Diversion Blood Sampling Arm™
The Terumo Experience

Jeffrey Miripol
Vice President and General Manager
Transfusion Business Company
Terumo Medical Corporation

Terumo's
Diversion Blood Sampling Arm (DBSA)

- Background and Development
- System Overview
- System Operation
- Customer Implementation

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DBSA Background & Development

- Original work (1999) focused on a method to take samples prior to WB collection to insure that samples were always available for testing

- Recognition that a method that prevents the initial bolus of donor blood from going into the final WB unit may reduce chance of skin-associated blood contamination

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DBSA Background & History

- Studies performed with the ARC/Holland Labs demonstrated utility of the concept (Transfusion 2000; 40:335-338, Wagner, Robinette, Friedman and Miripol)

- In a model system, bacterially contaminated an injection site, then using either Saline or WB passage thru site, diverted initial aliquots of blood

- Demonstrated reduction in bacterial load of @1 log by sample diversion

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DBSA Background & History

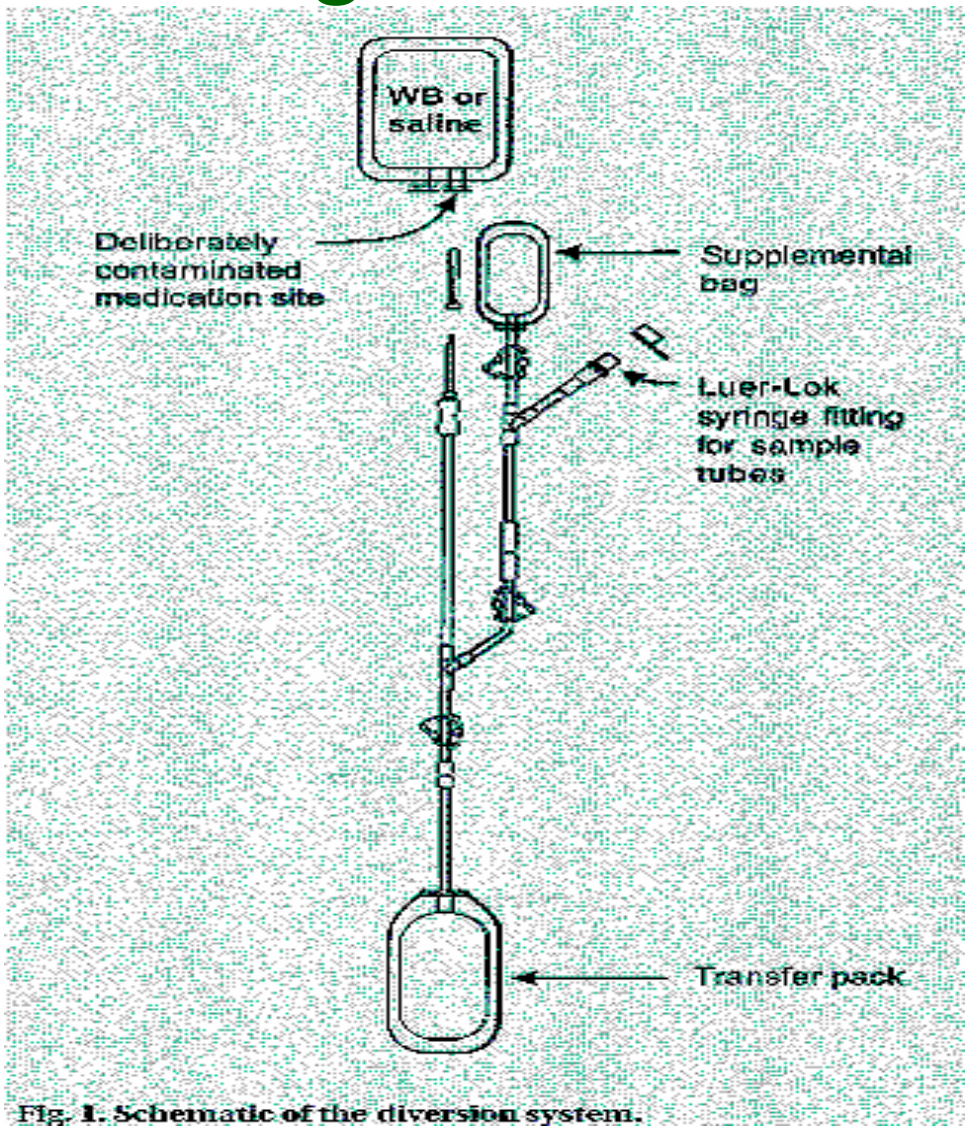

Fig. 1. Schematic of the diversion system.

