Synovis®

Surgical Innovations

Peri-Guard®

Pericardium • with Apex Processing®
Péricarde • avec Apex Processing®
Perikard • mit Apex Processing®
Pericardio • con Apex Processing®
Pericardio • con Apex Processing®
Pericardium • met Apex Processing®
Pericardium • med Apex Processing®
Perikardium • med Apex Processing®
Perikard • med Apex Processing®
Perikardiyum • ile Apex Processing®
Περικάρδιο • με Apex Processing®
Sydänpussi • mukana Apex Processing®
Pericárdio • com Apex Processing®
Pericard • cu Apex Processing®
Perikard • s technologií zpracování Apex Processing®
Perikardium • Apex Processing®-gel
Osierdzie • z Apex Processing®

CE 0086

SYMBOL DEFINITIONS:

DO NOT FREEZE	Do not freeze
0°C / 32°F	Lower limit of temperature
	Do not reuse
	Consult *Instructions for Use*
STERILE A	Sterilized using aseptic processing techniques
NaOH	This product is treated with sodium hydroxide
BOVINE	This product is derived from U.S.D.A.-inspected cattle
MADE IN THE U.S.A.	Made in the U.S.A.
Rx Only	CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician
CONTENT	Content
REF	Catalog number
	Use by date
LOT	Lot number
	Manufacturer
EC REP	Authorized Representative in the European Community
PN	SSI part number
IC	SSI internal code

INDICATIONS:

For use as a prosthesis for pericardial closure and soft tissue deficiencies which include: defects of the abdominal and thoracic wall, hernias (diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal and umbilical), and intracardiac and great vessel repair.

DESCRIPTION:

Peri-Guard® is prepared from bovine pericardium which is cross-linked with glutaraldehyde. The pericardium is procured from cattle originating in the United States. Peri-Guard is chemically sterilized using ethanol and propylene oxide. Peri-Guard has been treated with 1 molar sodium hydroxide for 60-75 minutes at 20-25°C.

Peri-Guard is packaged in a container filled with sterile, non-pyrogenic water containing propylene oxide. The contents of the unopened, undamaged container are sterile.

CONTRAINDICATIONS:

Peri-Guard is not designed, sold or intended for use except as indicated.

INSTRUCTIONS FOR USE:

I. RINSE PROCEDURE

1. Remove inner container from outer cardboard package. Do not place the container in the sterile field.
2. Examine the freeze indicator. Do not use if activated.
3. Inspect container and package. Do not use if there is evidence of moisture or leakage.
4. Open inner container. Use sterile, atraumatic forceps to grasp the edge of the patch and remove from the container using aseptic technique. Rinse surgical gloves to remove glove powder prior to touching the patch.
5. Immerse and agitate Peri-Guard, for a minimum of 3 minutes, in a sterile basin containing 500 ml of sterile physiologic saline (0.9% NaCl). Do not pour the storage solution into the sterile physiologic saline. At the surgeon's discretion the 500 ml rinse solution may contain one of the following antibiotic treatments: ampicillin & gentamicin, bacitracin, cefazolin, cefotaxime, neomycin, and vancomycin. Testing has shown that Peri-Guard is not adversely affected by treatment with the antibiotics listed. The effects of other antibiotics on Peri-Guard have not been tested. The long term effects of antibiotic treatments of Peri-Guard have not been assessed. Do not use antibiotics contrary to the antibiotic manufacturer's instructions.
6. Keep the patch immersed in sterile saline until ready to use.
   THE PATCH MUST REMAIN MOIST AT ALL TIMES.

II. IMPLANT INSTRUCTIONS

1. The patch may be tailored during surgery to meet the surgeon's needs.
2. Visually examine both sides of the Peri-Guard patch. If one side appears smoother, implant the smoother surface so that it faces the blood flow surface.
3. Peri-Guard may be sutured, clipped, or stapled to the edge of the host tissue or vessel.
4. When implanting by suture, suture bites should be taken 2 to 3 millimeters from the edge of the graft.
5. The graft should be applied and fixed in place carefully to obtain best results.
6. Discard any unused pieces of Peri-Guard. Peri-Guard cannot be resterilized or reused.

