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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:

PERI-GUARD Repair Patch (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 a minimum of 60 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.

PERI-GUARD is MR Safe.

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

INDICATIONS FOR USE:

PERI-GUARD is intended for repair of pericardial structures and for use as a prosthesis for surgical repair of soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal and umbilical hernias). PERI-GUARD is also intended for use as a patch material for intracardiac defects, great vessel, septal defect and annulus repair, and suture-line buttressing.

PERI-GUARD Product Models and Sizes

PERI-GUARD Model Number	Size (cm)
PC-0404N	4X4
PC-0608N	6X8
PC-0814N	8X14
PC-1016N	10X16
PC-1225N	12X25

CONTRAINDICATIONS:

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

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

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, thrombosis, effusion, occlusion, stenosis, recurrence or failure, adhesion and fistula formation. Monitor patient for adverse reactions and take appropriate therapeutic action.

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 this 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.

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.

When bovine pericardium is used for pericardial closure, cases of epicardial inflammatory reaction and adhesion 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.

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

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 rate 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.

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

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

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

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 as biohazardous waste. Failure to observe these warnings may result in surgical infection.

The product must remain moist at all times.

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

Clinical experiences with glutaraldehyde fixed porcine xenograft heart valves indicate that fixed tissues 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 later 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.

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 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 on 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 in biohazardous waste. PERI-GUARD cannot be resterilized or reused.

III. SPECIFIC INSTRUCTIONS FOR CARDIAC APPLICATIONS

7. Implant techniques: physician knowledge of surgical techniques used in cardiac and valve surgery is required for the use of PERI-GUARD in intracardiac and great vessel surgical procedures. A summary of the surgical techniques used in the PERI-GUARD retrospective study is included in the Clinical Summary Section.
8. Implant techniques for atrial septal defect and atrial patch repair are similar to the techniques described in the literature.[5] Implant techniques for coronary graft buttressing and aortic patching are summarized in the Clinical Summary Section.
9. Use of PERI-GUARD in annulus repair is similar to the techniques described in the literature for annulus repair using autologous pericardium.[1, 3]
10. PERI-GUARD has been successfully used in applications exposed to peak systolic pressure (i.e., ventricular septal defect (VSD), ventricular aneurysm and aortic graft suture line buttress), using either a single patch or reinforced patch technique. The single patch technique using PERI-GUARD has been used to repair post-infarction ventricular septal defects.[4] The reinforced patch technique is described in the literature[2, 4] and was used for ventricular aneurysm repair, ventricular septal defect patching, and aortic graft suture line buttressing in the PERI-GUARD retrospective study.

For further information on the reinforced patch technique, refer to the Clinical Summary Section.

CLINICAL SUMMARY FOR CARDIAC APPLICATIONS:

The surgical methods for the implantation of the PERI-GUARD used by the surgeons participating in the retrospective study are summarized here. Surgical teams from two institutions participated in this study from June 1996 to February 1997. Between January 1988 and November 1995, 139 PERI-GUARD implants were performed on 108 patients according to each surgeon's practice of medicine and can be described as either a "single patch technique" or a "reinforced patch technique." See the table for a breakdown of uses in the retrospective study. Patients under the age of 18 were excluded from this retrospective study. Disease states of the patients included: ischemic disease, congenital defects, acquired defects, tumor excisions, valve disease, hypertension, and atherosclerotic. The primary endpoints of this study were to retrospectively identify the number and type of device-related adverse events. The techniques used by the implant surgeons are described below.

PERI-GUARD Use	Number of uses Single Patch Technique	Number of uses Reinforced Patch Technique	Study Totals
Atrial Patch Repair	9	1	**10**
Atrial Septal Defect Repair	12	0	**12**
Right Ventricular Patch Repair	2	0	**2**
Right Ventricular Outflow Tract Repair	4	0	**4**
IVC, Svc, And Pulmonary Artery Patch Repair	4	0	**4**
Annulus Repair	14	1	**15**
Aortic Patch	6	3	**9**
Left Ventricular Patch (Aneurysm Resection)	0	38	**38**
Ventricular Septal Defect Repair	2	15	**17**
Suture Line Buttress: Prosthetic Aortic Graft	0	21	**21**
Suture Line Buttress:Coronary Artery To Prosthetic Graft	7	0	**7**
Total Study Uses Of PERI-GUARD			**139**

SINGLE PATCH TECHNIQUE

PERI-GUARD was used to patch the intracardiac and great vessels. It provided hemostasis and strength in this application and no other material was used in the reinforcement of the suture line.

Examples include:

Atrial Septal Defect (ASD): PERI-GUARD was fashioned to the approximate shape (of the ASD), and sewn to close the defect with two 4-0 polypropylene (sutures) in a running technique.

Coronary Graft Buttress: PERI-GUARD was used as a "gasket" to seal the anastomosis between the coronary artery and the prosthetic ascending aortic graft.

REINFORCED PATCH TECHNIQUE

PERI-GUARD was used in conjunction with various synthetic materials (PTFE, polyester) to patch the left ventricle and other structures that are exposed to peak systolic pressure. These structures include the left ventricular outflow tract and the ascending and descending aorta.

Examples include:

Patch Ventriculoplasty: Following complete debridement of the aneurismal wall, the edges of the aneurysm were encircled with multiple interrupted pledgeted sutures. These were then placed circumferentially through a low porosity (polyester) patch that was cut to size, coated on the inside with bovine pericardium, which had been stapled to the patch. The sutures were all individually ligated, cut and the edge of the aneurismal repair was run with polypropylene sutures.

Closure of Ventriculotomy: PERI-GUARD was used in the same manner as described by Fiore, et al.[4] When the ventriculotomy was ready for closure, strips of PERI-GUARD were placed on both

sides and secured with interrupted horizontal mattress sutures. Closure was complete with a running monofilament suture and excess PERI-GUARD was trimmed.

Aortic Graft Suture Line Buttress: PERI-GUARD was used with either composite grafts (for ascending aortic aneurysm) or woven polyester grafts (for descending aortic aneurysm) and was used in a "sandwich fashion." PERI-GUARD provided an "inner buttress" to seal the artery to the prosthetic graft while other materials, such as PTFE felt, were used as an "outer buttress" on the anastomosis.

CLINICAL RESULTS

Six device-related adverse events were reported for the 139 PERI-GUARD implants in the study. All events resulted in device explant or patient expiration. Two events (1.4%) were for patch separation from the ventricular septum after VSD repair. Two events (1.4%) were for postoperative infection and/or sepsis. One event (0.7%) was for combined VSD and sepsis. One event (0.7%) was for active endocarditis and paravalvular leak.

STORAGE:

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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4. Fiore AC, McKeown PP, Misbach GA, et al. The use of autologous pericardium for ventricular aneurysm closure. Ann Thor Surg, 1988; 45: 570 – 1.
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