

AIGISRx[®] Antibacterial Envelope “Can-in” Explantation Process

Explantation Approach*

The AIGISRx and CIED generator can be explanted using the following approach:

- Surface landmarks corresponding to the CIED generator are defined.
- The integrity of the AIGISRx is preserved by making an incision down to, but not through, the AIGISRx. Dissection along the first available plane immediately external to the AIGISRx releases the AIGISRx containing the CIED generator from the surrounding tissue.
- The AIGISRx, containing the CIED generator, is removed from the pocket.
- The CIED generator is removed from the AIGISRx through an incision and the AIGISRx is discarded.



Explantation Procedure

1

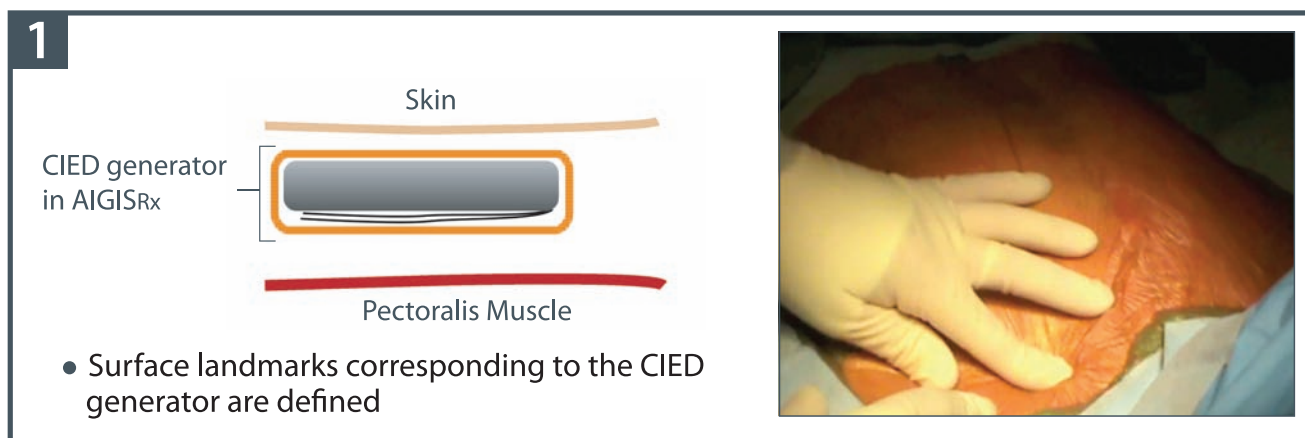



Diagram labels: Skin, CIED generator in AIGISRx, Pectoralis Muscle.

- Surface landmarks corresponding to the CIED generator are defined



2

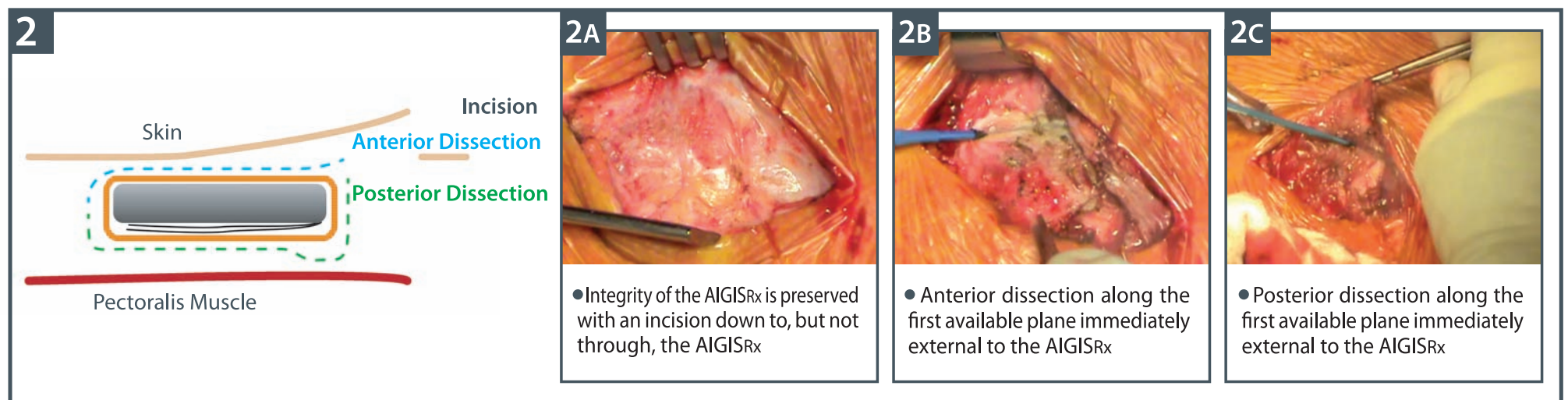
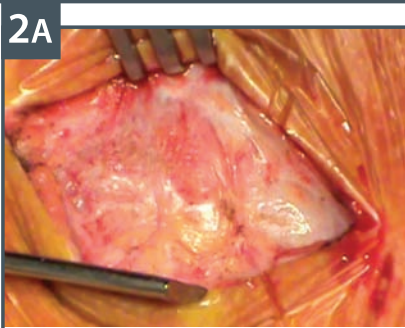


