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LATE-BREAKING CLINICAL TRIAL RESULTS ANNOUNCED AT HEART RHYTHM 2017:

NOVEL STRING-SHAPED IMPLANTABLE DEFIBRILLATOR PROVES EFFECTIVE IN TREATING PATIENTS WITH IRREGULAR HEARTBEATS

First-in man study proves feasibility of implanting the first-ever, string-shaped rechargeable device

CHICAGO, May 12, 2017 – A new study examines the effectiveness of the Implantable Subcutaneous String Defibrillator (ISSD™), a flexible, string-shaped and first-ever rechargeable implantable cardioverter-defibrillator (ICD). This is the first-in-man study to report on the feasibility of the innovative device and was presented today at Heart Rhythm 2017, the Heart Rhythm Society's 38th Annual Scientific Sessions.

Each year, about 300,000 worldwide receive an ICD to protect against irregular heartbeats.[1] In fact, ICDs are proven to be 98 percent effective in treating dangerous ventricular (VT) arrhythmias that can lead to sudden cardiac arrest.[2,3] Although traditional ICDs have been utilized to deliver painless pacing therapy, a subcutaneous (under the skin) ICD does not require leads, but requires an electrically active, metal-encased generator (or can) implanted over the ribs.

The new, first-of-its-kind ISSD™ was designed by NewPace Ltd. in an effort to eliminate the need for an active generator and places only small, flexible device including coils below and over the ribs and totally subcutaneously. The ISSD™ does not have leads within the heart nor an implantable pulse generator (or can) and provides a minimally invasive approach compared to the S-ICD™, because it only requires two very small incisions with no need to create a pulse generator pocket. This results in minimal anatomical protrusion, for improved patient comfort and aesthetic appearance.

The study enrolled 22 patients ages 69.5 ±8.9 years and 82 percent male with BMI 26.9±3.5 and LVEF 28.9±8.2. The common diagnoses for which the ISSD™ was used included: non-ischemic cardiomyopathy (18 percent), prior cardiac surgery (14 percent), and primary prevention patients (91 percent). The average implant time was 20 minutes and results include an average defibrillation testing threshold (DFT) of 25.8 joules and a SD of 10.7 joules in successfully screened patients.

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[1] McMaster University. "Common test used on heart patients who need defibrillator implants unnecessary: Study." ScienceDaily. ScienceDaily, 8 May 2014. <www.sciencedaily.com/releases/2014/05/140508172051.htm>

[2] Zipes, DP, Roberts, D. for the Pacemaker-Cardioverter-Defibrillator investigators. Results of the International Study of the Implantable Pacemaker Cardioverter-Defibrillator: A Comparison of Epicardial and Endocardial Lead Systems. Circulation. 1995;92:59-65.

[3] Volosin et. al. "Virtual ICD: A Model to Evaluate Shock Reduction Strategies." Heart Rhythm. Vol. 7, N. 5, May supplement 2010. (PO3-125).

“The results are very promising because not only does the subcutaneous string device provide a minimally invasive approach that lowers the risk of infection for patients, but we were also able to successfully implant the device in a short amount of time when compared to other defibrillators,” says lead author, Petr Neužil, MD, CSc. FESC, Chairman at the Department of Cardiology at Na Homolce Hospital in Prague, Czech Republic. “We’re optimistic about this innovative technology and what it means for the future of healthcare. It’s an example of how advancing technology has the potential to improve the quality of life for patients and, ultimately, improve patient outcomes.”

Patients indicated for standard ICD implantation underwent acute subcutaneous insertion of the ISSD™ device comprised of: a 10 centimeters (cm) long, 5 millimeters (mm) diameter sternal coil, a 10 cm long, 3 mm diameter side coil and a 4 cm long, 1.5 cm diameter cylindrical metal tube called the "active segment". Defibrillation energy from an external defibrillator was delivered through these surfaces so that both the side coil and the active segment were one pole and the sternal coil was the other.

The author notes interest in expanding clinical studies to further test the device for larger patient populations and long-term efficacy.

Sessions details:

“Late-Breaking Innovations: *First-in-man Feasibility Study Of Subcutaneous Defibrillation Utilizing An Integrated Flexible String Shaped Defibrillator”* [May 12, 2017 4:30 p.m. – 6:00 p.m. Room 375C]

Heart Rhythm 2017 is the most comprehensive educational program for heart rhythm professionals, featuring more than 250 educational sessions and more than 130 exhibitors showcasing innovative products and services. The Heart Rhythm Society’s Annual Scientific Sessions have become the must-attend event of the year, allowing the exchange of new vital ideas and information among colleagues from every corner of the globe. For more information, visit www.hrssessions.org.

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About the Heart Rhythm Society

The Heart Rhythm Society is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. Its mission is to improve the care of patients by promoting research, education and optimal health care policies and standards. Incorporated in 1979 and based in Washington, DC, it has a membership of more than 5,900 heart rhythm professionals in more than 70 countries around the world. For more information, visit www.HRSonline.org.