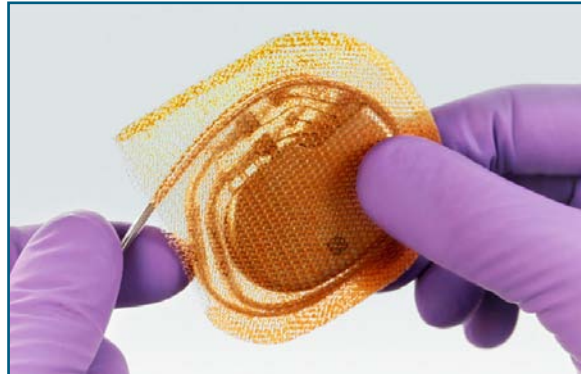


## Who Needs AIGISRx<sup>®</sup>?

The AIGISRx<sup>®</sup> Antibacterial Envelope is a mesh pouch or envelope that carries or holds the implanted pacemaker and/or implantable cardioverter defibrillator (ICD) when placed into the patient.

The AIGISRx Envelope creates a stable environment surrounding the device and leads after surgical placement and the biocompatible mesh is coated with antibiotics that elute (dissolve) within a 14 day-period.<sup>1</sup>



The AIGISRx Envelope may be used for a patient's first implant or when the pacemaker or ICD needs to be replaced, (battery life is typically 3 to 5 years). The AIGISRx delivers antibiotics "locally", or at the surgical site, and can be used in addition to intravenous or oral ("systemic") antibiotics.

While all patients can potentially benefit from the AIGISRx<sup>1</sup>, there are patients who are at higher risk for infections.<sup>2</sup>

Infection Risk Factors for Pacemaker and ICD Patients <sup>2-5</sup>
■ Congestive Heart Failure (CHF)
■ Dialysis and pre-dialysis renal (kidney) failure
■ Diabetes
■ Immunosuppressed (including patients undergoing cancer therapy)
■ Corticosteroid use
■ Anticoagulant use
■ Pacemaker or ICD replacement or revision
■ Previous device infection

You and your Doctor will determine whether you could benefit from the AIGISRx Envelope.

## Discussion with Your Doctor

Ask your Doctor if you fall in any of the following risk categories:

- Patient and procedure characteristics that significantly increase the risk of pacemaker or ICD-related infection (multivariate analyses):

### Multiple Patient Types At Increased Risk For Infection

Risk factors for a CIED Infections<sup>2-6</sup>

PATIENT PROCEDURES	ODDS RATIO FOR DEVELOPING A CIED INFECTION
Early Reintervention*	15.04
CRT-D vs ICD/PM	7.57
>2 Leads in Place	5.41
Device Replacement/Revision**	3.67
Temporary Pacing Wire	2.46

PATIENT MEDICATIONS	ODDS RATIO FOR DEVELOPING A CIED INFECTION
Corticosteroid Use***	13.9
Oral Anticoagulant	2.82

PATIENT CHARACTERISTICS	ODDS RATIO FOR DEVELOPING A CIED INFECTION
Renal Failure	11.97
Fever <24 hr Prior to Implantation	5.83
Renal Insufficiency	5.46
Congestive Heart Failure	2.57
Male Gender	2.23

Be prepared to answer the following questions from your Doctor:

#### General

- Have you felt faint or dizzy?
- Have you had any chest pain or shortness of breath?
- Have you felt palpitations or a very irregular heartbeat?
- Have you had any prior surgeries?
- Have you experienced any infections?
- What medications are you taking?
- Notice anything unusual or unexpected, such as new symptoms?

\* Early Reintervention: new procedure to manage non-infectious complication before discharge

\*\* Device Replacement/Revision: generator exchange or lead-related procedure involving opening the device pocket

\*\*\* Corticosteroid Use: >20mg ≥1 month in preceding year

**Pacemaker or ICD Implant Follow-up Visit** (in addition to the above questions)

- What primary concerns do you have with your pacemaker or ICD?
- Is your implant site painful to the touch? Yes  No
- Does your implant site feel warm to the touch? Yes  No
- Is the implant site area red and irritated? Yes  No
- Has your implant site leaked blood or pus? Yes  No
- Are the leads (wires) exposed or have the leads broken the skin? Yes  No
- Has your pacemaker changed or moved positions? Yes  No
- Other items you wish to discuss with your doctor.

Notes:

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**References:** 1. AIGISRx<sup>®</sup> reduction in infection is based on preclinical *in vitro* and *in vivo* data. Use of AIGISRx in contaminated wounds is not recommended. The device is not indicated for the treatment of infection. 2. Sohail MR *et al.* Clin Infect Dis. 2007;45:166-173. 3. Bloom H *et al.* Pacing Clinical Electrophysiology. 2006;29(2):142-145. 4. Klug D *et al.* Circulation. 2007;116(12):1349-1355. 5. Lekkerkerker JC *et al.* Heart. 2009;95(9):715-720. 6. Margey R *et al.* Europace. 2010;12(1):64-70.

**CAUTION:** Federal law limits the device to sale by, or on the order of, a licensed practitioner. For full prescribing information, including indications, warnings, cautions and contraindications, see instructions for use.