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DBSA Background & History

- **FDA established the following Design Criteria at the March 2001 BPAC Meeting:**
  - **Closed system.**
  - **Diverted blood separated from final product by unidirectional flow.**
  - **Sufficient volume of diverted blood –**
    - **For all required testing.**
    - **To potentially reduce bacterial contamination.**

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Terumo DIVERSION BLOOD SAMPLING ARM™ (DBSA)

Features to Incorporate FDA Design Criteria

- Big CLIKTIP™ below the ‘Y’ on the primary collection tubing:
  - Prevents flow to the primary collection bag.
  - Provides Unidirectional flow from the phlebotomy to the DBSA pouch.
  - Prevents anticoagulant from entering the DBSA pouch.

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Features to Incorporate FDA Design Criteria

- Small pouch in short tubing segment integrally attached to donor tubing.

  - Pouch designed to assist in visualization of fill level with notches at approximately 35 mL volume
  - Total Pouch fill volume of up to @ 50mL
  - Pouch allows sufficient volume of diverted blood to obtain all required test samples and potentially reduce bacterial contamination of the primary collection

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Features to Incorporate FDA Design Criteria

- HR clamp and a twist port female luer connector below the pouch.
- Subsequent to pouch fill, tubing above pouch is sealed (use of ‘permanent” seal)
  - Blood collection to primary bag initiated by snapping open CLIKTIP™
  - After attaching luer adapter and holder to pouch, donor test samples obtained.

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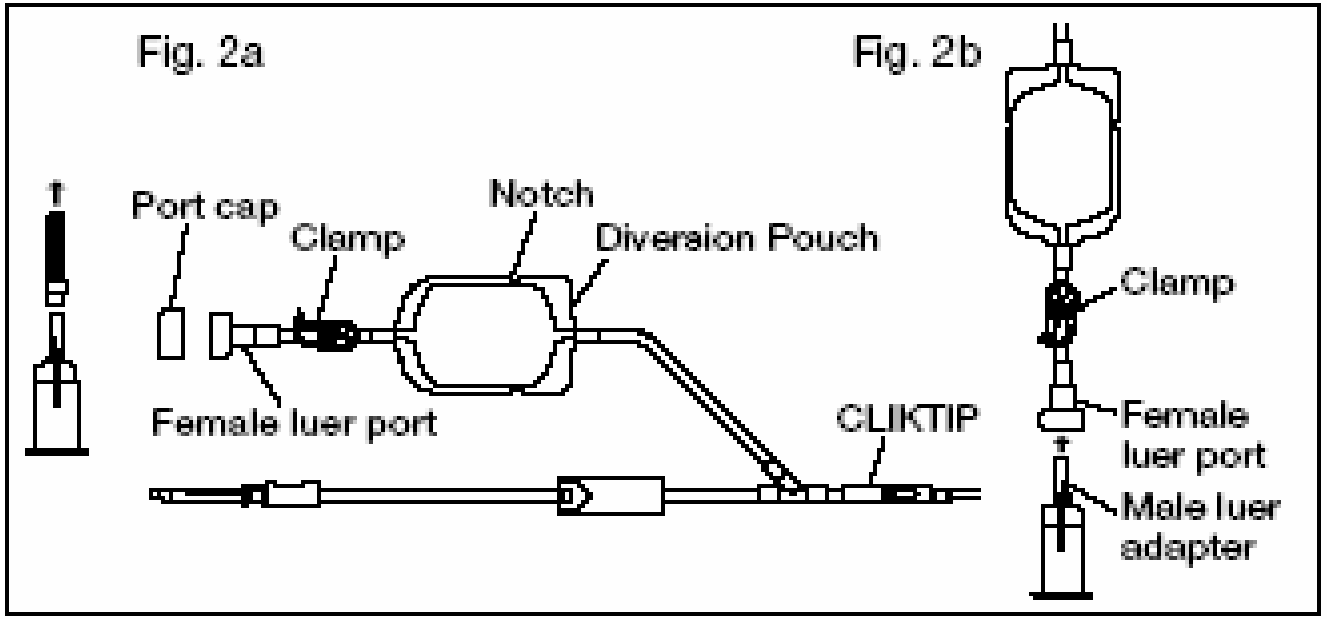
DBSA SYSTEM OVERVIEW



