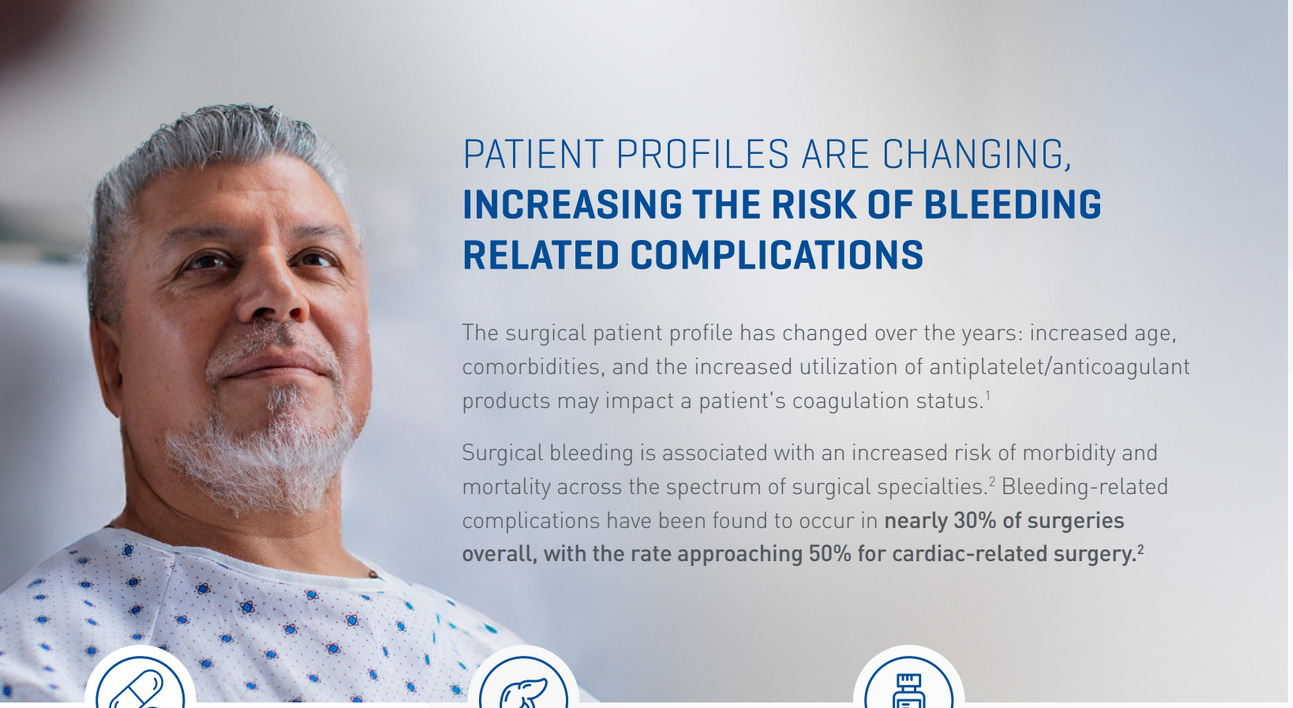
Baxter

Floseal

HEMOSTATIC MATRIX

# **UNMATCHED** SPEED.
# RELIABLE **HEMOSTASIS**.


Please see Indication and Important Risk Information on page 12



# PATIENT PROFILES ARE CHANGING, **INCREASING THE RISK OF BLEEDING RELATED COMPLICATIONS**

The surgical patient profile has changed over the years: increased age, comorbidities, and the increased utilization of antiplatelet/anticoagulant products may impact a patient's coagulation status.[1]

Surgical bleeding is associated with an increased risk of morbidity and mortality across the spectrum of surgical specialties.[2] Bleeding-related complications have been found to occur in **nearly 30% of surgeries overall, with the rate approaching 50% for cardiac-related surgery.**[2]

**2/3**
**of surgical patients are treated with anticoagulants and/or antiplatelets[3]***

**1 in 50**
**adults have liver disease, a comorbidity that negatively impacts coagulation status[4]**

**~30%**
**of the US population uses low-dose aspirin[5]**

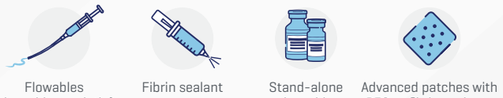
*Based on Premier Database

## Understand the difference to select the right product

Managing bleeding requires a patient-centric approach. Surgical teams benefit from an understanding of the different types of hemostatic agents available to supplement a surgeon's skills in achieving meticulous hemostasis.

