi. Longevity estimates are confirmed based on real-world data from more than 100,000 LATITUDE-monitored patients. Data on file. Boston Scientific single-chamber ICDs, dual-chamber ICDs and CRT-Ds are projected to last an average of 13.2, 11.5 and 9.2 years, respectively. Data on file.

<https://news.bostonscientific.eu/2014-06-26-Boston-Scientific-Welcomes-New-Guidance-on-the-use-of-Cardiac-Technologies-for-Patients-With-Arrhythmia-or-Heart-Failure>