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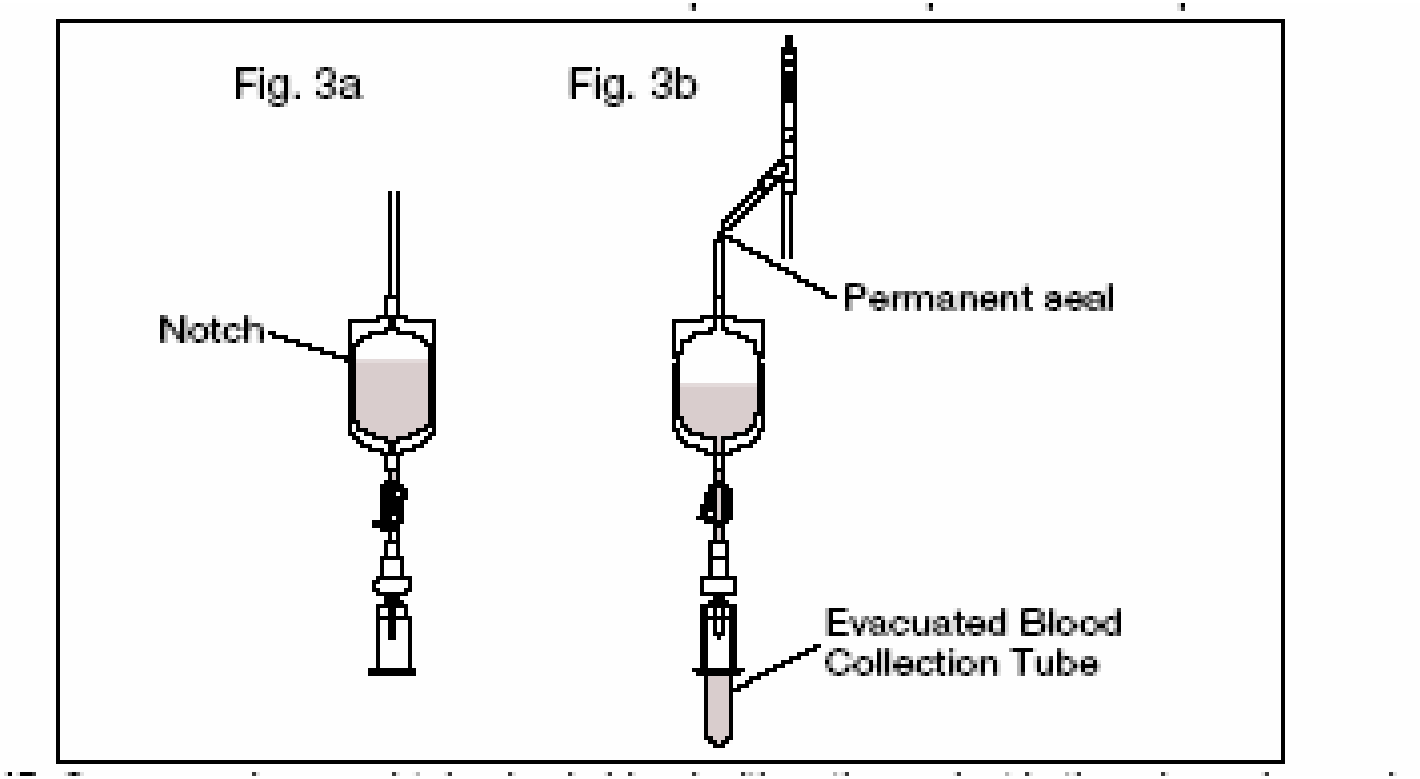
DBSA SYSTEM OVERVIEW



