Medtronic

TYRX™

Absorbable Antibacterial Envelope

TYRX™ Absorbable Antibacterial Envelope
(Tyrosine Polyarylate-coated, Multifilament Absorbable Mesh Envelope
Containing the Antimicrobials Rifampin and Minocycline)

INSTRUCTIONS FOR USE
USA

STERILE: Contents sterile unless package has been opened or damaged. Single Use Only. Do Not Resterilize.

CAUTION: Read instructions prior to use.

Rx Only

PRODUCT DESCRIPTION

The TYRX™ Absorbable Antibacterial Envelope is a fully absorbable sterile prosthesis designed to hold a pacemaker pulse generator or defibrillator to create a stable environment when implanted in the body.

The absorbable antibacterial envelope is constructed from multifilament knitted mesh (polymer made of glycolide, caprolactone, and trimethylene carbonate) that is coated with an absorbable polyarylate polymer. The absorbable antibacterial envelope absorbable polymer coating contains antimicrobial agents in concentrations of 8.0 mg rifampin and 5.1 mg minocycline (Medium size), and 11.9 mg rifampin and 7.6 mg minocycline (Large size).

INDICATIONS FOR USE

The 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 absorbable antibacterial envelope contains the antimicrobial agents rifampin and minocycline, which have been shown to reduce infection in an *in vivo* model of bacterial challenge following surgical implantation of the generator or defibrillator. This device is only intended to be used in conjunction with pacemakers and implantable defibrillators.

ACTIONS

The absorbable antibacterial envelope is constructed of knitted filaments of standard, absorbable suture materials (a combination of glycolide, caprolactone, and trimethylene carbonate) that are coated with an absorbable polyarylate polymer. The purpose of the absorbable coating is to act as a carrier for the antimicrobial agents. Animal data demonstrates that the absorbable antibacterial envelope absorbs in approximately 9 weeks.

The absorbable antibacterial envelope releases the antimicrobial agents rifampin and minocycline to reduce the risk of infection of the implanted pulse generator following surgery. In *in vitro* studies, the absorbable antibacterial envelope demonstrated antimicrobial activity against *Staphylococcus aureus,* methicillin-resistant *Staphylococcus aureus* (MRSA), *Staphylococcus epidermidis, Staphylococcus lugdunensis, Escherichia coli, and Acinetobacter baumannii.*

The absorbable antibacterial envelope also demonstrated *in vivo* effectiveness in reducing infections in a series of studies in which a pulse generator canister placed into an absorbable antibacterial envelope and a generator canister alone (control) were implanted into an appropriate model of infectivity (rabbits). Both the absorbable antibacterial envelope and the control groups were inoculated with bacteria and observed for a minimum of 7 days to document the presence or absence of infection in the animals. The bacteria tested included methicillin-resistant *Staphylococcus aureus (MRSA), Staphylococcus aureus, Staphylococcus epidermidis, Acinetobacter baumannii, Escherichia coli,* and *Staphylococcus lugdunensis*, which represent a majority of the pathogens reported in pacemaker and defibrillator infections.

It should be noted that the *in vitro* and *in vivo* activity of the absorbable antibacterial envelope antimicrobials is variable against non-*epidermidis* and non-*lugdunensis* strains of coagulase-negative *staphylococci*.

CONTRAINDICATIONS

The Absorbable Antibacterial Envelope is **NOT indicated** for use in the following situations:

- Allergy or history of allergy to tetracyclines, rifampin, or resorbable sutures
- In patients with systemic lupus erythematosus (SLE) because minocycline has been reported to aggravate this condition**.**
- Contaminated or infected wounds.

WARNINGS

This device is supplied sterile. Inspect the packaging to be sure that it is intact and undamaged prior to use.

This device is for single use only. Do not resterilize. Product should be used once the exterior foil wrapper has been broken. Do not store for later use. Unused portions of the prosthesis should be discarded.

If the unused prosthesis has been in contact with instruments or supplies used on a patient or contaminated with bodily fluids, discard with care to prevent risk of transmission of any disease.

The use of any surgical mesh in a contaminated or infected wound could lead to fistula formation and extrusion of the prosthesis. If infection develops, treat the infection aggressively as per standard practice, including removal of the prosthesis, if indicated.

As in any antimicrobial therapy, the possible teratogenic potential in women capable of having children should be carefully weighed against the benefit of therapy.

This device has not been evaluated in pediatric patients.

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 carefully considered because rifampin and minocycline can cause additional stress on the hepatic and renal systems. Patients who are implanted with this device and are also receiving methoxyflurane should also be carefully monitored for signs of renal toxicity.

Patients who are implanted with this device who are also taking warfarin should have their International Normalized Ratio (INR) monitored because tetracyclines have been reported to potentiate the anticoagulant effect of warfarin. The use of this product in patients being treated with thionamides, isoniazid, or halothane should be carefully considered due to potential hepatic side effects that have been reported in patients using these drugs and higher doses of rifampin.

