**Baxter**

**FLOSEAL Hemostatic Matrix, 5 mL/20 mL**

**Manufacturing Details:**
- Baxter: 07-10-18 DMAT
- Date: 04/10/2018
- No.: 1
- Baxter Reference: 1

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**Indications:**

- **Carcinogenesis, Mutagenesis, Impairment of Fertility:**
  - Baxter is contraindicated in patients with bovine allergies.
- **Virus Reduction Factor:**
  - Baxter is contraindicated in patients with BVDV PPV virus.

- **Warnings:**
  - Baxter is contraindicated in patients with bovine allergy.
- **Contraindications:**
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Use of FLOSEAL Matrix as a Hemostatic Agent for Nasal/Sinus Bleeding:

FLOSEAL Matrix is indicated as a hemostatic agent for the control of bleeding during or between operations in the nasal cavity, sinuses, or paranasal sinuses of patients with non-neoplastic conditions and who are undergoing sinus surgery. The FLOSEAL Matrix Hemostatic Matrix Kit is intended for one use, or for use on a single patient during a single procedure. It is not intended for use on more than one patient. 

FLOSEAL Matrix is placed on the bleeding site to deliver fresh FLOSEAL Matrix as close as possible to the tissue surface. After re-application of the FLOSEAL Matrix, no systemic absorption occurs. The FLOSEAL Matrix is non-toxic and is absorbed in the body. Do not re-use.

For best results, FLOSEAL Matrix should be in complete contact with the bleeding tissue surface. The portion of the FLOSEAL Matrix that is not in contact with blood or other fluids will be non-adhesive and can be removed. Maximum volume is achieved within 10 minutes.

For tissue defects that are greater than 1/2" in diameter, begin applying FLOSEAL Matrix in a circular pattern around the bleeding defect, and allow it to dry in place. This will create enough adhesive pressure to aid in the control of bleeding. Apply additional FLOSEAL Matrix to the non-adhesive portion of the previously applied Matrix if it is not in sufficient contact with the defect.

FLOSEAL Matrix, Thrombin Solution, and Thrombin Adaptor Components

- 1 x Thrombin (Thrombin 0.4 units/mL Solution)
- 1 x Thrombin Adapter
- 1 x Clotting Activator Solution
- 1 x Gelatin Matrix Pouch
- 5 mL Kit

Preparing the Thrombin Solution

- Remove and discard the Luer cap from the Gelatin Matrix Pouch.
- Insert the Thrombin syringe into the Thrombin vial. Push the plunger to expel the excess contents of the vial.
- Tilt the syringe to dislodge any Thrombin that may have adhered to the syringe adapter.
- Loosen the syringe connection one quarter turn to allow the Thrombin to flow smoothly.
- With a gentle upward motion, attach the Thrombin vial and Thrombin adapter to facilitate reconstitution of the Thrombin by holding the Thrombin adapter to deliver fresh FLOSEAL Matrix as close as possible to the tissue surface. Apply additional FLOSEAL Matrix to the non-adhesive portion of the previously applied Matrix if it is not in sufficient contact with the defect.

Add 2 mL of Thrombin to the Clotting Solution. Stir the mixture gently for up to 10 minutes. When ready to prepare the FLOSEAL Matrix, disconnect the Thrombin syringe from the Thrombin Adapter and process it with the Thrombin Adaptor so that the Thrombin is in contact with the Clotting Solution. Gently stir the mixture for up to 10 minutes. Do not apply the mixture to the FLOSEAL Matrix until it reaches a "mound" of material at the source of bleeding. Apply enough FLOSEAL Matrix to create a small "mound" of material at the source of bleeding.

Use of FLOSEAL Matrix as a Hemostatic Agent for Nasal/Thoracic Aortic Operations:

FLOSEAL Matrix is indicated as a hemostatic agent for the control of bleeding during or between operations in the nasal cavity, sinuses, or paranasal sinuses of patients with non-neoplastic conditions and who are undergoing sinus surgery. The FLOSEAL Matrix is intended for use on a single patient during a single procedure. It is not intended for use on more than one patient.

FLOSEAL Matrix is intended for use in the nasal cavity, sinuses, or paranasal sinuses of patients with non-neoplastic conditions and who are undergoing sinus surgery. The FLOSEAL Matrix is non-toxic and is absorbed in the body. Do not re-use.

For tissue defects that are greater than 1/2" in diameter, begin applying FLOSEAL Matrix in a circular pattern around the bleeding defect, and allow it to dry in place. This will create enough adhesive pressure to aid in the control of bleeding. Apply additional FLOSEAL Matrix to the non-adhesive portion of the previously applied Matrix if it is not in sufficient contact with the defect.

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Applying the FLOSEAL Matrix after completing the preparation and mixing steps:

- Once reconstituted, the Thrombin Solution is used to prepare FLOSEAL Matrix as an applicator tip. Thrombin is added as needed to reconstitute the Thrombin Solution.
- Apply the Thrombin Solution to the Bleeding site to allow the Thrombin to engage the blood. Apply the Thrombin Solution to the tissue surface to create a mucosal seal. After re-application of the FLOSEAL Matrix, no systemic absorption occurs. The FLOSEAL Matrix is non-toxic and is absorbed in the body.

Avoid applying the Thrombin Solution to the bleeding site. Do not inject the Thrombin Solution into blood vessels or into the body. Do not inject the Thrombin Solution into the body. Do not inject the Thrombin Solution into the body.

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Application Technique:

- Identify the source of bleeding at the tissue surface. This is the area into which FLOSEAL Matrix will be applied.
- Monitor application of the FLOSEAL Matrix and Thrombin Solution to ensure that the entire bleeding surface is covered. Apply the FLOSEAL Matrix as a "mound" of material at the source of bleeding. Apply additional FLOSEAL Matrix to the non-adhesive portion of the previously applied Matrix if it is not in sufficient contact with the defect.

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Avoid applying the Thrombin Solution to the bleeding site. Do not inject the Thrombin Solution into blood vessels or into the body. Do not inject the Thrombin Solution into the body. Do not inject the Thrombin Solution into the body.