NEW CLINICAL DATA

TYRX™ WRAP-IT Study

Antibacterial Envelope to Prevent Infections of Cardiac Implantable Devices
Khaldoun Tarakji, M.D.

Study Objective
To evaluate the safety and effectiveness of TYRX in reducing the risk of CIED (Cardiac Implantable Electronic Device) infection.

Study Design
- Randomized 1:1 (TYRX vs. no TYRX) clinical trial (RCT) of CIEDs
- N = 6,983 patients at an increased risk for pocket infection*
- Patients received standard-of-care pre-op antibiotic prophylaxis
- 25 countries, 181 centers, 776 implanters

40% REDUCTION OF MAJOR INFECTIONS†1

Major CIED Infection Rate (%)

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Hazard ratio through 12 months: 0.60 (95% CI: 0.36-0.98)
P-value 0.04

61% REDUCTION OF POCKET INFECTIONS1

Major CIED Pocket Infection Rate (%)

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<td>Envelope: 14, 0.4%</td>
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Hazard ratio through 12 months: 0.39 (95% CI: 0.21-0.72)
P-value < 0.01

NO INCREASED COMPLICATION RISK OR PROCEDURE TIME1

- No increased complication risk with the use of TYRX through 12 months, which met the safety endpoint
- Complications occurred in 6.0% of patients receiving TYRX and in 6.9% of patients in the Control group (p < 0.001 for non-inferiority)
- Procedure success rate with TYRX was 99.7%
- No difference in procedure time between the Envelope arm and the Control arm

* CIED revision, generator replacement, upgrade or de novo CRT-D.
† Primary endpoint included CIED infections requiring system extraction or revision, long-term antibiotic therapy with infection recurrence, or resulting in death within 12 months of the CIED procedure.
Indications, Safety, and Warnings

If you are located in the United States, please refer to the brief statement(s) at right to review applicable indications, safety, and warning information. See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-763-514-4000 and/or consult the Medtronic website at www.medtronic.com.

If you are located outside the United States, see the device manual for detailed information regarding instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan™ device, see the MRI SureScan technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.com.

Consult instructions for use at this website. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat Reader® with the browser.

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References

5. Sinclair Labs Study D13599.

Brief Statement

The TYRX™ Absorbable Antibacterial Envelope is intended to hold a pacemaker pulse generator or defibrillator securely in order to provide a stable environment when implanted in the body. The TYRX Absorbable Antibacterial Envelope contains the antimicrobial agents minocycline and rifampin, which have been shown to reduce infection in an in vivo model of bacterial challenge following surgical implantation of the generator or defibrillator. The TYRX Absorbable Antibacterial Envelope is NOT indicated for use in patients who have an allergy or history of allergies to tetracyclines, rifampin, or absorbable sutures. The TYRX Absorbable Antibacterial Envelope is also NOT indicated for use in patients with contaminated or infected wounds, or Systemic Lupus Erythematosus (SLE). The use of this product in patients with compromised hepatic and renal function, or in the presence of hepatotoxic or renal toxic medications, should be considered carefully, because minocycline and rifampin can cause additional stress on the hepatic and renal systems. Patients who receive the TYRX Absorbable Antibacterial Envelope and who are also taking methoxyflurane should be monitored carefully for signs of renal toxicity.

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