Patient Information Leaflet

PERI-STRIPS Dry Staple Line Reinforcement with VERITAS Collagen Matrix (PSDV)

Description of Device and its Intended Purpose

PSDV is an implantable medical device created from the lining covering the heart of cattle (pericardium). PSDV consists of the PSDV pericardial tissue strips and PSD Gel. PSDV strips are intended to be used with medical devices called surgical staplers. PSD Gel is used to temporarily bond the tissue strip to the surgical stapler during application. You may also hear PSDV referred to as a staple-line buttress, staple-line reinforcement or surgical mesh.

Weight loss and other surgical procedures of the stomach may involve tissue removal, or the creation of connections between tissues in the body, through the use of surgical staplers. Surgical staplers deliver staples to internal tissues to close surgical cuts or wounds that cannot be closed with traditional stitches. The use of surgical staples alone can lead to potential complications, including bleeding and staple-line leaking. Your physician may choose to use PSDV strips to increase the strength of the staple-line and/or reduce the risk of bleeding.

Model and catalogue numbers for PSDV are listed in the table below. The different PSDV models are intended for use with different sizes and brands of surgical staplers.

Catalogue Number	Model Number
PSD4506UVCE	PSD 4506-U-V
PSD4506ECHVCE	PSD 4506-ECH-V
PSD6006UVCE	PSD 6006-U-V
PSD6006ECHVCE	PSD 6006-ECH-V

PSDV is intended for use by healthcare professionals only. Patients who have sensitivity to cattle-derived materials should not receive these devices. All cattle that Baxter obtains tissue from are subject to strict requirements from the United States Department of Agriculture as the animals are intended and approved to become human food.

PSDV tissue strips are chemically treated per World Health Organization guidelines to ensure it is safe for human use. Chemical treatment additionally includes ethanol and propylene oxide. 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. Product is additionally exposed to sterilant residuals and heavy metals during the manufacturing process. International standards govern exposure limits to these materials and testing supports the product is well below such limits.

Risk Information

All medical devices carry risks. If your physician is considering using PSDV, they have determined that the benefits of use outweigh the risks. Reasons your physician may choose to use PSDV are demonstrated reduction of bleeding and staple-line leaks, structural similarity to human tissue, and low likelihood of a negative patient reaction to the material. PSDV has been on the market since 2004 and is a commercially available medical device 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 PSDV 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, pain, nausea, fever, allergic reaction or worsening of patient condition.

Additionally, as with any surgical procedure, infection, bleeding, allergic reaction or an immune system response (when your body does not recognize a foreign object and tries to fight it) are possible complications. Other potential complications, which may or may not be related to PSDV use, include staple-line leaks, tissue injury or abnormal narrowing of the digestive tract. 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

Implanted PSDV strips will eventually be replaced with patient tissue. The rate at which this occurs is different for each patient and depends on factors such as implant location within the body, the type of procedure, surgical complications, whether a patient has other diseases or conditions, and presence of an infection at the implant site or after surgery.

PSDV creates no limitations on daily life, does not interfere with the performance of other medical or electrical equipment, and requires 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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