



## INDICATIONS<sup>2</sup>:

FLOSEAL Matrix is indicated in surgical procedures (other than in ophthalmic) as an adjunct to haemostasis when control of bleeding, ranging from oozing to spurting, by ligature or conventional procedures is ineffective or impractical

### WHEN TO USE

- **Active bleeding**  
Open and laparoscopic procedures

### WHY USE

- **Stops bleeding in 2 mins or less<sup>1,2</sup>**

### WHO PREPARES

- **Scout** (Non-Sterile)- reconstitute thrombin & ¼ turn.
- **Scrub** (Sterile)- mix thrombin & gelatine granules.

### HOW IT WORKS

- Gelatin initiates contact activation and Floseal granules swell (10-20%) creating a **Tamponade effect**.
- Thrombin converts Fibrinogen forming a **stable fibrin clot. Then irrigate.**

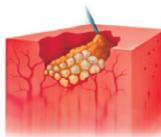
Floseal IFU indicates FLOSEAL Matrix may be used up to 8 hours.



## MECHANISM OF ACTION:

Biophysical Haemostasis<sup>1,2</sup>

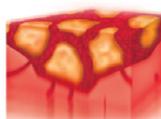
- 1 Floseal is applied to the tissue surface at the base of the lesion. Its granules fill the wound and conforms to its shape.



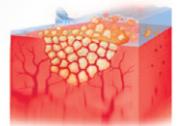
- 2 Floseal granules expand approximately 20% within about 10 minutes and physically restrict the flow of blood. Blood percolates through the spaces and is exposed to thrombin.



- 3 A clot forms around the mechanically stable matrix provided by the granules. The structural integrity of the gelatin fibrin matrix enables it to remain in place at the tissue surface.



- 4 Floseal granules not incorporated in the clot should be removed with gentle irrigation without disrupting the haemostatic seal.



- 5 Floseal is resorbed by the body within 6-8 weeks, consistent with the time frame of normal wound healing.





## ORDERING INFORMATION

Description	Qty	Order Code	Rebate Code
Floseal Haemostatic Matrix 5mL VHS	1 Each	1504610	BX258
Floseal Haemostatic Matrix 10mL VHS	1 Each	1504612	BX259
EasyGrip FLO-41 Endoscopic applicator 41cm	Box of 6	ADS201865	BX341
Endoscopic Applicator 41cm	Box of 6	0600125	BX273
Malleable & Trimmable Applicator Tips 14 cm	Box of 6	1502186	BX282

### References:

1. Oz MC, Cosgrove DM, Badduke BR, et al. Controlled clinical trial of a novel hemostatic agent in cardiac surgery. *Ann Thorac Surgery*, 69(5): 1376-82, 2000.
2. Floseal Haemostatic Matrix Indications For Use, 04/2012.

FLOSEAL is indicated in surgical procedures as an adjunct to haemostasis when control of bleeding, ranging from oozing to spurting, by ligature or conventional procedures is ineffective or impractical.

### CONTRAINDICATIONS

Do not use FLOSEAL in patients with known allergies to materials of bovine origin.

### WARNINGS

Do not inject or compress FLOSEAL into blood vessels.

Do not apply FLOSEAL in the absence of active blood flow, e.g., while the vessel is clamped or bypassed. Extensive intravascular clotting and even death may result.

FLOSEAL is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for haemostasis.

FLOSEAL is not intended to be used as a prophylactic haemostatic agent to prevent postoperative bleeding.

Excess FLOSEAL Matrix (material not incorporated in the haemostatic clot) should always be removed by gentle irrigation from the site of application. Meticulous irrigation is required when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, the brain and/or cranial nerves.

As with any implantable material, the use of FLOSEAL is not recommended in the presence of an active infection.

FLOSEAL should be used with caution in contaminated areas of the body. If signs of infection or abscess develop where FLOSEAL has been applied, re-operation may be necessary in order to remove the infected material and allow drainage.

Regardless of the type of surgical procedure, surgeons should consider the maximum swell volume of FLOSEAL, which is between 10 – 20%, after product is applied to source of bleeding and its potential effect on the surrounding anatomic areas. Maximum swell volume is achieved within about 10 minutes.

The safety and effectiveness of FLOSEAL for use in ophthalmic procedures has not been established.

FLOSEAL should not be used for controlling intrauterine post-partum bleeding or menorrhagia.

The safety and effectiveness of FLOSEAL has not been established in children and pregnant women.

Do not use FLOSEAL in the closure of skin incisions because it may interfere with the healing of the skin edges due to mechanical interposition of gelatin. The safety and effectiveness of the use of FLOSEAL Matrix as a carrier for antibiotic solutions or powders has not been established.

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