# Patient Information Leaflet

# FLOSEAL HEMOSTATIC MATRIX (FLOSEAL)

## Description of Device and its Intended Purpose

FLOSEAL is an all-in-one package including bovine derived Gelatin Matrix, human-derived Thrombin and a pre-filled sodium chloride syringe. FLOSEAL is indicated in surgical procedures (other than in ophthalmic) as an adjunct to hemostasis when control of bleeding, ranging from oozing to spurting, by ligature or conventional procedures is ineffective or impractical. FLOSEAL can be applied focally at the target site of bleeding to provide fast, effective bleeding control. FLOSEAL material is biocompatible and absorbed within 6 to 8 weeks, consistent with normal wound healing.

FLOSEAL is intended to be used only by trained clinicians during an operation. If you are sensitive to cattle-derived materials, you should not receive FLOSEAL. 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. The animal tissue is treated to ensure it is safe for human use.

Thrombin (Human) is prepared from pooled human plasma through a series of separation and filtration steps followed by activation of Thrombin. The Thrombin (Human) solution subsequently undergoes multiple careful steps to purify the product and remove potential hazards such as bacteria and viruses. The pooled human plasma is obtained from U.S. licensed plasma collection centers.

FLOSEAL is available in 2 sizes as shown below:

| PRODUCT NAME | PRODUCT CODE |
|---|---|
| FLOSEAL Hemostatic Matrix, 5mL | 1504610 |
| FLOSEAL Hemostatic Matrix, 10mL | 1504612 |

## Risk Information

All medical devices carry risks. If your clinician is considering using FLOSEAL, they have determined that the benefits of use outweigh the risks. Reasons your clinician may choose to use FLOSEAL include the demonstrated effectiveness on surgical bleeding, low likelihood of a negative patient reaction to the material, and capable of being fully absorbed into living tissue after surgery. FLOSEAL has been of the market since 1999 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 FLOSEAL are very low. Baxter assesses and manages product risks according to international standards.

However, as with any surgical procedure, infection, bleeding, allergic reaction or an immune system response, where 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 FLOSEAL use, include anemia, irregular heart rate, or local inflammation.

The manufacturing procedure for FLOSEAL Matrix includes processing steps designed to reduce the risk of viral transmission. Nevertheless, residual product risks exist and include, but may not be limited to, exposure to allergens, contaminants of human or 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.

As with any other plasma-based products, severe allergic reactions may occur in rare cases. No adverse events of this type were reported during the course of clinical trials using a different product containing the same human Thrombin component. Mild reactions can be managed with antihistamines; severe low blood pressure reactions require immediate intervention by the clinician. Allergic reactions may be encountered in people who are sensitive to bovine materials. Gelatin-based hemostatic agent adverse events include infection, fever, failure of absorption.

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 FLOSEAL will eventually be absorbed within 6 to 8 weeks by 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.

FLOSEAL 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 clinician will provide you with instructions on how to take care of yourself after your surgery and any restrictions on activities.

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