

Peri-Guard®

Repair Patch

INSTRUCTIONS FOR USE

Read these instructions carefully before use

SYMBOL DEFINITIONS:

	Do not freeze
0°C/32°F 	Lower limit of temperature
	Do not reuse
	Consult <i>Instruction for Use</i>
	Sterilized using aseptic processing techniques
	This product is treated with sodium hydroxide
	This product is derived from U.S.D.A.-inspected cattle
	Made in the U.S.A.
	CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician
	Content
	Catalog number
	Use by date
	Lot number
	Manufacturer  SSI part number  SSI internal code

DESCRIPTION:

Peri-Guard® Repair Patch (Peri-Guard) is a biologic tissue prepared from bovine pericardium 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 is treated with 1 molar sodium hydroxide for 60-75 minutes at 20-25°C.

INDICATIONS FOR USE:

Peri-Guard is intended for repair of pericardial structures and for use as a prosthesis for the surgical repair of soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric binding, 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.

CONTRAINDICATIONS:

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

ADVERSE REACTIONS:

As with any surgical procedure, adverse reactions are possible and include but are not limited to: infection, rejection, erosion, and allergic reaction.

When used as a bioprosthetic heart valve, bovine pericardium has been reported to show mechanical disruption of leaflets and mineralization resulting in early failure 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 to 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 with 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 the interface between bovine pericardium and surrounding host tissues (with focal degradation of implant collagen) consistent with a host-versus-graft reaction.

The incident rate of host reactions (calcification, infection, rejection, adhesion, and hematological compatibility) during use for hernia repair and peripheral vascular reconstruction have not been investigated.

WARNINGS/PRECAUTIONS:

Do not resterilize.

Do not use if freeze indicator is activated.

Do not use product if there is damage to the inner container.

The product must be moist at all times.

The characteristics of Peri-Guard may be compromised if exposed to solutions other than those specified in the product instructions.

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

Antimycotics must not encounter Peri-Guard, these are believed to alter the cross-link characteristics of tissue fixed in aldehyde preparations.

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

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.

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. THE PATCH MUST REMAIN MOIST AT ALL TIMES. If the surgical site is not ready, keep Peri-Guard in sterile saline until ready to use.

II. Implant Instructions

1. Peri-Guard may be tailored to meet the needs of the surgeon.
2. Visually examine both sides of the Peri-Guard patch material. If one appears smoother, implant the smoother side facing the blood flow surface.
3. Peri-Guard may be sutured, clipped, or stapled to the edge of the host tissue and should be fixed in place carefully to obtain best results.
4. When implanting by suture, suture bites should be taken 2 to 3 millimeters from the edge of the patch material.

Specific Instructions for Cardiac Applications

5. 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 Study Section.

6. 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.
7. Use of Peri-Guard in annulus repair is similar to the techniques described in the literature for annulus repair using autologous pericardium.^{1,3}
8. 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 Study Section.
9. Discard any unused portion of the patch material, do not resterilize or reuse.

STORAGE CONDITIONS:

- Do not freeze.
- Store at room temperature.

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.

1. 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.

2. 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.

3. 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.

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

DISCLAIMER OF WARRANTIES:

Synovis Surgical Innovations, 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 Synovis 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, Synovis 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. Synovis will replace any device that is defective at the time of shipment. No representative of Synovis may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

REFERENCES:

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