

# Comparison Testing of Needles and Packaging of various Blood Collection Sets

## **Background:**

The Greiner Bio-One portfolio includes various blood collection sets. The product range encompasses blood collection sets as well as safety blood collections sets with various needle sizes. One of the most frequently used needle size is 23G x 19 mm. In order to enable phlebotomists to perform venipunctures which cause as little pain as possible, 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 of the needles may vary.

The test was carried out by way of mechanical testing done by Melab Medizintechnik und Labor, a German laboratory accredited to carry out tests according to the standards listed below.

## **Study Objective:**

This test was carried out to investigate the effect of these various attributes on needle sharpness and to determine Greiner Bio-One's needle quality when comparing it to well-established as well as new competitor products. To that purpose, penetration and friction force as well as geometry tests and optical inspections were carried out.

## **Study design and procedure:**

The following needles were all of the size 23G x 19mm.

Sample	Description	Size(mm)	Bevel Type	Needle tube thickness	Sterilisation method
A	SAFETY Blood Collection Set	23G (0,6 x 19)	3-bevel	Thin walled	EO
B	Safety blood collection set with manually activated sliding mechanism	23G (0,6 x 19)	3 bevel	Thin walled	EO
C	Semi-automatic safety blood collection set with ultra thin walled needles	23G (0,6 x 19)	5 bevel	Extra thin walled	Radiation
D	Semi-automatic safety blood collection set	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 damage during 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 is piercing the polyurethane foil. The testing material polyurethane is described in the Standard DIN 13097-4. It is sensitive for the

## 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: GBO 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 package. The needles were cut from the tube and fixed on the needle holder. A new foil area was then fixed in the foil holder. The test was started by the needle penetrating the foil. The load and testing length charts were recorded and a statistical protocol prepared.

## 2. Geometry

Equipment: Facet Angle Measurements Station FACET  
 Stereomicroscope Olympus SZH  
 Profileprojector Werth  
 Micrometer Mitutoyo

The geometry was measured for 6 samples to determine the bevel geometry.

## 3. Optical Inspections

The needles were inspected under the microscope. Significant deviations were documented by printed video images. Type and size of the deviation were determined.

Equipment: Stereo-Microscope Olympus SZH  
 Video-Printer

## Results:

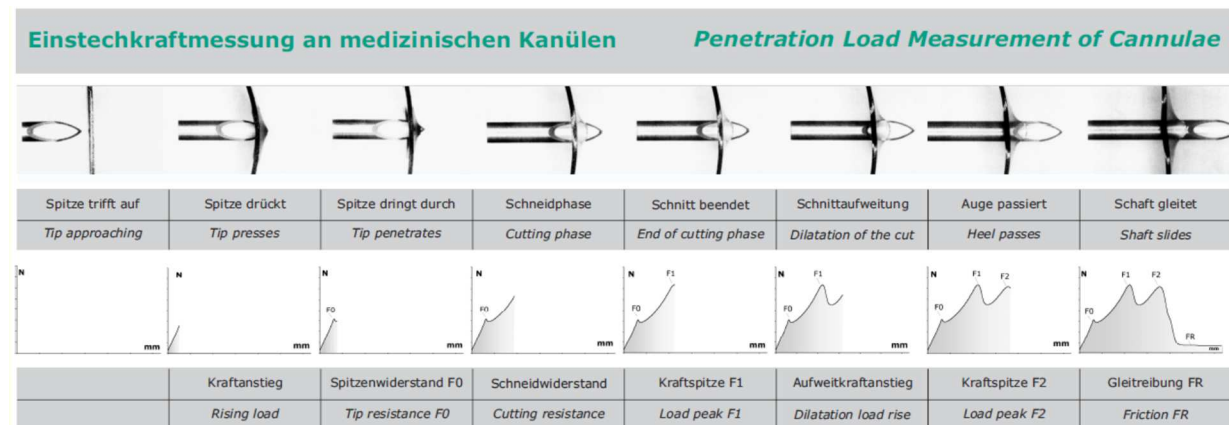
### Results of the Penetration Load Tests (DIN 13097-4)

