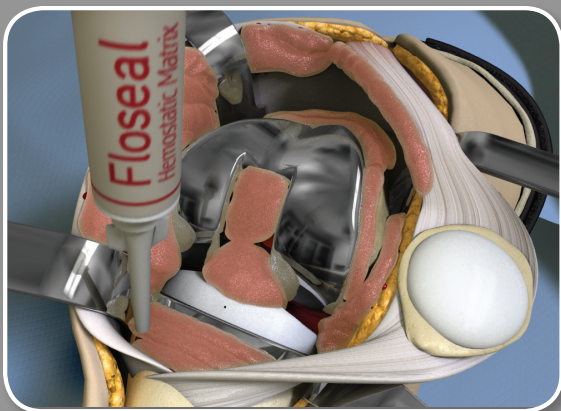




Floseal
Hemostatic Matrix

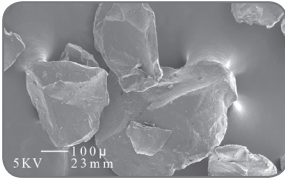


Total Knee & Hip Replacement with
FLOSEAL Hemostatic Matrix

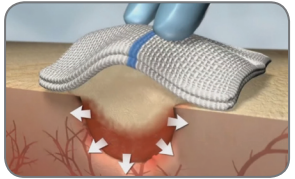
The FLOSEAL Hemostatic Matrix Advantage

A Unique Combination

FLOSEAL Hemostatic Matrix's unique patented gelatin granules and human thrombin provide fast and effective haemostasis.¹



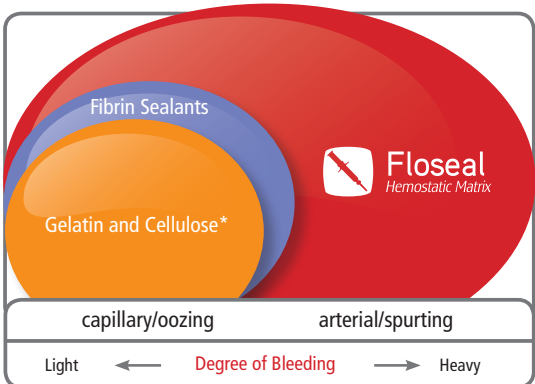
FLOSEAL Patented Granules



Mechanically Stable Clot

- Specially designed round-shaped patented gelatin granules allow for a large contact surface with thrombin for fast efficacy
- Thrombin converts fibrinogen into a stable fibrin clot¹
- Works at the beginning and the end of the clotting cascade, for action less susceptible to coagulopathies from factor deficiencies or platelet dysfunctions¹

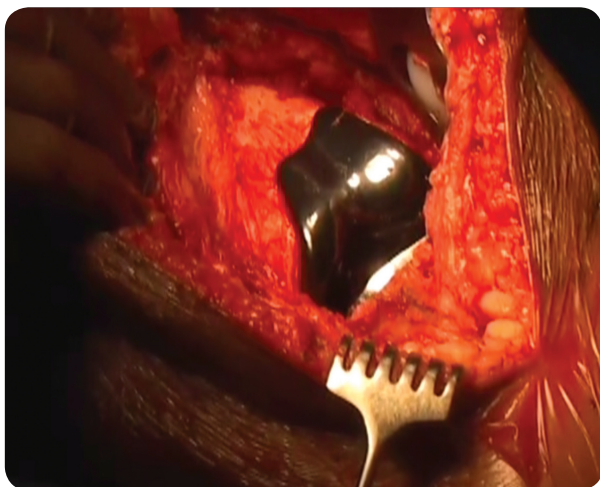
IFU Comparison²⁻⁸



**Gelatin and cellulose do not contain thrombin.*

Benefits of FLOSEAL Hemostatic Matrix for Orthopedic Surgery

- Stops bleeding fast in 90 seconds (median time to hemostasis)⁹
- Reduces blood transfusions and post operative bleeding¹⁰
- Helps protect against rebleeding by forming a mechanically stable clot^{3,10}
- Proven 89% effective in heparinised patients within 10 minutes³

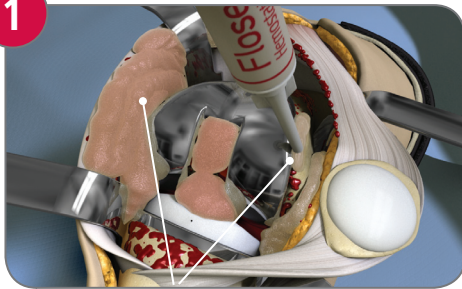


Haemostasis achieved with FLOSEAL prior to closing and after the tourniquet has been turned down

