INTEGRICOL Bovine Pericardial Tissue Patch

Symbol legend

Rx only	CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician
MD	Medical Device
	Do not use if package is damaged
	Sterilized by liquid Chemical Sterilant Single sterile barrier system with protective packaging outside.
	Sterilized by liquid Chemical Sterilant Single sterile barrier system.
	Do not reuse
	Do not resterilize
	Caution
	Consult instructions for use
RINSE	Rinse before use!
Glutaraldehyde	Storage Solution: Contains Glutaraldehyde
	Manufacturer
	Date of Manufacture
	Storage temperature
SN	Serial Number
	Use by
SIZE	Size
REF	Catalog number
Q.ty	Quantity
	Fragile/Handle with care
	Contains material of animal origin
	Non-pyrogenic
UDI	Unique Device Identifier

Description

The Bovine Pericardial Tissue Patch consists of a single piece of bovine pericardial tissue that is cross-linked during manufacturing and selected to have minimal thickness variation.

The device is provided **sterile**. A variety of sizes and tapered models are available but may also be tailored by the surgeon if required. The device models are labeled from CR-04 to CR-23. The size specifications are printed on the product label.

Indications For Use

Bovine Pericardial Tissue Patch is intended for use as a surgical patch for cardiac and vascular reconstruction and repair, soft tissue deficiency repair, and reinforcing the suture line during general surgical procedures.

Contraindications

Do not use to bridge a hernia defect.

Warnings

The Bovine Pericardial Tissue Patch should only be used for procedures stated in the Indications For Use section. The safety and efficacy of Bovine Pericardial Tissue Patch has not been demonstrated for other procedures outside of the scope of the Indications For Use.

Prior to implantation, the rinsing procedure described in the Rinse Procedure section must be performed to reduce the amount of glutaraldehyde storage solution present on the Bovine Pericardial Tissue Patch. Additions of other solutions, drugs, chemicals, or antibiotics to the glutaraldehyde or rinse solution may cause irreparable damage to the tissue.

Precautions

Careful handling and preparation of the Bovine Pericardial Tissue Patch is required to avoid damage to the device. Devices that have been dropped, damaged, or mishandled in any way may not be used for human implantation.

- Discard unused pieces of Bovine Pericardial Tissue Patch. Do not reuse, re-process or re-sterilize the device as it may result in patient injury, illness, or death.
- Do not use expired or damaged Bovine Pericardial Tissue Patch. Do not repair damaged Bovine Pericardial Tissue Patch.
- Keep Bovine Pericardial Tissue Patch moist until use, do not let it dry.

Potential Complications

Potential complications include the following: Restenosis, Pseudoaneurysm formation, Infection, Thrombosis, Calcification, Fibrosis, Vessel occlusion, Patch rupture, Dilatation, Myocardial infarction, Bleeding, Cerebrospinal fluid leakage, Stroke, Death, and Vascular stenosis.

Complications may also result from individual patient reaction to the implanted device or to physical or chemical changes in the components. Such complications may require reoperation and replacement of the bovine pericardial tissue patch.

Medical literature has also reported complications relating to bovine pericardium preserved using glutaraldehyde which include inflammatory reaction, sterile abscess, infection, fibrous thickening and severe hemorrhaging.

The principal complications that have been reported for bovine pericardial tissue patch are fibrosis and infection. These complications are observed only in a small minority of patients after implantation of the bovine pericardial tissue patch.

Adverse Effects

The Bovine Pericardial Tissue Patch is designed for cardiac and vascular reconstruction and repair, soft tissue deficiency repair, and reinforcing the suture line during general surgical procedures. The symptoms experienced from improper functioning of an implanted Bovine Pericardial Tissue Patch are similar to symptoms that arise from deficiencies in the natural organ. The implanting surgeon is responsible for informing the patient of the symptoms that indicate improper functioning of the Bovine Pericardial Tissue Patch which include the following:

1. Complete heart block and right bundle branch block in procedures involving cardiac repair near the A-V conduction bundles.
2. Late immune system attacks on glutaraldehyde-fixed bovine pericardium with subsequent tissue deterioration.
3. Calcification and histological signs of deterioration have been reported in animal studies with bovine pericardium. Phagocytosis accompanied by chronic inflammatory infiltrate between bovine pericardium and surrounding host tissue with focal degradation of implant collagen consistent with host vs. graft reaction.