### A ACTIVE HEMOSTATIC AGENTS[1]

Function independently of the patient's ability to generate clotting factors to achieve hemostasis and are effective regardless of patient coagulation status in a wide range of bleeding.[1]



Flowables (thrombin + gelatin) | Fibrin sealant | Stand-alone thrombin | Advanced patches with PEG or fibrin sealants

### P PASSIVE HEMOSTATIC AGENTS[1]

Aid in platelet aggregation and/or contact activation for platelet plug formation and rely on the patient's ability to generate clotting factors to convert fibrinogen to help form the fibrin clot.[1]

Oxidized cellulose | Collagens | Polysaccharide spheres | Powders | Gelatin sponges



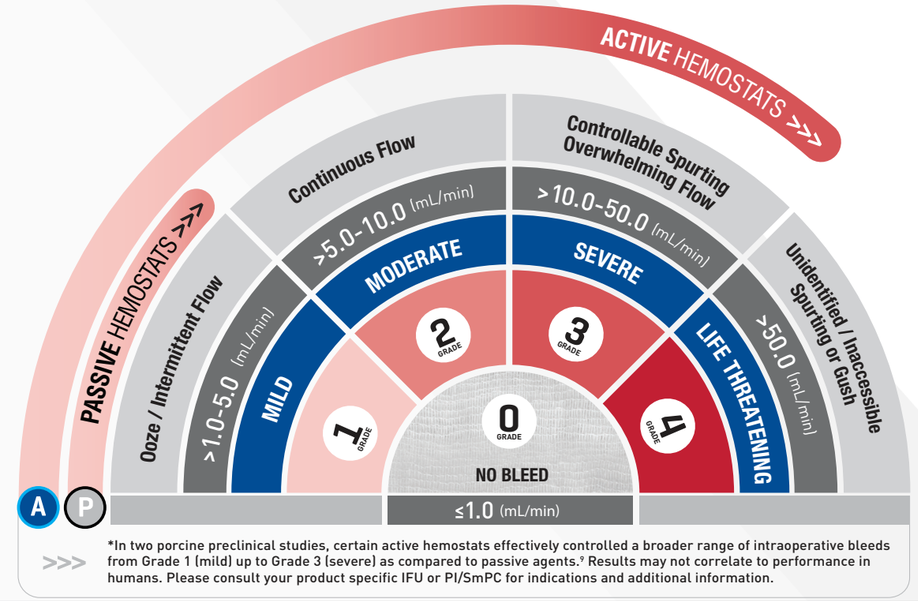
# IMPORTANCE OF CHOOSING THE **RIGHT** HEMOSTATIC AGENT

**Not knowing which adjunctive hemostatic agent to select can have negative impacts[1,6,7]**

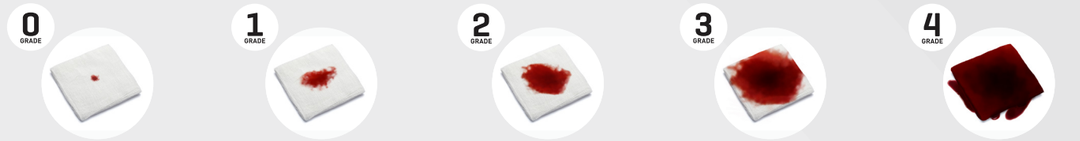
- Delays in hemostasis
- Excessive use of multiple hemostatic agents
- Increased intraoperative times
- Postoperative complications
- Extended hospital stay
- Increased costs

# **LEARN THE VIBE SCALE TOOL:** SEVERITY OF BLEED INFORMS CHOICE OF ADJUNCTIVE HEMOSTATIC AGENT[8,9]

**The Validated Intraoperative Bleeding (VIBe) SCALE** tool classifies bleeding severity by amount of blood loss, allowing surgical teams to effectively communicate the level of bleed.[8,9] Passive hemostatic agents are appropriate for Grade 1 bleeds for patients with intact coagulation.[1] For patients with compromised coagulation, consider an active hemostatic agent that can address bleeds that are mild, moderate, or severe - regardless of the patient's coagulation status.[1]




***In two porcine preclinical studies, certain active hemostats effectively controlled a broader range of intraoperative bleeds from Grade 1 (mild) up to Grade 3 (severe) as compared to passive agents.[9] Results may not correlate to performance in humans. Please consult your product specific IFU or PI/SmPC for indications and additional information.**



