TYRX™ CARDIAC AND NEURO ABSORBABLE ANTIBACTERIAL ENVELOPES

TYRX™ Absorbable Antibacterial Envelopes (TYRX™ Envelope) contain the antimicrobial agents rifampin and minocycline which have been shown to help reduce infection in an in vivo model of bacterial challenge following surgical implantation of a pulse generator or defibrillator. The antimicrobial agents coat the biocompatible mesh and elute over a minimum of 7 days. This antibiotic combination has been shown to help reduce infections associated with cardiovascular medical devices. TYRX Envelopes are intended for single-patient, one-time use only.

Although there is currently no additional reimbursement beyond the generator placement procedure for use of a TYRX Antibacterial Envelope, for tracking purposes it’s critical to code procedures performed to the greatest possible specificity. Therefore, report the following for use of a TYRX Envelope.

INPATIENT SETTING

<table>
<thead>
<tr>
<th>ICD-10-PCS CODE</th>
<th>DESCRIPTOR</th>
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<tbody>
<tr>
<td>3E0102A</td>
<td>Introduction of Anti-Infective Envelope into Subcutaneous Tissue, Open Approach</td>
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Generator placement is reported separately.

OUTPATIENT SETTING

N/A—There are no separately reportable or reimbursable code(s) for the hospital for TYRX Envelopes used in an outpatient setting.

PHYSICIAN

N/A—There are no separately reportable or reimbursable code(s) for the physician for use of TYRX Envelopes.

TYRX™ CARDIAC ABSORBABLE ANTIBACTERIAL ENVELOPE

- Holds a pacemaker pulse generator or defibrillator securely to provide a stable environment when implanted in the body.
- Intended to be used in conjunction with implantable pacemaker pulse generators and defibrillators.

TYRX™ NEURO ABSORBABLE ANTIBACTERIAL ENVELOPE

- Holds a vagus nerve stimulator, spinal cord neuromodulator, deep brain stimulator or sacral nerve stimulator securely to provide a stable environment when implanted in the body.
- Intended to be used with vagus nerve stimulators or deep brain stimulators implanted in the infraclavicular fossa, or in conjunction with spinal cord neuromodulators or sacral nerve stimulators implanted laterally to the body midline and slightly superior to the gluteal region.

**BRIEF STATEMENT**

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 law restricts this device to sale by, or on the order of, a physician. For Full Prescribing Information, including warnings, cautions, and contraindications, see Instructions for Use.

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