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Terumo DIVERSION BLOOD SAMPLING ARM™ (DBSA)

ADVANTAGES

- Samples taken before blood goes to primary bag
- Always get tubes/samples first for infectious disease and ABO, etc. tests
- Aids in securing/insuring adequate phlebotomy performance
- Aids in establishing blood flow and in ‘seeing’ blood flow
- Captures the initial bolus of blood, and reduces chance of skin-associated contaminants going to the unit

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DBSA Background & History
Field Study Data

- Two Field Trials
  - 1st field trial conducted in April/May 2002
    - 11 phlebotomists
  - 2nd field trial conducted in October 2002
    - 8 phlebotomists

- Same three participating Blood Centers

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DBSA Background & History
Field Study Data

- 1st Field Trial n=31

  Overall ratings:

  - 80% superior/above average
  - 20% acceptable

- 2nd Field Trial n=30

  Overall ratings:

  - 88% superior/above average
  - 12% acceptable

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DBSA Background & History
Field Study Data

- **Changes implemented:**

1. Addition of identification mark on the pouch indicating approximate fill volume

2. Improved sampling pouch to reduce sheet "sticking"—faster fill of pouch

3. Revised IFU

Correct orientation of pouch and tubes.

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DBSA
Implementation Data

- 5 Blood Centers
- Approximately 2900 collections
- Approximately 82 phlebotomists
- Overall Ratings:

  74.3% Superior/above average

  22.0% Acceptable

  3.7% Needs Improvement

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DBSA Post Implementation Follow Up Data

- 2 Blood Centers
- Approximately 3400 collections
- Approximately 63 phlebotomists
- Overall Ratings:
  - 67.9% Superior/above average
  - 21.5% Acceptable
  - 3.6% Needs Improvement
  - 7.2% No Rating

