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Pall Leukotrap® Systems with Sample Diversion Pouch

BSAC Meeting
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Problem:

Addressing the challenge of residual skin flora

Even the most stringent skin disinfection techniques may not be able to ensure a sterile venipuncture site because:

- Subcutaneous hair follicles, sebaceous glands and skin dimpling – a result of multiple needle punctures – may contain bacteria that are not disinfected during normal processes [1,2].
- Skin cores can occur during needle puncture. [3] The skin harbors bacteria.

The above conditions may account for the high incidence of skin flora isolated from contaminated blood products. [4]

The majority of bacteria are present in the first few mL of blood collected.

1. *Krishman LAG and Brecher ME.; Transfusion Medicine II 9(1): 167-185, 1995*
2. *Anderson KC, Lew MA, Gorgone BC et al; Am J Med 81: 405-411, 1986*
3. *Gibson T, Norris W; Lancet 2: 983-985, 1958*
4. *Blajchman MA, Ali AM, Richardson HL. Vox Sang. 1994; 67-Suppl 3:25-33. Review.*

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Solution:

Sample Diversion Collection Pouch

Blood collection processes designed to discard or divert the initial 10-20mL of blood during blood donation *result in a significant reduction in the incidence of bacterial contaminated blood products.* [5, 6]

*5. de Korte, D., *et al*. Vox Sang 83: 13-16, 2002

6. Bruneau, C. , *et al*. Transfusion 41: 74-81, 2001

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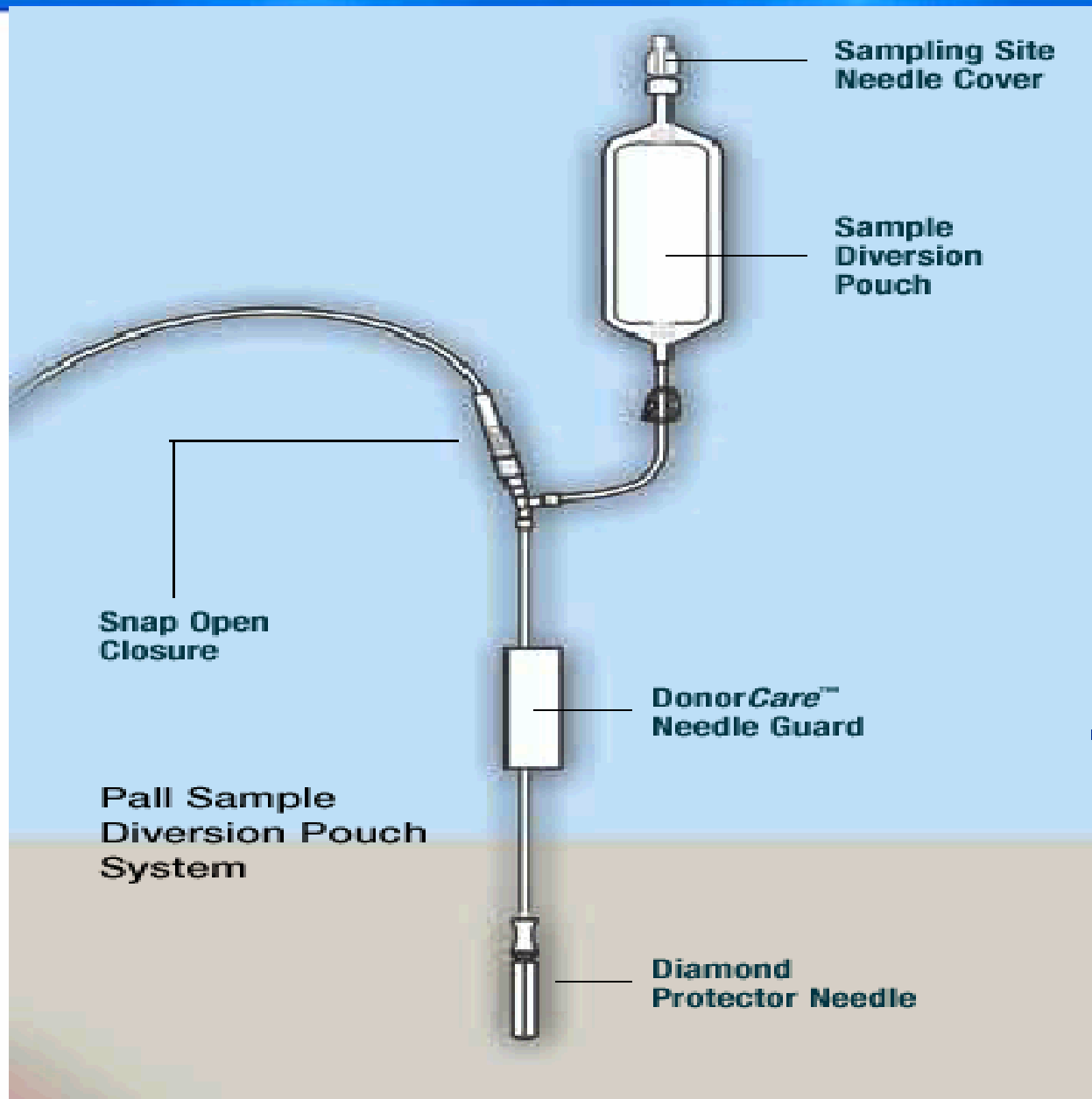
Pall Sample Diversion Pouch

