Haemostasis in Cardiovascular Surgery with FLOSEAL Hemostatic Matrix
A Unique Combination

FLOSEAL Hemostatic Matrix’s patented gelatin granules and human thrombin provide fast and effective haemostasis.¹²

• Specially-designed round-shaped patented gelatin granules allow a large contact surface with thrombin for fast efficacy
• Thrombin converts fibrinogen into a stable fibrin clot¹
• Works at the beginning and the end of the clotting cascade, for action less susceptible to coagulopathies from factor deficiencies or platelet dysfunctions¹

IFU Comparison¹⁰

*Gelatin and cellulose do not contain thrombin.
Benefits of FLOSEAL Hemostatic Matrix in Cardiovascular Surgery

- Stops bleeding fast in 2 minutes\(^\#\)
- 3x faster at stopping bleeding than Gelfoam with Thrombin\(^1\)
- Can be applied to wet actively bleeding tissue or pooled blood sites\(^2\)
- Only haemostatic agent proven effective on all degrees of bleeding from oozing to spurting\(^1\)
- Proven 89% effective in heparinised cardiac patients within 10 minutes\(^3\)

\(^\#\) Stopped bleeding in 2 minutes (median time to haemostasis) in patients undergoing cardiac, vascular, or spinal/orthopedic surgery; some, but not all patients received heparin and/or protamine.

\(^1\) Gelfoam & Thrombin

\(^2\) floSeal hemostatic matrix

\(^3\) FloSeal & Gelfoam & Thrombin

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Reduced transfusion of blood products (%)

<table>
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<tr>
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<th>FLOSEAL Group (n=110)</th>
<th>COMPARATOR Group (n=104)</th>
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<tr>
<td>Percentage of Patients Receiving Transfusion</td>
<td>28.2%</td>
<td>60.6%</td>
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Proven 89% effective in heparinised patients within 10 minutes

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<tr>
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<th>FLOSEAL Hemostatic Matrix</th>
<th>GELFOAM &amp; THROMBIN</th>
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<tr>
<td>% Hemostasis Success Within 10 Minutes Before Protamine Administration</td>
<td>89%</td>
<td>36%</td>
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</table>
FLOSEAL may be used for haemostasis in any cardiovascular procedure where there are wet, active bleeding sites such as:

- Epicardial bleeding
- Arterial suture line bleeding
- Sternal edge bleeding
- Bleeding arising from generator site implantation pocket
- Anastomotic sites
- Vein harvest beds
FLOSEAL Hemostatic Matrix Application*
Endoscopic Vessel Harvesting

Easy, precise FLOSEAL delivery to the vein harvest site through the FLOSEAL laparoscopic applicator in the presence of active bleeding.

Endoscopic Applicator cannula is attached to the luer lock syringe containing FLOSEAL. The plunger of the syringe is depressed to fill the cannula with FLOSEAL.

The syringe is detached and the preloaded applicator is inserted through the trocar and down to the base of tunnel. The stylet is inserted into the applicator cannula and held spatially while the cannula is retracted against the stylet; thereby laying down a 2mm bead along the length of the tunnel.

The tunnel is approximated to ensure that the FLOSEAL properly interacts with the bleeding sites through the tunnel. If a specific area is bleeding more profusely, FLOSEAL can be applied more liberally in that area.

*For the instructions on preparation of the thrombin, please consult your IFU.
As the irrigation device is retracted from the tunnel, the tunnel is gently flushed by depressing the syringe to remove any excess FLOSEAL.

When the leg incision is ready for closure, the irrigation device is inserted back into the tunnel. A 20mL luer-lock syringe filled with sterile saline is attached to the end of the irrigator.

Once FLOSEAL has been applied to satisfaction, the incision hole is then plugged with an X-ray detectable resorbable sponge (e.g. Raytec sponge) and left until after the patient comes off the cardiopulmonary bypass machine.
CABG Procedure – Sternal Edge Bleeding

1. Apply FLOSEAL to active bleeding along both sides of the suture line.

2. Gently approximate FLOSEAL with a moistened lap pad or moistened gauze for approximately 2 minutes to maintain product on site at the time of fibrin polymerization. NOTE: for heparinised patients, you may need to approximate for a longer period of time.