Epicardial inflammatory reactions and patch adhesions to the heart is an adverse effect from bovine pericardium used for pericardial closure. Pericardial adhesions may increase the difficulty of repeat sternotomy.

How Supplied

One Bovine Pericardial Tissue Patch is provided sterile, non-pyrogenic, and packaged in glutaraldehyde storage solution in a sealed container. The glutaraldehyde may cause irritation of the skin, eyes, nose, and throat and may also cause skin sensitization. Ensure adequate ventilation and avoid breathing in storage solution vapor during handling. Minimize skin contact. In case of contact, immediately flush area with water. If contact with the eyes occurs, seek immediate medical attention.

Storage

The Bovine Pericardial Tissue Patch should be stored at room temperature, 25°C (77°F). Do not expose the device to temperatures below 0°C (32°F) or above 40°C (104°F) as serious damage to the Bovine Pericardial Tissue Patch may result. Do not store in direct sunlight exposure.

Direction to Prepare Implant

Exercise care and caution while handling the Bovine Pericardial Tissue Patch. Wash surgical gloves thoroughly to remove all powder residues before handling.

Choose the required Bovine Pericardial Tissue Patch model as appropriate for the type of procedure being performed. Verify that the correct Bovine Pericardial Tissue Patch model is selected. Carefully inspect the container and seal for damage. If the seal is broken or if the container is damaged, contents may not be sterile and may cause infection in the patient, **do not use**. If no damage is observed, open the container, inspect the contents to ensure that an adequate amount of glutaraldehyde storage solution is present to cover the tissue and tissue is not dry. Do not use if there is damage, leaks or if the container lacks an adequate amount of glutaraldehyde storage solution or tissue is dried.

Rinse Procedure

Ensure that the tissue and rinse solution does not contact with sources of lint or particulates such as towels and linens. Handle the contents of the container aseptically to prevent contamination. Take two sterile containers and fill with the appropriate amount of sterile saline as determined for the model. For the models listed in the table below use **1000 ml of Saline** per container and use **500 ml of saline** per container for rest of the models.

Model	CR16	CR18	CR20	CR21	CR22	CR23

Remove the Bovine Pericardial Tissue Patch by grasping its corners with sterile, atraumatic forceps and immediately transfer to the first container of sterile saline and submerge the Bovine Pericardial Tissue Patch completely. Using the same forceps, gently agitate the Bovine Pericardial Tissue Patch in the container for one minute. Transfer to the second container of sterile saline and repeat. Allow the Bovine Pericardial Tissue Patch to remain in the final rinse container until ready for use.

Implantation

If required, cut and/or trim the Bovine Pericardial Tissue Patch to the desired shape after rinsing. Excess Bovine Pericardial Tissue Patch material should be treated as biological waste and discarded according to hospital procedure. During implantation, prevent drying by irrigating the Bovine Pericardial Tissue Patch with sterile saline.

Surgical Technique

It is at the discretion of the implanting surgeon to carefully evaluate the short- and long-term risks and benefits and to consider alternative methods of treatments for each patient on a case-by-case basis. It is beyond the scope of this Instructions For Use to instruct the surgeon on specific surgical procedures. The implanting surgeon is responsible for employing the appropriate surgical techniques in accordance with the Warnings, Precautions, and Directions For Use.

The benefits and risks of using the Bovine Pericardial Tissue Patch should be disclosed to the patient before surgery. Medical follow-up with the patient is advised so that complications can be promptly diagnosed and properly treated to minimize danger to the patient.

Distributed in USA by:
Corcym Inc.
9800 Mount Pyramid Court, Suite 400
Englewood CO 80112 USA
www.corcym.com