When difficult-to-access bleeding limits your visibility, SURGIFLO® Hemostatic Matrix Kit works fast to make things clear.¹
SURGIFLO® Hemostatic Matrix Kit helps achieve visibility fast during critical moments

SURGIFLO® achieves similar clinical outcomes compared to Floseal and offers so much more.

Safety and Efficacy
• Achieves hemostasis within approximately 60 seconds.*

Consistency
• Preferred consistency among surgeons †
• Remains uniformly consistent throughout lengthy, complex procedures.

Ease Of Use
• Flexibility to prepare inside or outside the sterile field
• Faster to prepare than Floseal and requires no measuring.

Economic Value
• SURGIFLO® was associated with significant cost reduction compared to Floseal.

*In animal models.
†Testing conducted with 101 US surgeons.

MECHANISM OF ACTION

Gelatin:
The flowable gelatin matrix provides an environment for platelets to adhere and aggregate within, building on the patient’s natural clotting cascade.

Thrombin:
Enhancing the tamponade of the gelatin matrix, the thrombin component of SURGIFLO® Hemostatic Matrix Kit acts as a catalyst and activates the patient’s endogenous fibrinogen, accelerating clot formation.

Once bleeding has ceased, excess SURGIFLO® may gently be withdrawn to allow for clot stabilization.

When used in appropriate amounts, SURGIFLO® is absorbed completely within 6-8 weeks.
**ECONOMIC OUTCOME**

**SURGIFLO® Hemostatic Matrix Kit offers cost savings with similar outcomes when compared to Floseal**

**Number of hospitals:** 121

**Number of procedures:** 16,586 (spine fusion or refusion)

**Average flowable cost savings per procedure:** $127.14

<table>
<thead>
<tr>
<th>Hospital flowable cost per procedure</th>
<th>SURGIFLO® with thrombin</th>
<th>Floseal (with thrombin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Cost</td>
<td>$227.66</td>
<td>$349.80</td>
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<tr>
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</table>

**Little or no difference in clinical outcomes (transfusions, hemorrhage, wound complications)**

**Peer-reviewed article in Journal of Medical Economics**

As the duration of the spinal surgery increases, so does the potential to reduce cost even further.

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**SAFETY and EFFICACY**

**Clinical and preclinical data yielded similar results for SURGIFLO® Hemostatic Matrix Kit and Floseal**

**Clinical**

A systematic review of 6 clinical studies across 39,660 patients comparing SURGIFLO® with thrombin and Floseal showed both products yielded similar safety and efficacy outcomes.

**Preclinical**

- In a porcine spleen model of bleeding injury, SURGIFLO® with thrombin performed similarly to Floseal with thrombin.
- Hemostasis was achieved within 3 minutes at all sites for both products regardless of level of initial bleeding.

**The studies found no statistically significant differences**

**Clinical Preclinical**

**Time to Hemostasis for Different Types of Bleeding:**

- **SURGIFLO® versus Floseal (Spleen Biopsy Model)**

  - **Spurting**: 72.3 s (SURGIFLO®) vs. 54.9 s (Floseal)
  - **Flowing**: 56.7 s (SURGIFLO®) vs. 44.3 s (Floseal)
  - **Oozing**: 51.8 s (SURGIFLO®) vs. 44.3 s (Floseal)

**Average Time to Hemostasis**

- **SURGIFLO®**: 59 s
- **Floseal**: 57 s

- Hemostasis in <7 minutes
- Length of hospital stay

**Blood transfusions**: No statistically significant differences.

**Surgical/operating room time**: No statistically significant differences.

**Minor complications**: No statistically significant differences.

**Major complications**: No statistically significant differences.

**Length of hospital stay**: No statistically significant differences.
**CONSISTENCY**

Get the consistency you prefer that stays uniform over an 8-hour procedure. In blind testing, surgeons prefer the consistency of SURGIFLO® Hemostatic Matrix Kit over Floseal.

- **Adherent**
  - Stays in place during active bleeding.
- **Precise**
  - Malleable tip allows precise placement in difficult-to-access areas, cavities, and crevices.
- **Better Packing**
  - Greater conformability and more tissue surface contact.

The premoistened gelatin mixes uniformly with the thrombin to ensure the matrix retains consistency throughout the length of the syringe and for up to 8 hours.

**EASE OF USE**

SURGIFLO® Hemostatic Matrix Kit:

Innovative fully sterile design gives you the flexibility to prepare thrombin inside or outside the sterile field.

- Fully sterile
- Faster and easier to prepare versus Floseal:
  - More than two minutes shorter thrombin reconstitution time versus Floseal (13 seconds for SURGIFLO® vs 136 seconds for Floseal).
  - Requires no measuring.
  - Does not require 30-second wait time after mixing.
- Needle-free design pioneered by Ethicon.

Three tip designs offer a variety of options:

- **Endoscopic applicator** delivers nearly 5 times more product than competition in a single expression.
- **Trimmable tip** offers a customizable length.
- **Flexible tip** offers precise placement at any angle.

*Testing conducted with 101 US surgeons.*
**CONSISTENCY**

Get the consistency you prefer that stays uniform over an 8-hour procedure\(^{10}\)

In blind testing, surgeons prefer the consistency of SURGIFLO\(^{®}\) Hemostatic Matrix Kit over Floseal\(^{®}\)\(^\text{a}^{16}\).

- **Adherent**
  - Stays in place during active bleeding\(^{1}\)
- **Precise**
  - Malleable tip allows precise placement in difficult-to-access areas, cavities, and crevices\(^{12}\)
- **Better Packing**
  - Greater conformability and more tissue surface contact\(^{13}\)

The premoistened gelatin mixes uniformly with the thrombin to ensure the matrix retains consistency throughout the length of the syringe and for up to 8 hours\(^{5,10}\).

