Baxter Peri-Guard
REPAIR PATCH

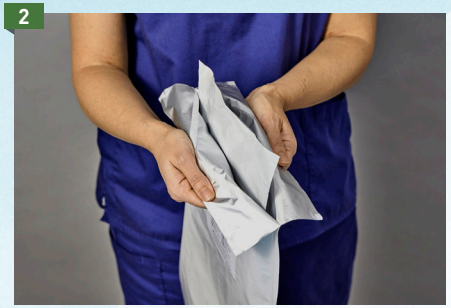
Baxter Supple Peri-Guard
REPAIR PATCH

Preparation Instructions

1

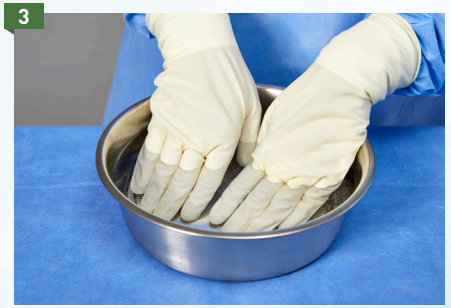
Open carton by tearing the seal tab and remove the outer pouch from the carton. Inspect the outer pouch. Do not use if the outer pouch is damaged or if the seals are not intact as sterility may be compromised. Do not place the outer pouch in the sterile field as the outside of the pouch is not sterile.

2



Open the outer pouch and aseptically transfer the inner pouch into the sterile field.

3



Rinse surgical gloves to remove glove powder prior to touching PERI-GUARD or SUPPLE PERI-GUARD.

4

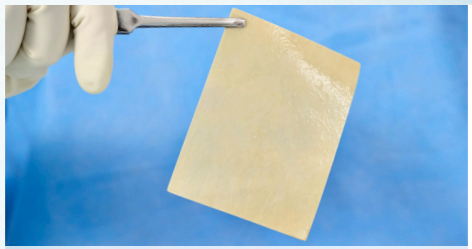
Inspect the inner pouch. Do not use if the inner pouch is damaged or if the seals are not intact. Open the inner pouch and examine PERI-GUARD or SUPPLE PERI-GUARD to ensure moisture of the patch has been maintained. Do not use if any folds, creases, or wrinkles are observed in the patch.

5

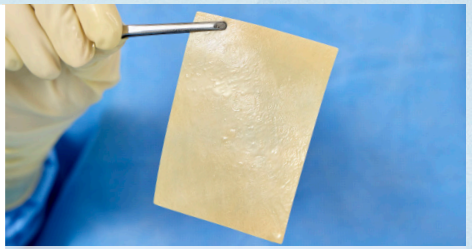
Using aseptic technique and sterile, atraumatic forceps, grasp the edge of the patch and remove the patch from the package.

6

Immerse and agitate PERI-GUARD or SUPPLE PERI-GUARD for a minimum of 3 minutes in a sterile basin containing 500 ml of sterile physiologic saline (0.9% NaCl). At the surgeon's discretion, a room temperature, pre-implant soak in solution may contain one of the following antibiotic treatments: ampicillin & gentamicin, bacitracin, cefazolin, cefotaxime, neomycin, or vancomycin. The effects of other antibiotics on PERI-GUARD or SUPPLE PERI-GUARD have not been tested. The long-term effects of antibiotic treatments on PERI-GUARD or SUPPLE PERI-GUARD have not been assessed.



SMOOTH SIDE



ROUGH SIDE

After 3 minutes, PERI-GUARD or SUPPLE PERI-GUARD are ready for implantation. Keep the patch immersed in sterile saline until ready to use. **The patch must remain moist at all times.**

PERI-GUARD or SUPPLE PERI-GUARD may be tailored during surgery to meet the surgeon's needs. Visually examine both sides of the patch. **If one side appears smoother, implant the smoother surface so that it faces the blood flow surface.**

PERI-GUARD or SUPPLE PERI-GUARD should be fixed in place according to standard surgical techniques. When implanting by suture, suture bites should be taken 2 to 3 millimeters from the edge of the patch. Discard any unused pieces of PERI-GUARD or SUPPLE PERI-GUARD in biohazardous waste. PERI-GUARD or SUPPLE PERI-GUARD must not be resterilized or reused.

PERI-GUARD INDICATIONS FOR USE

PERI-GUARD Repair Patch (PERI-GUARD) is intended for use as a prosthesis for surgical repair of pericardial structures 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, scrotal and umbilical hernias). PERI-GUARD is also intended for use as a patch for intracardiac defects, great vessel, septal defects and annulus repair, and suture-line buttressing.

IMPORTANT RISK INFORMATION

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.

