HACKETTSTOWN REGIONAL MEDICAL CENTER

**OR**

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**TITLE: FIBRINOTHERM**

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**PURPOSE:** To outline nursing responsibilities in set up and use of the Fibrinotherm Device

**SUPPORTIVE DATA**: The Fibrinotherm Device is used to warm and stir the fibrin sealant. This device is used in the application of Fibrin Sealant Tisseel onto wound surfaces.

**EQUIPMENT LIST**:

**Components**

1. Fibrinotherm device
2. Fibrin Sealant Tisseel

Before reconstitution, identify the appropriate package requested by the surgeon (1ml, 2ml or 5ml)

a. Vials
   1. Sealer Protein Concentrate
   2. Calcium Chloride
   3. Thrombin
b. Accessories for Reconstitution (**Packet A**) Circulating Nurse
   1. 1 blue-scaled syringe
   2. 1 black-scaled syringe
   3. 2 needles
c. Accessories for Duploject Preparation – (**Packet B**) Scrub Nurse
   1. 1 blue scaled syringe
   2. 1 black-scaled syringe
   3. 2 needles
   4. Duploject applicator
      i. 1 syringe holder
      ii. 2 joining pieces
      iii. 4 cannula tips

**CONTENT:** **PROCEDURE STEPS:**

**A. Instructions for the Circulating Nurse**

**Step 1**

Warm vials in the Fibrinotherm device: Turn on the Fibrinotherm device (amber switch) and place all vials in their wells. Use the appropriately sized adapter ring in the largest well. **Do not** turn the magnetic stirring at this time (green switch. Allow vials to warm for several minutes after the indicator light goes out (indicating proper warming temperature) while vials are warming proceed to Step 2.

**Step 2**

Assemble syringes (**packet A**): Open the sterile accessories and separate the two packets. Attach one needle to the blue scaled syringe and one to the black-scaled syringe.

**Step 3**
Mix the first component: Remove the following two vials from the Fibrinotherm device.
Sealer Protein Concentrate
Fibrinolysis inhibitor
a. Using the blue scaled syringe, withdraw the entire volume of Fibrinolysis inhibitor
b. Inject this into the sealer protein concentrate vial
c. Place the sealer protein concentrate vial back into its well in the Fibrinotherm device.

**Step 4**
Activate magnetic stirring: Turn on the green switch to activate magnetic stirring.

**Step 5**
Mix the second component: Remove the following two vials from the Fibrinotherm device:
Calcium Chloride
Thrombin
a. Using the black-scaled syringe, withdraw the entire volume of calcium chloride
b. Inject this into the thrombin vial
c. Mix by swirling briefly, then place the Thrombin back into its well in the Fibrinotherm device.

**Step 6**
After several minutes of stirring, turn off the green switch. Give the sterile accessories **packet B** containing the Duploject applicator to the scrub nurse. Reconstituted sealer protein solution may be kept in the Fibrinotherm device for up to 4 hours.

**B. Instructions For The Scrub Nurse**

**Step 1**
Withdraw the first component (**packet B**): Attach a needle to the blue scaled syringe and withdraw all of the solution from the Sealer Protein Concentrate Vial.

**Step 2**
Withdraw the second component: Attach a needle to the black-scaled syringe and withdraw all of the solutions from the Thrombin vial.

**Step 3**
Remove air bubbles: Strike the side of each syringe one or two times while keeping the tip in an upright position; eject air.

**Step 4**
Place syringes into the Duploject applicator: **Important**: Assemble with syringe tips in the **up** position and the Duploject applicator oriented toward you.
**A -** Fit the blue syringe into the **left** Duploject slot (black in right slot)
**B -** Syringe plunger fits into the recessed plunger handle
**C -** Syringe flange fits into the open so the barrel snaps into the holder in an upright position.

**Step 5**
Attach the joining piece and safety clasp: Attach the joining pieces to the syringe hubs and secure by fastening the safety clasp to its corresponding clip on the Duploject applicator.

**Step 6**
Attach a cannula tip: Fit a cannula tip onto the joining piece. Tisseel VH fibrin sealant is now ready for application.

**C. Thrombin Dilution – Instructions** (Thrombin 500 IU/ml to 5 IU/ml to achieve delayed clots formation) Use 0.9% Sodium Chloride with **no** preservatives

**Dilution of Tisseel 2ml Kit**

1 vial 0.9% Sodium Chloride (10ml) with **no** preservatives. Use the **same black-scaled syringe** throughout this process

1. Reconstitute the Sealer Protein (blue vial) as usual
2. Using the **black-scaled** syringe, draw up **1.0ml Calcium Chloride ($CaCl_2$)** from the **small black vial**, and discard this solution
3. Draw up **2.0ml Sodium Chloride (Nacl)** and inject into Thrombin vial dissolve completely.
4. Draw up **0.2ml** of this reconstituted Thrombin solution
5. Add **1.8ml Nacl** (2.0ml of solution total), rotate syringe to mix components.
6. Discard **1.8ml** (0.2ml remaining)
7. Add **0.8ml Nacl** (1.0ml of solution total)
8. Inject this **1.0ml** of solution into the **$CaCl_2$ vial**
9. Label small black vial as **Thrombin 5 IU/ml**

The resulting 2.0ml of solution (5 IU/ml of Thrombin) is now in the **small black vial** and is ready to be drawn up to the field

**Dilution of Tisseel 5ml Kit**

2 vial 0.9% Sodium Chloride (10ml) with **no** preservatives. Use the **same black-sealed syringe** throughout this process

1. Reconstitute the Sealer Protein (blue vial) as usual
2. Using the **black-scaled** syringe, draw up **2.5ml Calcium Chloride ($CaCl_2$)**
3. Draw up **5.0ml Sodium Chloride (NaC1)** and inject into **Thrombin** vial, dissolve completely.
4. Draw up **0.5ml** of this reconstituted Thrombin solution.
5. Add **4.5ml Nacl** (5.0ml of solution total), rotate syringe to mix components
6. Discard **4.5ml** (0.5ml remaining).
7. Add **2.0ml Nacl** (2.5ml of solution total).
8. Inject this **2.5ml** of solution into the **$CaCl_2$ vial**
9. Label black vial as **Thrombin 5 IU/ml**

The resulting 2.0ml of solution (5 IU/ml of Thrombin) is now in the **black vial $CaCl_2$** and is ready to be drawn up to the field.

Reference: TISSEEL Dilution Process – Baxter Instruction Sheets