Multiple neurologic events were reported when absorbable gelatin-based hemostatic agents were used in laminectomy operations, including cauda equina syndrome, spinal stenosis, meningitis, arachnoiditis, headaches, paresthesias, pain, bladder and bowel dysfunction, and impotence.

Compression of the brain and spinal cord resulting from the accumulation of sterile fluid have been observed. Giant cell granulomas have been observed at implant sites when used in the brain.

SURGIFLO® should not be used in conjunction with methylmethacrylate adhesives.

Safe and effective use of SURGIFOAM® Sponge has been reported in a published neurologic retrospective study involving 1700 cases in Europe. Safe and effective use in neurosurgery has not been proven through randomized, controlled clinical studies in the United States.

The use of absorbable gelatin-based hemostatic agents during the repair of dural defects associated with laminectomy and craniotomy operations has been associated with postoperative headaches, neck pain, and back pain.

The use of absorbable gelatin-based hemostatic agents has been associated with postoperative headaches, neck pain, and back pain.

Fever, failure of absorption, and hearing loss have been observed when absorbable hemostatic agents were used during tympanoplasty.

Toxic shock syndrome was reported in association with the use of absorbable gelatin-based hemostatic agents in nasal surgery.

No data of absorption and long-term tissue observation when absorbable hemostatic agents were used during craniotomy procedure.

EVITHROM® Thrombin

The use of absorbable gelatin-based hemostatic agents during the repair of dural defects associated with laminectomy and craniotomy operations has been associated with postoperative headaches, neck pain, and back pain.

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Fever, failure of absorption, and hearing loss have been observed when absorbable hemostatic agents were used during tympanoplasty.

Toxic shock syndrome was reported in association with the use of absorbable gelatin-based hemostatic agents in nasal surgery.

No data of absorption and long-term tissue observation when absorbable hemostatic agents were used during craniotomy procedure.

The safety and effectiveness of SURGIFLO® Hemostatic Matrix has not been established in children and pregnant women.

SURGIFLO® Hemostatic Matrix should not be used for controlling post-partum intrauterine bleeding or menorrhagia.

SURGIFLO® Hemostatic Matrix should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confluence, the spinal cord, and areas of serious injury, such as head trauma.

SURGIFLO® Hemostatic Matrix will not act as a tampon or plug in a bleeding site. SURGIFLO® will not act as a tampon or plug in a bleeding site.
SURGIFLO® Hemostatic Matrix Kit fills and envelops bleeding sites—
to stop bleeding fast

SURGIFLO® stays in place even during active bleeding so you can count on it to deliver fast hemostasis right where you need it.1

SURGIFLO® maintains uniform viscosity better from beginning to end than FLOSEAL.

VARIATION IN MATRIX FLOWABILITY (as measured immediately after preparation)**

<table>
<thead>
<tr>
<th>TIME</th>
<th>FLUIDITY</th>
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<tr>
<td>Begin</td>
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<tr>
<td>FLOSEAL</td>
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<tr>
<td>SURGIFLO</td>
<td>0.00005</td>
</tr>
</tbody>
</table>

SURGIFLO® with Thrombin achieved hemostasis in under a minute in an animal model1

*Based on in vitro viscosity testing of SURGIFLO® 8 mL and FLOSEAL® Hemostatic Matrix 5 mL, each product was prepared following Instructions for Use.

References:

SURGIFLO® is backed by robust clinical data demonstrating proven efficacy, safety, and efficiency6

SURGIFLO® is backed by extensive clinical data. A systematic review and meta-analysis of 6 clinical studies across 39,660 patients demonstrated efficacy and safety across the following endpoints6:

- Blood transfusions
- Minor/major complications
- Surgical/operating time

SURGIFLO® stops bleeding fast to help surgeries flow faster

SURGIFLO® is ready over 2 minutes faster than FLOSEAL, so you can stop bleeding without interrupting the flow of your procedure.7

Ready to use in
30 seconds
or less once thrombin or saline solution is delivered to sterile field.

SURGIFLO® is backed by extensive clinical data. A systematic review and meta-analysis of 6 clinical studies across 39,660 patients demonstrated efficacy and safety across the following endpoints6:

- Blood transfusions
- Minor/major complications
- Surgical/operating time

Stops bleeding before FLOSEAL is ready to use9

Reconstituting thrombin takes
13 seconds
vs. 136 seconds for FLOSEAL.

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• Compression of the brain and spinal cord resulting from the accumulation of sterile fluid have been observed.

