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SUPPLE PERI-GUARD

REPAIR PATCH

Symbols Referenced on Labeling
Symbol Glossary per US FD&C Act:

Standard	Symbol	Symbol Title	Symbol Meaning	Symbol Number
ISO 15223-1*		Manufacturer	Manufacturer	5.1.1
ISO 15223-1		Use-by date	Use-by date	5.1.4
ISO 15223-1	LOT	Batch code	Lot number	5.1.5
ISO 15223-1	REF	Catalogue number	Catalog number	5.1.6
ISO 15223-1	STERILE A	Sterilized using aseptic processing techniques	Sterilized using aseptic processing techniques	5.2.2
ISO 15223-1		Do not resterilize	Do not resterilize	5.2.6
ISO 15223-1		Do not use if package is damaged	Do not use if the product sterile barrier or its packaging is compromised	5.2.8

Standard	Symbol	Symbol Title	Symbol Meaning	Symbol Number
ISO 15223-1		Temperature limit	Store at controlled room temperature	5.3.7
ISO 15223-1		Do not re-use	Do not re-use	5.4.2
ISO 15223-1		Consult instructions for use	Consult instructions for use	5.4.3
ISO 15223-1		Caution	Caution: Consult instruction for use for warning and precaution information	5.4.4
	CONTENT		Content	
	Rx Only		Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	

*ISO 15223-1: 2016, Medical Devices-Symbols to be used with medical device labels, labeling and information to be supplied, Part 1: General requirements

Additional symbols on the product labeling that are not required by the US FD&C Act:

Symbol	Symbol Meaning
MADE IN THE U.S.A.	Made in the U.S.A.
PN	Manufacturer part number
DO NOT FREEZE	Do not freeze
BOVINE	This product is derived from cattle
MODEL	Model number
SEE IFU FOR SYMBOL DEFINITIONS	See IFU for symbol definitions

DESCRIPTION:

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

SUPPLE PERI-GUARD is MR Safe.

SUPPLE PERI-GUARD utilizes animal tissue; patient must be informed prior to any procedure.

INDICATIONS FOR USE:

For use as a prosthesis for pericardial closure and soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, and hernias (diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal and umbilical).

CONTRAINDICATIONS:

SUPPLE PERI-GUARD is not designed, sold or intended for use except as indicated.

Do not use SUPPLE PERI-GUARD in patients with a known sensitivity to bovine material.

SUPPLE PERI-GUARD Product Models and Sizes

SUPPLE PERI-GUARD Model Number	Size (cm)
PC-0404SN	4X4
PC-0608SN	6X8
PC-0814SN	8X14
PC-1016SN	10X16

ADVERSE REACTIONS:

As with any surgical procedure, dehiscence at the surgical site, hematoma, seroma, fever and infection are possible complications. Other potential surgical complications associated with the use of surgical mesh include, but are not limited to: death, myocardial infarction, stroke, patch rupture, aneurysm/ pseudoaneurysm, effusion, recurrence or failure, adhesion, and fistula formation. Monitor patient for adverse reactions and take appropriate therapeutic action.

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

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.

Glutaraldehyde-treated bovine pericardium may undergo accelerated calcific infiltration in patients with high calcium metabolic activity (e.g. children). This may not be a concern where the patch is exposed to systolic pressures.

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

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.

Synovis products differ; substitution of one product for another product may be harmful to the patient.

To avoid damage to the product, do not expose to any chemicals or substances other than those specified in this Rinse Procedure. Antimycotics (anti-fungals) must not come in contact with

SUPPLE PERI-GUARD as they are believed to alter the cross-link characteristics of tissue fixed in aldehyde preparations.

Do not freeze. Damage to the sterile barrier may result. Do not use if freeze indicator is activated.

The product must remain moist at all times.

Do not use SUPPLE PERI-GUARD in patients with a known sensitivity to bovine material.

Do not resterilize. Do not subject to steam, gas (ethylene oxide), or radiation sterilization as these may damage SUPPLE 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 SUPPLE PERI-GUARD. Any unused pieces of SUPPLE PERI-GUARD must be discarded as biohazardous waste. Failure to observe these warnings may result in surgical infection.

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 SUPPLE PERI-GUARD.

Before surgery, prospective patients or their representatives should be informed about complications which may be associated with use of this product.

INSTRUCTIONS FOR USE:

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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 located inside the lid of the outer cardboard package. Do not use if activated.
3. Inspect container and package. Verify shrink wrap and tamper-evident tape are intact. Do not use if there is evidence of tampering, 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 SUPPLE 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 SUPPLE PERI-GUARD is not adversely affected by treatment with the antibiotics listed. The effects of other antibiotics on SUPPLE PERI-GUARD have not been tested. The long term effects of antibiotic treatments on SUPPLE 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 SUPPLE PERI-GUARD patch. If one side appears smoother, implant the smoother surface so that it faces the blood flow surface.
3. SUPPLE PERI-GUARD may be sutured, clipped, or stapled to the edge of the host tissue.
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 SUPPLE PERI-GUARD in biohazardous waste. SUPPLE PERI-GUARD cannot be resterilized or reused.

STORAGE CONDITIONS:

Do not freeze. Store at room temperature 20°C – 25°C (68°F – 77°F).

DISPOSAL

Any packaging or components exposed to human tissue/fluids should be disposed of per hospital protocols. Any opened, unused components should be discarded due to compromised sterility.

DISCLAIMER OF WARRANTIES:

Synovis Life Technologies, Inc. (SLT) (A Subsidiary of Baxter International Inc.) warrants that reasonable care has been used in the manufacture of this device. As a result of biological differences in individuals, no product is 100% effective under all circumstances. Because of this fact and since SLT 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, SLT does not warrant either a good effect or against an ill effect following its use. SLT will replace any device, which is defective at the time of shipment. No representative of SLT may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

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MS-0742146A
2021-03-05