STORAGE:

Do not freeze. Store at room temperature.

WARNINGS:

The Rinse Procedure must be followed or a sterile inflammatory reaction in the adjoining host tissue may result. Do not pour the storage solution into the rinse bath.

To avoid damage to the product, do not expose to any chemicals or substances other than those specified in this Rinse Procedure. Antimycotics must not come in contact with Peri-Guard as they are believed to alter the cross-link characteristics of tissue fixed in aldehyde preparations.

Do not freeze. Damage may result. Do not use if freeze indicator is activated.

Do not resterilize. Do not subject to steam, gas (ethylene oxide), or radiation sterilization as these may damage Peri-Guard.

Do not use if the container is not properly sealed prior to opening, as sterility may be compromised. Do not place container in sterile field as the outside of the container is not sterile. This product is for single use only. Once the container seal is broken, use immediately,

do not reseal container or reuse Peri-Guard. Any unused pieces of Peri-Guard must be discarded. Failure to observe these warnings may result in surgical infection.

Complete heart block and complete right bundle heart block have been reported for procedures involving cardiac repair near the atrial-ventricular conduction bundles, most notably for repair of atrial septal defects.

Clinical experience with glutaraldehyde fixed porcine xenograft heart valves indicates that fixed tissue may be subject to late attack by the body and subsequent tissue deterioration. In a like manner, the glutaraldehyde fixed bovine pericardium may be subject to late deterioration. The benefits of the use of this tissue in cardiovascular repair or repair of soft tissue deficiencies must be weighed against the possible risk of aneurysm or hemorrhage or patch weakening resulting from tissue deterioration.

PRECAUTIONS:

Rinse surgical gloves to remove glove powder prior to touching Peri-Guard.

Before surgery, prospective patients or their representatives should be informed about complications which may be associated with use of this product. As with any surgical procedure, dehiscence at the surgical site and infection are possible complications. Monitor patient for infection and take appropriate therapeutic action.

ADVERSE REACTIONS:

Failure to rinse the product may result in a sterile inflammatory reaction (see Warnings and Rinse Procedure).

The effect on long term surgical outcome of damaging bovine pericardium by contact with chemicals or substances (other than saline), by freezing, or by exposure to steam, gas (ethylene oxide), or radiation sterilization has not been investigated (see Warnings).

Use of product following compromise in sterility may result in infection (see Warnings).

When used as a bioprosthetic heart valve, bovine pericardium has been reported to show mechanical disruption of leaflets and mineralization resulting in early failures in some cases.

When bovine pericardium is used for pericardial closure, cases of epicardial inflammatory reactions and adhesions of the bovine pericardium to the heart have been reported. Pericardial adhesions may increase the difficulty of repeat sternotomy.

When used to correct simple complete transposition of the great arteries with pericardium augmentation of the pulmonary venous channel, bovine pericardium has been reported to demonstrate calcification, inflammation, and formation of fibrous tissue which obstructed pulmonary venous flow.

When used in animal studies for pericardial closure, bovine pericardium has been reported to show signs of calcification. Animal studies have reported histological signs of deterioration of implanted bovine pericardium. Findings include active phagocytosis with accompanying chronic inflammatory infiltrate and the formation of giant cell infiltrate at the interface between bovine pericardium and surrounding host tissues (with focal degradation of implant collagen) consistent with a host-versus-graft reaction.

The incidence rates of host reactions (calcification, infection, rejection, adhesion, and hematological compatibility) during use for hernia repair have not been investigated.

DISCLAIMER OF WARRANTIES:

Synovis Surgical Innovations (SSI), a division of Synovis Life Technologies, Inc., warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties whether expressed, implied, written or oral, including, but not limited to, any implied warranties of merchantability or fitness. As a result of biological differences in individuals, no product is 100% effective under all circumstances. Because of this fact and since SSI has no control over the conditions under which the device is used, diagnosis of the patient, methods of administration or its handling after it leaves its possession, SSI does not warrant either a good effect or against an ill effect following its use. The manufacturer shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of this device. SSI will replace any device which is defective at the time of shipment. No representative of SSI may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

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