Welcome to eSessions

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USING THE WHITE BLOOD CELL – FUNCTIONALLY CLOSED TUBING SET

COBE® SPECTRA APHERESIS SYSTEM

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Getting Around

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- This button toggles between **PLAY** and **PAUSE**. Click the **PLAY** button to continue.
- Go to **PREVIOUS** screen.
- Go to **NEXT** screen.
- Click this icon to toggle between **FULL SCREEN** and **STANDARD** view.
Presentation Overview

- Features of the White Blood Cell-Functionally Closed (WBC-FC) tubing set
- Advantages of the WBC-FC tubing set
- Features that ensure the set is functionally closed
- When is the closed system compromised
Presentation Overview (cont)

- Use of WBC-FC set:
  - Before using the set
  - Loading and priming the set
  - Adding AC to the product bag
  - Obtaining a product sample
  - Removing a product sample from the sample bulb
  - Performing Rinseback: Changes to the process
Presentation Objectives

Participants will be able to:

- List four features that make the WBC-FC set a functionally closed system.
- Identify three situations which make the set no longer functionally closed.
- Describe how to add anticoagulant to the product bag using the accessory line.
Presentation Objectives (cont)

- Explain how to obtain a sample using the sample bulb assembly.
- State why it is necessary to reduce the inlet flow during Rinseback.
What is the Meaning of Functionally Closed?

The FDA defines a functionally closed system as a system that is “…totally closed at the point of manufacture except for preconnected solutions and/or preconnected FDA approved bacteriostatic filters on spike and port connections.”

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1. FDA definition.
WBC-FC Set

Terumo BCT developed the WBC-FC tubing set to:

- Address customer needs
- Meet worldwide regulatory requirements for prevention of infectious diseases and cross contamination
- Comply with current good manufacturing processes and good tissue practices
Advantages of the WBC-FC Set

The WBC-FC set allows the COBE Spectra system operator to do the following within a functionally closed system:

- Collect WBCs
- Collect up to three in-process samples
- Add anticoagulant during the procedure
- Collect plasma without the addition of a separate plasma bag
Features of the WBC-FC Set

- Pre-attached plasma bag
- Clear 0.2-micron sterile barrier filter
- Green 0.2-micron sterile barrier filter
- Pre-attached removable needle with needleguard
- Accessory line
- Sample bulb assembly
Features that ensure the Set is Functionally Closed

- 0.2-micron sterile barrier filters on the access saline and AC lines

[Diagram showing green filter on the access saline line and clear filter on the AC line]
Features that ensure the Set is Functionally Closed

- Pre-attached removable needle with needleguard on access line
- Pre-attached plasma collection bag
  - Allows collection of plasma without the need to add a separate plasma bag
Features That Ensure the Set is Functionally Closed (cont)

- Accessory line with frangible and sterile barrier filter for adding anticoagulant to the product bag.
- Sample bulb assembly containing two sample bulbs with sampling ports for in-process or post-procedure sampling.
When is the Closed System Compromised

The WBC-FC set is no longer functionally closed if one or more of the following occur:

- Set is primed with any anticoagulant other than ACD-A.
- Access needle is removed at the luer connection.
- First attempt to insert the access needle is unsuccessful.
When is the Closed System Compromised (cont)

- A needle is placed in the access manifold or the injection port on the plasma line.
- Plasma bag or collect bag is disconnected before the tubing to the bag is permanently sealed.
- Product sample is withdrawn from the sample bulb prior to permanently sealing the tubing above the sample bulb.
- Integrity of the tubing set is compromised for any reason.
Use of the WBC-FC Set
Before Using the Set

1. Ensure all of the slide clamps are **open** when the tubing set is removed from the packaging.

2. On the sample bulb assembly, close the slide clamp between the product bag and the Y connector to prevent product from prematurely entering the sample bulbs.
   - **Do not** close the slide clamp on the collect line.
Loading and Priming the Set

- Load and prime the tubing set according to the instructions in the *COBE Spectra Apheresis System Operator’s Manual*.
  - You **must** use ACD-A instead of a sedimenting agent/trisodium citrate solution to prime the WBC-FC set for a PMN procedure or the sterile barrier filter on the access saline line may fail and the tubing set will no longer be functionally closed.
  - After Prime mode is complete, change the ACD-A to a sedimenting agent/trisodium citrate solution to perform the procedure.
Adding Anticoagulant to the Product Bag

1. Close the slide clamp above the frangible on the accessory line.
2. *Completely* break the frangible by bending the tubing containing the frangible back and forth.
3. Use aseptic technique to remove the cap from the luer connector below the sterile barrier filter, and attach a syringe containing the desired amount of anticoagulant.
4. Open the slide clamp above the frangible.

5. *Slowly* inject the anticoagulant through the sterile barrier filter into the product bag.

