Quick Reference Guide

**Instructions for Circulating Nurse**

1. Turn on the FIBRINOTHERM device (amber switch) and place all vials in their wells. Allow vials to warm for several minutes (the indicator light goes on and off automatically indicating proper warming temperature). Do not turn on magnetic stirring at this time (green switch).

2. Attach one needle to the blue-scaled syringe and one to the black-scaled syringe. If using the DUPLOJECT EASY PREP System, please refer to the DUPLOJECT EASY PREP assembly instructions.

3. A. Using the blue-scaled syringe, withdraw the entire volume of fibrinolysis inhibitor.
   B. Inject this entire volume into the sealer protein concentrate vial.
   C. Discard empty syringe and needle in sharps container.

4. Turn on the green switch to activate magnetic stirring.

5. Remove the calcium chloride vials from the FIBRINOTHERM device.
   A. Using the black-scaled syringe, withdraw the entire volume of calcium chloride.
   B. Inject this entire volume into the Thrombin vial.
   C. Mix by swirling briefly, then place the Thrombin vial back into its well in the FIBRINOTHERM device.
   D. Discard empty syringe and needle in sharps container.

6. Sealer protein (blue vial) is sufficiently reconstituted once there are no visible clumps of the powder. At this time, turn off the green switch on the FIBRINOTHERM device. If not dissolved within 20 minutes discard product.

   Give the sterile accessories packet B containing the DUPLOJECT applicator to the scrub nurse.

   Reconstituted solutions may be kept in the FIBRINOTHERM device, or on the sterile field, for up to 4 hours.

**Instructions for Scrub Nurse**

1. Attach a needle to the blue-scaled syringe and withdraw all of the solution from the sealer protein concentrate vial.

2. Attach a needle to the black-scaled syringe and withdraw all of the solution from the Thrombin vial.

3. A. Remove air bubbles by striking the side of each syringe one or two times while keeping the tip in an upright position.
   B. Pull syringes all the way back and load into DUPLOJECT applicator.

4. IMPORTANT: With the syringe tips in the UP position and the DUPLOJECT applicator oriented towards you, expel all air from the syringes simultaneously to ensure equal volume in both syringes.

5. Attach the joining piece to the syringe hubs and secure by fastening the safety clasp to its corresponding clip on the DUPLOJECT applicator.

6. Fit a cannula tip onto the joining piece. TISSEEL is now ready for application.

   Note: The cannula tip must be changed with each new application.

   Reconstituted solutions may be kept in the FIBRINOTHERM device, or on the sterile field, for up to 4 hours.

**Vials**

- **Blue**
  - Sealer protein concentrate
  - Fibrinolysis inhibitor

- **Black**
  - Calcium chloride
  - Thrombin

**Accessories for Reconstitution**

(Plug A) Circulating Nurse

- Blue-scaled syringe (1)
- Black-scaled syringe (1)
- Needles (2)

(Plug B) Scrub Nurse

- Blue-scaled syringe (1)
- Black-scaled syringe (1)
- Needles (2)
- DUPLOJECT syringe holder (1)
- Joining piece (2)
- Cannula tip (4)

**For technical assistance please call 1-877-TISSEEL (1-877-847-7335)**

RX Only. For safe and proper use of the device, please refer to the appropriate Instructions for Use. Please see Indications and Important Risk Information on the back.
TISSEEL [Fibrin Sealant] Indications

Hemostasis: TISSEEL is a fibrin sealant indicated for use as an adjunct to hemostasis in patients undergoing surgery when control of bleeding by conventional surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. TISSEEL is effective in heparinized patients.

Sealing: TISSEEL is a fibrin sealant indicated as an adjunct to standard surgical techniques (such as suture and ligature) to prevent leakage from colonic anastomoses following the reversal of temporary colostomies.

Important Risk Information for TISSEEL

For Topical Use Only. Do not inject TISSEEL directly into the circulatory system or into highly vascularized tissue. Intravascular application of TISSEEL can lead to intravascular coagulation, may result in life-threatening thromboembolic events, and may increase the likelihood and severity of acute hypersensitivity reactions in susceptible patients. Exercise caution to minimize the risk of intravascular application when using TISSEEL in surgery.

Do not use TISSEEL in individuals with a known hypersensitivity to aprotinin.

Do not use TISSEEL for the treatment of severe or brisk arterial or venous bleeding. In these situations, TISSEEL will be washed away in the flow of blood before hemostasis can be attained.

Hypersensitivity or allergic/anaphylactoid reactions may occur with the use of TISSEEL. Such reactions may especially be seen if TISSEEL is applied repeatedly over time or in the same setting, or if systemic aprotinin has been administered previously.

Aprotonin is known to be associated with anaphylactic reactions. Even in the case of strict local application of aprotinin, there is a risk of anaphylactic reactions to aprotinin, particularly in the case of previous exposure.

Discontinue administration of TISSEEL in the event of hypersensitivity reactions. Remove remaining product from the application site.

Air or gas embolism has occurred when fibrin sealant was administered using pressurized gas. This may occur if a spray device is used at higher than recommended pressures and in close proximity to the tissue surface.

When using the EASYSPRAY device, or an equivalent spray device for open surgical procedures cleared by FDA, TISSEEL must not be sprayed in enclosed body areas and must be sprayed onto only visible application sites.

TISSEEL is denatured when exposing to solutions containing alcohol, iodine or heavy metals. If any of these substances have been used to clean the wound area, the area must be thoroughly rinsed before the application of TISSEEL.

Apply TISSEEL as a thin layer by dripping or spraying using cannula or spray set. Excess clot thickness may negatively interfere with wound healing.

The safety and effectiveness of TISSEEL used alone or in combination with biocompatible carriers in neurosurgical procedures or other surgeries involving confined spaces have not been evaluated; its use in this setting is not FDA approved.

TISSEEL is made from human plasma. It may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Please see accompanying full Prescribing Information.

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