NEW Sample Diversion Pouch

- Diverts initial 42mL of blood collected
- Provides test sample access while collection bag is filling — reducing donor chair time



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Pall Sample Diversion Pouch System

Blood Collection Instructions

1 Set Preparation

- Load blood agitation device or donor scale.
- Clamp donor tubing between DonorCare™ Needle Guard (DCNG) and Y connector (Fig. 1).
- Secure donor tubing above Y connector.

Figure 1

2 Start of Donation

- Accomplish phlebotomy and establish flow.
- Secure DCNG midway over needle hub; Sample Diversion Pouch (SDP) automatically fills (Fig. 2).

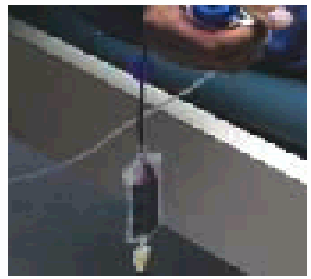

Figure 2

- Close clamp immediately on tubing between SDP and Y connector.

Warning: *Do not squeeze SDP while clamp is open to avoid risk of air embolism to donor.*

- Open snap open closure to start whole blood collection (Fig. 3).

Figure 3

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Blood Collection Instructions

3 Test Sample Collection

- Permanently seal tubing between SDP and Y connector.
- Remove the sampling site needle cover and attach vacuum tube holder.
- Hold SDP with the sampling site needle downward. Air should be at top of pouch (Fig. 4).

Figure 4

- Collect blood into vacuum tubes within 4 minutes. Center tubes within holder and maintain forward pressure.

4 End of Donation

- Collect appropriate volume of whole blood.
- Seal donor tubing between snap open closure and collection bag.
- Withdraw donor needle into DCNG.
- Seal donor tubing adjacent to DCNG.
- Detach and discard DCNG, SDP and tubing.

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Pall Sample Diversion Pouch System

Product Use History:

- **Product Launch:**
  - Canada – implemented December 2002
  - United States – implemented August 2003

- **Volume in Use:**
  - Over 1.3 million units used in North America

- **Customer Feedback:**
  - Ergonomics:
    - ✓Easy to Use
    - ✓Request for pre-attached sample tube holder
  - Training Materials Helpful

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Current Status:

- **Canada:**
  - Conversion of all in-line filter systems to Sample Diversion Pouch;
  - Currently in use – no problems encountered

- **USA:**
  - Conversion in over 20 centers
  - Limited reports of hemolysis in sample vacuum tubes
    - Reported in late February
    - Based on a visual check

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Pall Sample Diversion Pouch System

Current Status:

- Testing conducted in three laboratories to investigate:
  - ✓ **No hemolysis observed in sample pouch**
  - ✓ Hemolysis observed in sample tubes *only* when customer use conditions simulated (same tubes):
    - Visual levels observed overestimated the quantitative values identified
  - ✓ Root Cause Identified
    - Variability in sample vacuum tubes
    - Vacuum pressure / size of tubes
    - Multiple Vendors

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Pall Sample Diversion Pouch System

In Progress for U.S. Product:

- **Design Enhancement:**
  - Incorporate piece of tubing between sample needle hub and sample collection pouch
  - Target: 90 days

- **Post Market Surveillance Program:**
  - All customers contacted in writing
  - Recommendations regarding proper product use provided
  - Periodic updates to FDA
  - Periodic on site customer visits
  - Follow up phone call

Pall Sample Diversion Pouch System

- ***Available in all Pall in-line collection, filtration, and storage systems*** as a method to minimize the risk of bacterial contamination

- Used as part of an integrated platform of donor process improvement, leukoreduction and bacteria screening providing a synergistic opportunity for bacteria risk management
  - ✓ Pall **Sample Diversion Pouch** System
  - ✓ Pall **Leukotrap® Systems** for Collection, Leukoreduction, and Storage
  - ✓ Pall ***e*BDS** for the detection of bacteria in leukocyte reduced platelets