6. Close the slide clamp on the tubing just above the frangible before removing the syringe to prevent back-flow of fluid.
Adding Anticoagulant to the Product Bag (cont)

7. To ensure you deliver all of the anticoagulant to the product bag:
   a. Attach a syringe containing at least 2.3 mL of saline to the luer connection. (The volume in the accessory line and filter is ~2.3 mL).
   b. Open the slide clamp above the frangible.
   c. _Slowly_ inject the saline through the sterile barrier filter to flush the anticoagulant into the product bag.
   d. Close the slide clamp on the tubing just above the frangible _before_ removing the syringe to prevent back-flow of fluid.
Obtaining a Product Sample

1. Ensure the slide clamp between the product bag and the Y connector on the sample bulb assembly is closed.

2. Close one of the slide clamps on the tubing between the sample bulbs and the Y connector.
Obtaining a Product Sample (cont)

3. Gently mix the product bag to ensure a representative sample.

4. Open the slide clamp on the line between the product bag and the Y connector on the sample bulb assembly.

5. Gently squeeze the sample bulb attached to the tubing with the open slide clamp to withdraw only the amount of product sample needed.
6. To express any excess product sample back into the product bag:
   a. Invert the sample bulb and hold it above the fluid level of the product bag.
   b. Gently squeeze the sample bulb to express excess sample back into the product bag.
7. To clear the tubing between the product bag and the sample bulb using residual air:
   a. Hold the sample bulb upright and below the product bag.
   b. Gently squeeze the sample bulb and use residual air in the sample bulb to push product sample from the tubing into the product bag.
   c. While maintaining pressure on the sample bulb, close the slide clamp just below the Y connector.
8. **Before** removing the product sample, permanently seal the tubing between the sample bulb and the Y connector just below the slide clamp.
   - If the product sample is removed from the sample bulb before the tubing has been permanently sealed, the tubing set will no longer be functionally closed.

9. Disconnect the sample bulb at the permanent seal.
Removing a Product Sample From the Sample Bulb

You have three options:

A. Use the sample bulb as a test tube.
B. Use the sample bulb to pour the product sample into a test tube or other container.
C. Aspirate the product sample from the sample bulb using a needle or needleless adaptor and syringe.
Removing a Product Sample From the Sample Bulb (cont)

Option A

- To use the sample bulb as a test tube, cut the top of the sample bulb where indicated.
  - The sample bulb will accommodate stoppers suitable for use with 12 mm x 75 mm test tubes.
Removing a Product Sample From the Sample Bulb (cont)

Option B

- To pour the product sample directly into a test tube, cut the tubing below the permanent seal and gently squeeze the sample bulb to express the product sample into the test tube.
Removing a Product Sample From the Sample Bulb (cont)

**Option C**

- To aspirate the product sample from the sampling port:
  1. Insert a needle or needleless adaptor with attached syringe into the sampling port.
  2. Invert the sample bulb.
Removing a Product Sample From the Sample Bulb (cont)

Option C (cont)

3. Slowly aspirate the product sample into the syringe. A small amount of product sample will remain in the sampling port.

4. Remove the needle or needleless adaptor with attached syringe from the sampling port.

5. Transfer the product sample to a test tube or other container.

6. Discard the sample bulb.
Performing Rinseback: Changes to the Process

- Due to the sterile barrier filter on the access saline line, *Access Pressure Low* alarms may occur during Rinseback when using flow rates greater than 50 mL/min.
  - The sterile barrier filter does not limit the inlet pump flow rate during the run.
- To prevent *Access Pressure Low* alarms during Rinseback, reduce the inlet flow rate for all procedures that use inlet flow rates greater than 50 mL/min.
  - The default inlet flow rate during Rinseback is 50 mL/min or the rate used during the run, whichever is greater.
Performing Rinseback: Changes to the Process (cont)

You have three opportunities to reduce the inlet flow rate for the rinseback process:

- During Run mode
- When the End of Run screen appears
- During Rinseback mode
Performing Rinseback: Changes to the Process (cont)

To reduce the inlet flow rate during Run mode:

1. Press the INLET key to bracket the current inlet flow rate on the run screen.
2. Use the keypad to reduce the inlet flow rate to 50 mL/min, and then press ENTER to accept the change.
Performing Rinseback: Changes to the Process (cont)

To reduce the inlet flow rate when the End of Run screen appears:
1. Press CLEAR to clear the screen message.
2. Press the INLET key to bracket the current inlet flow rate.
3. Use the keypad to reduce the inlet flow rate to 50 mL/min, and then press ENTER to accept the change.
4. Press ENTER to redisplay the End of Run screen.
5. Press 1 for Rinseback.

End of Run: 1=Rinseback 2=Continue Run
MNC
Performing Rinseback: Changes to the Process (cont)

- To reduce the inlet flow rate during Rinseback mode, you must reduce the rate for each step of Rinseback that uses the inlet pump (Returning RBCs and Rinsing Channel).

  Rinseback: Returning RBCs.
  Rinse.

  Rinseback: Rinsing Channel.
  Rinse.
Performing Rinseback: Changes to the Process (cont)

1. To reduce the inlet flow rate during Rinseback mode:
   1. Press CLEAR to clear the rinseback screen and display the pump flow rates:

<table>
<thead>
<tr>
<th>AC</th>
<th>INLET</th>
<th>PLASMA</th>
<th>COLLECT</th>
<th>INLET:AC</th>
<th>SPIN</th>
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<tbody>
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<td>0.0</td>
<td>0.0</td>
<td>12.0</td>
<td>0</td>
</tr>
<tr>
<td>677</td>
<td>8105</td>
<td>0</td>
<td>0</td>
<td>123</td>
<td>MNC</td>
</tr>
</tbody>
</table>
Performing Rinseback: Changes to the Process (cont)

2. Press the INLET key to bracket the inlet flow rate:

<table>
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<th>AC</th>
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</tr>
</tbody>
</table>

3. Use the keypad to reduce the inlet flow rate to 50 mL/min, then press ENTER.

4. Repeat for each step of Rinseback that uses the inlet pump (Returning RBCs and Rinsing Channel).
Conclusion

The WBC-FC set allows the COBE Spectra system operator to do the following within a functionally closed system:

- Collect WBCs
- Perform multiple in-process sampling
- Add anticoagulant at any point during the procedure
- Collect plasma
Resources

