FLOSEAL Hemostatic Matrix is applied to the tissue surface at the base of the lesion. Its granules fill the wound and conform to its shape. FLOSEAL granules expand approximately 20% within 10 minutes and physically restrict the flow of blood. Blood percolates through the spaces and is exposed to thrombin. 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. FLOSEAL granules not incorporated in the clot can and should be removed with gentle irrigation without disrupting the hemostatic seal.

FLOSEAL is resorbed by the body within 6–8 weeks, consistent with the time frame of normal wound healing.

Mechanism of Action: Biophysical Hemostasis

1. FLOSEAL stops bleeding in 2 minutes (median time to hemostasis).

2. Surgical Examples:
   - www.floseal.com
   - www.baxterbiosurgery.com

3. References:
   5. FLOSEAL Hemostatic Matrix Indications for Use, US, 03/2005
   6. FLOSEAL Hemostatic Matrix, Instructions for Use, Europe, 08/06
Stop Bleeding

**FAST**

†Please refer to the Instructions For Use for complete application techniques.

- Stops bleeding in 2 minutes (median time to hemostasis)
- Stops bleeding 96% of the time within 10 minutes
- Proven to control bleeding from oozing to pulsatile flow
- Effective among heparanized patients

Rapid, Effective, Consistent...

- Works on wet, actively bleeding tissue and conforms to irregular wound surfaces
- FLOSEAL Hemostatic Matrix can be applied to both hard and soft tissue
- FLOSEAL can be applied focally or dispensed and spread to cover a large area of diffuse bleeding

Convenient kit contains all items necessary for use, including bovine thrombin, and can be prepared in 60 seconds

Easy to Handle and Use

- Consequences of Surgical Bleeding
  - Prolonged Operating Time
  - Risk of Transfusion
  - Patient Complications
  - Decreased Visibility

- Treatment of Surgical Bleeding (Illustrative)

Controlled Prospective Clinical Trial

309 patients were randomized after bleeding was identified to FLOSEAL or bovine thrombin (Control) groups. Success was defined as hemostasis within 10 minutes and bleeding was checked at 1, 2, 3, 6 and 10 minutes. Bleeding was rated as "oozing," "flowing" or "pulsatile," with approximately one-third of the patients falling into the latter two categories.

FLOSEAL Thrombin soaked gelatin sponge

*Cumulative Percent of Patients with Complete Hemostasis per protocol analysis

**Controlled Prospective Clinical Trial**

N=309; Cardiovascular/Vascular/Spinal-Orthopedic Surgery

Collagen, cellulose and gelatin have limited haemostatic effect on heparinized patients or if platelet function is compromised by drugs or other means.
Stop Bleeding

**FAST**

- Please refer to the Instructions For Use for complete application techniques.
- Stops bleeding in 2 minutes (median time to hemostasis).
- Stops bleeding 96% of the time within 10 minutes.
- Proven to control bleeding from oozing to pulsatile flow.
- Effective among heparinized patients.
- Works on wet, actively bleeding tissue and conforms to irregular wound surfaces.
- FLOSEAL Hemostatic Matrix can be applied focally or dispensed and spread to cover a large area of diffuse bleeding.
- Convenient kit contains all items necessary for use, including bovine thrombin, and can be prepared in 60 seconds.
- Easy to handle and use.

**Consequences of Surgical Bleeding**
- Prolonged operating time
- Risk of transfusion
- Patient complications
- Decreased visibility

**Treatment of Surgical Bleeding**

**Haemostatic Agents in the Coagulation Cascade**

- Fibrinogen
- Fibrin monomer
- Fibrin polymer

- By providing thrombin, FLOSEAL starts activation

**Rapid, Effective, Consistent...**

- Faster bleeding in 2 minutes than in haemostatic agents.
- Stop bleeding 96% of the time within 10 minutes.
- Proven to control bleeding from oozing to pulsatile flow.
- Effective among heparinized patients.

**Easy to Handle and Use**

- Works on wet, actively bleeding tissue and conforms to irregular wound surfaces.
- FLOSEAL Hemostatic Matrix can be applied focally or dispensed and spread to cover a large area of diffuse bleeding.
- Convenient kit contains all items necessary for use, including bovine thrombin, and can be prepared in 60 seconds.

