

# Penetration Force Comparison Testing of Semi-Automatic Safety Blood Collection Sets

## **Background:**

To enable phlebotomists to perform venipunctures with as little pain as possible for the patient, sharp needles without any burrs are required. Such products are offered on the market by various companies. The needle points can vary in terms of shape, size and number of bevels. In addition, the wall thickness and, therefore, inner diameter of the needles may vary.

The Greiner Bio-One portfolio includes various safety blood collection sets used by phlebotomists to perform venipunctures. The product range encompasses safety blood collection sets with various needle gauges and wall thickness allowing the phlebotomist to select the most suitable safety blood collection set for the vein condition of the patient. Typically, needles of safety blood collection sets are thin walled or extra thin walled with sizes of 21G and 23G. This study focuses on the comparison of our newest safety blood collection set, the VACUETTE® EVOPROTECT SAFETY Blood Collection Set, comparing it with two competitive devices with similar semi-automatic safety mechanisms.

## **Study Objective:**

Two studies involving mechanical testing were performed by Melab, a German laboratory accredited to carry out tests according to the standards specified in the process below. The testing included evaluation of the effect that the various attributes, as indicated in the table below, have on needle sharpness and determination of Greiner Bio-One's needle quality when comparing it to competitive products according to standard DIN 13097-4. To that purpose, penetration and friction force as well as optical inspections were carried out.

## **Study design and procedure:**

The two tests checked and compared a total of 10 products. In comparing the attributes of semi-automatic safety blood collection sets, the results of the following products are detailed:

Table 1 includes the samples of the comparison of semi-automatic sets with 21 Gauge and 23 Gauge needles:

Table 1: Comparison of semi-automatic sets with 21 Gauge and 23 Gauge needles

Sample	Description	Size(mm)	Bevel Type	Needle wall thickness	Sterilization method
B	VACUETTE® EVOPROTECT SAFETY Blood Collection Set	21G (0.8 x 19)	3-bevel	Extra thin walled	Radiation (e-beam)
D	Semi-automatic safety blood collection set with ultra thin walled needles from a main competitor	21G (0.8 x19)	5-bevel	Extra thin walled	Radiation
E	Semi-automatic safety blood collection set from a main competitor	21G (0.8 x 19)	3-bevel	Thin walled	Radiation

Sample	Description	Size(mm)	Bevel Type	Needle wall thickness	Sterilization method
C	VACUETTE® EVOPROTECT SAFETY Blood Collection Set	23G (0.6 x19)	3-bevel	Extra thin walled	Radiation (e-beam)
A	Semi-automatic safety blood collection set with ultra thin walled needles from a main competitor	23G (0.6 x 19)	5-bevel	Extra thin walled	Radiation
F	Semi-automatic safety blood collection set from a main competitor	23G (0.6 x 19)	3-bevel	Thin walled	Radiation

The penetration tests were performed immediately after unpacking in order to minimize the chances of unintended impact due to handling.

## 1. Penetration Force Tests according to DIN 13097-4

### Testing Method:

The penetration force tests were performed according to the Standard DIN 13097-4. The penetration characteristics were recorded as load/penetration length chart while the cannula pierced the polyurethane foil. The polyurethane testing material is described in the Standard DIN 13097-4. It is sensitive to the testing parameters as follows.

Piercing resistance of the tip  
 Sharpness of the cutting edges  
 Dilatation resistance  
 Surface Treatment – Friction

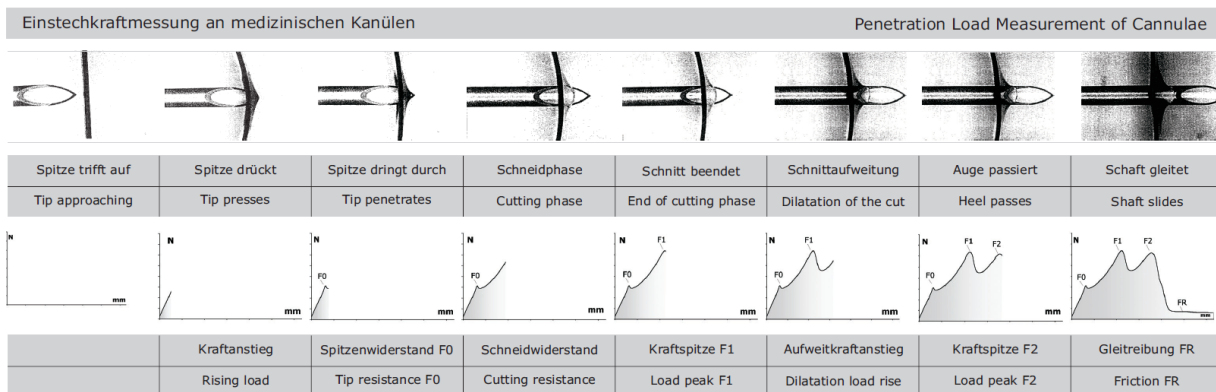
Equipment: Penetrometer DEKA 9, load cell +/- 200 N

Parameter: Testing Medium: PU Foil 0.4 mm  
 Testing Speed: 100 mm/min  
 Testing Length: 10 mm  
 Testing Direction: perpendicular

Testing Procedure: The samples were prepared by unpacking them from the sterile packaging. The needles were cut from the tubing and fixed on the needle holder. A new foil area was then fixed in the foil holder and the actual test done as set out in DIN 13097-4.