• Gelatin-based hemostatic agents may serve as a nidus for infection and abscess formation and have been reported to potentiate bacterial growth.

The following adverse events have been reported with the use of absorbable porcine gelatin-based hemostatic agents:

### ADVERSE EVENTS

- **In urological procedures**, SURGIFLO® should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.
- SURGIFLO® should not be used in conjunction with methylmethacrylate adhesives.
- SURGIFLO® should not be used for packing unless excess product that is not needed to maintain hemostasis is removed. SURGIFLO® may swell up to 20%.
- Safe and effective use of SURGIFOAM® Sponge has been reported in a published neurologic retrospective study involving 1700 cases in Europe.
- The white straight applicator tip should be trimmed away from the surgical area. Cut a square angle to avoid creating a sharp tip.
- SURGIFLO® should not be used for controlling post-partum intrauterine bleeding or menorrhagia.
- Excess SURGIFLO® should be removed once hemostasis has been achieved.
- SURGIFLO® should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confluence, the spinal cord, and/or the optic nerve and chiasm because it may swell resulting in nerve damage.

### WARNINGS

- SURGIFLO® should not be used in instances of pumping arterial hemorrhage. SURGIFLO® will not act as a tampon or plug in a bleeding site.

### CONTRAINDICATIONS

SURGIFLO®, mixed with thrombin solution, is indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostasis when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

### INTENDED USE/INDICATIONS

ACTIONS

- May carry a risk of transmitting infectious agents such as viruses and theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite manufacturing steps.
- There is a potential risk of thrombosis if absorbed systemically.
- Do not use for the treatment of severe or brisk arterial bleeding.
- The amount of EVITHROM® required depends upon the area of tissue to be treated and the method of application. In clinical studies, volumes up to 10 ml were used in conjunction with absorbable gelatin-based hemostats in nasal surgery.
- EVITHROM® is a topical thrombin indicated as an aid to hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible and control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

### PRECAUTIONS

- SURGIFLO® may swell up to 20%.
- The blue flexible applicator tip should not be trimmed to avoid exposing internal guidewire.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix for use in ophthalmic procedures has not been established.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix has not been established in children and pregnant women.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix for use in ophthalmic procedures has not been established.
- SURGIFLO® Hemostatic Matrix should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confluence, the spinal cord, and/or the optic nerve and chiasm because it may swell resulting in nerve damage.

### ADVERSE EVENTS

The following adverse events have been reported with the use of absorbable gelatin-based hemostatic agents: erythema, induration, swelling, pain, tenderness, and/or the optic nerve and chiasm because it may swell resulting in nerve damage.

Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin-based sponges were used in severed tendon repair.

### PRECAUTIONS

- SURGIFLO® should not be used in conjunction with methylmethacrylate adhesives.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix has not been established in children and pregnant women.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix for use in ophthalmic procedures has not been established.
- SURGIFLO® Hemostatic Matrix should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confluence, the spinal cord, and/or the optic nerve and chiasm because it may swell resulting in nerve damage.

### ADVERSE EVENTS

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Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin-based sponges were used in severed tendon repair.

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- SURGIFLO® should not be used in conjunction with methylmethacrylate adhesives.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix has not been established in children and pregnant women.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix for use in ophthalmic procedures has not been established.
- SURGIFLO® Hemostatic Matrix should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confluence, the spinal cord, and/or the optic nerve and chiasm because it may swell resulting in nerve damage.
Compression of the brain and spinal cord resulting from the accumulation of sterile shortluid have been observed. Giant cell granulomas have been observed at implant sites when used in the brain.

ADVERSE EVENTS
- SURGIFLO® should not be used in conjunction with autologous blood salvage circuits.
- SURGIFLO® should not be used for packing unless excess product that is not needed to maintain hemostasis is removed. SURGIFLO® may swell up to 20% upon contact with additional shortluid.
- SURGIFLO® is supplied as a sterile product and cannot be resterilized.
- Safe and effective use of SURGIFOAM® Sponge has been reported in a published neurosurgical retrospective study involving 1700 cases in Europe. Safe and effective use in neurosurgery has not been proven through randomized, controlled clinical studies in the United States.
- The safety and effectiveness of SURGIFLO® has not been established in children and pregnant women.
- SURGIFLO® should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony con/f.shortine, the spinal cord, and/or the optic nerve and chiasm because it may swell resulting in nerve damage.

