Preparation Instructions (10 mL)

FLOSEAL Haemostatic Matrix

Open all packages and place the components in a sterile field.



Inspect the integrity of the contents of the FLOSEAL Kit. If the packaging or vial has been damaged or opened, do not



Open the package containing the Sodium Chloride ampoule and deliver the ampoule to the sterile field using an aseptic



Open the outer pouch of the thrombin component and deliver the inner pouch to the sterile field Once placed in the sterile field, the inner package may be opened at



Open the outer pouch of the gelatin matrix component and deliver the inner pouch to the sterile field. Once placed in the sterile field, the inner package may be opened at any time.



Take care not to misplace the

Floseal HAEMOSTATIC MATRIX

Product Ordering code Floseal Haemostatic Matrix 10 mL 1503354 Laparoscopic Applicator, 6 pack 0600125

Preparing the Thrombin Solution



Remove the Tyvek lid from the vial adapter packaging



Remove twist-off can from the Sodium Chloride ampoule.



While gripping the vial adapter packaging, attach the vial adapter to the pre-filled Sodium Chloride ampoule using a luer lock motion and remove the vial adapter packaging.



Remove the plastic flin-off cap from the Thrombin vial.



Once mixed, the Thrombin Solution can be used immediately or may be stored at 2-25°C in the vial up to 4 hours,

While holding the vial adapter, pierce the rubber stopper of the Thrombin vial. Transfer the entire contents of the Sodium Chloride ampoule into the Thrombin vial.



Gently swirl the Thrombin vial with vial adapter and ampoule attached until the Thrombin is completely dissolved. Remove the empty Sodium Chloride ampoule and discard.

Components:



ampoule



Mixing the components



Attach the white luer connector to the empty 10mL syringe. With the white luer connector in place connect the empty syringe to the vial adapter on the Thrombin vial



Draw the thrombin solution from the vial to the indicated mark (8 mL). Discard the empty Thrombin vial and the vial adapter appropriately ensuring that the white luer connector remains connected to the syringe.



Remove the cap from the Gelatin Matrix Syringe carefully to avoid spilling the Gelatin Matrix granules. Connect the Gelatin Matrix Syringe to the syringe containing 8 mL of Thrombin solution using the white luer connector



Push the plunger of the Thrombin solution syringe to quickly pass the solution into the syringe containing the Gelatin Matrix This constitutes "one pass." Transfer the Gelatin Matrix Thrombin solution mixture back and forth between the syringes for a total of 10 passes back and



Ensure the syringe labeled FLOSFAL contains the reconstituted FLOSEAL Matrix. If desired, connect an Applicator Tip or Malleable Tip to the FLOSEAL syringe.



FLOSEAL may be used up to 8 hours after mixing with the Thrombin Solution. Allow 30 seconds after preparation before FLOSEAL is applied to ensure optimal product consistency.

Components:



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