3. Once haemostasis is achieved, gently irrigate any excess FLOSEAL that has not been incorporated into the clot.
FLOSEAL is applied

Significant arterial bleeding due to an aortic tear in a proximal bypass anastomosis

Gently approximate FLOSEAL with a moistened lap pad or moistened gauze for approximately 2 minutes to maintain product on site at the time of fibrin polymerization. NOTE; for heparinised patients, you may need to approximate for a longer period of time.

Once haemostasis is achieved, gently irrigate any excess FLOSEAL that has not been incorporated into the clot.
Tips for Application

1. **Swoosh**
   Transfer the gelatin matrix-thrombin solution mixture back and forth between the syringes for a total of at least twenty passes.

2. **Place**
   Identify the source of bleeding at the tissue surface. This is the target site for FLOSEAL Matrix application. Do not inject FLOSEAL Matrix into blood vessels.

3. **Approximate**
   Manually approximate a gauze sponge moistened with sterile (non-heparinised) saline against the bleeding surface. Use the applicator tip to dispense FLOSEAL between the sponge and the bleeding surface.

4. **Rinse and Continue**
   After approximately two minutes, lift the gauze sponge and inspect the wound site.
   If bleeding has ceased, excess FLOSEAL Matrix (not incorporated in the hemostatic clot) should be removed by gentle irrigation. FLOSEAL may be reapplied if necessary to control bleeding.
1. **Can I use FLOSEAL Hemostatic Matrix while on cardiopulmonary bypass?**

As long as there is active bleeding, the current techniques for FLOSEAL application are:

1. Prior to initiating the use of FLOSEAL, remove cardiopulmonary bypass suction tips from the surgical wound and exchange for a wall suction device.
2. Apply FLOSEAL according to the IFU until haemostasis is satisfactory.
3. Gently irrigate excess FLOSEAL with your preferred irrigation solution, using the wall suction to remove all loosened matrix. All matrix not removed by gentle irrigation is incorporated into the fibrin clot and should be left in situ.

2. **Can I use FLOSEAL Hemostatic Matrix for vein harvesting?**

FLOSEAL is effective on surgical bleeding, from oozing to spurting. The endoscopic applicator may be utilized in this difficult-to-reach area.

3. **Can I use FLOSEAL Hemostatic Matrix in the absence of bleeding?**

FLOSEAL should not be used in the absence of active blood flow.

4. **Can FLOSEAL Hemostatic Matrix be used in the same procedure that a cell saver is being used?**

The use of FLOSEAL with a cell saver is not contraindicated. Make sure to use proper technique when using FLOSEAL in conjunction with a cell saver. As with other haemostatic agents, FLOSEAL should not be aspirated into autologous blood salvage circuits. The technique currently used to ensure that FLOSEAL is not aspirated into such devices is as follows:

1. Prior to initiating the use of FLOSEAL, remove blood salvaging suction tips from the surgical wound and exchange for a wall suction device.
2. Apply FLOSEAL according to the IFU until haemostasis is satisfactory.
3. Gently irrigate excess FLOSEAL with your preferred irrigation solution, using the wall suction to remove all loosened matrix. All matrix not removed by gentle irrigation is incorporated into the fibrin clot and should be left in situ.

5. **Can FLOSEAL Hemostatic Matrix be used with other hemostatic and sealing products?**

There are no contraindications surrounding use of FLOSEAL with other products. The use of FLOSEAL with other products has not been investigated.
References

8. Tisseel VH Fibrin Sealant [Instructions For Use]. Deerfield, IL: Baxter International Inc; 2009.

FLOSEAL [Hemostatic Matrix] Indications

FLOSEAL is indicated in invasive*1 or surgically invasive*2 procedures as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.

*1 Invasive means penetration inside the body through a body orifice

*2 Surgically invasive means penetration inside the body through the surface of the body, with the aid or in the context of a surgical operation

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. For a complete list of all warnings please refer to your IFU.
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<th>Description</th>
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<td>1502186</td>
<td>Malleable/Trimmable Tips</td>
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☐ Please add FLOSEAL to my preference card.

Surgeon name (please print) ______________________________________

Signature ___________________________________________ Date ________

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