ELUTIA
Medicine *Humanized*™

# ProxiCor®

## FOR CARDIAC TISSUE REPAIR

## INSTRUCTIONS FOR USE

Manufacturer:
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### INDICATIONS FOR USE
ProxiCor® for Cardiac Tissue Repair is indicated for use as an intracardiac patch or pledget for tissue repair [i.e., atrial septal defect (ASD), ventricular septal defect (VSD), etc.] and suture-line buttressing.

**CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.**

**CONTENTS**: One (1) sterile, non-pyrogenic ProxiCor for Cardiac Tissue Repair

### PRODUCT DESCRIPTION
ProxiCor for Cardiac Tissue Repair acts as a decellularized scaffold for use as an intracardiac patch or pledget for tissue repair [i.e., atrial septal defect (ASD), ventricular septal defect (VSD), etc.] and suture-line buttressing. The extracellular matrix (ECM) scaffold is a bio-material derived from porcine small intestinal submucosa (SIS). The SIS is developed from a select layer of tissue that is recovered from porcine small intestine. The decellularized ECM scaffold allows the patient's own cells to migrate and attach within the ECM to naturally repair the tissue defect. ProxiCor for Cardiac Tissue Repair is MR (Magnetic Resonance) Safe in that it poses no known hazards in MR environments.

### HOW SUPPLIED
ProxiCor for Cardiac Tissue Repair 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" (expiration) date printed on the pouch.

### CONTRAINDICATIONS
ProxiCor for Cardiac Tissue Repair is derived from a porcine source and should not be used in patients with a known sensitivity to porcine material.

### WARNINGS AND PRECAUTIONS
- 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.
- ProxiCor for Cardiac Tissue Repair product is not indicated for the construction or replacement of total valves or conduits.
- Discard all open or unused portions of ProxiCor.
- Device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- The device must be used prior to the expiration date.
- Discard device if mishandling has caused possible damage or contamination.
- Always handle the device using aseptic technique.
- Ensure that the device is hydrated prior to suturing. Without proper hydration, ProxiCor will tear and not retain sutures. Additionally, excessive hydration may result in delamination. If delamination is observed, do not use ProxiCor.
- Device is not recommended to be used with glue containing glutaraldehyde.
- Device must be sutured to viable native tissue and must not be sutured to homografts, synthetic or chemically cross-linked materials.
- Device is not recommended to be used with platelet gel.
- Device is not recommended to be used with resorbable suture material.
- This material has not been extensively tested in the systemic arterial circuit.

### POTENTIAL COMPLICATIONS
The following complications are possible. If any of these conditions occur, a medical professional should evaluate if removal of ProxiCor is required.

- Acute or chronic inflammation (Initial application of the ProxiCor may be associated with transient, mild, localized inflammation.)
- Allergic reaction
- Aneurysm
- Bleeding
- Calcification
- Fever
- Hematoma
- Infection
- Migration/embolization of ProxiCor
- Patch dehiscence or rupture
- Pseudoaneurysm
- Reformation of intracardiac defect
- Stenosis
- Thromboembolism
- Thrombosis formation
- Undesired remodeling (e.g. poor tissue integration, excessive scar tissue formation, adhesions, or rapid degradation of the ProxiCor)

### STORAGE
This device should be stored in a clean, dry location at 10°C – 30°C.

### STERILIZATION
This device has been sterilized with ethylene oxide gas.

### REQUIRED MATERIALS
- A sterile dish (kidney dish or other bowl)
- Sterile forceps
- Hydration fluid: At least 50mL of room temperature sterile water, sterile saline or sterile lactated Ringer's solution

### SUGGESTED INSTRUCTIONS FOR USING PROXICOR FOR CARDIAC TISSUE REPAIR
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. Using aseptic technique, remove the inner pouch from the outer pouch, and place the inner pouch containing ProxiCor into the sterile field.
2. Open the inner pouch carefully, and aseptically remove ProxiCor with sterile forceps.
3. Hydrate ProxiCor by placing it in a bowl of sterile saline or other sterile isotonic solution for 1 – 2 minutes prior to use. Use at least 50mL of the sterile solution for hydration. It is recommended that ProxiCor not be excessively handled or manipulated prior to use.
4. Prepare the tissue deficiency/defect or treatment area using standard methods.
5. If required, ProxiCor can be cut to the appropriate size, using aseptic technique, in order to adequately cover the tissue deficiency/defect or treatment area.
6. Ensure that ProxiCor is adequately hydrated prior to suturing in place. If any delamination of the edges is observed, trim the affected area of ProxiCor. If delamination is still observed after trimming, do not implant the delaminated ProxiCor.
7. Place the edge of ProxiCor in contact with viable tissue.
8. Suture ProxiCor to the area of treatment or tissue deficiency/defect. A non-absorbable monofilament suture is preferred.
9. Complete the standard surgical procedure.
10. Discard any unused portions of ProxiCor.

### RETURN GOODS POLICY
For information on product returns and return authorization, contact Elutia by calling +1 470-514-4080. All products returned to Elutia must be accompanied by a Return Goods Authorization Number.

### MEDICAL DEVICE REPORTING
Any potential adverse incident involving Elutia products should be reported immediately by calling +1 470-514-4080.

### SYMBOLS AND THEIR EXPLANATIONS

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| | Use By |
| | Consult Instructions for Use |
| REF | Catalog Number |
| LOT | Lot Number |
| 10° 30° | Store at 10°C – 30°C |
| STERILE EO | Sterilized using Ethylene Oxide |
| | Do Not Reuse |
| | Manufacturer |
| MR | MR Safe |
| 2 STERILIZE | Do Not Resterilize |
| | Do Not Use if the Package is Damaged or Open |
| | Non-pyrogenic |
| | Contents |
| BIO | Contains Biological Material of Animal Origin |
| | Double Sterile Barrier System |