Floseal
Hemostatic Matrix

# How to prepare Floseal 5mL & 10mL


## Outside The Sterile Field

Sodium chloride solution syringe

Thrombin Vial

Needle-free Vial Adapter

## Inside the Sterile Field

Thrombin Bowl

Empty syringe

FLOSEAL Gelatin Matrix

Applicator Tips



**Floseal 10mL Only**

Malleable Tip

Luer connector

**Important Points**

**STORE** at room temperature

**USE** within 8 hours after mixing

## 1 Preparing the Thrombin Solution

Instruction for Scout Nurse – Outside the sterile field


**Remove caps** from NaCl syringe and Thrombin vial


**Attach** NaCl syringe to vial adapter


**Connect** the vial adapter to Thrombin vial and transfer NaCl solution into vial


**Gently swirl** until Thrombin powder dissolves


**To facilitate transfer, quarter turn** the syringe and re-tighten before aspirating Thrombin solution into the attached syringe

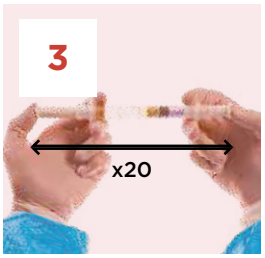

Scout nurse **transfer Thrombin solution** into bowl on sterile field

## 2 Mixing the components

Instruction for Scrub Nurse – Inside the sterile field


**Aspirate Thrombin solution** to empty syringe
5ml: Aspirate 4ml
10ml: Aspirate 8ml and attach luer connector


Remove cap from gelatin syringe. **Connect gelatin and Thrombin syringes**




Push Thrombin solution into gelatin syringe. **Mix together for 20 passes**

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# Floseal® Hemostatic Matrix

**Abreviated Instructions for Use**

**DO NOT INJECT.** Floseal Hemostatic Matrix ("Floseal Matrix") must not be injected into blood vessels.

## Indications

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

## Contraindications

- Do not inject or compress Floseal Matrix into blood vessels. Do not apply Floseal Matrix in the absence of active blood flow, eg., to clamped or bypassed vessels as extensive intravascular clotting & even death may result.
- To avoid a risk of allergic-anaphylactoid reaction and/or thromboembolic events, which may be life-threatening, do not inject Floseal Matrix into a vessel or tissue.
- Do not use Floseal Matrix in the closure of skin incisions because it may interfere with the healing of the skin edges due to mechanical interposition of gelatin.
- Do not use Floseal Matrix in patients with known allergies to materials of bovine origin.

## Warnings

- Floseal Matrix contains Thrombin made from human plasma. Products made from human plasma may contain infectious agents that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening and 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. The physician should discuss the risks and benefits of this product with the patient.
- FLOSEAL Matrix is not intended as a substitute for meticulous surgical technique or other conventional procedures for hemostasis.
- Excess FLOSEAL Matrix (material not incorporated in the hemostatic 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.
- FLOSEAL Matrix swells by approximately 10-20% after product is applied and surgeons should consider its potential effect on the surrounding anatomic areas. Maximum swell volume is achieved within about 10 minutes.
- FLOSEAL Matrix should not be used in the presence of infection. FLOSEAL Matrix should be used with caution in contaminated areas of the body.

## Precautions

- For single use only. Do not resterilize.
- Since the Thrombin Solution can be denatured by contact with solutions containing alcohol, iodine, or heavy metalions, Floseal Matrix should not be applied before the application site is cleaned to remove any antiseptics that may contain such substances.
- 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.
- As with other hemostatic agents, do not aspirate Floseal Matrix into extracorporeal cardiopulmonary bypass circuits or autologous blood salvage circuits. It has been demonstrated that fragments of collagen based hemostatic agents may pass through 40um (ie: micron) transfusion filters of blood scavenging systems.
- Floseal Matrix should not be used in conjunction with methylmethacrylate or other acrylic adhesives. Microfibrillar collagen has been reported to reduce the strength of methylmethacrylate adhesives used to attach prosthetic devices to bone surfaces.
- Floseal Matrix should not be used for the primary treatment of coagulation disorders. • The safety and effectiveness of the combined use of Floseal Matrix with antibiotic solutions or powders has not been established.
- The safety and effectiveness for use in neurosurgical and urological procedures has not been established through randomized clinical study.
- In urological procedures, Floseal Matrix should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.
- Circumstances that result in a negative peripheral venous pressure (eg: patient positioning) may draw material into the vascular system, potentially resulting in life threatening events.
- The Applicator tips should not be cut

