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## **TYRX AIGISRx® Antibacterial Envelope Shows Low Infection Rate and High Implantation Success for CIED Procedures**

**Results of Large *COMMAND* Clinical Study of AIGISRx Antibacterial Envelope Published by *Pacing and Clinical Electrophysiology (PACE)***

**Monmouth Junction, NJ (October 19, 2010)** – Patients undergoing CIED (Cardiac Implantable Electronic Device) implantation with TYRX, Inc.'s FDA-cleared AIGISRx Antibacterial Envelope enjoyed a 99.5% rate of successful implantation with an overall infection rate of 0.48% in the first 1.9 months following the procedure, as reported in newly published results of TYRX's *COMMAND* Clinical Study. There were no infections in patients receiving initial implantations of pacemakers, implantable cardioverter-defibrillators, or cardiac resynchronization therapy devices. The infection rate within the highest risk cohort, ICD/CRT-D replacements/revisions, demonstrated 70% fewer infections than some previous studies.

Results of the *COMMAND* Study included data from 642 consecutive CIED implantation or revision/replacement procedures utilizing the AIGISRx Antibacterial Envelope at 10 U.S. medical centers. The results were published in the October on-line issue of *Pacing and Clinical Electrophysiology*, the official journal of the International Cardiac Pacing and Electrophysiology Society.

"The *COMMAND* Study provides additional evidence that the AIGISRx Antibacterial Envelope offers physicians an effective means for addressing the significant unmet clinical need for additional CIED infection prophylaxis as described in the American Heart Association and Heart Rhythm Society CRM Infection Guidelines published earlier this year," stated Heather Bloom, MD, Director of Electrophysiology at the Atlanta VA Medical Center, Assistant Professor of Medicine, Emory University, and lead author on the *COMMAND* Study report.

The *COMMAND* Study, the first clinical study of patients undergoing CIED implantation with the AIGISRx Antibacterial Envelope, was a retrospective cohort study in patients receiving implantation of a pacemaker, implanted cardioverter-defibrillator (ICD), or cardiac

resynchronization therapy (CRT) device. The primary endpoints of the study were successful CIED implantation and CIED infection. The study enrolled a high proportion of patients with established risk factors for CIED infection: 67.5% underwent revision or replacement procedures, and 36.5% had procedures with a CRT- defibrillator (CRT-D).

Currently, more than 500,000 CIEDs are implanted in the United States each year. CIED infections occur in association with 1-7% of these devices and are associated with significant morbidity, mortality, and expense. The AIGISR<sup>x</sup> Antibacterial Envelope is designed to reduce infection risk by eluting the antibiotics minocycline and rifampin for 7-10 days after implantation with the CIED. This antibiotic combination has been shown to reduce infections associated with medical devices in multiple randomized controlled trials.

TYRX Chief Medical Officer, Daniel Lerner, M.D. commented, "Previous studies have demonstrated that coating or impregnating medical devices with the antibiotics minocycline and rifampin significantly reduces device-related infections. The *COMMAND* Study is important because it generated data on the clinical performance of an FDA-cleared device that provides sustained local delivery of these antibiotics in the generator pocket after CIED implantation, in a population at high risk for CIED infection."

#### **About TYRX, Inc.**

TYRX, Inc. commercializes innovative, implantable combination drug/device products focused on infection control including the AIGISR<sup>x</sup> Antibacterial Envelope and AIGISR<sup>x</sup> FS products. AIGISR<sup>x</sup> products contain antimicrobial agents, rifampin and minocycline, which have been shown to reduce infection by organisms representing a majority of the infections reported in cardiac rhythm device (CRDM) related endocarditis, including "superbugs" or MRSA\*.

Following commercial release in 2008, the AIGISR<sup>x</sup> Envelope has been implanted in over 12,000 patients nationwide. The company estimates that approximately 2% of all U.S. CIED patients in 2010 will receive an AIGISR<sup>x</sup> product during their procedure.

TYRX, Inc. is an ISO 13485:2003 certified medical device manufacturer and its products utilize technology licensed exclusively from Rutgers, Baylor College of Medicine, and The University of Texas M. D. Anderson Cancer Center. For more information, please visit <http://www.tyrx.com>.

\* Based upon preclinical *in vitro* and *in vivo* data. Data on file at TYRX and published in *PACE* 2009; 32(7) 898-907.

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