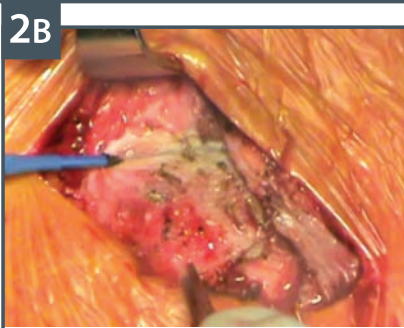
Diagram labels: Skin, Incision, Anterior Dissection, Posterior Dissection, Pectoralis Muscle.

2A




- Integrity of the AIGISRx is preserved with an incision down to, but not through, the AIGISRx

2B



- Anterior dissection along the first available plane immediately external to the AIGISRx

2C



- Posterior dissection along the first available plane immediately external to the AIGISRx

3

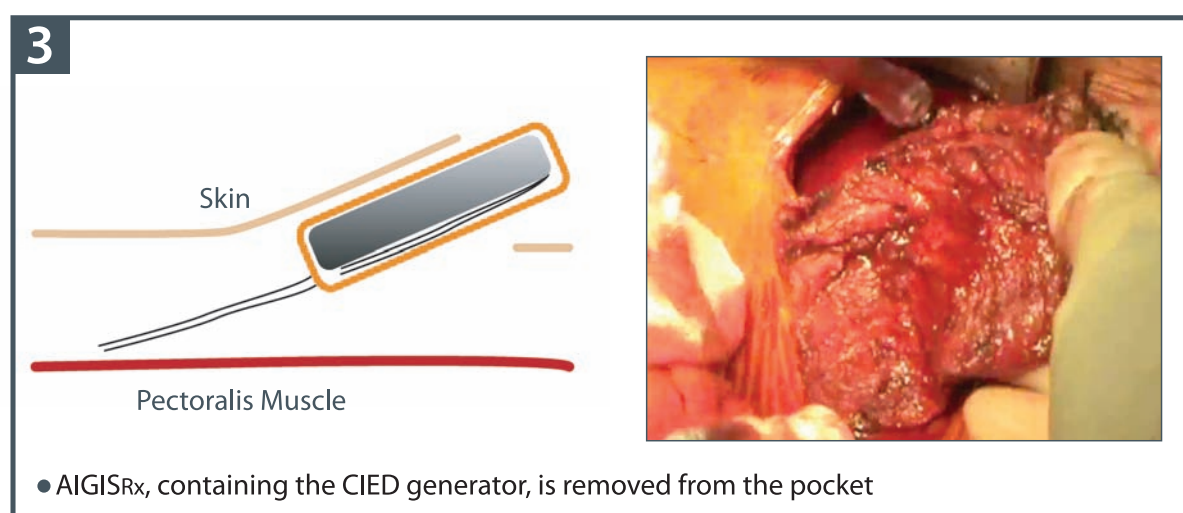



Diagram labels: Skin, Pectoralis Muscle.

- AIGISRx, containing the CIED generator, is removed from the pocket



4

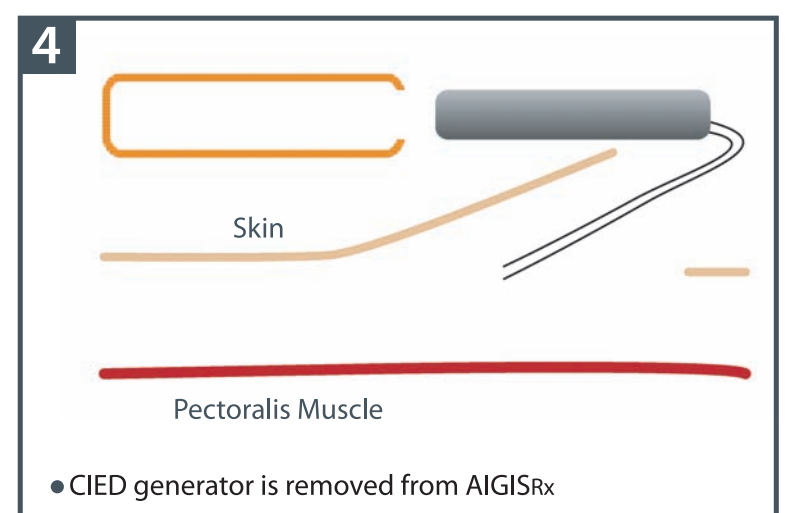


Diagram labels: Skin, Pectoralis Muscle.

- CIED generator is removed from AIGISRx

*TYRX is providing this information as part of an ongoing process to provide educational information for physicians.

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.

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