

TYRX™ Cardiac and Neuro Absorbable Antibacterial Envelopes

Coding information

TYRX™ Absorbable Antibacterial Envelopes (TYRX™ Envelope) significantly reduces CIED infections, showing a 40% reduction in major infections, 61% reduction in pocket infections, and no increased complication risk with the use of TYRX through 12 months, meeting the safety endpoint.¹

The antimicrobial agents coat the absorbable mesh and elute over a minimum of 7 days.² The envelope has been shown to help reduce infections associated with cardiovascular medical devices.³⁻⁷ 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, it's critical to code procedures performed to the greatest possible specificity.

Therefore, **report the following** for the use of a TYRX envelope:



Inpatient setting

ICD-10-PCS code: **3E0102A**

Descriptor: Introduction of anti-infective envelope into subcutaneous tissue, open approach

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 the use of TYRX envelopes.

TYRX™ Cardiac Absorbable 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 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.

References

1. Tarakji KG, et al. *N Engl J Med*. 2019;380:1895-1905.
2. Huntingdon Life Sciences Study TR-2013-001.
3. Kolek MJ et al. *J Cardio Electrophysiol*. 2015;26(10):1111-1116.
4. Mittal S et al. *Heart Rhythm*. 2014;11(4):595-601.
5. Bloom HL et al. *Pacing Clin Electrophysiol*. 2011;34(2):133-142.
6. Shariff N et al. *J Cardio Electrophysiol*. 2015;26(10):783-789.
7. Henrikson CA et al. *JACC EP*. 2017: Online Publication.

Brief Statement

TYRX™ Cardiac 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.

TYRX™ Neuro Absorbable Antibacterial Envelope

The TYRX™ Neuro Absorbable Antibacterial Envelope is intended to hold a vagus nerve stimulator, a spinal cord neuromodulator, a deep brain stimulator or a sacral nerve stimulator securely in order to create a stable environment when implanted in the body. The Neuro 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 a pulse generator. The Neuro Antibacterial Envelope is NOT indicated for use in patients who have an allergy or history of allergies to tetracyclines, Rifampin, or absorbable sutures. The Neuro Antibacterial Envelope is also NOT indicated for use in patients with contaminated or infected wounds, or Systemic Lupus Erythematosus (SLE). This device is intended to be used in conjunction 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. 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 Neuro Antibacterial Envelope and who are also taking methoxyflurane should be monitored carefully for signs of renal toxicity.

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