WARNINGS
- Do not use SURGIFLO® in patients with known allergies to porcine gelatin.
- Do not use SURGIFLO® in intravascular compartments because of the risk of embolization.
- The white straight applicator tip should be trimmed away from the surgical area. Cut a square angle to avoid creating a sharp tip.
- The blue /f.shortlexible applicator tip should not be trimmed to avoid exposing internal guidewire.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix for use in ophthalmic procedures has not been established.
- Do not use SURGIFLO® Hemostatic Matrix in patients with known allergies to porcine gelatin.
- Do not use SURGIFLO® Hemostatic Matrix in intravascular compartments because of the risk of embolization.
- SURGIFLO® Hemostatic Matrix should not be used in the presence of infection and should be used with caution in contaminated areas of the body.
- SURGIFLO® Hemostatic Matrix should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.
- SURGIFLO® Hemostatic Matrix should not be used in conjunction with autologous blood salvage circuits.
- SURGIFLO® Hemostatic Matrix is supplied as a sterile product and cannot be resterilized.
- The use of absorbable gelatin-based hemostatic agents during the repair of dural defects associated with lumbar puncture, neurosurgical operations, has decreased the incidence of subarachnoid hemorrhage, headaches, and pain. In the presence of subarachnoid hemorrhage, headaches, and pain, an absorbable gelatin sponge may be used to tamponade the defect before closure.

CONTRAINDICATIONS
- Do not use SURGIFLO® Hemostatic Matrix in patients with known allergies to porcine gelatin.
- Do not use SURGIFLO® Hemostatic Matrix in intravascular compartments because of the risk of embolization.
- The white straight applicator tip should be trimmed away from the surgical area. Cut a square angle to avoid creating a sharp tip.
- The blue /f.shortlexible applicator tip should not be trimmed to avoid exposing internal guidewire.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix for use in ophthalmic procedures has not been established.

PRECAUTIONS
- Do not use SURGIFLO® Hemostatic Matrix in patients with known allergies to porcine gelatin.
- Do not use SURGIFLO® Hemostatic Matrix in intravascular compartments because of the risk of embolization.
- The white straight applicator tip should be trimmed away from the surgical area. Cut a square angle to avoid creating a sharp tip.
- The blue /f.shortlexible applicator tip should not be trimmed to avoid exposing internal guidewire.
- The safety and effectiveness of SURGIFLO® Hemostatic Matrix for use in ophthalmic procedures has not been established.

ADVERSE EVENTS
- Do not use SURGIFLO® Hemostatic Matrix or any other absorbable gelatin sponge during clinical trial comparing SURGIFLO® to another absorbable gelatin sponge. In general, the following adverse events have been reported for use of absorbable gelatin sponge-based hemostatic agents:
- Bleeding
- Nausea
- Tachycardia
- Hypertension
- Hypotension
- Shock
- Fever
- Failure of absorption
- Hearing loss
- Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin-based sponges were used in severed tendon repair.
- Foreign body reactions, “encapsulation” of shortluid, and hematoma have been observed at implant sites.
- Due to the risk of immune reaction and possible anaphylaxis, emergency medical and resuscitation equipment should be immediately available.
- Due to the potential risk of thrombosis if absorbed systemically, the use of absorbable gelatin-based hemostatic agents should be considered only after the local physician concludes that mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.
- The third-party trademarks used herein are trademarks of their respective owners.
SURGIFLO® Hemostatic Matrix Kit—
helping surgeries flow faster

<table>
<thead>
<tr>
<th>Ordering code</th>
<th>Size</th>
<th>Package</th>
</tr>
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<tbody>
<tr>
<td>2994</td>
<td>8 mL SURGIFLO® Hemostatic Matrix Kit</td>
<td>Case of 6</td>
</tr>
<tr>
<td>2991</td>
<td>8 mL SURGIFLO® Hemostatic Matrix</td>
<td>Case of 6</td>
</tr>
<tr>
<td>MS3205</td>
<td>34 cm Endoscopic Applicator</td>
<td>Case of 6</td>
</tr>
</tbody>
</table>

For technical support, call 1-877-ETHICON.
For additional information, visit www.ethicon.com.
Call 1-800-255-2500 to order.
Table 1: Incidence of treatment emergent adverse events by treatment group