**0 GRADE**
**NO BLEED**
≤1.0 mL/min

**1 GRADE**
**MILD**
>1.0 - 5.0 mL/min

**2 GRADE**
**MODERATE**
>5.0 - 10.0 mL/min

**3 GRADE**
**SEVERE**
>10.0 - 50.0 mL/min

**4 GRADE**
**LIFE THREATENING**
>50.0 mL/min

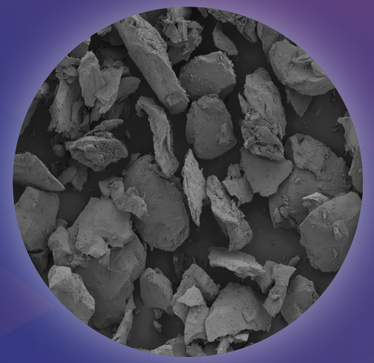
# FLOSEAL MATRIX: FAST HEMOSTASIS AND PREPARATION[10,12]

## Hemostasis[10]

FLOSEAL Matrix has the potential to achieve hemostasis in as little as

**60 seconds***

*For spinal/orthopedic specialty, median time to hemostasis was 1.5 min (95% CI, 1, 1.5)



Proprietary **Floseal** Matrix Smooth Granules[11]

## Preparation[12]

FLOSEAL Matrix can be prepared in approximately

**1 minute**

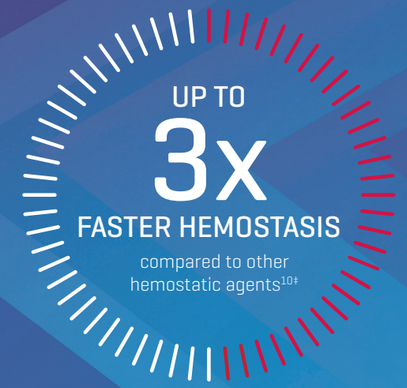
# FLOSEAL MATRIX IS EFFECTIVE AND PROVEN[10,14]

## Effective[10]

FLOSEAL Matrix is effective across multiple surgical specialties at a rate of

**96%***

*Hemostasis within 10 minutes - first lesion only




‡**Floseal** Matrix vs. **Gelfoam** Hemostat + Thrombin. Median time to hemostasis 2 minutes vs. 6 minutes.

## Proven[10,14]

Proven hemostasis and relative reductions in blood transfusions in cardiac surgery of

**54%†**

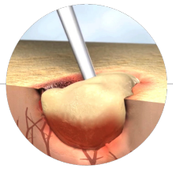
†Transfusion of blood products for **Floseal** Matrix n=31 [28.2%] vs comparator group [**Surgicel Nu-Knit** Hemostat or **Gelfoam** sponge n=63 [60.6%, p<0.001]].

SCAN TO WATCH THE MECHANISM OF ACTION

# UNIQUE MECHANISM OF ACTION

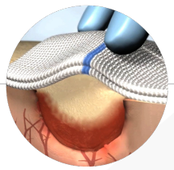
**Floseal** Matrix targets the beginning and end of the coagulation cascade: the **gelatin granules** assist with contact activation and platelet aggregation while the **thrombin** converts fibrinogen to fibrin to accelerate clot formation.[13] The gelatin granules swell approximately 10-20% within 10 minutes upon contact with blood or other fluids creating a **tamponade effect.**[10]

# PRODUCT APPLICATION[10]



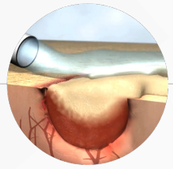
### APPLY

Identify the source of bleeding at the tissue surface and apply a small "mound" of **Floseal** Matrix to the target site. Do not inject or compress **Floseal** Matrix into blood vessels. Do not apply **Floseal** Matrix in the absence of blood flow.



### APPROXIMATE

Immediately and gently approximate **Floseal** Matrix to the bleeding surface with a gauze sponge moistened with sterile (non-heparinized) saline for approximately 2 minutes.



### IRRIGATE EXCESS

Once bleeding has ceased, excess **Floseal** Matrix not incorporated into the clot should always be removed by gentle irrigation and suctioned away.

### LEAVE IN SITU

Do not disrupt the clot by physical manipulation. **Floseal** Matrix incorporated in the hemostatic clot should be left in situ. **Floseal** Matrix is biocompatible and resorbed within 6 to 8 weeks, consistent with normal wound healing.

# FIRST AND ONLY[10]

**Floseal** Matrix is the **FIRST AND ONLY** active flowable hemostat to use recombinant DNA technology.
The thrombin component is **Recothrom** Thrombin Topical (Recombinant) and has the following key benefits:

- **No human blood components**
- **Structurally similar to human thrombin**
- **Eliminate reliance on human blood donations**

**Selected Risk Information for FLOSEAL Matrix:** Do not administer to patients with a history of or hypersensitivy to **Recothrom** Thrombin Topical [Recombinant], any component of **Recothrom** or hamster proteins.



