Virus; Porcine parvovirus, a model for non-enveloped virus, is Hepatitis A virus, B and C virus; BVDV MMV n. d. = not determined

• Thrombin must be added to the Gelatin Matrix component and is not used to be a prophylactic heparin.

• Excess FLOSEAL, material not incorporated in the Hemostatic Gel, should be irrigated into the area of spillage or contamination, by irrigation from the site of application. All materials should be handled in a manner to prevent cross-contamination between areas of aorto-bypass surgery.

• The safety and effectiveness of FLOSEAL for use in application to bone injuries was determined by the clinical trial design. If FLOSEAL is used for bone injuries, the material should only be used to remove the material that can cause complications.

• When placed into closed or tissue structures, gentle approximation is advanced.

• As a hemostatic agent, its use does not distort FLOSEAL to large extracellular compartmental sites or anterior structures. In its performance, it has been demonstrated that fragments of collagen-based hemostatic agents may pass through the blood vessel walls and enter the systemic circulation.

• FLOSEAL, should be in blood, bones or wound, with addresses, such as the material from the other of the same nature. It can be used to attach synthetic devices to bone bodies.

• FLOSEAL should not be used for the primary treatment of osteomyelitis or immunosuppressive condition. FLOSEAL has demonstrated extensive clinical evidence in bone-related conditions.

• In occasional procedures, FLOSEAL should not be left in the body for an extended period of time in order to prevent the potential for local infection.

• The safety and effectiveness of use in immunosuppressive and systemic conditions has been established through randomized clinical studies.

• In unsuitable procedures, FLOSEAL should not be left in the body in order to prevent the potential for local infection.

• The primary uses of FLOSEAL are not to be re-injected. FLOSEAL is a sterile and sterile product and is not to be re-administered.

• Some viruses, such as human parvovirus B19, are particularly common in children and adolescents. Human parvovirus B19 most often affects pregnant women. There is an occasional report of fetal infections in humans with parvovirus B19 infection including neonatal deaths, stillbirth, spontaneous abortion, and low birth weight when used in the brain.

• After repeated exposure to the local environment, FLOSEAL has been demonstrated to be effective in the reduction of the material that can cause complications.

• Long-term animal studies to evaluate the carcinogenic potential of FLOSEAL or studies to evaluate the effect of FLOSEAL on fertility in animals have not been performed.

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FLOSEAL Placement/Application Steps:

1. Place the Thrombin Solution into the sterile field. Once reconstituted, the Thrombin Solution can be used for up to two (2) hours after mixing with the Gelatin Matrix.

2. Place the Thrombin bowl provided in the Gelatin Matrix Syringe. An empty 5 mL syringe with an integral female Luer connector and a Needle-free vial adapter are provided in the Syringe. Ensure that the syringe and vial adapter are firmly attached prior to drawing the solution into the syringe.

3. After transferring the Thrombin Solution, manually approximate a gauze sponge moistened with sterile (non-heparinized) saline against the bleeding surface.

4. While holding the gauze adhesive, insert the Applicator tip through the center of the mass of previously placed FLOSEAL, and continue the procedure until the bleeding stops and the lesion is sealed.

5. Do not use if package is damaged or opened, do not use.

Directions for Use:

Thrombin must be added to the Gelatin Matrix prior to use. Inspect the integrity of the contents of the FLOSEAL kit. If the package contents have been damaged or opened, do not use.

Opening the Package:

- Place the Thrombin vial, pre-filled Sodium Chloride Solution syringe, and the vial adapter outside of the sterile field.

- Open the outer package containing the Gelatin Matrix Component and deliver the sterile inner package to the sterile field. Once transferred to the sterile field, the inner package may be opened at any time.

Preparing the Thrombin Solution:

- Remove the packaging and Luer cap from the pre-filled Sodium Chloride Solution syringe. Remove the syringe flip-off cap from the Thrombin vial. Discard the rubber stopper from the Thrombin vial with a sterilized solution and allow to dry. Do not use iodine-containing preparations such as betadine for disinfection.

- Remove the lid from the vial adapter packaging. While gripping the vial adapter packaging, attach the pre-filled Sodium Chloride Solution syringe to the Luer connector of the vial adapter and remove the remaining packaging from the vial adapter.

- While holding the vial adapter, place the rubber stopper of the Thrombin vial. Transfer the entire contents of the Sodium Chloride Solution syringe into the Thrombin vial. Leave the syringe attached to the vial adapter and affix the Thrombin vial to it.

- Gently swirl the Thrombin vial with vial adapter and syringe attached until the Thrombin is completely dissolved. Once reconstituted, the Thrombin Solution can be used immediately or may be stored in the vial up to four (4) hours.

- Aspirate the Thrombin Solution into the syringe (non-heparinized) saline to approximate the FLOSEAL at the target site for FLOSEAL application.