<table>
<thead>
<tr>
<th>Term</th>
<th>SURGIFOAM® (n = 142)</th>
<th>Control Sponge (n = 159)</th>
<th>Total (n = 301)</th>
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<tbody>
<tr>
<td>Fever</td>
<td>20 (14.1%)</td>
<td>11 (7.0%)</td>
<td>31 (10.3%)</td>
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<td>Tachycardia</td>
<td>27 (19.0%)</td>
<td>26 (16.5%)</td>
<td>53 (17.6%)</td>
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<td>Tachypnea</td>
<td>23 (16.2%)</td>
<td>17 (10.8%)</td>
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<tr>
<td>Hiccups</td>
<td>13 (9.2%)</td>
<td>7 (4.4%)</td>
<td>20 (6.7%)</td>
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<td>Edema</td>
<td>32 (22.7%)</td>
<td>30 (19.3%)</td>
<td>62 (20.6%)</td>
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<tr>
<td>Pruritus</td>
<td>12 (8.5%)</td>
<td>12 (7.7%)</td>
<td>24 (8.0%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>19 (13.5%)</td>
<td>17 (10.8%)</td>
<td>36 (12.0%)</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>11 (7.7%)</td>
<td>10 (6.3%)</td>
<td>21 (7.0%)</td>
</tr>
<tr>
<td>Headache</td>
<td>17 (12.0%)</td>
<td>12 (7.7%)</td>
<td>29 (9.7%)</td>
</tr>
<tr>
<td>Rash</td>
<td>13 (9.2%)</td>
<td>12 (7.7%)</td>
<td>25 (8.3%)</td>
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<tr>
<td>Hemoptysis</td>
<td>16 (11.3%)</td>
<td>13 (8.3%)</td>
<td>29 (9.7%)</td>
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<tr>
<td>Back pain</td>
<td>21 (15.0%)</td>
<td>16 (10.2%)</td>
<td>37 (12.3%)</td>
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<tr>
<td>Headache</td>
<td>17 (12.0%)</td>
<td>11 (7.0%)</td>
<td>28 (9.3%)</td>
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<td>Ear pain</td>
<td>13 (9.2%)</td>
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<tr>
<td>Pruritus</td>
<td>12 (8.5%)</td>
<td>10 (6.3%)</td>
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<tr>
<td>Influenza</td>
<td>10 (7.0%)</td>
<td>13 (8.3%)</td>
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<tr>
<td>Urinary tract infection</td>
<td>31 (22.0%)</td>
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<td>55 (18.3%)</td>
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<td>13 (9.2%)</td>
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Table 2: Summary of effectiveness results comparing SURGIFOAM® Spray to another gelatin based adhesive hemostat

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<td>6</td>
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<tr>
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<td>24</td>
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</tr>
<tr>
<td>48</td>
<td>62.5%</td>
<td>60.2%</td>
<td>61.7%</td>
<td>61.7%</td>
<td></td>
</tr>
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</table>

A statistical analysis showed that SURGIFOAM® Spray and the control spray were equivalent in the ability to achieve hemostasis. The study also collected hematoma data at 3 and 6 minutes. These results are also summarized above.

Immunogenic Responses: Patient sera were tested for the presence of anti-porcine collagen antibodies using an optical plate technique. The study also collected hematoma data at 3 and 6 minutes. Results are also summarized above.

Use of SURGIFOAM® Hemostatic Matrix as a hemostatic agent for nasal/oral bleeding: SURGIFOAM® Hemostatic Matrix has been successfully used with bovine thrombin intranasally as an hemostatic agent for the control of bleeding post nasal/oral sinus surgery in 10 patients (44 site patients).
STORAGE AND HANDLING

SURGIFLO® Hemostatic Matrix Kit should be stored dry at controlled room temperature 36°F to 77°F (2°C to 25°C).

The Flowable Gelatin Matrix may be used up to eight (8) hours after mixing with the Thrombin Solution. For prescribing information on the Hemostatic component, please refer to the ETRIFLO™ Thrombin, Topical (Human) Prescribing Information on page 9.

SURGIFLO® Hemostatic Matrix Kit is for single use only.

DIRECTIONS FOR USE

 chị. Before use

Open packages of SURGIFLO® Hemostatic Matrix Kit should be discarded, since they are not intended for reuse or recontamination.

Opening the tray with Flowable Gelatin Matrix and the tray with Thrombin kit components:

Open the outer packages and deliver the sterile inner tray to the sterile field using aseptic technique. Once opened on sterile field, the sterile inner tray may be opened.