Please see Indication and Important Risk Information on page 12

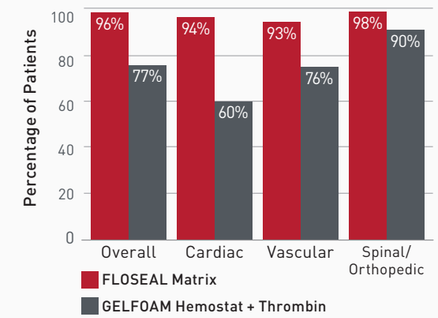
# PROVEN CLINICAL DATA[10,15-17]

## Study Design

Prospective, randomized controlled trials (RCT) have demonstrated that **Floseal** Matrix acts fast to achieve hemostasis, decreasing the potential for complications and reducing the procedure time. The objective of the pivotal studies was to evaluate the safety and effectiveness of **Floseal** Matrix compared to a **Gelfoam** Hemostat + Thrombin in controlling intraoperative bleeding. **Floseal** Matrix is effective across surgical specialties: 309 patients participated in the RCTs for procedures in cardiac, vascular, spinal or orthopedic surgeries.

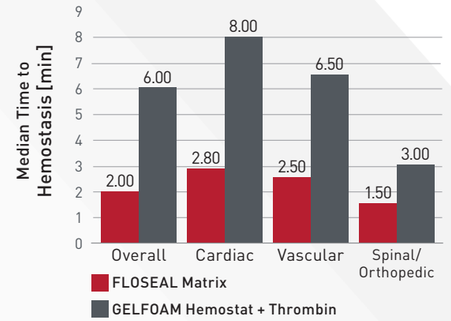
### Primary Endpoint: Cessation of Bleeding Within 10 Minutes

**Hemostasis Within 10 Minutes**
First Lesion Only (Intent-to-Treat Patients)




### Secondary Endpoint: Time To Hemostasis

**Median Time to Hemostasis**
(Minutes)




**Selected Risk Information for FLOSEAL Matrix: Floseal** Matrix is not intended as a substitute for meticulous surgical technique and proper application of ligatures or other conventional procedures for hemostasis. **Floseal** Matrix is not intended as a prophylactic hemostatic agent.



Please see Indication and Important Risk Information on page 12

PROVEN IN

# CARDIOVASCULAR SURGERY

**FLOSEAL** Matrix is effective in heparinized patients.[10,15]

## **EFFECTIVE HEMOSTASIS** IN HEPARINIZED CARDIAC SURGERY PATIENTS[10,15]

### Study Design

A prospective, randomized, multi-center trial comparing **Floseal** Matrix with a control hemostat (**Gelfoam** Hemostat + Thrombin) in stopping intraoperative bleeding during cardiovascular surgery was undertaken.

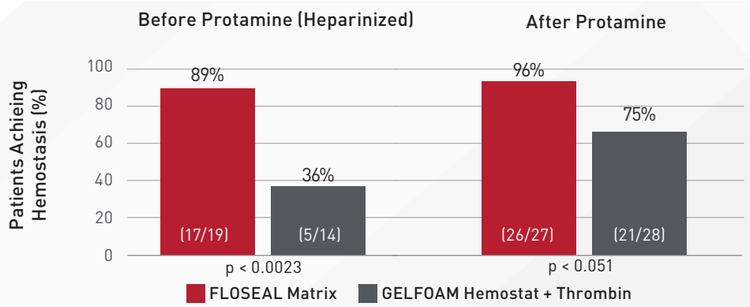
Four cardiac centers randomized 93 patients; 88 of 93 patients underwent extracorporeal cardiopulmonary bypass. Randomization occurred after bleeding requiring a topical hemostatic agent was identified. The primary endpoint was hemostasis for the first treated bleeding site within 10 minutes.

All patients were heparinized during the operation. The average heparin dose was 41,542 ± 21,010 U (mean ± SD) in the **Floseal** Matrix group and 38,289 ± 15,506 U (mean ± SD) in the control group.

The success rate for **Floseal** Matrix did not appear to be affected by whether or not the patient had received protamine sulfate administration. This was demonstrated by the success rate for **Floseal** Matrix before protamine sulfate administration which was similar to the success rate after protamine sulfate administration whereas the Control hemostat success rate was clearly lower before protamine sulfate reversal of heparin was administered.

There was no difference in the adverse event profile between the two groups.

