

Patient Information Leaflet for ***SURGIFLO™ Haemostatic Matrix Kit with Thrombin***

This leaflet has information about SURGIFLO™ Haemostatic Matrix Kit with Thrombin, a product used to stop bleeding during your recent surgery. It does not contain all the information and if you have any questions, please talk to your healthcare team. All products have risks and benefits. Follow your healthcare team's advice even if it differs from what is in this leaflet. Please read this leaflet carefully and keep it in a safe place so you may refer to it in the future if needed.

Intended use

SURGIFLO™ Haemostatic Matrix Kit with Thrombin is used in surgical procedures (other than those related to the eyes) as an aid to stop a bleeding when ligature and other conventional methods to stop a bleeding are ineffective or impractical. Only the minimum amount of SURGIFLO™ Haemostatic Matrix Kit with Thrombin needed to stop a bleeding should be used.

Product Description

SURGIFLO™ Haemostatic Matrix Kit with Thrombin is a flowable gelatin matrix which is made of porcine gelatin and Thrombin. It provides an environment for cells in the blood to join and stick together, building on the natural blood clotting processes to stop bleeding.

Expected product Lifetime

SURGIFLO™ Haemostatic Matrix Kit with Thrombin has been applied during your surgery, and excess of SURGIFLO® Haemostatic Matrix Kit with Thrombin has been removed by the surgeon. Remains of SURGIFLO™ Haemostatic Matrix is completely absorbed by the body within 4-6 weeks.

Symptoms after use of SURGIFLO® Haemostatic Matrix Kit with Thrombin you should be aware of

Always contact your doctor or medical team if you have any signs of infection, swelling, or pain.

Adverse reactions

There is always a risk of adverse reactions with the use of any type of medical products. Some reactions could be due to your overall health condition and some reactions could be related to just having the surgery. Some reactions could be related to the product used during surgery. If any questions please contact your medical team.

Adverse events

In rare cases hypersensitivity or allergic reactions towards gelatin or Thrombin may occur. SURGIFLO™ Haemostatic Matrix Kit contains Thrombin made from human plasma. Products made from human plasma may carry a risk of transmitting infectious agents, such as viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. The risk of transmitting an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and removing certain viruses. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown

infectious agents may be present in such products. The physician should discuss the risks and benefits of this product with the patient. The measures taken are considered effective for enveloped viruses such as HIV, HCV, HBV, and for the non-enveloped virus HAV. The measures taken may be of limited value against non-enveloped viruses such as parvovirus B19. Parvovirus B19 infection may be serious for pregnant women (foetal infection) and for individuals with immunodeficiency or increased erythropoiesis (e.g. haemolytic anaemia).

If any questions please contact your medical team.

Reporting Adverse Effects

If you wish to report any adverse effects you believe are a result of use of SURGIFLO® Haemostatic Matrix Kit with Thrombin during your recent surgery, please speak with your medical team or report the information to Johnson & Johnson Medical Product Safety Department at productsafetyjjmanz@its.jnj.com or the Therapeutic Goods Administration at <https://www.tga.gov.au>

For access to this leaflet, please visit: <https://www.jnjmedicaldevices.com/en-AU/patient-information-leaflets>

Sponsor

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