**Controlled Prospective Clinical Trial**

- 309 patients were randomized after bleeding was identified to FLOSEAL or bovine thrombin (control) groups. Success was defined as hemostasis within 10 minutes and bleeding was checked at 1, 2, 3, 6 and 10 minutes. Bleeding was rated as “oozing,” “flowing” or “pulsatile,” with approximately one-third of the patients falling into the latter two categories.

**Fibrous Agents in the Coagulation Cascade**

- Collagen, cellulose and gelatin have limited haemostatic effect on heparinized patients or if platelet function is compromised by drugs or other means.

**Conclusion**

- FLOSEAL Hemostatic Matrix applied here may prevent further consequences of surgical bleeding and helps save time, operating costs, product consumption and reduce stress in OR.

**Keyline for Dieline Only—Do Not Print**
Stop Bleeding
FAST

FLOSEAL Hemostatic Matrix is applied to the tissue surface at the base of the lesion. Its granules fill the wound and conform to its shape.

1. FLOSEAL is an elastic, gecko-like molecule that consists of gelatin fibrin granules
   that form a matrix when mixed with a thrombin solution.

2. FLOSEAL granules expand approximately 20% within 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 can and should be removed with gentle irrigation without disrupting the hemostatic seal.

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

Surgical Examples

Cardiac

- Bleeding in anastomotic site
- FLOSEAL application

Vascular

- Bleeding from PTFE needle holes
- FLOSEAL application

References

5. FLOSEAL Hemostatic Matrix Indications for Use, US, 03/2005
6. FLOSEAL Hemostatic Matrix, Instructions for Use, Europe, 08/06

When you have to work fast, FLOSEAL works at the speed you do because FLOSEAL stops bleeding in 2 minutes (median time to hemostasis).
FLOSEAL Hemostatic Matrix is applied to the tissue surface at the base of the lesion. Its granules fill the wound and conform to its shape. FLOSEAL granules expand approximately 20% within 10 minutes and physically restrict the flow of blood. Blood percolates through the spaces and is exposed to thrombin. 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. FLOSEAL granules not incorporated in the clot can and should be removed with gentle irrigation without disrupting the hemostatic seal. FLOSEAL is resorbed by the body within 6–8 weeks, consistent with the time frame of normal wound healing.

Mechanism of Action: Biophysical Hemostasis

1. Mechanical: FLOSEAL granules temporarily occlude the microvasculature, resulting in immediate reduction of blood flow. FLOSEAL granules are structurally similar to fibrinogen, which is a key component of the blood clotting cascade.

2. Physiochemical: FLOSEAL granules expand quickly within the wound, providing a physical barrier to blood flow. The expansion of the granules is due to the rapid release of thrombin from the wound, which in turn activates the clotting cascade.

3. Physical restriction: FLOSEAL granules physically restrict blood flow by occluding the microvasculature.

4. Chemical restriction: FLOSEAL granules release a variety of chemicals that promote clot formation, including thrombin and fibrinogen.

5. Biophysical restriction: FLOSEAL granules provide a mechanical barrier to blood flow, which can result in a delay in clot formation.

6. Biophysical restriction: FLOSEAL granules provide a mechanical barrier to blood flow, which can result in a delay in clot formation.

Surgical Examples

1. Cardiac
2. Vascular
3. Bariatric
4. Endoscopic

References

5. FLOSEAL Hemostatic Matrix Indications for Use, US, 03/2005
6. FLOSEAL Hemostatic Matrix, Instructions for Use, Europe, 08/06

When you have to work fast, FLOSEAL works at the speed you do because FLOSEAL stops bleeding in 2 minutes (median time to hemostasis).
**Mechanism of Action: Biophysical Hemostasis**

1. **FLOSEAL** is applied directly to the tissue surface at the base of the lesion. Its granules fill the wound and conform to its shape.

2. **FLOSEAL** granules expand approximately 20% within 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 can and should be removed with gentle irrigation without disrupting the hemostatic seal.

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

**Surgical Examples**

**Cardiac**
- Anastomotic site
- Needle holes
- Other sites

**Vascular**
- Bleeding from vein, artery, or aorta
- Arteriovenous shunts
- PTFE needle holes
- After vascular surgery

**References**

5. FLOSEAL Hemostatic Matrix Indications for Use, US, 03/2005
6. FLOSEAL Hemostatic Matrix, Instructions for Use, Europe, 08/06

When you have to work fast, FLOSEAL works at the speed you do because FLOSEAL stops bleeding in **2 minutes** (median time to hemostasis).