**Hemostasis in Cardiovascular Surgery**



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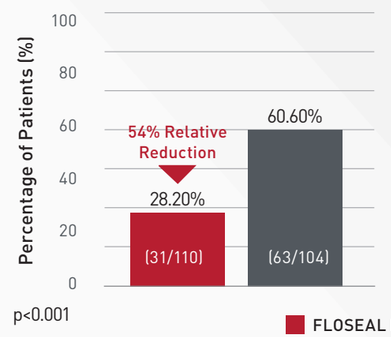
## REDUCTION IN **BLOOD PRODUCT TRANSFUSIONS, SURGICAL REVISION RATES, OPERATIVE HEMOSTASIS TIME** AND **MINOR COMPLICATIONS**[10,14]

### Study Design

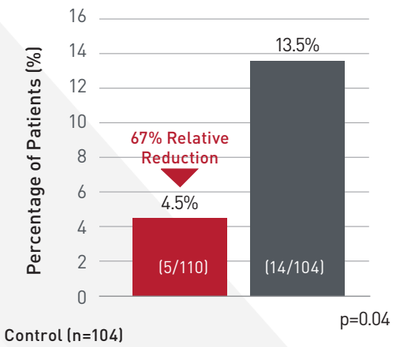
In a prospective, randomized controlled trial for cardiovascular surgery, patients were assigned to a **Floseal** Matrix group (n=209) or the comparator group (n=206). The comparator group was treated with either **Surgicel Nu-Knit** Absorbable Hemostat (oxidized regenerated cellulose) or **Gelfoam** sponge (purified porcine skin gelatin).

A sub-analysis of patients who suffered from intraoperative bleeding (**Floseal** Matrix [n=110] and comparator [n=104]) revealed that **Floseal** Marix is proven to reduce transfusion of blood products (p<0.001), reduce surgical revision rate for bleeding (p=0.04), reduce operative hemostasis time* (p<0.001), and reduce minor complications† (p=0.04).

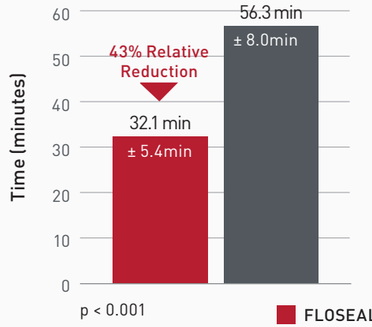
**Transfusion of Blood Products**




**Surgical Revision Rate for Bleeding**

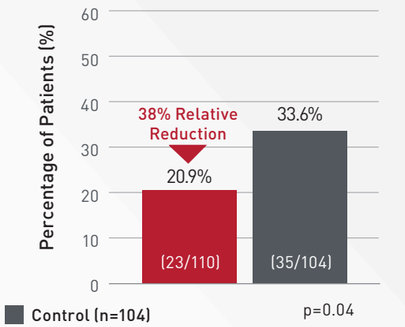



**Operative Hemostasis Time***




*Operative time comprised between decannulation and closure of the sternum

**Minor Complications†**




†Defined as either renal failure, respiratory insufficiency, or inotropic support lasting more than 24 hours.



Please see Indication and Important Risk Information on page 12

PROVEN IN

# SPINE SURGERY

FLOSEAL Matrix is

## 2x faster*

at achieving hemostasis[10,16]

*Compared to **Gelfoam** Hemostat + Thrombin.


FLOSEAL Matrix


**Median time to hemostasis: 1.5 minutes[10,16]**

The safety and effectiveness of **Floseal** Matrix in spinal surgery procedures have been proven.[10,16]

A prospective, multi-center, randomized controlled trial comparing **Floseal** Matrix with **Gelfoam** Hemostat + Thrombin in stopping intraoperative bleeding during spinal surgery was undertaken. Four centers randomized 127 patients, 21 years of age or older. Randomization occurred after a bleeding lesion requiring a topical hemostatic agent was identified.[10,16]

The primary endpoint was hemostasis for the first treated bleeding site. There was no difference in the adverse event profile between the two groups.[10,16]

In this trial, the median time to hemostasis was 1.5 minutes (95% confidence interval [CI], 1, 1.5) for **Floseal** Matrix and 3 minutes (95% CI, 2, 4.5) for **Gelfoam** Hemostat + Thrombin.[10,16]