F0 – Maximum of the piercing phase (Tip resistance F0 / tip penetrates)

F1 – Maximum of the cutting phase (Load peak F1 / end of cutting phase)

F2 – Maximum of the dilatation phase (Load peak F2 / heel passes)

FR – Mean Value of the Friction Phase (55% to 95% of the testing length; Friction FR / shaft glides)



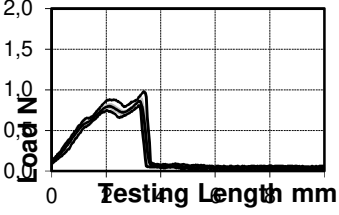

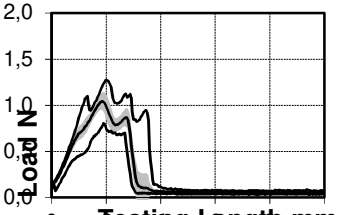

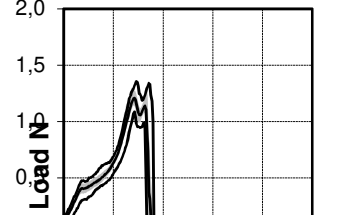

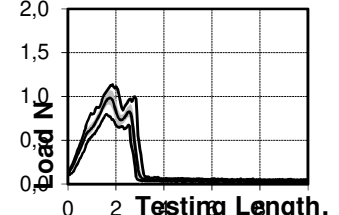

(For an explanation of the meaning of these results when relating them to the sensation of pain felt during a venepuncture please refer to the Conclusion in the Annex at the end of the document.)

Table: Results of the penetration load tests

Sample	Size (mm)	Number of pieces tested	F0 min-max in N	F1 min-max in N	F2 min-max in N	FR min-max in N
A	23G (0,6 x 19)	30	<b>0,60</b> 0,55-0,65	<b>0,80</b> 0,75-0,85	<b>0,85</b> 0,80- 0,98	<b>0,04</b> 0,03-0,06
B	23G (0,6 x 19)	30	<b>0,70</b> 0,50-1,10	<b>1,05</b> 0,80-1,27	<b>0,80</b> 0,70- 1,05	<b>0,05</b> 0,04-0,07
C	23G (0,6 x 19)	30	<b>0,40</b> 0,30-0,48	<b>1,20</b> 1,10-1,36	<b>1,15</b> 1,00- 1,35	<b>0,04</b> 0,03-0,06
D	23G (0,6 x 19)	30	<b>0,60</b> 0,50-0,80	<b>0,98</b> 0,80- 1,14	<b>0,80</b> 0,65- 1,00	<b>0,04</b> 0,05-0,03

Statistical graphs of the Penetration Forces in the testing foil

Pictures of the needle points

<p style="text-align: center;">Sample A</p> 	<p style="text-align: center;">Sample A</p> 
<p style="text-align: center;">Sample B</p> 	<p style="text-align: center;">Sample B</p> 
<p style="text-align: center;">Sample C</p> 	<p style="text-align: center;">Sample C</p> 
<p style="text-align: center;">Sample D</p> 	<p style="text-align: center;">Sample D</p> 

## Geometry

The geometrical measures are listed in the table below. The nomenclature of the measures is according to DIN 13097 (ISO 7864) and ISO 9626:

OD - outside diameter

ID - inside diameter

s - wall thickness (not standard)

A - Point Length

C - Secondary Bevel Length

$\alpha$  - Primary Bevel Angle

$\gamma$  - Combined Secondary Bevel Angle (Facet Angle)