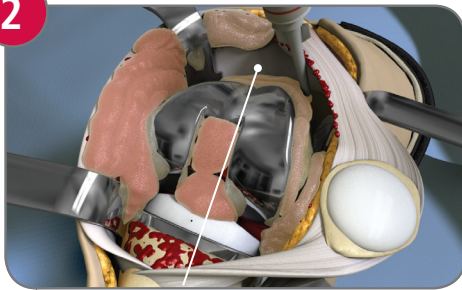
FLOSEAL Hemostatic Matrix Application*

Total Knee Replacement

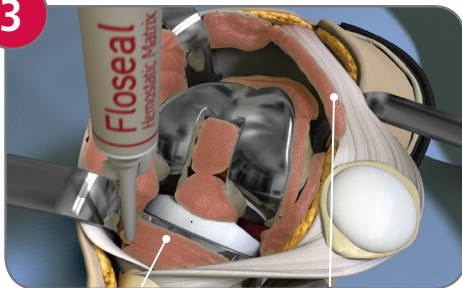
FLOSEAL can be applied throughout the intraarticular space of the knee. Once all excess cement has been removed from around the prosthesis, and the knee has been lavaged, FLOSEAL can be applied to all sites of active bleeding, preferably while the tourniquet has been turned down. These include:



The medial and lateral gutters



The suprapatellar pouch



*The exposed surface
of the tibia*

*The retinacular
incision*

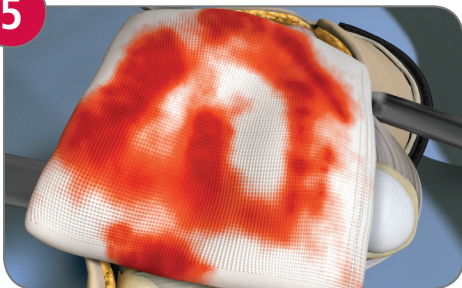
*For the instructions of the preparation of the thrombin solution, please consult your IFU.

4



Gently approximate a damp lap pad or moistened gauze

5



Hold for approximately 2 minutes to maintain product on site at the time of fibrin polymerization

6

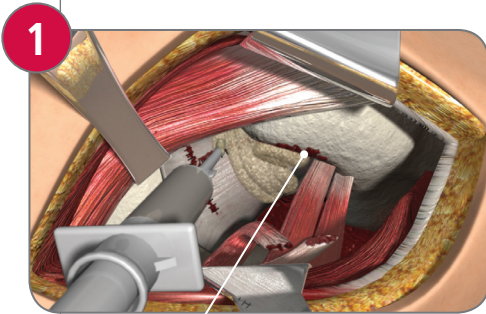


Once haemostasis is achieved, gently irrigate any excess FLOSEAL that has not been incorporated into the clot

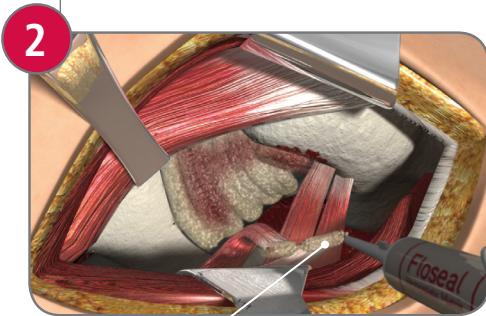
FLOSEAL Hemostatic Matrix Application

Total Hip Replacement

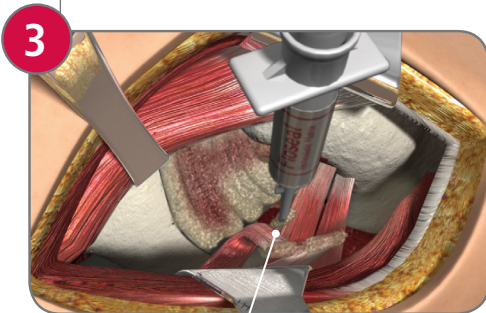
FLOSEAL Hemostatic Matrix can be applied to actively bleeding tissue, including:



