

Vascu-Guard

VASCULAR 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.



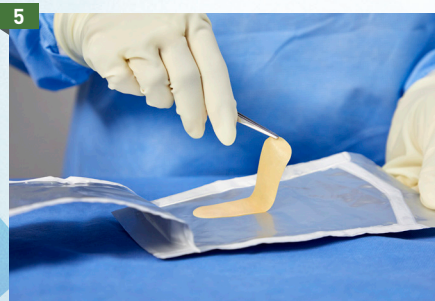
2 Open the outer pouch and aseptically transfer the inner pouch into the sterile field.



3 Rinse surgical gloves to remove glove powder prior to touching VASCU-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 VASCU-GUARD to ensure moisture of the patch has been maintained. Do not use if any folds, creases, or wrinkles are observed in VASCU-GUARD.



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 VASCU-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.



SMOOTH SIDE



ROUGH SIDE

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

VASCU-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.**

VASCU-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 VASCU-GUARD in biohazardous waste. VASCU-GUARD must not be resterilized or reused.

VASCU-GUARD Indications for Use

VASCU-GUARD Vascular Repair Patch is used in peripheral vascular reconstruction including the carotid, renal, iliac, femoral, profunda and tibial vessels and arteriovenous access revisions.

Contraindications

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

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

Warnings

Failure to rinse the product may result in a sterile inflammatory reaction in the adjoining host tissue.

The product must remain moist at all times.

Do not place outer pouch in sterile field as outside of pouch is not sterile.

Do not use if any folds, creases, or wrinkles are observed in VASCU-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 VASCU-GUARD may change or be compromised.

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

Do not resterilize.

Product is single use only.

Failure to observe warnings may result in surgical infection.

Do not substitute one Synovis product for another.

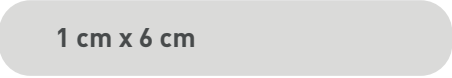



Clinical experience with glutaraldehyde fixed porcine xenograft heart valves indicates that fixed tissue may be subject to late attack by the body and subsequent tissue deterioration. In like manner, the glutaraldehyde fixed bovine pericardium may be subject to late deterioration. The benefits of the 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 VASCU-GUARD.

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

PRODUCT SIZE [PATCHES REPRESENT ACTUAL SIZE]

PRODUCT SIZE [PATCHES REPRESENT ACTUAL SIZE]	ORDER CODE	QUANTITY
 1 cm x 6 cm	VG0106	1 EA
 0.8 cm x 8 cm (tapered end)	VG0108	1 EA
 1 cm x 10 cm	VG0110	1 EA
 2 cm x 9 cm	VG0209	1 EA

For questions or ordering information, please contact your Baxter representative or call 888-229-0001.

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