

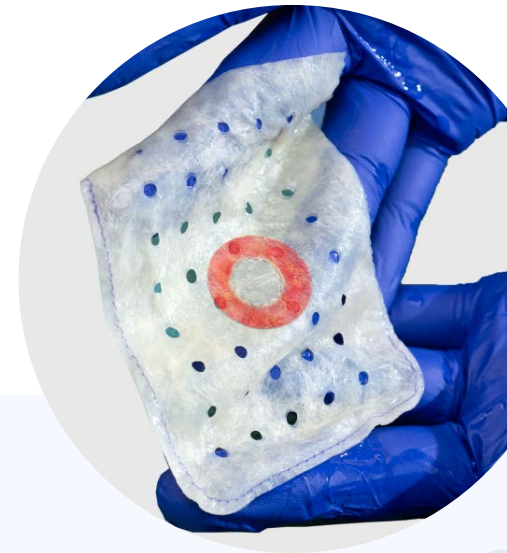


**EluPro™**

Antibiotic-Eluting BioEnvelope

## EluPro™ is designed to do more than protect the pocket – it's designed to improve it.

By combining localized antibiotic delivery with a regenerative extracellular matrix (ECM) scaffold, EluPro introduces a fundamentally different approach to cardiac implantable electronic device (CIED) pocket management: **protect early, optimize healing long term.**<sup>1</sup>



### ECM vs Synthetic: A clear difference in design philosophy



Conventional envelopes are made from synthetic, knitted, absorbable polymer mesh. Synthetic meshes have been shown to create an inflammatory foreign body response.<sup>2</sup>

In contrast, EluPro is the first and only FDA cleared antibiotic eluting bioenvelope built on an extracellular matrix (ECM) foundation, enabling it to actively participate in tissue remodeling and healing. This material has been used throughout the body to regenerate healthy functional tissue in areas of the body such as cardiac tissue repair and esophagus reconstruction.<sup>3, 4</sup>

### Designed with handling in mind



EluPro's soft, conforming biomatrix is designed to easily adapt to various CIED shapes and sizes. Its natural lubricity supports device placement and requires no modification to the bioenvelope or device pocket.<sup>5, 6</sup>

### Local antibiotic delivery



EluPro is designed to provide local, extended-release delivery of the trusted broad spectrum antibiotics rifampin and minocycline. During preclinical testing, the bioenvelope demonstrated 99.999% bacterial eradication.<sup>1, 7</sup>

## How the Extracellular Matrix (ECM) changes Healing

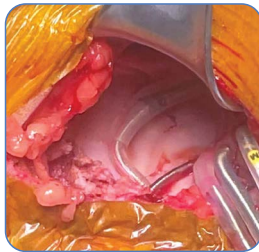
When a synthetic envelope is implanted, the body initiates a foreign body response that can lead to scar proliferation, fibrotic capsule formation, and reduced vascularization. ECM helps redirect that response. Acting as a scaffold for cell migration and remodeling, it shifts the healing cascade away from chronic inflammation and fibrotic scar formation, and instead supports a regenerative healing cascade in which new blood vessels form, and the matrix remodels into healthy, vascularized tissue around the device.<sup>1,5</sup>

## Clinical Experience: HEAL Study

In the HEAL study, using a bioenvelope around CIED's was associated with:

- 46% easier generator mobilization
- 41% easier lead mobilization
- 50% less fibrous lead entrapment
- 78% reduction in capsulectomy

Physicians also scored lead adhesions as less severe and reoperation as less difficult.<sup>5</sup>



**BioEnvelope Patient**

Vascularized, healthy-tissue pocket

Pro-Remodeling Response



**No-Envelope Patient**

Fibrotic tissue

Chronic Inflammatory Response

## Designed for Improved Long-term Pocket Management

The bioenvelope is designed to make long term pocket management more predictable by mitigating complications associated with scar formation. In addition, the healthy tissue stabilizes the device which may help reduce migration and erosion as well.<sup>1, 4-6</sup>

## The EluPro Difference

EluPro pairs local antibiotic delivery with regenerative ECM technology in a cutting edge approach to CIED pocket healing. It combines trusted broad spectrum antibiotic protection with a biologic scaffold designed to provide a physiologic implant environment, reduce fibrosis, reduce migration and erosion, and allow for a more manageable pocket over time.



EluPro Antibiotic Eluting BioEnvelope  
Indications, Safety, and Warnings  
<https://qrco.de/bgcGyo>

**Caution:** Federal Law (U.S.) restricts this device to sale by or on the order of a licensed medical practitioner. For full prescribing information, including indications, contraindications, warnings, and precautions, refer to the Instructions For Use (IFU).

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CRM-2517013-AA