## 2. Results of the Penetration Force Tests (DIN 13097-4)

F0 – Maximum of the piercing phase (Tip resistance / tip penetrates)  
 F1 – Maximum of the cutting phase (Load peak / end of cutting phase)  
 F2 – Maximum of the dilatation phase (Load peak / heel passes)  
 FR – Mean Value of the Friction Phase (55% to 95% of the testing length; Friction FR / shaft glides)



The explanation of these results relative to the sensation of pain felt during a venipuncture is provided in the conclusion.

The following table 2 shows the results of the semi-automatic sets with 21 Gauge needles:

Table 2: Results of the semi-automatic sets with 21 Gauge needles (the lowest values of each phase are highlighted in yellow)

Sample	Size (mm)	Number of pieces tested	F0 min-max in N	Peak penetration force (F1/F2) min-max, in N	FR min-max in N
B	21G (0.8 x 19)	10	<b>0.75</b> 0.70-0.80	<b>1.00</b> 0.85-1.12	<b>0.10</b> 0.07-0.13
D	21G (0.8 x 19)	10	<b>0.55</b> 0.50-0.70	<b>1.25</b> 1.10-1.56	<b>0.17</b> 0.07-0.24
E	21G (0.8 x 19)	10	<b>0.75</b> 0.55-1.20	<b>1.00</b> 0.80-1.20	<b>0.06</b> 0.01-0.13

The following table 3 indicates the results of the semi-automatic sets with 23 Gauge needles:

Table 3: Results of the semi-automatic sets with 23 Gauge needles (the lowest values of each phase are highlighted in yellow)

Sample	Size (mm)	Number of pieces tested	F0 min-max in N	Peak penetration force (F1/F2) min-max, in N	FR min-max in N
C	23G (0.6 x 19)	10	<b>0.60</b> 0.55-0.80	<b>0.80</b> 0.75-1.10	<b>0.09</b> 0.06-0.10
A	23G (0.6 x 19)	30	<b>0.40</b> 0.30-0.48	<b>1.20</b> 1.10-1.36	<b>0.04</b> 0.03-0.06
F	23G (0.6 x 19)	30	<b>0.60</b> 0.55-0.70	<b>0.85</b> 0.75-1.00	<b>0.06</b> 0.04-0.10

The maximum penetration forces can happen either during the end of the cutting phase (F1 phase) or when the heel passes (F2 phase) – refer to diagram above. The table includes the higher of those two values.

While both 21G and 23G samples of the ultra thin walled needle have the lowest F0 piercing force, they also have the highest maximum penetration force (F1 or F2).



## Optical inspections

Tip defects which the products were checked for were:

Hook to inside

Hook to outside

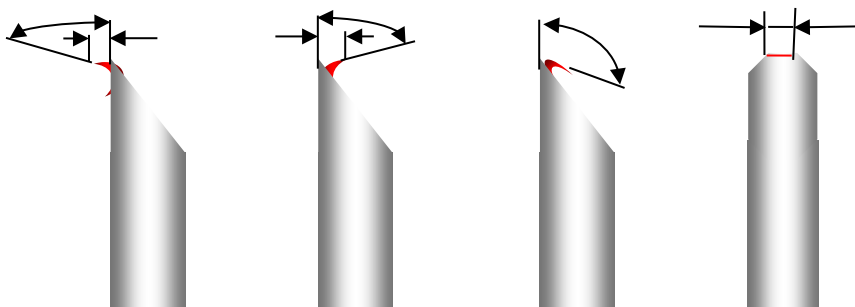
Tip blunt

Tip polished to blunt or

Angle of the Hook > 90 degree regarding the needle's axis,

Tip missing

Burrs



**Sketch 1:** Tip defects – left to right

1: Hook to outside

2: Hook to inside

3: Tip blunt (side view)

4: Tip blunt (back view)

## 4. Results Optical Inspections

No remarkable defects were detected in the tested needles. The only evidence was given by the needle of sample D. The needle showed large tip length with 5-bevel-points. The external lab assessed the product with the 5-bevel point geometry to have tissue coring tendencies. Coring can lead to hematomas after a blood collection and coring effects have been stated by that lab to be just as painful as cutting effects of a needle.

The testing laboratory noted that some samples of the 5-bevel needle showed particles, some inside the lumen.

## 5. Conclusion:

The comparison of the EVOPROTECT with the comparable semi-automatic set with 3 bevels shows that the initial piercing as well as maximum penetration forces are comparable.

The samples with a 5-bevel design have lower initial piercing force but considerably higher maximum penetration forces (F1 and F2) than the 3 bevel design products.

The force during the cutting phase, together with the piercing and dilation phase, is the most relevant measure with respect to the sensation of pain, as it depicts the force necessary for needle tip penetration through the skin during a venipuncture. The penetration forces associated with most samples were very low, including the VACUETTE® EVOPROTECT SAFETY Blood Collection Set.

The friction forces are also relevant regarding pain, as high friction forces mean a difficult movement of the needle through the tissue after it has been penetrated by the needle tip. This resistance also correlates to sensation of pain. The friction force of all samples was noted to be very low by the testing lab. However, sample D, the 5-bevel 21G competitive product, showing considerably higher friction forces than the EVOPROTECT and other products tested.

In summary, it can be concluded that the EVOPROTECT device achieved remarkably good results by external assessment with respect to the measurements which correlate to the sensation of pain. No additional problematic observations were made by the external laboratory performing the tests.

The needle quality of the VACUETTE® EVOPROTECT SAFETY Blood Collection Set is comparable to the competitive 3-bevel semi-automatic safety blood collection set. It is, however, manufactured with extra-thin walled needles without requiring higher penetration forces as seen with the ultra thin-walled needles.