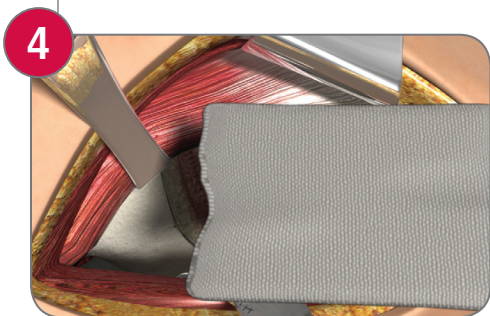
The posterior/inferior capsule



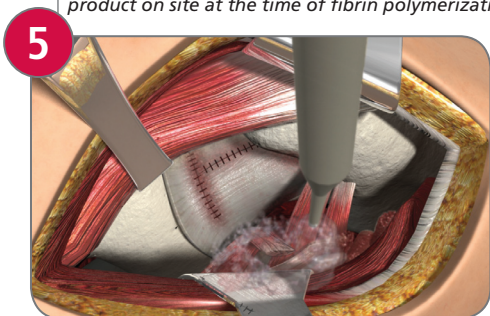
The short external rotator muscles



*The area just inferior to external rotators
(often a source of vascular oozing)*



Gently approximate FLOSEAL with a moistened lap pad or moistened gauze pad for approximately 2 minutes to maintain product on site at the time of fibrin polymerization

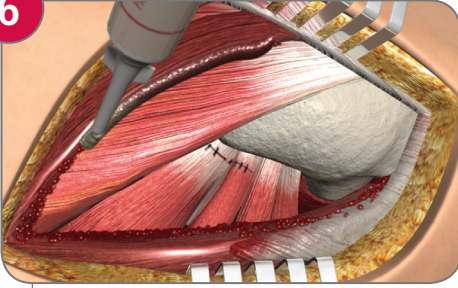


Once haemostasis is achieved, gently irrigate any excess FLOSEAL that has not been incorporated into the clot

FLOSEAL Hemostatic Matrix Application

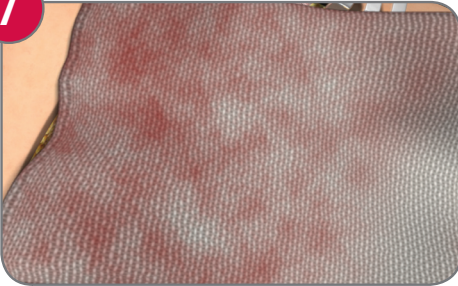
Total Hip Replacement

6



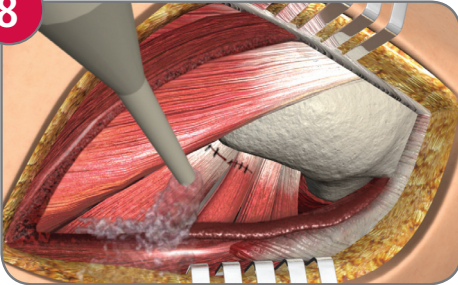
FLOSEAL may be applied to the broad surface area of the gluteus maximus following repair of the short external rotators, just prior to fascial closures

7



Gently approximate FLOSEAL with a moistened lap pad or moistened gauze pad for approximately 2 minutes to maintain product on site at the time of fibrin polymerization

8



Once haemostasis is achieved, gently irrigate any excess FLOSEAL that has not been incorporated into the clot

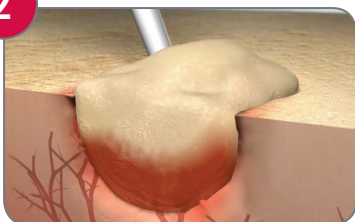
Tips for Application²

1 Swoosh



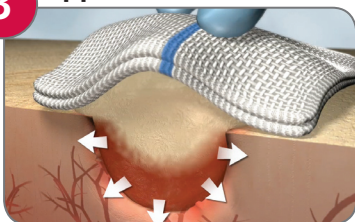
Transfer the gelatin matrix-thrombin solution mixture back and forth between the syringes for a total of at least twenty passes.

2 Place



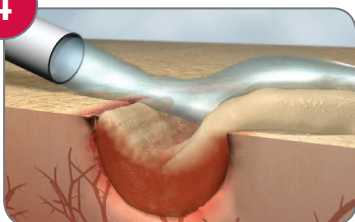
Identify the source of bleeding at the tissue surface. This is the target site for FLOSEAL Matrix application. Do not inject FLOSEAL Matrix into blood vessels.

3 Approximate



Manually approximate a gauze sponge moistened with sterile (non-heparinized) saline against the bleeding surface. Use the applicator tip to dispense FLOSEAL between the sponge and the bleeding surface.

4 Rinse and Continue



After approximately two minutes, lift the gauze sponge and inspect the wound site.

