

A Heritage of Healing

A Clinically Proven and Convenient Biologic Solution

SUPPLE PERI-GUARD Pericardial Patch is a well-established, off-the-shelf biologic solution that:

- Provides high levels of biocompatiblity as demonstrated in vitro and in animal models¹
 - Low Glutaraldehyde levels under 4ppm^{1,2} (in vitro data)
 - Does not promote mineralization or calcification³⁻⁵
 - Supports endothelialization as demonstrated in animal studies⁶⁻⁸
- Resists suture line bleeding^{3,9-11}
- Is easy to handle and suture, similar to autologous tissue^{3,9,10}
- Allows short, equivalent prep time regardless of tissue size¹²

SUPPLE PERI-GUARD

Excellent reapproximation around suture³



expanded
Polytetraflourethylene
(ePTFE)



SUPPLE PERI-GUARD Surgical Applications

- Pericardial Closure
- Thoracic Wall Defect Repair
- Intracardiac and Great Vessel Repair



A Track Record that Speaks for Itself

As part of the Baxter TISSUE-GUARD Family of Products, SUPPLE PERI-GUARD and PERI-GUARD have over 256,000* patches sold and are backed by a 30 year clinical history, 13 which has shown:

- No infection, rupture or dilation reported in a nine year follow-up study³
- Good long term patency rates and minimal to no thrombosis or pseudoaneurysm formation^{3,6,7,14}
- An exceptionally low adverse event rate¹⁴

*Data as of June 30, 2013





The Choice is Yours

- SUPPLE PERI-GUARD when a more compliant, flexible patch is of benefit
- PERI-GUARD for those procedures needing a flat, more rigid tissue patch application

Your local sales rep can help you determine the best tissue patch configuration for your procedural needs.

Available in a Variety of Sizes

SUPPLE PERI-GUARD is easily trimmed to desired shape and size

| Product Code | Product Size |
|--------------|---------------|
| PC0404SN | 4 cm x 4 cm |
| PC0608SN | 6 cm x 8 cm |
| PC0814SN | 8 cm x 14 cm |
| PC1016SN | 10 cm x 16 cm |



SUPPLE PERI-GUARD



Indications For Use:

SUPPLE PERI-GUARD is indicated for use as a prosthesis for pericardial closure and soft tissue deficiencies which include: defects of the abdominal and thoracic wall, hernias (diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal and umbilical), and intracardiac and great vessel repair.

Contraindications:

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

Adverse Reactions:

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

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

References:

- 1. Data on File. Baxter Healthcare Corporation, V-0144R.
- 2. Data on File. Baxter Healthcare Corporation, DS-1011 and DS-1012.
- 3. Biasi GM, Sternjakob S, Mingazzini PM, Ferrari S. Nine-year experience of bovine pericardium patch angioplasty during carotid endarterectomy. *J Vasc Surg.* 2002;36:271-277.
- 4. Data on File. Baxter Healthcare Corporation, SI-0021 and SI-0021R.
- 5. David TE. The use of pericardium in acquired heart disease: a review article. J Heart Valve Dis. 1998;7(1):13-17.
- 6. Data on File, 2003. Baxter Healthcare Corporation, SI-0020 and SI-0020R.
- 7. Li X, Jadlowiec C,Guo Y, et al. Periardial patch angioplasty heals via an ephrin-B2 and CD34 positive cell mediated mechanism. PLoS One. 2012;7(6):1-8.
- 8. Wiebe D, Megerman J, L'Italien GJ, Abbott WM. Glutaraldehyde release from vascular prostheses of biologic origin. Surgery. 1988;104(1):26-33.
- 9. Marien BJ, Raffetto JD, Seidman CS, LaMorte WW, Menzolan JO. Bovine pericardium vs dacron for patch angioplasty after carotid endarterectomy. *Arch Surg.* 2002;137:785-788.
- 10. Li X, Guo Y, Ziegler K, et al. Current usage and future directions for the bovine pericardial patch. Ann Vasc Surg. 2011;25(4):561-568.
- 11. Papakostas JC et al. Use of the Vascu-Guard Bovine Pericardium Patch for Arteriotomy Closure in Carotid Endarterectomy. Early and Long-Term Results. Ann Vasc. Surg. 2014; 28:1213-1218.
- 12. SUPPLE PERI-GUARD Instructions for Use. MS-0720125, 11/12.
- 13. Data on file. Baxter Healthcare Corporation, TGCS2013.
- 14. Grimsley BR, Wells JK, Peral GJ, et al. Bovine pericardial patch angioplasty in carotid endarterectomy. Am Surg. 2001;67(9):890-5.



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