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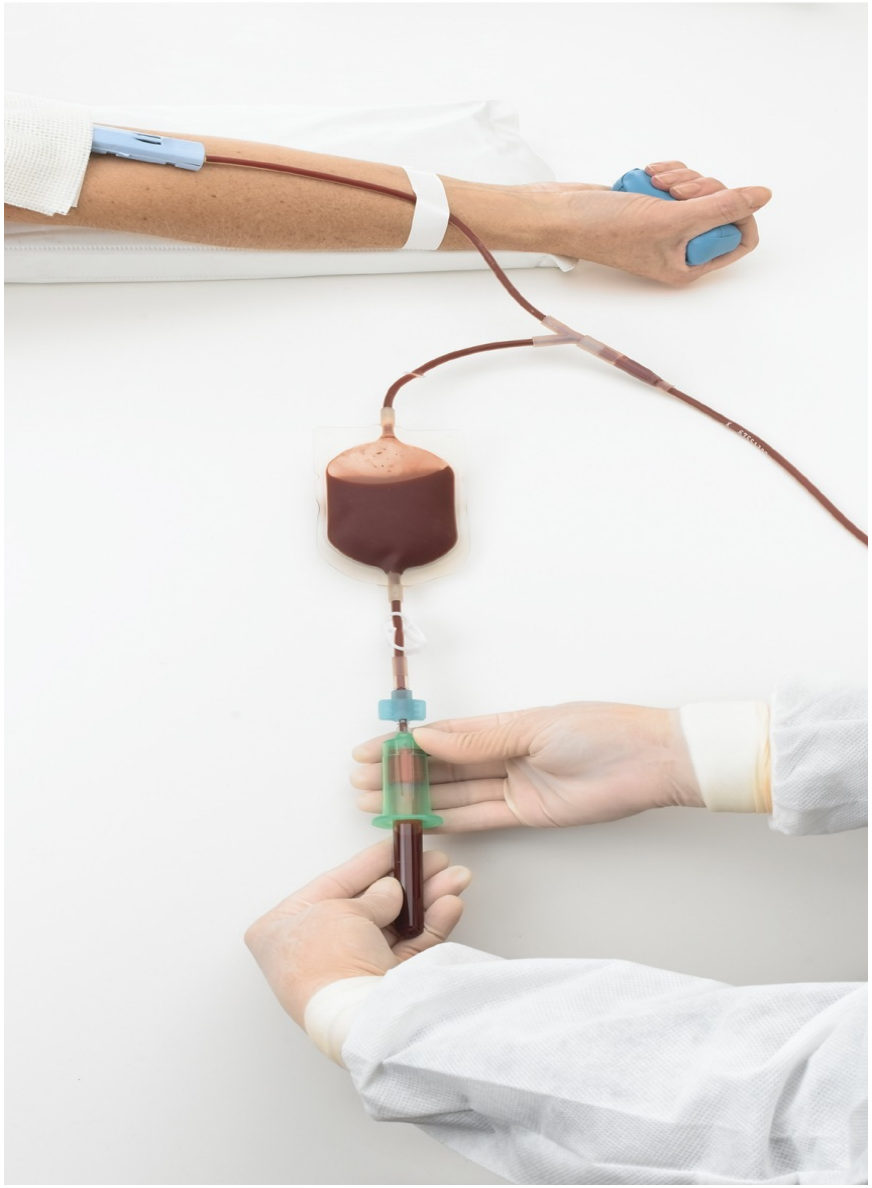
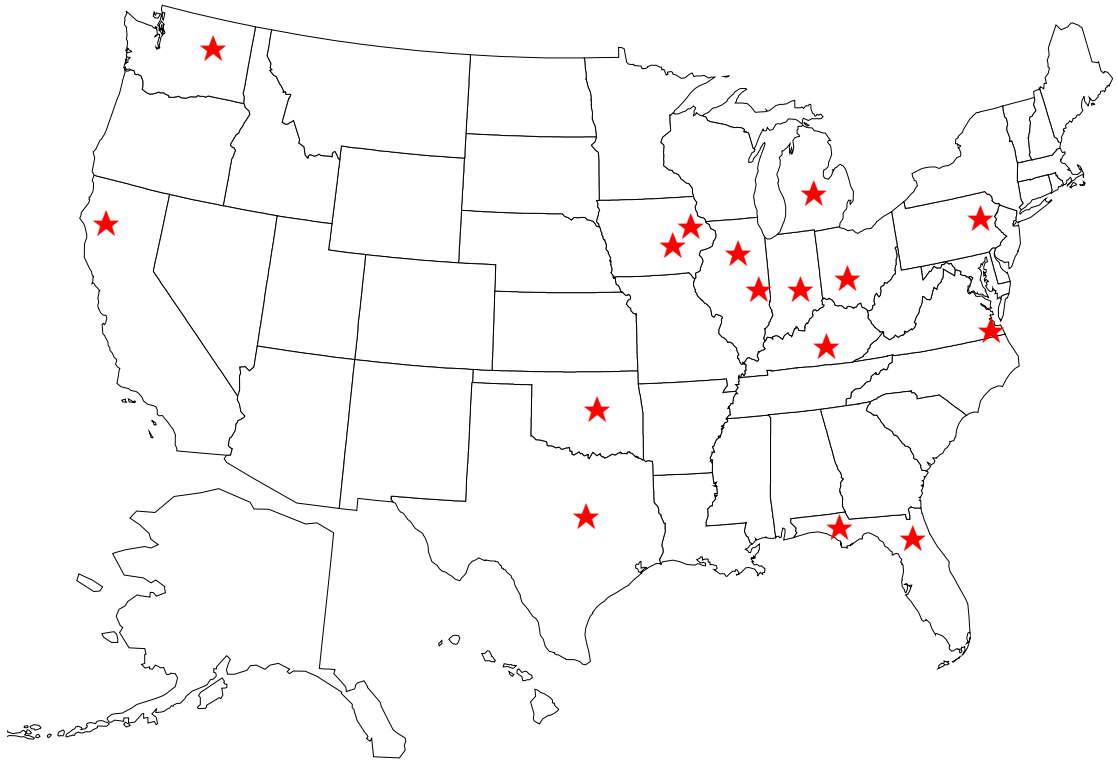
SYSTEM OVERVIEW

TERUFLEX BLOOD BAG WITH DIVERSION BLOOD SAMPLING ARM



TERUMO DBSA USERS:
AS OF 4-01-04



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DBSA SYSTEM VIDEO

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- Tracy Manlove/TMC
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- Our Customers and Terumo Field Implementation staff

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