

**Evaluation of VACUETTE[®] QUICKSHIELD
Safety Tube Holder Evaluation**

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Background:

The Greiner VACUETTE® QUICKSHIELD Safety Tube Holder is a single-use, non-sterile safety evacuated blood collection tube holder. It 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® QUICKSHIELD Safety Tube Holder is used together only with VACUETTE® Multi-sample Needles and VACUETTE® Blood Collection Tubes as a system in routine blood collection procedures. The holder is designed with a safety shield, which is activated to cover the needle immediately following venipuncture to help protect against accidental needlestick injury. The QUICKSHIELD holder is used in conjunction with VACUETTE® Multi-Sample Needles (20, 21, 22 gauges). The needle has been orientated for optimum bevel location and safety use with the QUICKSHIELD holder.

Handling Technique

The safety shield is easily activated by gently pressing the shield toward the needle on a stable surface. An audible “click” is produced, ensuring the user that the safety shield has been properly and fully activated. The Greiner VACUETTE® QUICKSHIELD Safety Tube Holder may be used by appropriately trained healthcare professionals in accordance with this manufacturer’s instructions, as well as the policies and procedures of your state, federal and regulatory agencies.

Study Objective:

A clinical evaluation was carried out to evaluate the performance of the Greiner Bio-One VACUETTE® QUICKSHIELD Safety Tube Holder.

Study design:

A study of the VACUETTE® QUICKSHIELD Safety Tube Holder was conducted at St. Vincent’s Ascension Health in Jacksonville, Florida in October 2003 to evaluate the device’s performance in simulated blood drawing procedures. Simulated blood drawing was performed by 50 medical professionals (15 doctors, 10 nurses, 11 medical technologists, 14 phlebotomists) testing 10 devices each for a total of 500 devices. Upon completion of each phlebotomy procedure, each user was asked to complete a questionnaire regarding the product.

The areas of query were stratified as follows:

- ease of use
- safety
- compatibility
- overall safety mechanism

The user was asked to answer each question according to a five-graded system: 1 – Strongly Agree, 2 – Agree, 3 – Neutral, 4 – Disagree, 5 – Strongly Disagree and 6- Not Applicable.

Conclusion:

The Greiner VACUETTE® QUICKSHIELD Safety Tube Holder scored acceptably on all questions regarding the safety mechanism and the overall safety of the device. The Greiner VACUETTE® QUICKSHIELD Safety Tube Holder can therefore be considered to be a “safety medical device” that is appropriate and effective.^{1,2,3,4}

Results/Discussion:

Questionnaire Form results are summarized in Table #1. There were no failures of the VACUETTE® QUICKSHIELD safety shield to activate properly or to safely cover the needle. With regards to the questionnaire, the device had high evaluation scores for all questions regarding the safety mechanism and the overall safety evaluation. The scores were 98,3% and 99,0% respectively, for respondents answering these questions with “Neutral” or above.

Eighteen participants (3,3%) answered “Disagree” or “Strongly Disagree” to the questions regarding ease of use, while six participants (1,6%) answered “Disagree” or “Strongly Disagree” to the questions regarding safety. All of these answers were related to the “misalignment of the needle relative to the safety shield”. If the needle is not threaded completely into the holder, the shield will not be perpendicular to the bevel and it will be out of position during the venipuncture. Thus, the perception of the user is that the bevel is misaligned. There were also seven (7) participants who answered “Yes” to the question regarding failure of the device. None of these responses, however, were related to the safety mechanism. After interviewing each of these users, it was determined that four of the comments were designated for “needle misalignment”. Again, by not threading the needle completely into the holder, there is a perception from the user that the bevel is misaligned. The remaining three comments were related to the dislike of the needle design and the dislike of the Advanced Venipuncture Training Aid™ used in this study.

