AZIYO®
BIOLOGICS

CanGaroo®

Envelope Instructions for Use

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Indications for Use
The CanGaroo® Envelope is intended to securely hold a cardiac implantable electronic device or an implantable neurostimulator to create a stable environment when implanted in the body. The cardiac implantable electronic devices that may be used with the CanGaroo® Envelope include pacemaker pulse generators, defibrillators, or other cardiac implantable electronic devices. The implantable neurostimulator devices that may be used with the CanGaroo® Envelope include vagus nerve stimulators, spinal cord neuromodulators, deep brain stimulators and sacral nerve stimulators.

Contents:
One (1) sterile, non-pyrogenic CanGaroo® Envelope

Product Description
The CanGaroo® Envelope is constructed from perforated, multilaminate sheets (4-ply) of decellularized, non-crosslinked, lyophilized extracellular matrix (ECM) derived from porcine small intestinal submucosa. The perforations in the ECM material allow the exit of any exudate. The ECM is assembled into pouch form with 5-0 polydioxanone suture. The CanGaroo® Envelope is MR safe in that it poses no known hazards in MR environments.

Tissue ingrowth into a properly sized CanGaroo® Envelope will promote stabilization of the device when compared to implantation with only standard fixation methods (e.g. sutures through the cardiac implantable electronic device (CIED) or neurostimulator header) or implantation with no fixation methods. By containing the CIED or neurostimulator in the CanGaroo® and through tissue ingrowth, a stable environment is created in which there is less room for movement of the CIED or neurostimulator in the tissue pocket. By creating a stable environment, the likelihood for complications associated with CIED or neurostimulator movement are reduced. Such complications may include migration of the CIED or neurostimulator, erosion of the CIED or neurostimulator through the skin, or complications associated with Twiddler's syndrome.

How Supplied
The CanGaroo® Envelope is supplied **STERILE**. Provided that the integrity of the sterile pouch is not compromised in any way, it serves as an effective sterile barrier until the "Use-by date" (expiration) date printed on the pouch.

The CanGaroo® Envelope is provided in five (5) sizes listed in Table 1. The appropriate size should be selected based on the external dimensions of the CIED or neurostimulator that is to be implanted.

Table 1 – CanGaroo® Envelope Sizes

Size	Envelope Height (cm)	Envelope Width (cm)
SMALL (S)	5.0	5.4
MEDIUM (M)	6.5	6.9
LARGE (L)	8.0	6.9
EXTRA LARGE (XL)	9.5	6.9
EXTRA EXTRA LARGE (XXL)	8.9	10.8

Preclinical Data
In the rabbit model, the CanGaroo® Envelope demonstrated effectiveness in providing a barrier surrounding a CIED compared to a pacemaker canister alone in rabbits. Ingrowth of vascularized tissue was observed in the CanGaroo® Envelopes after six weeks. The ingrowth of tissue provided additional stabilization for the CIED canister in the rabbit model compared to CIEDs implanted without the CanGaroo®.

Contraindications
The CanGaroo® Envelope is derived from a porcine source and should not be used in patients with a known sensitivity to porcine material.

Warnings and Precautions
- Only physicians qualified in the placement of CIEDs, such as pacemaker pulse generators or defibrillators, or implantable neurostimulators, such as vagus nerve stimulators, spinal cord neurostimulators, deep brain stimulators or sacral nerve stimulators, should use this device.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization will compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
- Discard all open or unused product.
- Device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Do not use if storage conditions have not been maintained.
- The device must be used prior to the "Use-by date" (expiration) date printed.
- Discard device if mishandling has caused possible damage or contamination.
- Always handle the device using aseptic technique.
- Do not use the CanGaroo® with fibrin glue or glue containing glutaraldehyde or other cross-linking agents.
- The use of the CanGaroo® has not been studied in the pediatric population. As with adult patients, an appropriately-sized CanGaroo® should be selected according to the size of the implantable device.
- Ensure that the device is properly hydrated prior to suturing. Without proper hydration, the ECM will tear and may not properly retain sutures.
- Once hydrated, the CanGaroo® Envelope should either be used or discarded. The CanGaroo® Envelope should not be rehydrated and reused.

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

Potential Complications
The following device-related complications are possible:
- Allergic reaction to ECM
- Bleeding
- Calcification
- Fever
- Fibrosis
- Hematoma
- Infection
- Inflammation
- Seroma
- Undesired remodeling

Storage
This device must be stored in a clean, dry location at 10º C - 30º C.

Sterilization
This device has been sterilized with ethylene oxide gas.

Required Materials
- Sterile dish (kidney dish or other bowl)
- Sterile forceps
- Hydration fluid: a sufficient quantity of room temperature sterile water, sterile saline or sterile lactated Ringer's solution to completely immerse the CanGaroo® Envelope
- Suture

Suggested Instructions for Implanting the CanGaroo® Envelope
These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

1. Select appropriate size CanGaroo® Envelope depending upon the size of the CIED or neurostimulator that will be implanted. The CIED or neurostimulator should fit snugly inside the CanGaroo®.
   NOTE: The CanGaroo® Envelope cannot be used with CIEDs or implantable neurostimulators that are larger than its internal dimensions.
   NOTE: Ensure that correct size Envelope is selected since sutured seam cannot be trimmed.
2. Inspect the CanGaroo® Envelope packaging/pouch for signs of damage. Do not use if package is damaged.
3. Using aseptic technique, remove the inner pouch from the outer pouch, and place the inner pouch containing the CanGaroo® Envelope into the sterile field.
4. Open the inner pouch carefully and aseptically remove the CanGaroo® Envelope.
5. Hydrate the CanGaroo® Envelope by completely immersing it in a bowl of sterile water, sterile saline or sterile lactated Ringers solution for 1-2 minutes prior to use.
6. Prepare the CIED or implantable neurostimulator as per manufacturer's instructions, making sure to secure the leads.
7. Slide the implantable electronic device into the pouch opening with lead wires emerging out of the envelope opening.
   NOTE: Nonabsorbable or absorbable monofilament sutures can be used to tack the opening of the pouch to secure the CIED or neurostimulator prior to implantation.
8. Place the CIED or neurostimulator into the patient as per standard practice.

Adverse Event Reporting
Any potential adverse incident involving the CanGaroo® Envelope should be reported immediately. Please report any device-related adverse events to Aziyo Biologics at +1 470-514-4080.

Return Goods Policy
For information on product returns and return authorization, contact Aziyo Biologics by calling +1 470-514-4080. All products returned to Aziyo Biologics must be accompanied by a Return Goods Authorization Number.

Symbols and Their Explanations

	Use-by date
	Temperature Limit
	Consult Instructions for Use
LOT	Lot Number
REF	Catalog Number
STERILE EO	Sterilized using Ethylene Oxide
	Do Not Reuse
	Do Not Resterilize
	Do Not Use if Package is Damaged
	Non-pyrogenic
	Manufacturer
MR	MR Safe
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