



AIGIS_{Rx}TM Anti-Bacterial Envelope
(Anti-Bacterial Bioresorbable Polymer-Coated Polypropylene Pacemaker Pouch Containing the Antimicrobials Rifampin and Minocycline)

INSTRUCTIONS FOR USE

Manufactured and distributed by: TYRX, Inc.

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

CAUTION: Read instructions prior to use.

CAUTION: Federal law limits the device to sale by, or on the order of, a licensed practitioner.

PRODUCT DESCRIPTION

AIGIS_{Rx}TM is a dual component (resorbable and non-resorbable), sterile prosthesis designed to hold a pacemaker pulse generator or defibrillator to create a stable environment when implanted in the body.

AIGIS_{Rx}TM is constructed of knitted filaments of polypropylene that are coated with a bioresorbable polyarylate polymer.

AIGIS_{Rx}TM bioresorbable polymer coating contains the antimicrobial agents rifampin and minocycline in concentrations of 86 µg/cm².

INDICATIONS FOR USE

AIGIS_{Rx}TM is intended to securely hold a pacemaker pulse generator or defibrillator in order to create a stable environment when implanted in the body. **AIGIS_{Rx}TM** 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

AIGIS_{Rx}TM is constructed of knitted filaments of polypropylene that are coated with a bioresorbable polyarylate polymer. The purpose of the resorbable coating is to act as a carrier for the antimicrobial agents. Once placed, the polymer resorbs in approximately 140 days, leaving a lightweight permanent mesh incorporated into the tissue.

AIGIS_{Rx}TM releases the antimicrobial agents rifampin and minocycline for a minimum of 7 days to reduce the risk of infection of the implanted pulse generator following surgery. In *in-vitro* studies, **AIGIS_{Rx}TM** demonstrated antimicrobial activity against methicillin-resistant *Staphylococcus aureus* (MRSA), *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus capitis*, *Acinetobacter baumannii*, *Enterobacter aerogenes*, and *Proteus mirabilis*.

AIGIS_{Rx}TM also demonstrated *in-vivo* effectiveness in reducing infections in a series of studies in which a pulse generator canister placed into an **AIGIS_{Rx}TM** pouch and generator canister alone (Control) were implanted into appropriate models of infectivity (dogs or rabbits). Both the **AIGIS_{Rx}TM** and the Control groups were inoculated with bacteria and observed for a minimum of 7 days to validate the presence of infection in the animals. The bacteria tested included *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus capitis*, *Acinetobacter baumannii* and *Escherichia coli* which represent a majority of the infections reported in pacemaker-related endocarditis.

It should be noted that the *in-vitro* and *in-vivo* activity of the **AIGIS_{Rx}TM** antimicrobials is variable against non-*epidermidis* strains of coagulase-negative staphylococci.

CONTRAINDICATIONS

AIGIS_{Rx}TM is **NOT** indicated for use in the following situations:

- Allergy or history of allergy to tetracyclines, or rifampin, or polypropylene.
- In patients with systemic lupus erythematosus (SLE) because minocycline has been reported to aggravate this condition.
- Use of **AIGIS_{Rx}TM** in contaminated wounds is not recommended. If used, it should be understood that any infection may adversely affect proper wound healing and integration into the tissue and may result in the removal of the material.

Use of **AIGIS_{Rx}TM** in contaminated wounds is not recommended. The device is not indicated for the treatment of infection. Because the **AIGIS_{Rx}TM** is impregnated with a combination of the antimicrobial agents rifampin (a derivative of rifamycinB) 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, although systemic levels of minocycline and rifampin in patients receiving this device are not likely.

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 permanent 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. The prosthesis may not have to be removed. An unresolved infection may require removal of the prosthesis.

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

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 since rifampin and minocycline can cause additional stress on the hepatic and renal systems. Patients who are implanted with this device and are also taking methoxyfluorane 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 prothrombin time monitored because tetracyclines have also been reported to slow coagulation. The use of this product in patients being treated with thionamides, isonazides, 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.

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

CAUTIONS

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

Caution: Federal Law restricts this device to sale by or on the order of a licensed medical practitioner.

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 **AIGIS_{Rx}TM** device will be equivalent to the Parsonnet device. As with any surgical procedure involving the implantation of a pacemaker/defibrillator, there may be complications to include seroma, adhesions, hematoma, inflammation, extrusion, or fistula formation. Any unresolved infection may require removal of the prosthesis. Please report any device-related adverse events to TYRX at 1.866.907.8979 or via e-mail at safety@tyrx.com.

STORAGE: **AIGIS_{Rx}TM** should be stored between 36 – 77 °F (2 – 25 °C). 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. Any postoperative infection should be aggressively treated as soon as possible. Any unresolved infection may require removal of the prosthesis.

PREPARATION

It is recommended that **AIGIS_{Rx}TM** be completely immersed for a few seconds in standard irrigation solution 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 1.38" opening in the pouch with lead wires emerging straight out as shown in Figure 1. Place generator/defibrillator into the patient as per standard practice. If the dimensions of the pulse generator/defibrillator are larger than the 1.38" opening, but of similar dimension to the **AIGIS_{Rx}TM**, the opening can be widened to accommodate placement. (NOTE: **AIGIS_{Rx}TM** cannot be used with generators and defibrillators that are larger than its internal dimensions.) For generators and defibrillators that are significantly smaller than **AIGIS_{Rx}TM**, 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 pouch to secure the generator/defibrillator prior to implantation.

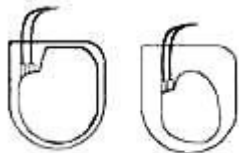


Figure 1 Figure 2

REMOVAL OF PULSE GENERATOR FROM INCORPORATED POUCH

It may be necessary to remove the pacemaker or defibrillator from the pouch after a period of implantation. First, surgically expose the pouch. Make an incision on the flat side of the pouch,

approximately the width of the pacemaker or defibrillator. Disconnect the electrode leads. Remove the pacemaker/defibrillator through the opening in the side of the pouch. If required, insert a drainage tube. A new pacemaker/defibrillator may be inserted into the pouch through the side opening. Connect the electrical leads. Suture the pouch 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 prosthesis, is attached to the foil label in every package. This label should be peeled off the label and affixed to the patient's permanent medical record to clearly identify the device that was implanted.

HOW SUPPLIED

AIGIS^{Rx}™ is supplied sterile in foil pouches in two sizes, a small and large envelope.

Manufactured by

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TYRX Products are protected under one or more of these patents: U.S. Patent Nos. 5099060, 5216115, 5217493, 5317077, 6120491, RE37160, RE37795

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