VANDERBILT HEART AND VASCULAR INSTITUTE STUDY WITH THE TYRX™ ABSORBABLE AND NON-ABSORbable ANTIbACTERIAL eNVeloPES

High-Risk Patients with the TYRX Antibacterial Envelopes Experienced Fewer Cardiac Implantable Electronic Device (CIED) Infections Versus Patients Without These Envelopes

DESIGN
A retrospective, matched-cohort study was performed to compare the incidence of CIED Infection in patients receiving a CIED with or without the TYRX Absorbable Antibacterial Envelope or the TYRX Non-Absorbable Antibacterial Envelope.

METHODS
Surgical procedures, medications, and patient characteristics significantly increase the risk of CIED-related Infection.

The following risk factors were used to identify patients at high-risk for CIED Infection: generator change or device/lead revision; early pocket re-entry < 72 hours; renal insufficiency (serum creatinine ≥ 1.5mg/dL); diabetes mellitus; systemic anticoagulation with heparin, warfarin or novel oral anticoagulants; chronic corticosteroid use; the presence of ≥ 3 leads (cardiac resynchronization or abandoned leads); prior CIED infection; fever (≥ 100.5°F) or leukocytosis (≥ 11,000 WBCs/µL) at time of implantation; and pacemaker dependence.

Patients with ≥ 2 risk factors received either the TYRX Absorbable Antibacterial Envelope, the TYRX Non-Absorbable Antibacterial Envelope, or no TYRX Envelope in the control group.

A total of 488 TYRX Absorbable and Non-Absorbable Antibacterial Envelopes were implanted from November 1, 2009 to June 30, 2014.

The incidence of CIED Infection in 488 TYRX Envelope recipients (135 receiving the Absorbable Envelope, 353 receiving the Non-Absorbable Envelope) was compared to 638 controls.

While the incidence of individual risk factors differed between the groups, the mean (standard deviation) number of risk factors was equivalent among the groups: 3.1 (1.4) for the Absorbable Envelope, 3.2 (1.3) for the Non-Absorbable Envelope, and 3.1 (1.3) for the control group, p=0.30.

RESULTS
After a minimum of 90 days post-implantation, the incidence of CIED Infection was significantly lower in the groups that received either the TYRX Absorbable or TYRX Non-Absorbable Antibacterial Envelope, compared to the control group:

- 0 (0%) infection in the TYRX Absorbable Antibacterial Envelope group (p=1)
- 1 (0.3%) infection in the TYRX Non-Absorbable Antibacterial Envelope group (p=0.03)
- 20 (3.1%) infections in the control group (p=0.002)

The results were adjusted using Propensity Score Matching (PSM) to control for risk factors as a confounding factor.

- All TYRX Envelope recipients vs. control: In a PSM cohort of 334 TYRX Antibacterial Envelope recipients (either Absorbable or Non-Absorbable) and 334 controls, the incidence of CIED Infection was 0 (0%) and 11 (3.3%) respectively, p=0.001.
- TYRX Absorbable Envelope recipients vs. control: In a PSM cohort of 125 TYRX Absorbable Envelope recipients and 125 controls, the incidence of CIED Infection was 0 (0%) and 6 (4.8%) respectively, p=0.03.

CONCLUSIONS
There was a 90% to 100% reduction in CIED Infection in high-risk patients who received either the TYRX Absorbable Antibacterial Envelope or the TYRX Non-Absorbable Antibacterial Envelope compared to those who did not. Using PSM to control for risk factors, there was a 100% reduction in CIED Infection.