Patient Information Leaflet

PERI-GUARD Repair Patch and SUPPLE PERI-GUARD Repair Patch

Description of the Device and Intended Use

PERI-GUARD Repair Patch and SUPPLE PERI-GUARD Repair Patch (PG/PGS) are implantable biological tissue patches that are derived from the lining covering the heart of cattle (pericardium). The primary difference between PG and PGS is an additional manufacturing treatment step within the PG process that makes the product slightly stiffer. Physicians choose PG or PGS based on their preference of handling repair patches that are more or less stiff.

The products are available in multiple patch sizes and are intended to be used in the chest, or within or around the heart or heart vessels, to support or replace body tissue that has become weak or is no longer there. The patches are secured in place using sutures, clips or staples. Examples of procedures that may include use of these products are:

- Pericardial closure following coronary artery bypass grafting or other cardiac procedure
- Repair of atrial or ventricular septal defects, or mitral valve prolapse
- Reconstruction of the superior vena cava, aorta or inferior vena cava
- Chest wall defects resulting from tumour removal

Model Number	Product	Size (cm)
PC-0404N	PERI-GUARD	4 x 4
PC-0608N	PERI-GUARD	6 x 8
PC-0814N	PERI-GUARD	8 x 14
PC-1016N	PERI-GUARD	10 x 16
PC-1225N	PERI-GUARD	12 x 25
PC-0404SN	SUPPLE PERI-GUARD	4 x 4
PC-0608SN	SUPPLE PERI-GUARD	6 x 8
PC-0814SN	SUPPLE PERI-GUARD	8 x 14
PC-1016SN	SUPPLE PERI-GUARD	10 x 16

PG/PGS are intended for use by healthcare professionals only. Patients who have sensitivity to cattle-derived materials should not receive these devices. All cattle that Baxter procures pericardium from are subjected to strict requirements from the United States Department of Agriculture as the animals are intended and approved to become human food.

PG/PGS tissue patches are chemically treated per World Health Organization guidelines to ensure they are safe for human use. Chemical treatment includes glutaraldehyde, ethanol and propylene oxide, which are intended to increase patch strength and/or sterilize the patches. Product may also be exposed to Isopropyl Alcohol (i.e. rubbing alcohol) which is used as a disinfecting agent in the manufacturing environment. Testing has confirmed that residual levels of these chemicals are very low and not at levels harmful to humans. The product also comes in contact with heavy metals during the manufacturing process. International standards govern exposure limits to metals and testing supports the product is well below such limits.

Risk Information

All medical devices carry risks. If your physician is considering using PG/PGS, they have determined that the benefits of use outweigh the risks. Reasons your physician may choose to use PG/PGS include the strength of the material, its similarity to human tissue and the

products long commercial history with low complaint rate. PG/PGS have been on the market for almost a combined 70 years and are commercially available medical devices in many geographies including the U.S., EU, Australia and Canada.

Continuous product monitoring has established that the percentage of patients with complications related to PG/PGS are very low. Baxter assesses and manages product risks according to international standards.

Nevertheless, residual product risks exist and include, but may not be limited to, exposure to allergens, contaminants of animal origin, endotoxins, impurities, microbial or particulate matter, or delay of or insufficient therapy. Possible patient harms as a result of these risks include, but are not limited to, infection, inflammation, thrombosis, pain, nausea, fever, allergic reaction, or worsening of patient condition.

Additionally, as with any surgical procedure, wound opening, bleeding or inflammation at the surgical site are possible complications, as are fever and infection. Other potential surgical complications associated with the use of repair patches include, but are not limited to: death, heart attack, stroke, patch deterioration or blood vessel bulging or blockage.

It is important to note that although product risks exist, reported patient harms are infrequent, and the risks are equivalent to alternative therapy options.

Post-Surgery

PG/PGS are considered “permanent” implants, however, the product may eventually become indistinguishable from new tissue that is generated by the body. The exact lifetime of the products is subject to patient variables and cannot be evaluated clinically since invasive procedures would be required that could weaken the patch.

PG/PGS create no limitations on daily life, do not interfere with other medical or electrical equipment, and require no actions by the patient to ensure or monitor product performance. Based on the type of surgical procedure performed, your physician will provide you with instructions on how to take care of yourself after your surgery and any restrictions on activities.

Contact your physician if you believe you are experiencing side-effects related to the device. This document is not intended to replace consultation with your physician if needed. Serious incidents and adverse events should be reported to Baxter Healthcare Pty Ltd by calling 1800 BAXTER (1800 229 837) or sending an email to ANZ_Product_Safety@baxter.com and to the Therapeutic Goods Administration on the following site: www.tga.gov.au.

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