Haemostasis in Spine Surgery with FLOSEAL Hemostatic Matrix
A Unique Combination

FLOSEAL Hemostatic Matrix’s patented gelatin granules and human thrombin provide fast and effective hemostasis.1,2

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

IFU Comparison3,4

*Gelatin and cellulose do not contain thrombin.
Benefits of FLOSEAL Hemostatic Matrix for Spine Surgery

- Stops bleeding fast in 90 seconds (median time to haemostasis)\(^1\)
- Improves visualization and speeds up re-access to the surgical field\(^1\)\(^4\)
- Helps protect against rebleeding by forming a mechanically stable clot\(^2\)
- Effective on bone bleeding and can be applied to blood submerged sites\(^4\)
- Proven 89% effective in heparinized patients within 10 minutes\(^3\)

*Haemostasis achieved with FLOSEAL with a single application in a laminectomy procedure.*
FLOSEAL may be used in any spine procedure where there is active bleeding.

Potential active bleeding sites include:

- Cut bone surfaces
  - Intervertebral foramina
  - Vertebral body subchondral bone
- Paravertebral musculature
- Pilot hole oozing
- Epidural and venous plexus oozing
- Facet decalcified surfaces
- Cut laminar surfaces

Several applicator tips are available to make FLOSEAL application easier in difficult-to-reach locations.
FLOSEAL may be used on punctuate bleeding from the cortical bone

After FLOSEAL is applied to the bleeding surface, gently approximate a moistened gauze or cottonoid pledget for approximately 2 minutes to maintain product on site at the time of fibrin polymerization

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

*For the instructions of the preparation of the thrombin solution, please consult your IFU.
FLOSEAL may be used for bleeding from the cancellous bone surfaces

After FLOSEAL is applied to the bleeding surface, gently approximate a moistened gauze or cottonoid pledget for approximately 2 minutes to maintain product on site at the time of fibrin polymerization

Once haemostasis is achieved, gently irrigate any excess FLOSEAL Hemostatic Matrix that has not been incorporated into the clot
FLOSEAL may be used for bleeding from the epidural veins, after the nerve root is retracted to expose disc space in order to perform the discectomy.

After FLOSEAL is applied to the bleeding surface, gently approximate a moistened gauze or cottonoid pledget for approximately 2 minutes to maintain product on site at the time of fibrin polymerization.

Once haemostasis is achieved, gently irrigate any excess FLOSEAL Hemostatic Matrix that has not been incorporated into the clot.
FLOSEAL may be used for bone bleeding from the interspace, prior to performing posterior lumbar interbody fusion, and once the discectomy is performed.

After FLOSEAL is applied to the bleeding surface, gently approximate a moistened gauze or cottonoid pledget for approximately 2 minutes to maintain product on site at the time of fibrin polymerization.

Once haemostasis is achieved, gently irrigate any excess FLOSEAL Hemostatic Matrix 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-heparinized) 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 haemostatic clot) should be removed by gentle irrigation. FLOSEAL may be reapplied if necessary to control bleeding.
1. **Can FLOSEAL Hemostatic Matrix be used on bony areas that will be fused?**
FLOSEAL is effective on all types of bleeding from oozing to spurting. Enough blood needs to be present for FLOSEAL to work, as it needs to interact with patient’s fibrinogen and platelets to be activated. Excess FLOSEAL (material not incorporated in the haemostatic clot) should be removed by gentle irrigation from the site of application, particularly when used in, around, or in proximity to foramina in bone, confined bony areas on the spinal cord, and/or the optic nerve and chiasm.

2. **Can FLOSEAL Hemostatic Matrix be used around nerves/dura?**
Yes. FLOSEAL has been used in various types of cervical and lumbar procedures. When placed into cavities or closed tissue spaces, gentle approximation is advised. When applied to a bleeding site, the particles of FLOSEAL Matrix swell approximately 20% upon contact with blood or other fluids. Maximum swell volume is achieved within about 10 minutes.

3. **Does FLOSEAL Hemostatic Matrix seal the dura or dural tears?**
No. FLOSEAL should not be used to seal dural tears. FLOSEAL acts as a haemostat only, and is not a sealant.
References


**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.
I would like to have the following products and quantities available:

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Surgeon name (please print) ____________________________________________

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