

PREANALYTIC PULSE

Evaluation of VACUETTE® Safety Devices

The Needlestick Safety and Prevention Act requires that healthcare employers evaluate safety-engineered sharp devices on an annual basis. In order to ensure that meaningful information is gathered, a plan for how the evaluation will be conducted and the criteria by which the device will be assessed should be established in advance. The evaluation process should begin by assembling an evaluation team that includes a few members that represent phlebotomy, nursing and any other staff that draw blood. The individuals selected should be open-minded about implementing change and experienced at objectively assessing the safety and benefits of new devices. They should be properly trained and allowed sufficient time to familiarize themselves with use of the device before performing a venipuncture on a patient. The team should then use the device for several procedures before completing an evaluation form that appropriately assesses attributes of the safety device.

Though there are several desirable characteristics of safety engineered devices that have been published by various sources, the overall objective is that the safety feature is easy to engage and consistently functions to protect the healthcare worker from injury. The purpose of the evaluation should be made clear to the evaluation team so they can assess the features of the device and whether or not they fulfill the criteria adequately.

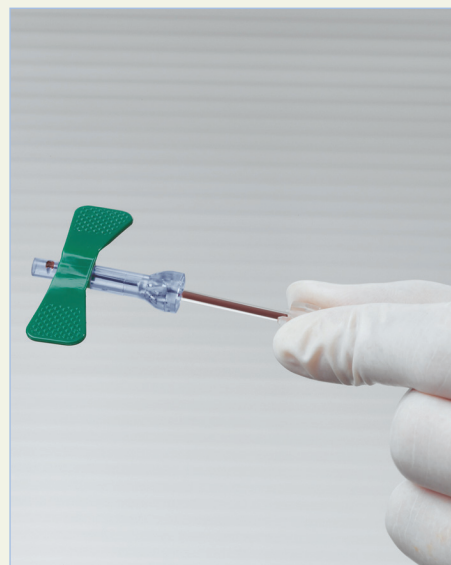
Observations and opinions should be captured by an evaluation form or survey. The evaluation form should include objective questions on the proper function of the safety feature and use of the device during normal venipuncture such as those included in the sample form included here. (This form is available as a separate document upon request.)

Completed forms should be assessed for the strengths and weaknesses of the device with regard to usefulness and safety. It is important to follow-up with the evaluation team to discuss comments and obtain additional feedback in the event that there were objections that can be resolved with additional training or education. If it is decided that the device will be implemented at the facility, information gathered during the evaluation will help in planning successful training for staff moving forward.

Finally, evaluation of safety products should be done within a defined time period. Though selection of devices to evaluate may take some time, the actual evaluation process can feasibly be completed in one to two weeks. This will allow sufficient time for participants to be trained on use of the device, perform a reasonable number of venipunctures to gain proficiency and then complete an evaluation to capture pertinent information. A sound decision can then be made on whether or not to move forward with a plan for implementation.

Safety Evaluation Process:

- 1 - Select device for evaluation.
- 2 - Define criteria for evaluation.
- 3 - Select evaluation team representing scope of users.
- 4 - Define evaluation period.
- 5 - Train team members on use of device.
- 6 - Team members use the device for multiple procedures to gain proficiency.
- 7 - Team members complete an evaluation form.
- 8 - Review evaluations for device strengths and weaknesses.
- 9 - Follow-up on training issues that may impact fair assessment.
- 10 - Make final decision on implementation of the device.



VACUETTE® Safety Evaluation Form Example

VACUETTE® Safety Blood Collection Set



Facility _____

Name _____ Title _____

Dept/Unit _____ Date _____

Please circle the number of times device was used.

1-5 6-10 11-25 25+

Safety Criteria	Agree	Disagree
1. The safety feature activates reliably.	<input type="checkbox"/>	<input type="checkbox"/>
2. Safety activation is a “click” that can be felt or heard, and visually confirmed.	<input type="checkbox"/>	<input type="checkbox"/>
3. The device provides in-vein activation for optimal protection.	<input type="checkbox"/>	<input type="checkbox"/>
4. Once activated, the safety feature remains locked.	<input type="checkbox"/>	<input type="checkbox"/>
5. The needle is permanently covered for disposal.	<input type="checkbox"/>	<input type="checkbox"/>

Overall Rating

I am capable of using this device in a safe and effective manner. Agree Disagree

Comments

Did you participate in training on use of the device? Yes No

Who provided the training? Device Representative Facility Employee Specify Title _____

Was the training adequate? Yes No Explain: _____

Thank you for participating in this evaluation.

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Please return this form to your supervisor.