GELFOAM Hemostat+Thrombin

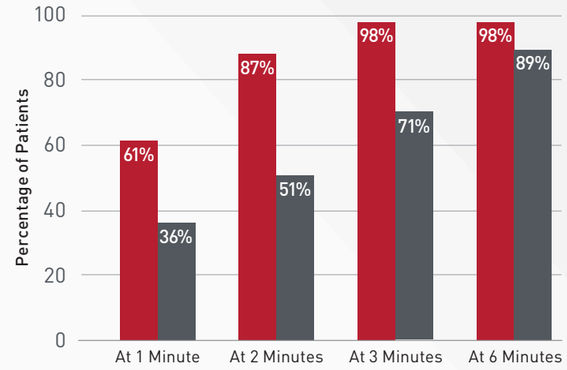

**Median time to hemostasis: 3.0 minutes[10,16]**



Please see Indication and Important Risk Information on page 12

## MORE EFFECTIVE AT **EACH TIME POINT**

**Time to hemostasis in spinal surgery, first bleeding site[10,16]**

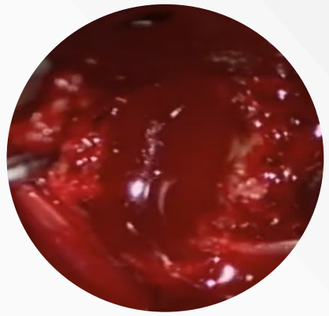



**Floseal** Matrix is More Effective than **Gelfoam** Hemostat + Thrombin at Each Time Point[10,16]

At each time point, the percentage of success in the **Floseal** Matrix group was greater than the **Gelfoam** Hemostat + Thrombin group; this was also true for all bleeding sites ($p<0.001$). The application was considered successful if the bleeding stopped within 10 minutes.[10,16]

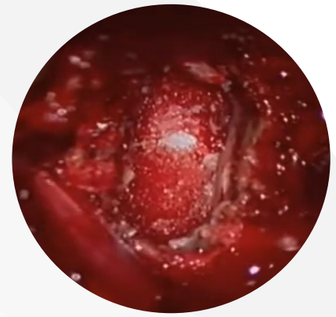
## IMPROVED VISUALIZATION

In spinal surgery procedures, excessive and/or uncontrolled bleeding imparts challenges related to adequate visualization.[6]



BEFORE
FLOSEAL MATRIX

Baxter Image on File



AFTER
FLOSEAL MATRIX

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**Selected Risk Information for FLOSEAL Matrix:** Do not inject or compress **Floseal** Matrix into blood vessels. Do not apply **Floseal** Matrix in the absence of active blood flow, e.g. while the vessel is clamped or bypassed, as extensive intravascular clotting and even death may result.



Please see Indication and Important Risk Information on page 12

*Based on 600 surgeries and US dollar.

# POTENTIAL FOR **SIZABLE COST SAVINGS** IN **CARDIAC SURGERY**

## Study Design

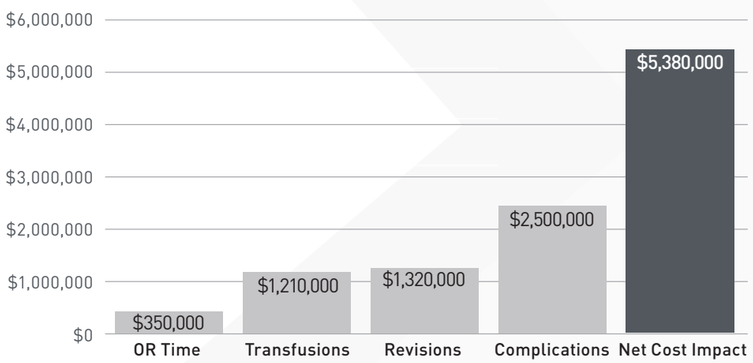
Based on clinical outcomes from a prospective randomized clinical trial, Nasso et al[14], a cost consequence framework was utilized to model the economic impact of comparator groups.[18] Clinical outcomes were obtained and analyzed for a flowable hemostatic matrix (**Floseal** Matrix) vs passive, basic (non-flowable) topical hemostats (**Surgicel** and **Gelfoam** Hemostats).[18]

Costing analyses focused on the following outcomes: complications, blood transfusions, surgical revisions, and operating room (OR) time.[18] The results suggest that if an active flowable hemostatic matrix (rather than a passive, basic hemostat) was utilized exclusively in 600 mixed cardiac surgeries annually, a hospital could improve outcomes by a reduction of 109 complications, 54 surgical revisions, 194 transfusions, and 242 hours of OR time.[18]

Study outcomes correspond to a **net annualized cost consequence savings of $5.38 million when using FLOSEAL Matrix** versus passive hemostats (**Surgicel**/**Gelfoam** Hemostats) with complication avoidance as the largest contributor.[18]

## Using **Floseal** Matrix Results in Significant Cost Savings[18]

**Cost Consequence Framework Based on a Hospital Conducting 600 Cardiac Surgeries Per Year***




Cost consequences avoided with use of FLOSEAL Matrix correspond to an **ANNUAL SAVINGS OF**

**$5.38 million**

*An avoidable cost consequence would result until the difference between **Floseal** Matrix and the **Surgicel/Gelfoam** reached $8,960.36 per average case. At this price differential, there would no longer be an economic cost consequence between the comparative groups.

