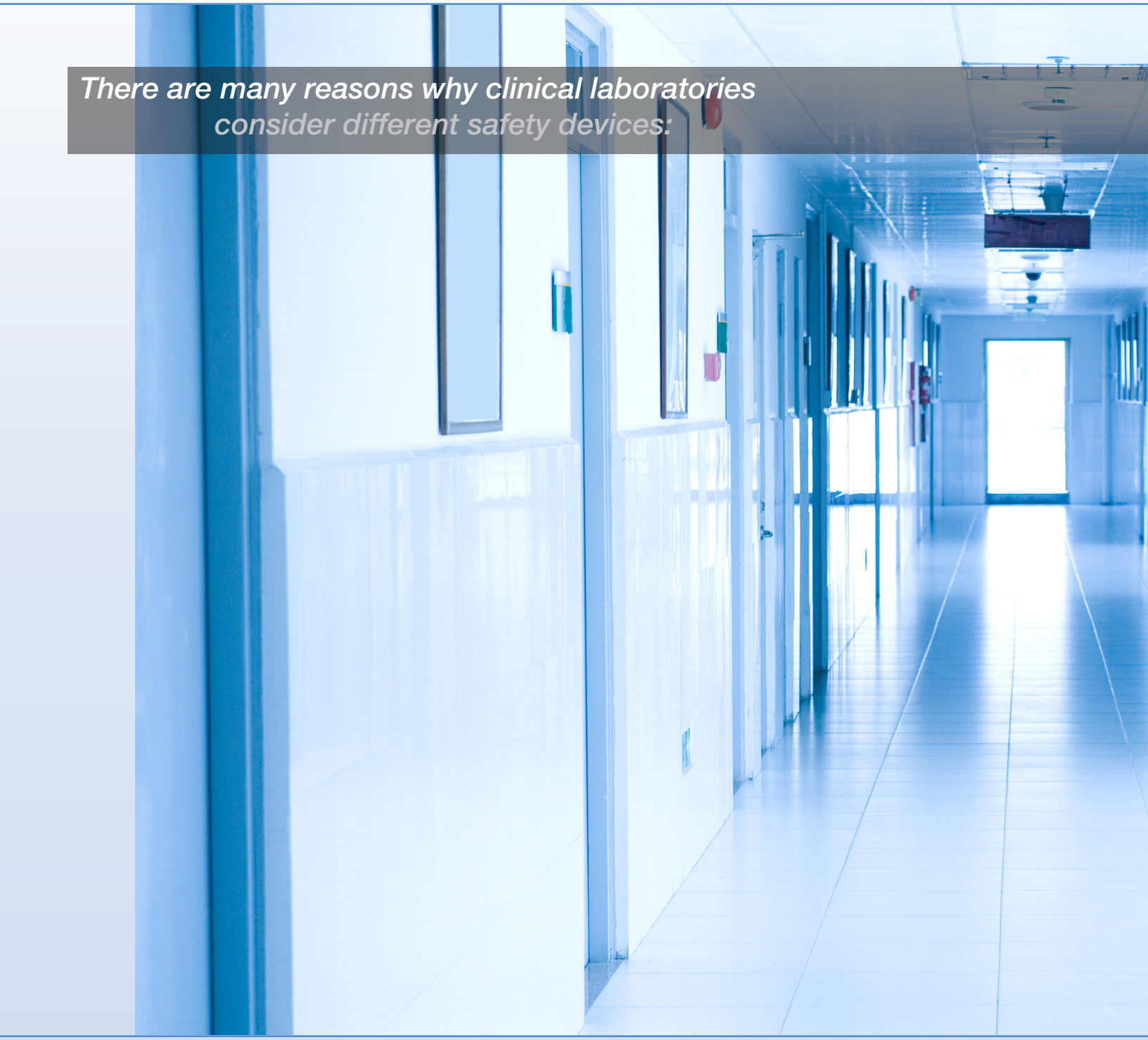
No matter what your reason,
you are in safe hands.

SAFETY EVALUATION PROGRAM

VACUETTE® Safety Devices

greiner
BIO-ONE



There are many reasons why clinical laboratories consider different safety devices:

- To experience a new and innovative device in their facility,
- To comply with the Needlestick Safety and Prevention Act requiring an annual review of effective safety devices, *or*
- To obtain a great product at an outstanding value.

No matter what your reason, we are happy that you have chosen to evaluate a **VACUETTE®** Safety Device.

Helping Implement Change

As one of the world's leading providers of specimen collection products and safety devices, helping our healthcare partners navigate change is at the center of what we do. Greiner Bio-One facilitates hundreds of safety product evaluations every year using the project plan outlined in this brochure.

