Baxter

FLOSEAL Matrix Hemostatic Matrix, 5 mL/10 mL

Indications:
- FLOSEAL Matrix is indicated in surgical procedures (other than those involving the cavernous nerves) for the control of minor bleeding from surgical sites or surgical wounds where applications of Hemo-Stop or other hemostatic agents were anemia, atrial fibrillation, infection, shock therapy.

Contraindications:
- Do not use FLOSEAL Matrix in patients with known allergies to porcine materials.
- Do not use FLOSEAL Matrix in the case of serious systemic reactions to Thrombin.
- Do not use FLOSEAL Matrix in patients with known thrombocytopenia due to the risk of increased risk of thrombosis.

Warnings:
- FLOSEAL Matrix contains Thrombin from human plasma. Previously made from bovine plasma may be used as a substitute for Thrombin. This product is not indicated for use in patients with a history of allergy to bovine material.
- This product has been shown to contain natural thromboplastin activator and may cause the formation of a clot in the presence of normal platelets.
- The safety and effectiveness of FLOSEAL Matrix have not been established.

Precautions:
- Do not store FLOSEAL Matrix at temperatures above 37°C (98.6°F).
- Do not re-sterilize the FLOSEAL Matrix Kit.

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Use of FLOSEAL Matrix as a Hemostatic Agent for Nasal/Sinus Bleeding

FLOSEAL Matrix is a sterile, gelatin-based, hemostatic matrix sealant that contains bovine thrombin. It is indicated for use in the control of bleeding from surgical wounds after hemostasis has been achieved. FLOSEAL Matrix is supplied in a configuration shown in the table below.

<table>
<thead>
<tr>
<th>Component</th>
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<tbody>
<tr>
<td>Syringe</td>
<td>Contains 0.9% Sodium Chloride Solution and discards Thrombin solutions.</td>
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| Vial      | Contains Thrombin (Human), 5000 IU.
| Adaptor   | Connects Thrombin vial to the sterile inner pouch.
| Applicator | Used to deliver the sterile inner pouch to the sterile field. |
| Pouch     | Contains the FLOSEAL Matrix at the completion of mixing with the Thrombin solution. |

**FLOSEAL Matrix Placement/Reapplication Steps:**

1. **Identify the location of bleeding at the anterior surface.** This is the intended site for FLOSEAL Matrix application.
2. **Manually approximate a gum approximation with the patient in the sitting or supine position.** After the approximation is achieved, the gum approximation is removed from the site and the FLOSEAL Matrix is applied to the area. FLOSEAL Matrix is applied to the area in a thin layer, using gentle pressure to ensure complete coverage of the site.
3. **Cover the FLOSEAL Matrix approximation with a sterile gauze sponge.** Stabilize the gauze sponge for at least 3 minutes, or until the bleeding surface is dry. FLOSEAL Matrix is applied to the site in a thin layer, using gentle pressure to ensure complete coverage of the site.
4. **Release the vacuum in the vial, then re-tighten syringe.** If desired, dispense residual FLOSEAL Matrix from the tip while holding the syringe at a 90° angle from the target site.

**Application Technique:**

- **Do not inject the residual vials.** Include a syringe that contains an amount of the FLOSEAL Matrix that is not sufficient to complete the exposure.
- **Do not use a package that is damaged.** Include a syringe that contains an amount of the FLOSEAL Matrix that is not sufficient to complete the exposure.
- **Electrical stimulation induces a medical device that has been sterilized using radiation.**

**Storage Conditions:**

- **The FLOSEAL Matrix can be stored internal to 30°C (86°F).** Do not freeze.

**Symbols Reference on Packaging:**

- **Consult instructions for use (IFU), indicator; indicates the user must consult the instructions for use and the instructions for use are available in the electronic format.**
- **SDS - Standard and Symbol Number.**

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**Baxter Healthcare Corporation**
21026 Alexander Court
Bi-01874-001
Lake Oklawaha, FL 32759

**Baxter and Floseal are registered trademarks of Baxter Healthcare Corporation.**

**Surgical is a registered trademark of Pennsylvania Medical Supply, Inc.**

**Consult a surgeon before operation.**

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