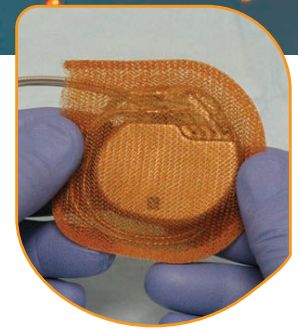




Antibacterial Envelope & Flat Sheet Specifications



Product:

AIGISR[®] is an Antibacterial Envelope and Flat Sheet that are made from knitted polypropylene mesh substrate, coated with a polyarylate bioresorbable polymer containing two antimicrobial antibiotics, minocycline and rifampin. AIGISR[®] is a dual component (resorbable and non-resorbable), sterile prosthesis designed to reduce infection and to stabilize the implantable pacemaker or defibrillator when implanted in the body.

AIGISR[®] Polypropylene Mesh:

Performance Properties
Burst Strength = 114 PSI
Tensile Strength = 348 N

Product Indications:

AIGISR[®] is intended to securely hold the pacemaker pulse generator or defibrillator in order to create a stable environment when implanted in the body. AIGISR[®] 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.

Non-resorbable Mesh Substrate:

A large-pore mesh knitted from monofilament polypropylene filaments, similar in composition and diameter to 5-0 suture. The knitted mesh comprises over 90% of the entire AIGISR[®] device by weight.

Resorbable Polymer Coating:

A bioresorbable, biocompatible polymer based upon the amino acid, tyrosine, which breaks down linearly, primarily via hydrolysis and is resorbed in approximately 140 days. This bioresorbable polymer breaks down into naturally occurring components which are considered Generally Regarded As Safe (GRAS). The primary purpose of this polymer is to act as a carrier for the antimicrobial agents, minocycline and rifampin. The tyrosine polymer and drug combination, which are spray coated onto the polypropylene mesh, comprise the remaining 10% of the entire AIGISR[®] device by weight.

Antibiotics:

Minocycline is a bacteriostatic antimicrobial which inhibits protein synthesis of the cell wall.

Minocycline has been shown to be effective against Gram positive (+) bacteria such as *S. aureus* and *S. pneumonia* and Gram negative (-) bacteria such as *E. coli*, *E. aerogenes*, *H. influenza* and *A. baumannii*.

Minocycline dose per AIGISR[®] device: up to 11mg (Pacemaker), 16mg (ICD). Sustained released over 7 to 10 days.

Rifampin is a bacteriocidal antimicrobial which interferes with DNA-dependent RNA polymerase activity.

Rifampin has been shown to be effective against Gram positive (+) bacteria such as *S. aureus* (including MRSA) and *S. epidermidis* and Gram negative (-) bacteria such as *H. influenza*.

Rifampin dose per AIGISR[®] device: up to 11mg (Pacemaker) 16mg (ICD). Sustained released over 7 to 10 days.

AIGISR[®] PM Antibacterial Pacemaker Envelope

Size: 2.5" (6.4cm) x 2.75" (7.0cm)
SKU # CMRM-3122-B (box of 6 individuals)
Single Use Only: Do Not Resterilize
Storage: Store between 36–77° F (2–25° C)

Each AIGISR[®] polymer-coated envelope is placed in a Tyvek folder insert which is packaged inside a single-barrier foil pouch.

AIGISR[®] ICD Antibacterial Defibrillator Envelope

Size: 3.0" (7.6cm) x 3.35" (8.5cm)
SKU # CMRM-3133-B (box of 6 individuals)
Single Use Only: Do Not Resterilize
Storage: Store between 36–77° F (2–25° C)

Each AIGISR[®] polymer-coated envelope is placed in a Tyvek folder insert which is packaged inside a single-barrier foil pouch.

AIGISR[®] FS PM Antibacterial Flat Sheet

Size: 3" (7.6 cm) x 4" (10.2 cm)
SKU # CMRM-3134-B (box of 6 individuals)
Single Use Only: Do Not Resterilize
Storage: Store between 36–77° F (2–25° C)

Each AIGISR[®] polymer-coated sheet is placed in a Tyvek folder insert which is packaged inside a single-barrier foil pouch.

AIGISR[®] FS ICD Antibacterial Flat Sheet

Size: 3.0" (7.6 cm) x 6.0" (15.2 cm)
SKU # CMRM-3136-B (box of 6 individuals)
Single Use Only: Do Not Resterilize
Storage: Store between 36–77° F (2–25° C)

Each AIGISR[®] polymer-coated sheet is placed in a Tyvek folder insert which is packaged inside a single-barrier foil pouch.

For full prescribing information see minocycline and rifampin package inserts. For full prescribing information for AIGISR[®], including warnings, cautions and contraindications, see package insert.

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

The TYRX polymers are protected under one or more of these patents: U.S. Patent Nos. 5217493, 6120491, RE37160

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