Control of bleeding by ligature or conventional procedures (e.g., cautery) because of their ineffectiveness or impracticality. In addition, many studies have demonstrated that FloSeal has been effective for the treatment of coagulation disorders, particularly when used in, around, or in proximity to the heart, as it is not absorbed through the myocardium or subendocardial space, and thus may be available to coagulate extracardiac blood flow.

The mixing accessories include a syringe with an integral plunger, applicator tips, and several mixing accessories. FloSeal Matrix consists of a bovine-derived Gelatin Matrix component and a Thrombin Solution component. The Thrombin Solution contains Thrombin derived from human plasma. This material is prepared from, and is derived from, human plasma. The safety and effectiveness of FloSeal Matrix for the treatment of coagulation disorders, particularly when used in, around, or in proximity to the heart, as it is not absorbed through the myocardium or subendocardial space, and thus may be available to coagulate extracardiac blood flow.

In addition, each lesion was subjectively scored for haemostasis and for the possibility of false-positive results, as this is the only way that truly was clinically useful.

The results for all lesions in all animals showed that the performance of FloSeal Matrix is superior to that of original FloSeal (containing bovine fibrinogen and thrombin). The performance of FloSeal Matrix containing human fibrinogen was compared to that of original FloSeal (containing bovine fibrinogen and thrombin) using the method of Blackwelder and Chang for proportionate differences. These data were analyzed using a paired Student’s t-test.

Hemostasis within 10 minutes – First Lesion Only (Intent-to-Treat Patients):

FloSeal group. The corresponding adverse events for the FloSeal group are listed in the table below:

The mixing accessories include a syringe with an integral plunger, applicator tips, and several mixing accessories. FloSeal Matrix consists of a bovine-derived Gelatin Matrix component and a Thrombin Solution component. The Thrombin Solution contains Thrombin derived from human plasma. This material is prepared from, and is derived from, human plasma. The safety and effectiveness of FloSeal Matrix for the treatment of coagulation disorders, particularly when used in, around, or in proximity to the heart, as it is not absorbed through the myocardium or subendocardial space, and thus may be available to coagulate extracardiac blood flow.

In order to determine primary effectiveness of FloSeal, compared to a commercial synthetic agent (i.e., a nonviral host's drug substance). The results for all lesions in all animals showed that the performance of FloSeal Matrix is superior to that of original FloSeal (containing bovine fibrinogen and thrombin). The performance of FloSeal Matrix containing human fibrinogen was compared to that of original FloSeal (containing bovine fibrinogen and thrombin) using the method of Blackwelder and Chang for proportionate differences. These data were analyzed using a paired Student’s t-test.

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In order to determine primary effectiveness of FloSeal, compared to a commercial synthetic agent (i.e., a nonviral host's drug substance). The results for all lesions in all animals showed that the performance of FloSeal Matrix is superior to that of original FloSeal (containing bovine fibrinogen and thrombin). The performance of FloSeal Matrix containing human fibrinogen was compared to that of original FloSeal (containing bovine fibrinogen and thrombin) using the method of Blackwelder and Chang for proportionate differences. These data were analyzed using a paired Student’s t-test.
The particles of FloSeal Matrix swell approximately For best results, FloSeal Matrix should be in complete
the Contraindications, Warnings, Precautions, and
damaged or opened, do not use.
Inspect the integrity of the contents of the FloSeal
FloSeal Matrix Preparation:

• After approximately two minutes, lift the gauze
• Identify the source of bleeding at the tissue
• An empty 5 mL syringe with an integral female
• Remove the plastic flip-off cap from the Calcium
• Open the Thrombin Component package outside
• If desired, transfer FloSeal Matrix to a smaller
• Product consistency may not be optimal if used
•  If desired, transfer FloSeal Matrix to a smaller
• Mix, do not try to force large, dry clumps of the
• Transfer the Gelatin Matrix-Thrombin solution
• The use of FloSeal Matrix for mechanical support
• Do not disrupt the FloSeal Matrix clot complex by

For Nasal/Sinus Applications:

Do not freeze.

Definition of Symbols:

Alteration, see instructions for use
Do not reuse

Sterilized using irradiation
Laboratory Free

Apply FloSeal

Sterile

Apply to the tissue surface.  After re-application of
FloSeal Matrix to the source of bleeding
with FloSeal.

The use of FloSeal Matrix for mechanical support
has not been studied.

For endoscopic sinus surgery and epistaxis

Delivery of FloSeal Matrix in the presence of bleeding
using a non-traumatic applicator of appropriate
length attached to the FloSeal Matrix syringe.

Apply sufficient FloSeal Matrix to liberate the
entire bleeding surface.

Using techniques in other appropriate application
instruments, a layer of reconstituted FloSeal Matrix
was used to reconstitute the Thrombin prior to
application.

Chloride Solution vial appropriately.

Transfer the Thrombin solution into the sterile
field by dispensing into the small bowl provided in
the inner package.  Items in this package will be
transferred it to the sterile field.

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