## Floseal Adverse Effects

In a randomized prospective, concurrently controlled clinical trial using a formulation of Floseal Matrix containing bovine Thrombin, (Floseal), a total of 309 patients received Floseal or the Control (Gelatin Sponge+ Thrombin). The most common adverse events recorded during and after the application of the hemostatic agents were anemia, atrial fibrillation, infection, and hemorrhage. The following is a complete list of adverse events reported in greater than 1 % of patients that were observed in the pivotal clinical trial for the Floseal group. The corresponding adverse events for the Control group are listed for comparison. None of the adverse events that occurred were judged by the surgeon to be "Probably Related" to the use of Floseal. Other adverse events observed in 1 % or less of the Floseal clinical trial patients were myocardial infarction, cellulitis, pneumo thorax, pain, cerebrovascular accident, hallucination, paresthesia, bradycardia, abscess, diarrhea, urinary retention, dehiscence, skin ulcer, transfusion reaction, dyspnea, heart arrest, lung edema, back pain, ventricular tachycardia, neuropathy, acute kidney failure, kidney tubule necrosis, gastritis, nausea and vomiting, skin rash, hyperglycemia, and heel ulcer.

The following adverse events, all rated "mild'; were deemed by the surgeon to be "Possibly Related" to the use of Floseal: anemia (2 patients, 1 %), mild postoperative bleeding (1 patient, <1 %), and local inflammation (1 patient, <1 %). No other adverse events were deemed by the surgeon to be related to the use of Floseal. Allergic reactions may be encountered in people known to be sensitive to bovine materials.

**Adverse Events Reported in Greater than 1% of Patients in the FLOSEAL Matrix Clinical Trial**

| Adverse Events | FLOSEAL Matrix | Control (Gelatin Sponge + Thrombin) |
|---|---|---|
| Anemia | 12 (8%) | 7 (4%) |
| Fibrillation Atrial | 10 (6%) | 8 (5%) |
| Infection | 10 (6%) | 11 (7%) |
| Hemorrhage | 6 (4%) | 6 (4%) |
| Pneumonia | 6 (4%) | 2 (1%) |
| Urinary Tract Infection | 6 (4%) | 3 (2%) |
| Rash | 5 (3%) | 3 (2%) |
| Edema | 5 (3%) | 1 (<1%) |
| Hypotension | 4 (3%) | 2 (1%) |
| Respiratory Distress | 4 (3%) | 3 (2%) |
| Confusion | 4 (3%) | 0 (0%) |
| Dural Tear | 4 (3%) | 4 (3%) |
| Fibrillation Ventricular | 4 (3%) | 3 (2%) |
| Arrhythmia | 4 (3%) | 0 (0%) |
| Heart Failure Right | 3 (2%) | 2 (1%) |
| Thrombosis Arterial | 3 (2%) | 8 (5%) |
| Fever | 3 (2%) | 2 (1%) |
| Atelectasis | 3 (2%) | 1 (<1%) |
| Pleural Effusion | 3 (2%) | 5 (3%) |

**Counts reflect number of patients in each treatment group reporting one or more adverse events that map to a Modified COSTART 5th edition body system. At each level of summerization (Adverse Event), patients are only counted once.**

## How Supplied

| | |
|---|---|
| **Gelatin Matrix Component (Floseal 5mL)**<br>• 1 x 5mL Syringe with Gelatin Matrix<br>• 1 x 5mL syringe for Matrix preparation with integral female Luer connector<br>• 1 x bowl for Thrombin<br>• 1 x 'Thrombin' sticker for Bowl<br>• 2 x Applicator tips | **Gelatin Matrix Component (Floseal 10mL)**<br>• 1 x 10mL Syringe with Gelatin Matrix<br>• 1 x 5 mL syringe for Matrix preparation with integral female Luer connector<br>• 1 x bowl for Thrombin<br>• 1 x 'Thrombin' sticker for Bowl<br>• 2 x Applicator tips'<br>• 1 x Malleable tip |
| **Thrombin Component (Floseal 5mL)**<br>• 1 x 5mL Syringe with Gelatin Matrix<br>• 1 x 5mL syringe for Matrix preparation with integral female Luer connector<br>• 1 x bowl for Thrombin<br>• 1 x 'Thrombin' sticker for Bowl<br>• 2 x Applicator tips | **Gelatin Matrix Component (Floseal 10mL)**<br>• 1 x vial Thrombin (Human), Vapor<br>• Heated, Solvent/Detergent treated, 5000 units<br>• 1x Pre-filled 0.9% Sodium Chloride<br>• Solution syringe, 10mL, USP Injection<br>• 1x Needle-free vial adapter<br>• 1x "Thrombin" sticker for Syringe. |

*The package also includes this Floseal Hemostatic Matrix Instructions for Use.*



Refer to Full Instructions for Use before prescribing. Full Instructions For Use is available from Baxter Medical Information 1300 302 409 or onecall@baxter.com

**For more information or a demonstration of the FLOSEAL Hemostatic Matrix Kit with needle-free adapter, please see your Baxter Product Specialist**

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