A retrospective, dual-cohort study was conducted in a large population of patients undergoing CIED procedures to determine the effect of the TYRX Antibacterial Envelope on CIED Infection rates, utilizing a novel scoring index to risk-stratify patients based on the specific combination of risk factors, rather than just the absolute number of risk factors.1

### METHODS

Two cohorts of patients who underwent CIED procedures were identified: 1,651 patients before the introduction of the TYRX Envelope at the site (January 2007-October 2009) and 1,240 patients after the introduction of the TYRX Envelope (October 2009-September 2011), including 275 patients who received the TYRX Envelope. Using propensity-score matching, the 275 patients who received the TYRX Envelope were matched to 275 patients prior to the introduction of the TYRX Envelope.1

### RESULTS

Compared to patients who did not receive a TYRX Envelope, those who did receive the Envelope were more likely to have the following risk factors associated with an increased risk of an infection: early pocket re-exploration, male gender, diabetes, device upgrade, congestive heart failure (CHF), hypertension, GFR < 60ml/min. All these variables have been associated with CIED Infection.1

The 6-month infection rate was significantly lower in patients who received a TYRX Envelope, compared to propensity score matched patients who did not (1.1% vs. 3.6%, p=0.048).1

### CONCLUSIONS

The TYRX Envelope reduced infections by 79% and 100% in the medium and high-risk groups, respectively.1 There were ~70% fewer infections in patients who received the TYRX Antibacterial Envelope, compared to those who did not, across all device types.1

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**6-MONTH CIED INFECTION RATE: STRATIFIED BY DEVICE AND PROCEDURE TYPE(%)**

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>Device</th>
<th>DeNovo</th>
<th>Generator</th>
<th>Upgrade</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRT-D</td>
<td>4.0%</td>
<td>3.1%</td>
<td>3.9%</td>
<td>33.0%</td>
<td></td>
</tr>
<tr>
<td>ICD</td>
<td>1.5%</td>
<td>1.7%</td>
<td>18.2%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>PM†</td>
<td>0.8%</td>
<td>0.3%</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>CRT-P‡</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
</tr>
</tbody>
</table>

Infection rates were higher in the Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Defibrillator (CRT-D) groups, and in upgrade and early pocket re-exploration group. 

† Pacemaker  ‡ Cardiac Resynchronization Therapy Pacemaker

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**COMPOSITE RISK SCORE**

- Pre-TYRX Envelope: n=204
- TYRX Envelope: n=140

**6-Month Infection Rate:**
- Pre-TYRX Envelope Era: 1.0%
- TYRX Envelope Era: 0.0%

**6-MONTH CIED INFECTION RATE: LIMITED TO ICD AND CRT-D PATIENTS1**

- Pre-TYRX Envelope, n=416
- TYRX Envelope, n=292

**6-Month Infection Rate:**
- Pre-TYRX Envelope: 1.4%
- TYRX Envelope: 0.0%

**CIED INFECTION DURING THE 6 MONTHS FOLLOWING CIED IMPLANTATION AS A FUNCTION OF ENVELOPE USE1**

- with TYRX Envelope: 1.1%
- without TYRX Envelope: 3.6%

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*Study performed utilizing the TYRX™ Non-Absorbable Antibacterial Envelope.

Medtronic TYRX, Inc. 1 Deer Park Drive, Suite G | Monmouth Junction, NJ | Medtronic CRHF / Infection Control
TYRX Customer Service: 800.848.9500 Technical Support/Services: 800.505.4636 (Brady) and 800.723.4636 (Tachy) | www.TYRX.com

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