PERI-GUARD should not be used in neurosurgery since the product endotoxin level may be higher than the allowable limit for cerebrospinal fluid-contacting devices.

The rinse procedure must be followed or a sterile inflammatory reaction in the adjoining host tissue may result.

Do not place the outer pouch in the sterile field as outside of pouch is not sterile. Do not use if the outer pouch is damaged or if the seals are not intact as sterility may be compromised. Do not use if the inner pouch is damaged or if the seals of the inner pouch are not intact.

Do not use if any folds, creases, or wrinkles are observed in PERI-GUARD patch.

Do not use if product has been exposed (1) to solutions above room temperature or (2) to chemicals, antibiotics, or substances other than specifically addressed in these instructions as the characteristics of PERI-GUARD may change or be compromised.

Animal studies to evaluate the safety and performance of PERI-GUARD placed in an intraperitoneal onlay for hernia repair have not been performed.

Clinical studies demonstrating the safety of PERI-GUARD in contaminated or infected surgical fields have not been performed.

Reinforced repairs should be used for abdominal wall reconstruction whenever possible to reduce the risk of complications and hernia recurrence.

Antimycotics (anti-fungals) must not come in contact with PERI-GUARD as they are believed to alter the cross-linked characteristics of tissue fixed in aldehyde preparations.

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

This product is for single use only. Do not reseal the pouch or reuse PERI-GUARD. Any opened, used or unused pieces of PERI-GUARD must be discarded as biohazardous waste due to compromised sterility. 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.

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, hemorrhage or patch weakening resulting from tissue deterioration.

The patch is not indicated for the construction or replacement of total valves or conduits.

Rinse surgical gloves to remove glove powder prior to touching PERI-GUARD.

Rx Only. For safe and proper use of this device refer to the complete Instructions for Use.

SUPPLE PERI-GUARD INDICATIONS FOR USE

SUPPLE PERI-GUARD is intended 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 (including diaphragmatic, femoral, incisional, inguinal, lumbar, scrotal and umbilical hernias).

IMPORTANT RISK INFORMATION

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 should not be used in neurosurgery since the product endotoxin level may be higher than the allowable limit for cerebrospinal fluid-contacting devices.

The rinse procedure must be followed or a sterile inflammatory reaction in the adjoining host tissue may result.

Do not place the outer pouch in the sterile field as the outside of pouch is not sterile. Do not use if the outer pouch is damaged or if the seals are not intact as sterility may be compromised. Do not use if the inner pouch is damaged or if the seals of the inner pouch are not intact.

Do not use if any folds, creases, or wrinkles are observed in SUPPLE PERI-GUARD patch.

Do not use if product has been exposed (1) to solutions above room temperature or (2) to chemicals, antibiotics, or substances other than specifically addressed in these instructions as the characteristics of SUPPLE PERI-GUARD may change or be compromised.

Antimycotics (anti-fungals) must not come in contact with SUPPLE PERI-GUARD as they are believed to alter the cross-linked characteristics of tissue fixed in aldehyde preparations.

Do not resterilize. Do not subject to steam, gas, or radiation sterilization as these may damage SUPPLE PERI-GUARD.

Animal studies to evaluate the safety and performance of SUPPLE PERI-GUARD placed in an intraperitoneal onlay for hernia repair have not been performed.

Clinical studies demonstrating the safety of SUPPLE PERI-GUARD in contaminated or infected surgical fields have not been performed.

Reinforced repairs should be used for abdominal wall reconstruction whenever possible to reduce the risk of complications and hernia recurrence.

This product is for single use only. Do not reseal the pouch or reuse SUPPLE PERI-GUARD. Any opened, used or unused pieces of SUPPLE PERI-GUARD must be discarded as biohazardous waste due to compromised sterility. 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.

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 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, hemorrhage or patch weakening resulting from tissue deterioration.

The patch is not indicated for the construction or replacement of total valves or conduits.

Rinse surgical gloves to remove glove powder prior to touching SUPPLE PERI-GUARD.

Rx Only. For safe and proper use of this device refer to the complete Instructions for Use.

PERI-GUARD PRODUCT CODES	SIZE (CM)	SUPPLE PERI-GUARD PRODUCT CODES	SIZE (CM)
PG0404	4 x 4	SPG0404	4 x 4
PG0608	6 x 8	SPG0406	4 x 6
PG0814	8 x 14	SPG0608	6 x 8
PG1016	10 x 16	SPG0814	8 x 14
PG1225	12 x 25	SPG1016	10 x 16

For questions or ordering information, contact your local Baxter representative or visit www.advancedsurgery.baxter.com. For customer service, call 1-888-229-0001.

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