## Clinical Outcomes AVOIDED by Using **Floseal** Matrix Instead of Passive Hemostats[18]

| Outcome | Number Avoided |
|---|---|
| Major complications* | 33 events |
| Minor complications | 76 events |
| Surgical revisions for bleeding | 54 events |
| Blood transfusions | 194 events |
| Operating room time | 242 hours |

*Difference in rate of major complications between **Floseal** Matrix group and comparator group was not found to be statistically significant in the trial outcomes.



Please see Indication and Important Risk Information on page 12



# POTENTIAL FOR **SIZABLE COST SAVINGS** IN **SPINE SURGERY**

## Study Design

Based on outcomes from Price et al[7], a cost consequence framework was utilized to model the economic impact of **Floseal** Matrix vs. **Surgiflo** Matrix in spine surgery.[7,19]

Compared to **Surgiflo** Matrix (base case of 182 major and 59 severe spine surgeries annually), **Floseal** Matrix required 3 fewer blood transfusions and reduced 53 hours of OR time, resulting in annual savings of $151 per major and $574 per severe spine surgery patient in addition to totally offsetting the product cost.[7,19]

Study outcomes indicate that using **FLOSEAL Matrix** instead of **SURGIFLO** Matrix in spine surgery potentially **leads to sizable cost savings for hospitals**. Monte-Carlo simulations demonstrated **annual savings in major and severe spine surgery were $27,412 and $33,839, respectively**.[19]

## Economic Outcomes for **Floseal** Matrix versus **Surgiflo** Matrix Base Case: Medium-Size Hospital*[7,19]

| MAJOR SPINE SURGERY | |
|---|---|
| Medium-Size Hospital, Mean Number of Surgeries (Range)* | 182 Major Spine Surgeries (101-300) |
| Number of OR Hours Saved | 27 |
| Number of Transfusions Avoided | 3 events |
| Net Cost Savings† | $27,412 (**$151 Per Surgery**) |
| **SEVERE SPINE SURGERY** | |
| Medium-Size Hospital, Mean Number of Surgeries (Range)* | 59 Severe Spine Surgeries (39-100) |
| Number of OR Hours Saved | 26 |
| Net Cost Savings† | $33,389 (**$574 Per Surgery**) |

Outcomes associated with FLOSEAL Matrix correspond to an **ANNUAL SAVINGS OF**

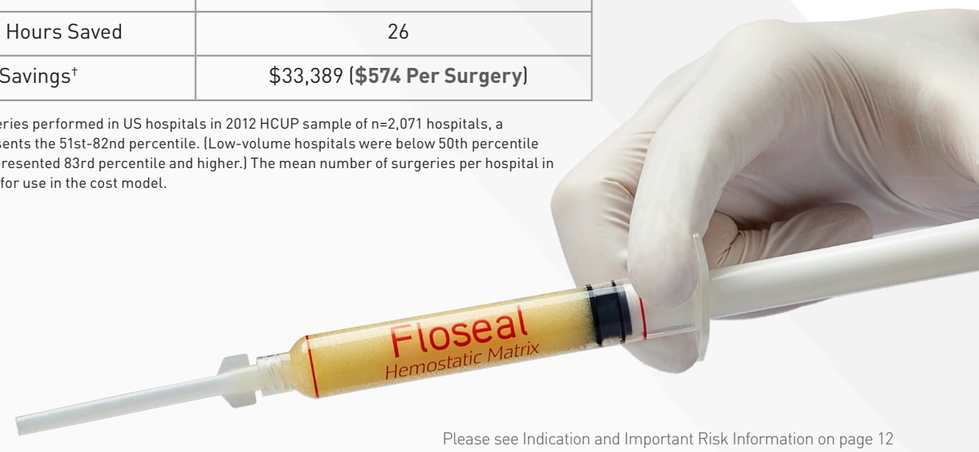
**$27,412**

**IN MAJOR SPINE SURGERIES AND**

**$33,839**

**IN SEVERE SPINE SURGERIES**

*In an analysis of all spinal surgeries performed in US hospitals in 2012 HCUP sample of n=2,071 hospitals, a medium-volume hospital represents the 51st-82nd percentile. (Low-volume hospitals were below 50th percentile while high-volume hospitals represented 83rd percentile and higher.) The mean number of surgeries per hospital in each group was then calculated for use in the cost model.
†Based on 2016 US Dollar.