- After transfer is complete, disengage the syringe containing Thrombin Solution from the vial adapter.

- Place the Thrombin bowl provided in the Gelatin Matrix Component package onto the sterile field and apply the Thrombin vial to it. Transfer the Thrombin Solution from the syringe onto the sterile field by dispersing its contents into the Thrombin bowl.

- Discard the empty Thrombin vial, the vial adapter, and the syringe labeled “Thrombin” appropriately.

- Do not inject into blood vessels.

- Do not re-use.

- Do not use if package is damaged.

- Do not disturb the clot by physical manipulation. FLOSEAL incorporated in the hemostatic clot should not be left exposed.

Storage Conditions:

The FLOSEAL Matrix Kit should be stored at 2 - 25°C (36 - 77°F). Do not freeze.

FLOSEAL Hemostatic Matrix Kit Configuration

<table>
<thead>
<tr>
<th>Gelatin Matrix Component</th>
<th>Thrombin Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 x 5 mL Syringe with Gelatin Matrix</td>
<td>1 x vial Thrombin (Human), Upper Hosted, Sulfate-Dextran treated, 2000 units</td>
</tr>
<tr>
<td>1 x 5 mL Syringe for Matrix Preparation with integral female Luer connector</td>
<td>1 x Pre-Filled 0.9% Sodium Chloride Solution syringe, Saline, USP injection</td>
</tr>
<tr>
<td>1 x Applicator tip for Bowl</td>
<td>1 x Needle-free vial adapter</td>
</tr>
<tr>
<td>2 x 2500 units</td>
<td>1 x “Thrombin” sticker for syringe</td>
</tr>
</tbody>
</table>

The package also includes the FLOSEAL Instructions for Use.

For best results, FLOSEAL should be in complete contact with the actively bleeding tissue surface.

The particles of FLOSEAL may be approximately 10-20% open contact with blood or other fluids. Minimum dwell volume is achieved within about 10 minutes.

Application Technique:

- Re-Application Steps:
  1. Apply FLOSEAL directly to the source of bleeding.
  2. Maintain FLOSEAL at the site (source of bleeding) for two (2) minutes with gentle approximation.
  3. Do not apply FLOSEAL away gently as to not disturb the new clot and use suction to remove excess.

- Details Application Steps:
  1. Identify the source of bleeding at the tissue surface. This is the target site for FLOSEAL application.
  2. Manually approximate a gauze sponge moistened with sterile (non-heparinized) saline against the bleeding surface and use the Applicator tip or (syringe tip) to dispense FLOSEAL between the syringe and the bleeding surface. The gauze sponge will hold FLOSEAL in place against the bleeding surface in the presence of active bleeding. Apply enough FLOSEAL to create a small “mound” of material at the source of bleeding.
  3. For tissue defects (“shunts” or “orifices”), begin applying FLOSEAL at the deepest part of the lesion, and continue applying material as the syringe (or Applicator tip if used) is withdrawn from the lesion. This “back-filling” action will ensure that FLOSEAL comes into contact with the entire bleeding surface at the tissue defect.
  4. Apply a gauze sponge impregnated with sterile (non-heparinized) saline to approximate the FLOSEAL against the bleeding surface, confirming it to the lesion.
  5. After approximately two (2) minutes, lift the gauze sponge and inspect the wound site. If bleeding has ceased, excess FLOSEAL (not incorporated in the hemostatic clot) should always be removed by gentle irrigation and suctioned away from the treatment site.
  6. If the gauze sponge adheres to the newly formed clot, irrigate with non-irritating saline to minimize disruption of the clot.
  7. In cases of persistent bleeding, induced by subarachnoid and bleeding through the gauze, insert the Applicator tip through the center of the mass of previously placed FLOSEAL to deliver more FLOSEAL as close as possible to the tissue defect. After re-aplication of FLOSEAL, resume application with a gauze sponge for up to another two (2) minutes, then inspect the site again. Repeat re-aplications if necessary.
  8. Once bleeding has ceased, excess FLOSEAL, material not incorporated in the hemostatic clot, should always be removed by gentle irrigation and suctioned away from the treatment site.
  9. Do not disrupt the FLOSEAL clot by physical manipulation. FLOSEAL incorporated in the hemostatic clot should be left intact.

Definition of Symbols:

- Cautions: Consult accompanying documents
- Consult instructions for use
- Do not re-use
- Do not inject into blood vessels
- Committed
- Refrigeration*: Refurb. Code (see label)

Rx ONLY

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

Baxter Healthcare Corporation
21028 Alexander Court
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U.S.A.

Baxter and Floseal are trademarks of Baxter International Inc., registered in the U.S. Patent and Trademark Office

Portions of this product are covered by U.S. Patents 6,963,381 and 6,003,329.

U.S. - Customer Service 1-800-423-2090

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