Considering a new safety device begins with conducting an impartial evaluation and establishing a close collaboration between your team and ours. With a commitment from you and your staff, the resources and expertise of Greiner Bio-One can be leveraged to achieve an efficient and productive evaluation process from beginning to end.

At the conclusion of this process, your facility will be able to determine if the **VACUETTE®** safety device meets the following criteria:

- The safety feature is easy to engage and reliably protects against needlestick injury,
- The safety device is compatible with good phlebotomy technique, and
- The safety device is effective for both patient care and user safety.

Let's get started...

Evaluation of VACUETTE® Safety Devices

Planning the Evaluation

Project Leaders, comprised of key contacts from the facility and the Greiner Bio-One Account Manager, should be designated to lead the evaluation project. These individuals will play a vital role in planning the evaluation, conveying the significance of the project to the Evaluation Team Members, and providing leadership throughout the process. One of the first orders of business will be to select the individuals who will evaluate the safety device.

Identify Evaluation Team Members: To keep the process manageable, the Project Leaders should select between 5-10 Evaluation Team Members that are responsible for assessing the product and recording their findings on the Safety Evaluation Form. Team members should represent all areas of the facility responsible for blood collection, such as Nursing, Emergency Room and Outpatient personnel. An individual's participation should be based on the following criteria:

- Routinely collects blood specimens according to facility procedure
- Is open-minded about implementing change
- Can objectively assess the safety and benefits of new devices
- Is properly trained in the use of the safety device
- Is allowed sufficient time to become proficient with the use of the safety device prior to completing the Safety Evaluation Form

The members of the Evaluation Team may potentially become Super Users to assist with implementation and ongoing training needs.

Super Users

These employees are a valuable resource for the facility and Greiner Bio-One for on-site continuing education and training needs. Super Users have reviewed the Instructions for Use, demonstrated proper use of the device with a Greiner Bio-One Representative and are able to instruct others.

Evaluation Launch

The project should be officially launched at a meeting where the Project Leaders review the expectations for the Evaluation Team Members and set the tone for an unbiased product assessment.

Greiner Bio-One will supply each Team Member with everything needed to complete the safety device evaluation.

The Evaluation Team will be trained on the correct use of the product. This is also an excellent opportunity for the facility staff to review proper phlebotomy technique and organizational protocol.

Initial feedback from Team Members is collected at the conclusion of this meeting to ensure that additional training needs are identified before the evaluation begins.

Training Aids

Training materials will be provided by Greiner Bio-One including, but not limited to, the items listed below:

- Instructional literature
- Access to videos and mobile apps
- Simulated vein blocks for practice

Follow-Up Meeting

Upon completion and submission of the Safety Evaluation Forms, the Project Leaders meet to review the results. Comments and feedback are discussed, and any need for further training/education is addressed.

Decision

The facility's Project Leaders communicate their decision to the Greiner Bio-One Account Manager following the completion of the product evaluation.

Implementation In-Service Scheduled

The Greiner Bio-One Account Manager/Product Specialist Team will work with appropriate staff at the facility to understand the scope of the in-service project. The number of employees that require product in-service and the associated locations within the facility (outpatient draw sites, emergency department, nursing stations, etc.) will be reviewed in order to plan and schedule the appropriate training resources.

Activity	Week 1		Week 2	
Identify Evaluation Team members				
Launch project to Evaluation Team (explain objective and Team's roles/responsibilities) – Include facility key contacts				
Greiner Bio-One provides instruction on using safety device				
Evaluation Team trains and practices using device				
Evaluation period - device in use				
Evaluation Team completes Safety Evaluation Form				
Review/Follow-up				
Decision rendered				
Implementation date scheduled				

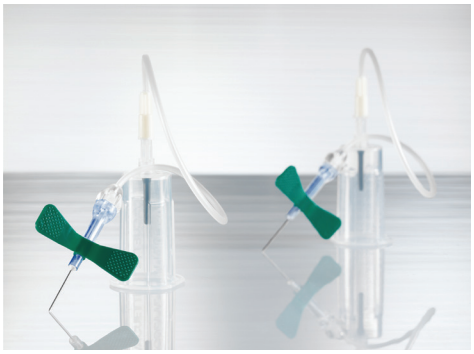
VACUETTE® Safety Evaluation Form Example

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.	☐	☐
2. Safety activation is a “click” that can be felt or heard, and visually confirmed.	☐	☐
3. The device provides in-vein activation for optimal protection.	☐	☐
4. Once activated, the safety feature remains locked.	☐	☐
5. The needle is permanently covered for disposal.	☐	☐

Overall Rating		
I am capable of using this device in a safe and effective manner.	☐	☐

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.

Please return this form to your supervisor.


No matter what your reason,
you are in safe hands.

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