The contraindications, warnings and precautions applicable to the use of specific antibiotic prophylaxis should be followed when prophylaxis is administered in conjunction with implantation of a pacemaker pulse generator or defibrillator enclosed in an absorbable antibacterial envelope.

Development of a hypersensitivity reaction should be followed by removal of the device and appropriate treatment initiated at the discretion of the attending physician.

Use of the absorbable antibacterial envelope in contaminated wounds is not recommended. The device is not indicated for the treatment of infection. Because the absorbable antibacterial envelope is impregnated with a combination of the antimicrobial agents rifampin (a derivative of rifamycin B) and minocycline (a derivative of tetracycline), the contraindications, warnings and precautions regarding the use of these antimicrobials apply and should be adhered to when using this device.

CAUTIONS

Only physicians qualified in the placement of pulse generators or defibrillators should use this prosthesis.

Rx Only

There are no known interactions between rifampin and minocycline. As with many drugs, the effectiveness of minocycline and rifampin may be reduced after direct contact with solutions containing iodine.

Do not alter usual practice of pre-, peri-, or post-operative administration of local or systemic antibiotics.

COMPLICATIONS AND ADVERSE REACTIONS

Possible complications for these procedures include bleeding and infection. (See **WARNINGS**.) There is currently no long-term data available to determine whether tissue reactions to the absorbable antibacterial envelope will be equivalent to the Parsonnet™ pacemaker pouch. As with any surgical procedure involving the implantation of a pacemaker/defibrillator, there may be complications, including seroma, adhesions, hematoma, inflammation, extrusion, or fistula formation. If infection develops, treat the infection aggressively as per standard practice, including removal of the prosthesis, if indicated. Please report any device-related adverse events to Medtronic, Inc. at 1-800-848-9300.

STORAGE
The absorbable envelope should be stored between 36 – 77 ºF (2 – 25 ºC). Do not freeze.

HANDLING
Use clean, sterile gloves and/or atraumatic instruments when handling the mesh.

MAINTAINING ASEPSIS
To help maintain strict asepsis during surgery, special precautions and careful preoperative site preparations are necessary. If infection develops, treat the infection aggressively as per standard practice, including removal of the prosthesis if indicated.

PRODUCT SELECTION
The medium absorbable antibacterial envelope is intended to hold a pacemaker pulse generator. The large absorbable antibacterial envelope is intended to hold a defibrillator.

PREPARATION
It is recommended that the absorbable antibacterial envelope be completely immersed in standard irrigation solution for a few seconds to facilitate placement.

INSERTION TECHNIQUE
Prepare the pulse generator or defibrillator as per manufacturer's instructions, making sure to secure the leads. Slide the pulse generator/defibrillator into the opening in the envelope with lead wires emerging straight out as shown in Figure 1. It is important to make sure that the pocket is created large enough to accommodate the additional volume of the absorbable antibacterial envelope, to ensure that closure of the incision does not place too much tension on the sutures on the adjacent skin, and that the layers of suture do not inadvertently ensnare the envelope. Place generator/defibrillator into the patient as per standard practice. If the dimensions of the pulse generator/defibrillator are larger than the opening, but of similar dimension to the absorbable antibacterial envelope, the opening can be widened to accommodate placement. (NOTE: the absorbable antibacterial envelope cannot be used with generators and defibrillators that are larger than its internal dimensions.) For generators and defibrillators that are significantly smaller than the absorbable antibacterial envelope, the generator/defibrillator should be placed as shown in Figure 2. Nonabsorbable or absorbable monofilament sutures can be used to tack the opening of the envelope to secure the generator/defibrillator prior to implantation.

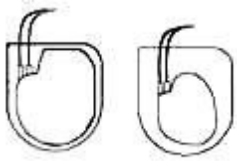

Figure 1 Figure 2

REMOVAL OF PULSE GENERATOR FROM INCORPORATED ENVELOPE

It may be necessary to remove the pacemaker or defibrillator from the envelope after a period of implantation. The absorbable antibacterial envelope is designed to facilitate explants by use of the absorbable mesh. Should it be necessary to remove the pacemaker or defibrillator prior to full absorption of the envelope, first surgically expose the envelope. Make an incision on the flat side of the envelope, approximately the width of the pacemaker or defibrillator. Disconnect the electrode leads. Remove the pacemaker/defibrillator through the opening in the side of the envelope. If required, insert a drainage tube. A new pacemaker/defibrillator may be inserted into the envelope through the side opening. Connect the electrical leads. Suture the envelope closed. Complete the procedure following standard accepted surgical techniques. Familiarization with the device and following proper

surgical techniques are important when explanting a device. Always use standard of care subject to the patient's condition and the surgical presentation in removing an implant.

TRACEABILITY
A traceability label, which identifies the type, size and lot number of the absorbable antibacterial envelope is attached to the foil label on every package. This traceability label should be peeled off and affixed to the patient's permanent medical record to clearly identify the device that was implanted.

HOW SUPPLIED
The absorbable antibacterial envelope is supplied sterile, in foil pouches, in two sizes: a Medium and a Large envelope.

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