If bleeding has ceased, excess FLOSEAL Matrix (not incorporated in the hemostatic clot) should be removed by gentle irrigation. FLOSEAL may be reapplied if necessary to control bleeding.

Frequently Asked Questions

1. For what type of procedures do you use FLOSEAL Hemostatic Matrix? Where and how?

FLOSEAL can be used in ALL orthopedic procedures in which oozing to active and spurting bleeding cannot be controlled by standard surgical techniques. FLOSEAL may be utilized to manage active bleeding in:

- Total knee replacement (TKA)
- Total hip replacement (THA)
- Total shoulder replacement (TSA)
- Osteotomies

Excess FLOSEAL (material not incorporated in the haemostatic clot) should be removed by gentle irrigation from the site of application. FLOSEAL is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for haemostasis.²

2. Can I use FLOSEAL Hemostatic Matrix when cementing?

FLOSEAL should not be used in conjunction with methylmethacrylate or other acrylic adhesives.

Microfibrillar collagen has been reported to reduce the strength of methylmethacrylate adhesives used to attach prosthetic devices to bone surfaces. Do not use FLOSEAL on bone surfaces where adhesives will be required to attach a prosthetic device.

3. Can FLOSEAL Hemostatic Matrix scratch/harm the implant?

No. FLOSEAL is absorbed in the body in 6–8 weeks.²

4. Can I use FLOSEAL Hemostatic Matrix in conjunction with a drain?

Yes. The use of FLOSEAL is not contraindicated for procedures where a drain may be utilized.² Drains should be applied AFTER hemostasis with FLOSEAL has been achieved.



References

1. Oz MC, Rondinone JF, Shargill NS. Floseal matrix: new generation topical hemostatic sealant. *J Card Surg.* 2003;18:486-493
2. Floseal VH S/D Hemostatic Matrix [instructions for use]. Zurich, Switzerland: Baxter Healthcare SA; 2009.
3. Oz MC, Cosgrove DM, Badduke BR. Controlled clinical trial of a novel hemostatic agent in cardiac surgery. *Ann Thorac Surg.* 2000; 69:1376-1382.
4. Avitene [Instructions For Use]. Murray Hill, NJ: CR Bard Inc; 2002.
5. Gelfoam [Instructions For Use]. Kalamazoo, MI: Pharmacia & Upjohn Co; 2003.
6. Surgicel, Surgicel Fibrillar, and Surgicel Nu-Knit Absorbable Hemostats [full prescribing information]. Somerville, NJ: Ethicon Inc; 2005.
7. Surgifoam [essential prescribing information]. Somerville, NJ: Ethicon Inc; 2004.
8. Tisseel VH S/D Fibrin Sealant [Instructions For Use]. Zurich, Switzerland: Baxter Healthcare SA; 2009.
9. Renkens KL Jr., Payner TD, Leipzig TJ, et al. A multicenter, prospective, randomized trial evaluating a new hemostatic agent for spinal surgery. *Spine.* 2001;26:1645-1650.
10. Nasso G et al. Prospective, randomized clinical trial of the Floseal matrix sealant in cardiac surgery. *Ann Thorac Surg.* 2009;88:1520-1526
11. US IMS data. 2008.
12. EU Market Research. Baxter International Inc; July 2008.
13. F&S Report: M2F8-54. Oct 2008.

FLOSEAL [Hemostatic Matrix] Indications

FLOSEAL is indicated in invasive*1 or surgically invasive*2 procedures as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.

*1 Invasive means penetration inside the body through a body orifice

*2 Surgically invasive means penetration inside the body through the surface of the body, with the aid or in the context of a surgical operation

Contraindications

Do not use FLOSEAL in patients with known allergies to materials of bovine origin.

Warnings

Do not inject or compress FLOSEAL into blood vessels. As with other hemostatic agents, FLOSEAL should not be aspirated into autologous blood salvage circuits. For a complete list of all warnings please refer to your IFU.



Floseal

Hemostatic Matrix

I would like to have the following products and quantities available:

Quantity	Code	Description	Packaging
_____	1501510	FLOSEAL Hemostatic Matrix 5 mL	6 pack
_____	934208	Curved Applicator Tip 8 cm	Single pack
_____	934210	Curved Applicator Tip 10 cm	Single pack
_____	1502186	Malleable/Trimmable Tips	6 pack

☐ Please add FLOSEAL to my preference card.

Surgeon name (please print) _____

Signature _____ Date _____



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