Manufactured by:
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Guideline Protocol

For

Activation Choices for:
Safe-T-Vue® 10
and Safe-T-Vue® 6

1. Purpose:
To provide choices and guidance about *Activation* of Safe-T-Vue Products, where Activation is the term used to describe the removal of the lid material on a Safe-T-Vue Product, exposing the red and white disks, and pressing the white disk into the red disk.

2. Scope:
This procedure applies specifically to Safe-T-Vue 10 and Safe-T-Vue 6 temperature indicators.

3. Reference:
3.1. *Safe-T-Vue* Product Sheet.
3.2. *American Association of Blood Banks* **Standards for Blood Banks and Transfusion Services**, Current Issue, Reissue of Blood and Components.
3.3. Package insert "*Instructions & FAQs".*

4. Responsibilities:
4.1. Training to assure consistent handling and application of Safe-T-Vue Products.

5. Safety:
N/A

6. Attachments:
N/A

7. Materials / Equipment:
7.1. Safe-T-Vue® 10 and Safe-T-Vue® 6.
7.2. Optional Cold Pack, 18 to 24 ounce for a 350 cc bag.
7.3. A refrigerator with temperature controlled between 1° and 4.0° C.
7.4. A simulated blood bag having 350 cc +/- capacity filled with the appropriate volume of 10%glycerol-water mixture to simulate blood mass and volume.
7.5. A calibrated electronic thermometer with an immersion probe or equivalent.
7.6. The thermometer (or electronic probe) is inserted into the bag and positioned so that it is in the approximate center of the glycerol-water mixture to assure temperature measurement of the 'core' temperature of the liquid mass.

8. Procedure:
8.1. Activation choices:
8.1.1. Immediately after adhering to blood bag.
8.1.2. Any time after adhering to blood bag.

8.2. General procedure for using a Safe-T-Vue Product.

8.2.1. Remove one Safe-T-Vue from the product box in refrigerator taking care to handle Safe-T-Vue by the round, color-coded end; [light green for Safe-T-Vue 10 or purple for Safe-T-Vue 6.

8.2.2. Peel off the “Remove” label to expose the adhesive and attach Safe-T-Vue directly to the blood bag where there is the greatest volume of liquid.

8.2.3. Timing of Activation:

8.2.3.1. Immediately after placing on blood bag, in preparation to dispense blood

8.2.3.2. Any time after placing on blood bag - while maintaining/storing blood bag in the blood refrigerator to assure blood is within compliance temperatures

8.2.4. **Activate** by stabilizing Safe-T-Vue against bag with fingertips and peel off the top foil lid to expose the red and white rounds.

8.2.5. Fold the white round into the red round, then press firmly together by pressing only on the colored, round label.

8.2.6. Blood bag with activated Safe-T-Vue applied may be dispensed immediately, or stored in the blood refrigerator until dispensed.

8.3. Critical Process Variables:

8.3.1. Refrigerator temperature range.

8.3.2. Calibration of temperature-measuring instruments.

8.3.3. Handling of Safe-T-Vue Product.

8.4. Conditions to be Monitored:

8.4.1. Storage of Safe-T-Vue Products in refrigerator so that ‘warm air wash’ from normal opening and closing of the door does not warm the indicators above compliance temperature prior to use.

8.4.2. Training to assure consistent handling and application of Safe-T-Vue Products.