

Evaluation of VACUETTE® Safety Blood Collection Set

Background:

The Greiner VACUETTE® Safety Blood Collection Set is a single-use, sterile winged blood collection set bonded to flexible tubing with a female luer adapter. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to help protect against accidental needlestick injury.

The Greiner VACUETTE® Safety Blood Collection Set is available in configurations consisting of three needle gauge sizes (21, 23, 25) and three tube lengths (10, 19, and 30 cm).

Handling Technique

The safety feature is easily operated by depressing both sides of the stopper and sliding it backward until the tip of the needle is completely retracted and covered by the protective mechanism. The “click” is the sound that the safety mechanism makes once it has been correctly activated. The Greiner VACUETTE® Safety Blood Collection Set may be used by appropriately trained healthcare professionals. It should also be used in accordance with this manufacturer’s instructions, as well as the policies and procedures of state, federal and regulatory agencies.

Study Objective:

A clinical evaluation was carried out to evaluate the performance of the Greiner Bio-One VACUETTE® Safety Blood Collection Set.

Study design:

A clinical evaluation of the Greiner VACUETTE® Safety Blood Collection Set was performed at the Nisho Niponn Tokai Hospital in Japan in September 1999 to assess the clinical performance of the device. It consisted of 11 licensed medical professionals (1 doctor and 10 nurses) testing 30 devices each for a total of 330 devices. Upon completion of each phlebotomy procedure, each user was asked to complete a questionnaire regarding the product. The areas of query were subdivided as follows:

- clinical usage
- the safety mechanism
- ease of use, and
- overall mechanism safety

The user was asked to answer each question according to a five-grade system:

A : Excellent,

B: Good,

C: Average,

D: Fair,

E: Poor

and No Comment.

Conclusion:

The Greiner VACUETTE® Safety Blood Collection Set scored acceptably on all questions regarding the safety mechanism and the overall safety of the device. ¹ The Greiner VACUETTE® Safety Blood Collection Set can therefore be considered to be a “safety medical device” that is appropriate and effective. ^{2,3}

Results/Discussion:

Questionnaire Form results are summarized in Table #1 (see Annex). There were no failures in the 330 devices studied. Failure is defined as “needlestick injury or significant problem with the safety feature that may lead to an injury”, per the FDA guidance. The calculated exact confidence limits from this study are presented in Table #2 (see Annex).

In summary, it can be concluded that the worst case approximation for the “true “ failure rate of the device is 1,1% with 97,5% confidence or 1,6% with 99,5% confidence. Using the 1-sided confidence limit, it can be concluded that the “true” failure rate is <1,1% with 95% confidence or <1,4% with 99% confidence. These figures are similar to the recommendation in the FDA guidance document that the study sample size enables detection of grossly defective devices at a 1% level. therefore, a sample size of 330, although different from the 500 recommended in the FDA guidance, is adequate to meet the goal of detection of 1% failure rate.

References:

1. Greiner Bio-One. Greiner VACUETTE® Safety Blood Collection Set 510(k) Summary. Monroe. NC. June 2001.
2. Greiner Bio-One North America. Inc. Greiner VACUETTE® Safety Blood Collection Set Product Insert. Monroe. NC. July 2001.
3. OSHA. Occupational Exposure to Bloodborne Pathogens; Needlestick an Other Sharps injuries; Final Rule. CFR Title: 29 Part 1910. January 18, 2001

Annex / Results in detail:

Table #1							
VACUETTE® Safety Blood Collection Set Clinical Evaluation Questionnaire Summary							
Question	A- Excellent	B- Good	C- Average	D- Fair	E- Poor	No Comment	% Score ≥ Average
Clinical Usage							
Easy handle of winged needle?	0	2	9	0	0	0	
Any disturbance of attachment of safety devices?	0	0	11	0	0	0	
Any pain or discomfort to patients?	0	1	10	0	0	0	
Subtotal Number of Answers	0	3	30	0	0	0	100%
Safety Mechanism							
Can handle it with fingers not placed on the front of the needle?	1	5	5	0	0	0	
Safety mechanism functioned easily – by click sound, visually	1	5	5	0	0	0	
Can lock the safety mechanism without exposure of the needle?	1	7	3	0	0	0	
Cannot unlock once the safety lock is functional?	4	5	2	0	0	0	
Safety mechanism did not accidentally malfunction?	2	8	1	0	0	0	
Can operate safety mechanism without moving the wings?	1	5	5	0	0	0	
Subtotal Number of Answers	10	35	21	0	0	0	100%
Ease of Use							
Operate easily without any trouble?	0	5	5	1	0	0	
Description of use is plain and understandable?	1	5	4	0	0	1	
Can operate easily following description?	0	4	5	1	0	1	
Subtotal Number of Answers	1	14	14	2	0	2	93,5%
Overall Mechanism Safety							
Quite safe for a user?	2	7	0	2	0	0	
Quite safe for a patient?	1	4	6	0	0	0	
Safer when it is disposed of?	3	6	2	0	0	0	
Disposal of it is easier?	2	4	5	0	0	0	
Subtotal Number of answers	8	21	13	2	0	0	95,5%
Grand Total	19	73	78	4	0	2	96,6%

Table #2		
VACUETTE® Safety Blood Collection Set Clinical Evaluation Results Exact Confidence Limits		
	2-Sided CL	1-Sided CL
95%Confidence Limit (CL)	98,9 – 100,0%	>98,9%
99%Confidence Limit	98,4 – 100,0%	>98,6%