Table #1							
Greiner VACUETTE® QUICKSHIELD Safety Tube Holder Evaluation							
Questionnaire Summary							
Question	Strongly Agree	Agree	Neutral	Disagree Strongly	Disagree	Not Applicable	Average-Score
	1	2	3	4	5	6	
Ease of Use							
The Greiner multi-sample needle can be easily threaded into the holder.	23	24	1	2	0	0	1,6
The safety feature is an integral part of the device.	33	16	1	0	0	0	1,4
The safety mechanism can be activated with a one-handed technique.	29	19	2	0	0	0	1,5
The device can be used by a left-handed person as easily as by a right-handed person.	10	14	7	3	0	16	2,1
The safety device does not interfere with normal use of the product.	14	21	6	8	1	0	2,2
The product does not require more time to use than a non-safety product or your current safety product.	26	18	4	1	1	0	1,7
The product is easy to learn and understand.	36	14	0	0	0	0	1,3
The product does not need extensive training to operate correctly.	32	17	1	0	0	0	1,4
The safety feature can be easily activated.	31	17	1	1	0	0	1,4
The product does not need extensive training in order to be properly operated.	30	19	1	0	0	0	1,4

Table #1 continued							
Greiner VACUETTE® QUICKSHIELD Safety Tube Holder Evaluation Questionnaire Summary							
Question	Strongly Agree	Agree	Neutral	Disagree Strongly	Disagree	Not Applicable	Average-Score
	1	2	3	4	5	6	
The Product is easy to identify from the packaging.	24	20	5	1	0	0	1,7
Subtotal Number of Answers	288	199	29	16	2	16	550
%	52,4%	36,2%	5,3%	2,9%	0,4%	2,9%	
Safety							
Activation of the safety feature does not require the user to place fingers near the contaminated needle.	33	16	1	0	0	0	1,4
Use of this product does not increase the number of needle sticks to the user.	22	22	5	0	0	1	1,7
A clear and unmistakable change (audible click) occurs when the safety feature is activated.	27	19	4	0	0	0	1,5
The safety feature does not interfere with the normal use of this product.	18	20	6	5	1	0	2,0
The safety feature operates reliably.	26	22	2	0	0	0	1,5
The device did not create any extra risks of sprays, leakage and/or drips.	25	22	3	0	0	0	1,6
The safety mechanism did not accidentally malfunction.	26	23	1	0	0	0	1,5
The exposed needle is safely covered after use and prior to disposal.	31	18	1	0	0	0	1,4
Subtotal Number of answers	208	162	23	5	1	1	400
%	52,0%	40,5%	5,8%	1,3%	0,3%	0,3%	
Compatibility							
The safety device is easy to dispose of in sharps containers of all sizes which are used at your facility.	22	25	3	0	0	0	1,6
Subtotal Number of Answers	22	25	3	0	0	0	1,6
%	44,0%	50,0%	6,0%	0,0%	0,0%	0,0%	
Overall Safety Mechanism							
The safety device is considered safe for the user.	28	21	1	0	0	0	1,5
The safety device is considered safe for the patient.	24	23	2	1	0	0	1,6
Subtotal Number of Answers	52	44	3	1	0	0	100
%	52,0%	44,0%	3,0%	1,0%	0,0%	0,0%	
Would you recommend using this product in your institution?	Yes=45 No=5						
Were there any failures encountered with the test device or comparison device during this study? If yes, identify device and describe failure.	Yes=7 No=43						

References:

1. Food and Drug Administration. General Hospital Devices Branch. Office of Device Evaluation. “Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical devices with Sharps Injury Prevention Features”. March 1995.
2. Greiner Bio-One. Greiner VACUETTE® QUICKSHIELD Safety Tube Holder 510 (k) Summary. Monroe. NC. October 2003
3. Greiner Bio-One Preamalytics. Inc. Greiner VACUETTE® QUICKSHIELD Safety Tube Holder Product Insert. Kremsmunster. Austria. October 2003.
4. OSHA. Occupational Exposure to Bloodborne Pathogens; Needlestick and Other Sharps injuries; Final Rule. CFR Title: 29 Part 1910. January 18, 2001.

VACUETTE is a registered trademark of Greiner Bio-One. Advanced Venipuncture Training Aid is a trademark of VATA. Inc.