For the manufacture of the Gelatin Matrix component are

wound healing. FLOSEAL Matrix is intended only for topical

component and the reconstituted Thrombin (Human)

Parvovirus B19. Pseudorabies virus, a model for enveloped DNA

Hepatitis A

• Pseudorabies virus, a model for enveloped DNA

Virus Reduction Factor

BVDV  PPV

Factor (ORF)>14.0 >6.4 >12.6 >15.6 5.8 >5.7

Base Treatment (NaOH) >5.4 4.0

Chromatography n.d. n.d. n.d. n.d. 3.6 n.d.

Virus

• Toxic shock syndrome was reported in association with the use of FLOSEAL Matrix as an adjunct to hemostasis when control of

• The safety and effectiveness of FLOSEAL Matrix has not been established in patients with concomitant upper respiratory tract infection and/or acute viral upper respiratory tract infection and/or acute viral or bacterial sinusitis.

• Do not use FLOSEAL Matrix into a vessel or tissue.

• Do not use FLOSEAL Matrix in patients with lower and anaphylactic reactions may occur in rare cases. No adverse

• In urological procedures, FLOSEAL Matrix should not be left

• As with other hemostatic agents, do not aspirate

• When placed into cavities or closed tissue spaces, gentle

• Since the Thrombin solution can be denatured by contact

• Do not use air to remove residual FLOSEAL Matrix from

• When FLOSEAL Matrix is placed into cavities or closed

• Thrombosis Arterial 3 (2%) 8 (5%)

• Arrhythmia 4 (3%) 0 (0%)

• Infection 10 (6%) 11(7%)

• Urinary Tract Infection 6 (4%) 3 (2%)

• Secondary events included anemia, atrial fibrillation, infection,

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix has not been established in patients with coagulopathy, and/or

• In patients with congenital or acquired coagulopathies, and/or

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in

• The safety and effectiveness of FLOSEAL Matrix for use in
**Preparation of the Thrombin Solution into the Gelatin Matrix**

- Aspirate 10 mL syringe with sterile Sodium Chloride Solution
- Remove the empty Thrombin vial, the vial adapter, and the syringe-labeled “Thrombin” appropriately.

**Mixing the Thrombin Solution into the Gelatin Matrix**

- Thrombin solution was added to the Gelatin Matrix.
- The small bowl containing the Thrombin Solution must be held securely; avoid shaking or tapping the small bowl containing the Thrombin Solution. This constitutes “one pass”.
- Transfer the Gelatin Matrix-Thrombin Solution mixture back and forth between the syringes to promote thorough mixing. The Gelatin Matrix material should be in the syringe volume at all times. Be sure to pass rapidly between the syringes to promote thorough mixing. The Gelatin Matrix material should be in the syringe volume at all times.
- After the first several passes, most of the Gelatin Matrix-Thrombin Solution mixture should be transferred from the small bowl into this empty 10 mL syringe to the indicated mark (8 mL).
- For rapid mixing, the Gelatin Matrix-Thrombin Solution mixture can be kept connected until product is applied to the surgical site.

**Key Application Steps**

- Thrombin must be added to the Gelatin Matrix prior to use.
- For tissue defects (‘divots’ or ‘craters’), begin applying FLOSEAL Matrix against the bleeding surface, conforming it to the target site for FLOSEAL Matrix application.
- Do not disrupt the FLOSEAL Matrix clot by physical compression.
- For tissue defects, apply FLOSEAL Matrix in a ‘mound’ of material at the source of bleeding.
- It is important for the FLOSEAL Matrix syringe and form the tip as necessary to access the surgical site.
- Do not inject into blood vessels.
- Use of FLOSEAL Matrix as a Hemostatic Agent in Cardiovascular Surgery
- Use of FLOSEAL Matrix as a Hemostatic Agent for Nasal/Sinus Bleeding
- Use of FLOSEAL Matrix as a Hemostatic Agent for Tampax or Tampons
- Use of FLOSEAL Matrix as a Hemostatic Agent in Obstetric and Gynecologic Surgery
- Use of FLOSEAL Matrix as a Hemostatic Agent in Ophthalmic Surgery
- Use of FLOSEAL Matrix as a Hemostatic Agent in Urologic Surgery
- Use of FLOSEAL Matrix as a Hemostatic Agent in Vascular Surgery
- Use of FLOSEAL Matrix as a Hemostatic Agent in Other General and/or Thoracic Surgical Operations.

**FLOSEAL Matrix Placement/Application**

- Do not inject FLOSEAL Matrix into body cavities. See the “Contraindications,” “Warnings,” “Therapeutic and/or Adverse Events” sections contained in this Instructions for Use.

**FLOSEAL Matrix Placement/Application**

- For best results, FLOSEAL Matrix should be in complete contact with the actively bleeding tissue surface.
- The particulate mass of FLOSEAL Matrix moves approximately 1.03 mm/second with blood flow.
- Use of FLOSEAL Matrix syringes can be kept connected until product is applied to the surgical site.
- After use, properly dispose of the FLOSEAL Matrix device with tip attached.

**Thrombin Solution**

- Do not inject into blood vessels.
- Use at least 30 seconds after preparation before product is applied to the surgical site.
- Use of FLOSEAL Matrix as a Hemostatic Agent for Tampax or Tampons
- Use of FLOSEAL Matrix as a Hemostatic Agent in Obstetric and Gynecologic Surgery
- Use of FLOSEAL Matrix as a Hemostatic Agent in Ophthalmic Surgery
- Use of FLOSEAL Matrix as a Hemostatic Agent in Urologic Surgery
- Use of FLOSEAL Matrix as a Hemostatic Agent in Vascular Surgery
- Use of FLOSEAL Matrix as a Hemostatic Agent in Other General and/or Thoracic Surgical Operations.

**Procedures (Use)**

- FLOSEAL Matrix is provided in the configuration shown in the image above.

**Surgical Field:**

- For surgical access, the surgical field is prepared for use.

**Surgical Technique:**

- The surgical field is prepared for use.

**Surgical Site:**

- The surgical site is prepared for use.

**Surgical Specimen:**

- The surgical specimen is prepared for use.

**Surgical Site:**

- The surgical site is prepared for use.

**Surgical Specimen:**

- The surgical specimen is prepared for use.

**Surgical Site:**

- The surgical site is prepared for use.

**Surgical Specimen:**

- The surgical specimen is prepared for use.

**Surgical Site:**

- The surgical site is prepared for use.

**Surgical Specimen:**

- The surgical specimen is prepared for use.