**CONSISTENCY**

0.0015
0.001
0.0005
0

**SURGIFLO\(^{®}\)**

0.002
6.3%
57.6%

**Floseal**

**START**

**FINISH**

**MIDDLE**

**EASE OF USE**

**SURGIFLO\(^{®}\) Hemostatic Matrix Kit:**

Innovative fully sterile design gives you the flexibility to prepare thrombin inside or outside the sterile field\(^{14}\).

- Faster and easier to prepare versus Floseal\(^{®}\)
  - More than two minutes shorter thrombin reconstitution time versus Floseal (13 seconds for SURGIFLO\(^{®}\) vs 136 seconds for Floseal\(^{®}\))
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  - Does not require 30 second wait time after mixing
  - Needle-free design pioneered by Ethicon\(^{®}\)

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  - Endoscopic applicator delivers nearly 5 times more product than competition in a single expression\(^{17}\)
  - Flexible tip offers precise placement at any angle\(^{12}\)
  - Trimable tip offers a customizable length

*Testing conducted with 101 US surgeons.

* Versus 10mL Floseal kit.

Not intended to convey comparative safety or efficacy.
SURGFLO® Hemostatic Matrix Kit offers cost savings with similar outcomes when compared to Floseal.

Number of hospitals: 121
Number of procedures: 16,586 (spine fusion or refusion)

Little or no difference in clinical outcomes (transfusions, hemorrhage, wound complications)

Peer-reviewed article in Journal of Medical Economics

As the duration of the spinal surgery increases, so does the potential to reduce cost even further.

Data source: Premier Perspective® Hospital Database

### ECONOMIC OUTCOME

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<thead>
<tr>
<th>Hospital flowable cost per procedure</th>
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</tr>
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<tbody>
<tr>
<td>SURGFLO® with thrombin</td>
<td>$222.66</td>
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<tr>
<td>Floseal (with thrombin)</td>
<td>$349.80</td>
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Average flowable cost savings per procedure—$127.14

Clinical and preclinical data yielded similar results for SURGFLO® Hemostatic Matrix Kit and Floseal.

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### SAFETY and EFFICACY

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**Time to Hemostasis for Different Types of Bleeding: SURGFLO® versus Floseal (Spleen Biopsy Model)**

- SURGFLO®
  - Spurting: 72.3 s
  - Flowing: 56.7 s
  - Oozing: 51.8 s
- Floseal
  - Spurting: 54.9 s
  - Flowing: 44.3 s
  - Oozing: 39.0 s

**Average Time to Hemostasis**

- SURGFLO®: 59 s
- Floseal: 57 s

- Hemostasis in <7 minutes
- Length of hospital stay

*60 pigs, 18 samples per pig.
**MECHANISM of ACTION**

**Gelatin:**
- The flowable gelatin matrix provides an environment for platelets to adhere and aggregate within, building on the patient’s natural coagulation cascade.

**Thrombin:**
- Enhancing the tamponade of the gelatin matrix, the thrombin component of SURGIFLO® Hemostatic Matrix Kit acts as a catalyst and accelerates the patient’s endogenous fibrinogen, accelerating clot formation.

Once bleeding has ceased, irrigate excess SURGIFLO® away gently so as not to disturb the new clot. When used in appropriate amounts, SURGIFLO® is absorbed completely within 4-6 weeks.
SURGIFLO® Hemostatic Matrix Kit with thrombin

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<td>8ML4805</td>
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**PRECAUTIONS**

- 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 flexible applicator tip should not be trimmed to avoid exposing internal guidewire.

**WARNINGS**

- Do not use SURGIFLO® in closure of skin incisions because it may interfere with the healing of skin edges. This interference is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.
- 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.

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

**DESCRIPTION**

- SURGIFLO® is supplied as a sterile product and cannot be resterilized.
- 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.

**REFERENCES**

1. [Link]
2. [Link]
3. [Link]
4. [Link]
5. [Link]
6. [Link]
7. [Link]
8. [Link]
9. [Link]
10. [Link]
• 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 fluid, and hematoma have been observed at implant sites.

• 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 incontinence, cauda equina syndrome, neurogenic bladder, impotence, and paresis.

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

A total of 142 patients received SURGIFOAM® Sponge during a clinical trial comparing SURGIFOAM® Sponge to another absorbable gelatin sponge. In general, the following adverse events have been reported with the use of absorbable porcine

ADVERSE EVENTS

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

• SURGIFLO® is supplied as a sterile product and cannot be resterilized.

• 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.

• SURGIFLO® should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm because it may swell, resulting in nerve damage.

• SURGIFLO® should not be used in the presence of infection and should be used with caution in contaminated areas of the body.

• Do not use SURGIFLO® in closure of skin incisions because it may interfere with the healing of skin edges. This interference is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.

• 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.

INTENDED USE/INDICATIONS

SURGIFLO® with Thrombin (SURGIFLO® Hemostatic Matrix Kit) is intended for hemostatic use by applying to a bleeding surface.

SURGIFLO® Hemostatic Matrix Kit Essential Product Information (Made from Absorbable Gelatin Sponge, USP) with Thrombin

EVITHROM® Thrombin, Topical (Human) for Topical Use Only

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.

EVITHROM® may be used in conjunction with an Absorbable Gelatin Sponge, USP.

Important Safety Information

•
SURGIFLO® Hemostatic Matrix Kit with thrombin

<table>
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<tr>
<td>092500</td>
<td>Evithrom® Hemostatic Matrix Kit (fully sterile)</td>
<td>Case of 6</td>
</tr>
</tbody>
</table>

For technical support, call ETHICON.
For additional information visit www.ethicon.com.
Call 1-800-282-9200 to order.