Preparing the SURGIFLO® Hemostatic Matrix Kit outside the sterile field:

1. Place the Thrombin vial on a flat surface, seat the vial adapter on the rubber stopper and the needle-free syringe until the Thrombin Solution is clear.
2. Snap the off the tamper cap on the needle-free syringe containing the Sterile Water for Injection (Sterile WFI).
3. Connect and screw on the needle-free syringe to the adapter. Transfer the entire Sterile WFI into the needle-free syringe.
4. Gently swivel the Thrombin vial until the Thrombin Solution is clear.
5. Draw up the Thrombin Solution into the needle-free syringe. Label the needle-free syringe “Thrombin 2000 IU”.
6. Disconnect the needle-free syringe from the vinyl adapter and transfer the Thrombin Solution into the sterile liquid transfer cup as shown in the next section (Figure 1).

After reconstitution, discard the components used for the Thrombin reconstitution.

Alternatively, the Thrombin may be reconstituted outside the sterile field. Be careful not to touch the rubber stopper of the vial. After reconstitution the Thrombin Solution should be transferred into the sterile liquid transfer cup using aseptic technique.

Flowable Gelatin Matrix Components

- A sterile pre-filled syringe containing the sterile Gelatin Matrix. The syringe is labeled SURGIFLO™ Hemostatic Matrix
- A sterile empty syringe
- A sterile liquid transfer cup
- A sterile blue flexible application tip that is bendable in all directions
- A sterile white applicator tip that can be trimmed to desired length

Thrombin Components

- A Thrombin vial, ETRIFLO™ Thrombin, Topical (Human), containing 2000 International Units (IU) of sterile lyophilized human thrombin powder for reconstitution
- A needle-free syringe containing 2 mL of Sterile Water for Injection (Sterile WFI)
- A sterile vial adapter

The package also contains the SURGIFLO™ Hemostatic Matrix Kit Instructions for Use and tracking labels.

HOW SUPPLIED

SURGIFLO® Hemostatic Matrix Kit consists of:

1. A sterile tray with all sterile components to prepare the Flowable Gelatin Matrix.
2. A sterile tray with all surface sterilized Thrombin kit components to prepare the Thrombin Solution.

For open procedures:

- Do not inject SURGIFLO® Hemostatic Matrix into blood vessels. See the Contraindications, Warnings, and Precautions.

For endoscopic and/or laparoscopic surgical procedures:

- Follow the selected endoscopic applicator according to the product's labeling.
- For tissue defects (cavities, divots, or craters) apply SURGIFLO® Hemostatic Matrix at the deepest part of the lesion, and continue applying material to the area (see applicator tip) until it is withdrawn from the lesion.
- Apply a sterile saline moistened gauze over the SURGIFLO® Hemostatic Matrix to ensure the material remains in contact with the bleeding tissue.
- After 1-2 minutes, lift the gauze and inspect the wound site. Once bleeding has ceased, irrigate excess SURGIFLO® Hemostatic Matrix away gently to not disturb the new clot.
- In cases of persistent bleeding indicated by saturation and bleeding through the material, repeat application of SURGIFLO® Hemostatic Matrix.

For endoscopic and/or laparoscopic surgical procedures:

- Prepare the selected endoscopic applicator according to the product's labeling.
- Attach the selected endoscopic applicator tip to the SURGIFLO™ Hemostatic Matrix syringe. Make sure that the head connection is secured.
- Express SURGIFLO™ Hemostatic Matrix to the end of the cannula. Introduce the cannula into the trocar port. Insert the cannula using caution not to express SURGIFLO™ Hemostatic Matrix. Check the cannulation port for syringe and remove the cannula from the site.
- Express SURGIFLO™ Hemostatic Matrix away gently to not disturb the new clot.
- In cases of persistent bleeding indicated by saturation and bleeding through the material, repeat application of SURGIFLO™ Hemostatic Matrix.

For endoscopic sinus surgery:

- Do not inject SURGIFLO® Hemostatic Matrix into blood vessels. See the Contraindications, Warnings, and Precautions.

For endoscopic sinus surgery and epistaxis:

- Do not inject SURGIFLO® Hemostatic Matrix into blood vessels. See the Contraindications, Warnings, and Precautions.

For endoscopic and/or laparoscopic surgical procedures:

- Use a needle-free syringe whenever necessary when satisfactory hemostasis is achieved.
- In cases of persistent bleeding indicated by saturation and bleeding through the material, repeat application of SURGIFLO™ Hemostatic Matrix.

Surgeons: The use of SURGIFLO™ Hemostatic Matrix for mechanical support has not been studied.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).