DEMONSTRATED CIED STABILIZATION, REDUCED INFECTION

TYRX™ Absorbable Antibacterial Envelope

Now available with up to 12 months shelf life.

Infections are a serious cardiac implantable electronic device (CIED) procedure-related complication, associated with significant morbidity, mortality, and cost.

1–4%
of CIED patients have been shown to develop infection[1,2]

>3x
mortality risk at 1 year[3]

$48K–83K
Range of average hospital cost to treat an infection[3-8]

$5K–36K
Range of average margin loss to treat an infection[3-11]

TYRX Envelope

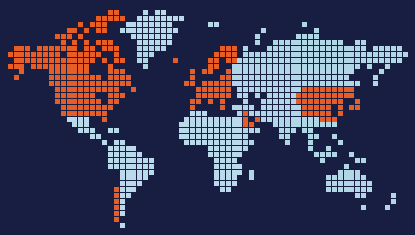
- Demonstrated CIED stabilization and infection reduction[2,12-19]
- Locally delivered minocycline and rifampin sustained for 7 days[20]
- Polymer-controlled antibiotic elution[20]
- Multifilament knitted mesh fully absorbs in approximately 9 weeks[20,21]

40%
reduction of major CIED infections.*[2]

61%
reduction of pocket infections[2]

SAFETY ENDPOINT MET
No increased risk of complications with use of TYRX through 12 months[2]

TYRX Envelope Significantly Reduces CIED Infections[1]



WRAP-IT STUDY
The largest randomized, controlled, global CIED trial[2]

- 6,983 patients at an increased risk for pocket infection†
- 25 countries
- 181 centers
- 776 implanters

MOVING CLOSER TO ZERO RISK OF CIED INFECTION WITH THE TYRX ENVELOPE[1,14-19]

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

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INTERNATIONAL CONSENSUS DOCUMENT RECOMMENDS TYRX ENVELOPE TO REDUCE CIED INFECTION[22]

INCREASED RISK[2]
(Randomized, Controlled Trial Data)

- > 1.0% major CIED infection rate through 12 months
- 40% reduction of major CIED infection and 61% reduction of pocket infection with TYRX

HIGHEST RISK
(Real-world Data)

- 1–4% major CIED infection rate through 12 months[23]
- 70–100% reduction of major CIED infection with TYRX*[14-19]

TYRX Envelope is recommended for the WRAP-IT Study population AND for patients with high risk factors[22]

CIED Infection Risk

CRT-D	Increased†	Increased†	Highest
ICD	Low	Increased†	
Pacemaker/ CRT-P	Low	Increased†	

- **Initial Procedure**
- **Replacement**
- **Revision**
- **Upgrade**
- **Dialysis**
- **Immunosuppressive Agents**
- **Recent Infection**

Considerations for patient selection include use of TYRX to hold a CIED securely in order to provide a stable environment.
*Studies included the nonabsorbable antibacterial envelope. †Included in the WRAP-IT Study patient cohort.

References

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Brief Statement
TYRX™ Absorbable Antibacterial Envelope

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.

Caution: Federal (USA) law limits the device to sale by, or on the order of, a licensed practitioner. For full prescribing information, including warnings, cautions, and contraindications, see Instructions for Use.

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