
(20.9% vs. 33.6%, p = 0.04) was observed in the FLOSEAL Matrix revision rate (4.5% vs. 13.5%, p=0.04) and minor complications for 96 hours postoperatively.

morbidity and intensive care unit stay. Patients were followed-up sternum), overall postoperative bleeding, rate of transfusion of.

FLOSEAL Matrix has been used as a hemostatic agent for the

Nasal/ Sinus Bleeding:

• While gripping the vial adapter packaging, attach the syringe

Preparing the Thrombin solution

Opening the package

•aring aseptically, open the syringe pouch containing the Thrombin. Remove the syringe from the package and attach the "Keyline" disposable needle to the syringe. After removing the rubber stopper, connect the syringe to the injection port of the "Keyline" syringe for use. When the syringe is not in use, it should be stored in the protective outer cap.

FLOSEAL Matrix Placement/Application Steps:

10x10

6. Remove and discard the Luer cap from the Gelatin Matrix applicator tip.

7. Using aseptic technique, open the MJN-202001-02, apply the sterile inner pouch to the FLOSEAL Matrix syringe. Next, slowly and steadily inject the contents of the syringe into the syringe until the contents are fully delivered.

8. If desired, dispense residual FLOSEAL Matrix from the tip through the center of the mass of previously placed FLOSEAL Matrix to deliver fresh FLOSEAL Matrix as close as possible to the tissue surface. After re-application of FLOSEAL Matrix, the treated site.

9. Do not disrupt the FLOSEAL Matrix clot by physical action. If the gauze sponge is removed, FLOSEAL Matrix will adhere to the newly-formed clot, should always be removed by gentle pressure and sucked out of the wound.

10. Do not discard the FLOSEAL Matrix clot by physical manipulation. FLOSEAL Matrix, once applied, is not designed to be removed. If the FLOSEAL Matrix clot is desired to be removed at the treated site.

BAXTER CONFIDENTIAL - INTERNAL USE ONLY

ADS201844

Part Number:  07-19-00-0361   Date:  10-JUN-2019 Proofread No.:  1

10 mL Kit

• 1 x 5 mL syringe

Component Pouch

2500 IU

Solvent /Detergent

Vapor Heated, (Human), Sterile (Non-Heparinized)

Not made with natural rubber latex; Indicates the device is not made with natural rubber latex as a material of construction. ISO 15223-1:2016, 5.4.3

Use-by date; Indicates the date after which the medical device can be safely used. ISO 15223-1:2016, 5.1.6

Catalog Number; Indicates the catalogue number so that the medical device can be identified. ISO 15223-1:2016, 5.4.5 and

Manufacturing lot number; Indicates the manufacturing lot number so that the medical device can be identified. ISO 15223-1:2016, 5.4.3

Symbols Referenced on Packaging

• Do not inject into blood vessels. Indicates a medical device that should not be injected into blood vessels.

• Do not use as injection or damage. Indicates a medical device that should not be used as an injection, or damage.

• Do not use in a patient with a medical device that should not be used in a patient. Indicates the need for the user to consult the catalogue number so that the medical device can be identified.

• Do not use in a patient with a medical device that should not be used in a patient. Indicates the need for the user to consult the manufacturing lot number so that the medical device can be identified.

• Do not use with intact rubber latex; Indicates the device is not intended for use with intact natural rubber latex. ISO 15223-1:2016, 5.4.2

Rev. Date: 2018-10-01

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