Patient Information Leaflet

HEMOPATCH Sealing Hemostat

Description of Device and its Intended Purpose

HEMOPATCH is an implantable medical device that consists of a soft, thin, pliable, flexible, pad of collagen derived from cattle skin, and a crosslinker coating that enhances tissue adhering properties. HEMOPATCH is an absorbable collagen pad intended for sealing tissue surface and stopping the flow of blood.

HEMOPATCH is intended to be used only by trained surgeons during an operation. Your surgeon may choose to use HEMOPATCH in surgical procedures in which control of bleeding or leakage of other body fluids by conventional surgical techniques is either ineffective or impractical.

If you are sensitive to cattle-derived materials, you should not receive HEMOPATCH. Collagen in HEMOPATCH is the only material that is derived from animal origin. The animal tissue is chemically treated according to World Health Organization guidelines to ensure it is safe for human use; testing has confirmed there are no chemicals in the product at levels harmful to humans.

HEMOPATCH is available in 3 sizes as shown below:

PRODUCT NAME	PRODUCT CODE
HEMOPATCH Sealing Hemostat 45 mm X 90 mm	1506253
HEMOPATCH Sealing Hemostat 45 mm X 45 mm	1506256
HEMOPATCH Sealing Hemostat 27 mm X 27 mm	1506257

Risk Information

All medical devices carry risks. If your surgeon is considering using HEMOPATCH, they have determined that the benefits of use outweigh the risks. Reasons your surgeon may choose to use HEMOPATCH are demonstrated effectiveness on control of bleeding or leakage of other body fluids during operation, low likelihood of a negative patient reaction to the material, and the capability of being fully absorbed into living tissue after surgery.

However, as with any surgical procedure, undesirable side effects may happen where your body does not recognize a foreign object and tries to fight it. These potential side effects include clear fluid collection at the site of product application, abnormal collection of blood outside of a blood vessel, infection, inflammatory reaction, foreign body reaction, adhesion formation and allergic reaction.

Post-Surgery

Implanted HEMOPATCH is intended to be absorbed in your body after 6-8 weeks. 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.

HEMOPATCH creates no limitations on daily life, does not interfere with the performance of other medical or electrical equipment, and requires no actions by yourself to ensure or monitor product performance. Based on the type of surgical procedure performed, your surgeon will provide you with instructions on how to take care of yourself after your surgery and any restrictions on activities.

Contact your surgeon if you believe you are experiencing side-effects related to the device. This document is not intended to replace consultation with your surgeon 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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