Please see Indication and Important Risk Information on page 12

## Ordering Information

| PRODUCT | QTY | PRODUCT NUMBER |
|---|---|---|
| **FLOSEAL Matrix 5mL** | Case of 6 | ADS202105 |
| **FLOSEAL Matrix 10mL** | Case of 6 | ADS202110 |
| **Endoscopic Applicator (41 cm)** | Pack of 6 | 0600225 |
| **13 cm Malleable Applicator Tip** | Pack of 6 | ADS201816 |
| **Disposable Curved Applicator Tip** | Pack of 10 | ADS201815 |

## FLOSEAL Hemostatic Matrix Indications and Important Risk Information

**FLOSEAL Hemostatic Matrix Indication**

**Floseal** Matrix is indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.

**Important Risk Information**

**Do not inject intravascularly.**

Do not inject or compress **Floseal** Matrix into blood vessels.

Do not apply **Floseal** Matrix in the absence of active blood flow, e.g., while the vessel is clamped or bypassed, as extensive intravascular clotting and even death may result.

Do not administer to patients with a history of hypersensitivity to **Recothrom** Thrombin topical (Recombinant), any components of **Recothrom**, or hamster proteins.

Do not use **Floseal** Matrix in patients with known allergies to materials of bovine origin.

Do not use **Floseal** Matrix in the closure of skin incisions because it may interfere with the healing of the skin edges due to mechanical interposition of gelatin.

**Floseal** Matrix is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for hemostasis. **Floseal** Matrix is not intended to be used as a prophylatic hemostatic agent.

As with other hemostatic agents, do not apply **Floseal** Matrix to sites where there is negative peripheral venous pressure, as material may be drawn into the vascular system potentially resulting in life-threatening thromboembolic events.

Excess **Floseal** Matrix (material not incorporated in the hemostatic clot) should always be removed by gentle irrigation and suctioned out of the wound.

The particles of **Floseal** Matrix swell approximately 10-20% (upon contact with blood or other fluids) and surgeons should consider its potential effect on the surrounding anatomic areas. Maximum swell volume is achieved within about 10 minutes.

**Floseal** Matrix should not be used in the presence of infection. **Floseal** Matrix should be used with caution in contaminated areas of the body.

The safety and effectiveness of **Floseal** Matrix for use in ophthalmic procedures has not been established.

**Floseal** Matrix should not be used for controlling post-partum bleeding or menorrhagia.

The safety and effectiveness of **Floseal** Matrix has not been established in children under 2 years of age and pregnant women.

It is not known whether **Floseal** Matrix can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **Floseal** Matrix should be administered to a pregnant woman only if clearly needed.

Do not use air to remove residual **Floseal** Matrix from Applicator tip. The Applicator tips should not be cut, as tissue injury from sharp edges may result.

Hypersensitivity reactions, including anaphylaxis, may occur. **Recothrom** thrombin is produced in a genetically modified Chinese Hamster Ovary (CHO) cell line and may contain hamster or snake proteins.

For single use only. Do not re-sterilize.

**Floseal** Matrix should not be applied before the application site is cleaned to remove any antiseptics that may contain alcohol, iodine, or heavy metal ions.

When placed into cavities or closed tissue spaces, gentle approximation is advised. Do not compress.

As with other hemostatic agents, do not aspirate **Floseal** Matrix into extracorporeal cardiopulmonary bypass circuits or autologous blood salvage circuits.

Do not use **Floseal** Matrix on bone surfaces where adhesives, such as methylmethacrylate or other acrylic adhesives, will be required to attach a prosthetic device.

**Floseal** Matrix should not be used for the primary treatment of coagulation disorders.

The safety and effectiveness of the combined use of **Floseal** Matrix with antibiotic solutions or powders has not been established.

The safety and effectiveness for use in neurosurgical and urological procedures has not been established through randomized clinical studies.

In urological procedures, **Floseal** Matrix should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.

Antibody formation to Recothrom thrombin occurred in <1% of patients. None of the antibodies detected neutralized native human thrombin.

Thrombin must be added to the Gelatin Matrix prior to use.

**Rx Only.** For safe and proper use of this device, refer to the full Instructions for Use.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