Bovine viral diarrhea virus, a model for Hepatitis C provided in the table below.

- The manufacturing procedure for FLOSEAL Matrix includes derivatives of human plasma (see “Warnings”).
- The manufacturing procedure has been shown to be capable of significant viral inactivation. However, no procedure has been shown to be 100% effective in the removal of all infectious agents, such as viruses, that can cause disease.
- Patients in the FLOSEAL Clinical Trial

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

<table>
<thead>
<tr>
<th>Event</th>
<th>FLOSEAL Clinical (Control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>12%</td>
</tr>
<tr>
<td>Fibrillation</td>
<td>10%</td>
</tr>
<tr>
<td>Infection</td>
<td>10%</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>6%</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>4%</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>3%</td>
</tr>
</tbody>
</table>

### FLOSEAL Matrix Hemostatic Matrix, 16 Instructions for Use

- Do not use FLOSEAL Matrix in patients with known allergies of components of thrombin.
- Do not use FLOSEAL Matrix in the absence of adequate blood flow. (e.g., when the vessel is clamped or ligated, an external inflator catheter and even death may occur).
- To avoid a risk of allergic anaphylactic reaction and/or immunological events, which may be life-threatening, discontinue and notify FLOSEAL Matrix into a vessel or tissue.
- Do not use FLOSEAL Matrix in patients with known allergies of components of thrombin.

### Treatment

- FLOSEAL Matrix is contraindicated for patients who have a history of anaphylactic or other allergic reactions to gelatin, porcine, human fibrin, or inflammatory agents in their manufacture.
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### Adverse Events
Mixing the Thrombin Solution into the Gelatin Matrix
• Place the Thrombin Solution vial into a sterile field and the Gelatin Matrix syringe into the sterile field. Secure the vial and syringe to the sterile field with skin clips or ties.
• Open the Thrombin Solution vial and the Gelatin Matrix syringe. Be sure to retain the syringe plunger caps (blue or red luer). Do not use reconstituted preparations such as the former.
• Transfer the Thrombin Solution to the Gelatin Matrix syringe. Transfer the entire contents of the Thrombin Solution vial into the Gelatin Matrix syringe. To assist in transferring, gently push the plunger of the Thrombin Solution vial to expel the solutions into the Gelatin Matrix syringe. Ensure that the contents of the Thrombin Solution vial are completely mixed with the Gelatin Matrix syringe contents.

Use of FLOSEAL as a Hemostatic Agent for Nasal/ Sinus Bleeding:
• Apply FLOSEAL directly to the source of bleeding. FLOSEAL syringe and form a "mound" of material at the source of bleeding. The gauze sponge will hold FLOSEAL Matrix in place against the bleeding surface in the presence of active bleeding. Apply enough FLOSEAL Matrix to create a small "mound" of material at the source of bleeding.
• For tissue defects that are "hidden" or "buried," begin applying FLOSEAL Matrix at the deepest part of the lesion, and then randomly apply FLOSEAL Matrix to fill in other lesions. Use sufficient pressure from the syringe to cause thrombin to release from the syringe tip. The "back-filling" action will ensure the FLOSEAL Matrix comes into contact with the entire bleeding surface at the tissue defect.
• Apply a grasp sponge moistened with sterile (non-irritating) saline to approximate the FLOSEAL Matrix against the bleeding surface, conforming it to the lesion.
• After approximately 2 to 3 minutes, lift the grasp sponge and inspect the wound. Once bleeding has ceased, excess FLOSEAL Matrix (not incorporated in the hemorrhagic clot) should always be removed by gentle irrigation and suctioned away from the treated site.

Storing Conditions: The FLOSEAL Matrix syringe should be stored at 2°C to 8°C (36°F to 46°F). Do not freeze.

Diluted Application Steps
• Identify the source of bleeding at the tissue surface. This is the target site for FLOSEAL Matrix application.
• Manually approximate a grasp sponge moistened with sterile (non-irritating) saline to approximate the bleeding surface on the target site for FLOSEAL Matrix application.

FLOSEAL Hemostatic Matrix Configuration

Gelatin Matrix Component

1 x 10 mL vial, 10 g of Gelatin Matrix Component
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1 x 0.9% Sodium Chloride Solution syringe
1 x 0.9% Sodium Chloride Solution syringe
1 x Hemostatic Matrix syringe
1 x Hydrate "Thrombin" sticker for Bottle
1 x THROMBIN Matrix syringe
1 x THROMBIN Matrix syringe
1 x Malleable Applicator

Thrombin Component

1 x 9 mL vial, Thrombin (Human), Unlabeled
1 x 9 mL vial, Thrombin (Human), Unlabeled
1 x Hydrate "Thrombin" sticker
1 x THROMBIN Matrix syringe

The package also includes FLOSEAL Matrix Instructions for Use.

Directions for Use:
Thrombin should be added to the Gelatin Matrix prior to use. To prepare the contents of the FLOSEAL Matrix kit, the package or vials have been damaged or opened, do not use.

Opening the Package
• Place the Thrombin vial, pre-filled Sodium Chloride Solution syringe, and the tip adapter outside of the sterile field.
• Open the outer packaging containing the Gelatin Matrix component and deliver the sterile inner package to the sterile field. Once opened on the sterile field, the inner package may be opened at any time.

Preparing the Thrombin Solution
• Remove the packaging and Logistic cap from the pre-filled Sodium Chloride Solution syringe. Remove the plastic cap from the Thrombin vial. Discard the rubber stoppers of the vial with a germicidal solution and allow to dry. Do not use reconstituted preparations such as the former.
• Remove the lid from the vial adapter packaging. While gripping this vial adapter package, attach the pre-filled Sodium Chloride Solution syringe to the vial adapter and remove the remaining packaging from the vial adapter.
• While holding the vial adapter, pour the sterile Sodium Chloride Solution syringe into the vial adapter and secure the vial adapter in place. Discard the vial adapter package.
• Gently twist the Thrombin vial with adapter and suction attached to the Thrombin vial is completely dissolved. Once recrystallized, the Thrombin Solution can be used immediately or may be stored in the refrigerator for up to 72 hours.

For intraoperative applications:
• Apply a grasp sponge moistened with sterile saline to approximate the FLOSEAL Matrix against the bleeding surface, conforming it to the lesion. The gauze sponge will hold FLOSEAL Matrix in place against the bleeding surface in the presence of active bleeding. Apply enough FLOSEAL Matrix to create a small "mound" of material at the source of bleeding.
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For preoperative applications:
• Do not disassemble FLOSEAL Matrix into blood vessels. See the “Contraindications,” “Warnings,” “Precautions,” and “Adverse Events” sections contained in these Instructions for Use for a complete list of contraindications and warnings.

For intraoperative applications:
• Do not disassemble FLOSEAL Matrix into blood vessels. See the “Contraindications,” “Warnings,” “Precautions,” and “Adverse Events” sections contained in these Instructions for Use for a complete list of contraindications and warnings.

Caution: Federal Law (United States) restricts this device to sale by or on the order of a healthcare provider.