RW - regular walled

TW - thin walled

ETW - extra thin walled

Table: Geometry of the Cannula

	OD mean mm	ID mean mm	Bevel	A mean min-max mm	C mean min-max mm	$\alpha$ mean min-max degree	$\gamma$ mean min-max degree
<b>Specification ISO 9626 23G</b>	<b>0,600-0,673</b>	<b>RW&gt;0,317 TW&gt;0,370 ETW&gt;0,460</b>					
Sample A	0,640	0,397 (TW)	<b>3- Bevel</b>	2,073 <b>2,009-2,141</b>	0,927 <b>0,879-0,952</b>	13,3 <b>13-14</b>	115 <b>114 - 116</b>
Sample B	0,633	0,405 (TW)	<b>3- Bevel</b>	2,031 <b>1,811-2,205</b>	1,027 <b>1,002-1,042</b>	11,9 <b>11,5-13</b>	95 <b>84-100</b>
Sample C	0,637	0,528 (ETW)	<b>5- Bevel</b>	2,369 <b>2,334-2,413</b>	1,869 <b>1,849-1,891</b>	11,1 <b>10,8-11,5</b>	2x100
Sample D	0,637	0,404 (TW)	<b>3- Bevel</b>	1,980 <b>1,911-2,056</b>	1,046 <b>0,948-1,129</b>	12,6 <b>12-13,5</b>	106 <b>91-122</b>

## Optical inspections

Tip defects which the products were checked for were:

Hook to inside

Hook to outside

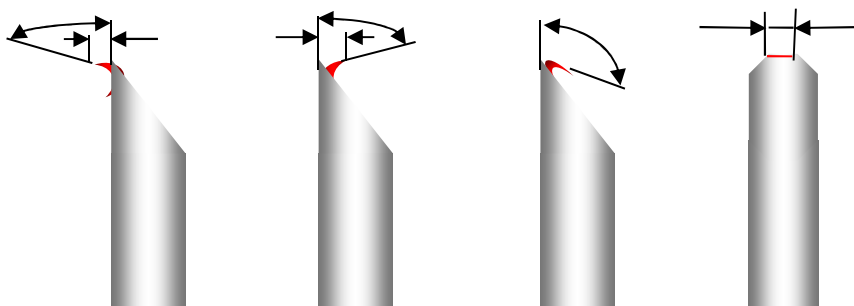
Tip blunt

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)

No remarkable defects were detected on the tested needles. This is also confirmed by the penetration charts as there is no significant peak at F0.

**Conclusion:**

The needle tubes of sample A, B and D were thin-walled, the needle tube of sample C was extra thin-walled. The needle points of sample A, B and D were three bevelled, the needle point of sample C was 5-bevelled.

The penetration forces of sample A, B and D were very low and showed similar behaviour. The Greiner Bio-One SAFETY Blood Collection Set had the lowest force during the cutting phase (F1). This, together with the piercing and dilation phase, is the most relevant measure in regards to the sensation of pain, as it depicts the force of needle tip penetration through the skin during a venepuncture. The friction forces are equally relevant in regards to 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 is also felt as a painful sensation. The friction forces (FR) of all samples were very low, with the SAFETY Blood Collection Set having the same low measurement as two of the competitor products, and the third competitor product showing higher forces.

Another important aspect, in addition to the average measurement results, is the variation of results within a sample group of tested items. In the laboratory report, large tolerances for the lancet angle Gamma at the samples B and D were noted. It was specifically pointed out by the external laboratory that Sample A (Greiner Bio-One SAFETY Blood Collection Sets) had remarkably good values with a very low variation within the sample group.

Also, it was stated by the external lab that according to their assessment the point geometry of sample C may have a tissue coring tendency.

In summary, sample A (Greiner Bio-One SAFETY Blood Collection Set) is the product which by external assessment achieved remarkably good results in regards to the measurements from which a conclusion regarding the sensation of pain can be drawn, and for which no additional problematic observations were made by the external laboratory carrying out the tests.

**Test of package opening force**

In addition to the sharpness of the needle, an aspect which has an impact on the usability of the device is the opening force of the individual package. A repeated difficult opening of a medical device package may even lead to a repeated strain injury, which is why in certain markets the opening force of the device is awarded certain points during a tender decision process.

The opening force of the Greiner Bio-One SAFETY Blood Collection Sets was tested in an internal test, carried out by Greiner Bio-One, in comparison with competitor devices.

**Tested products**

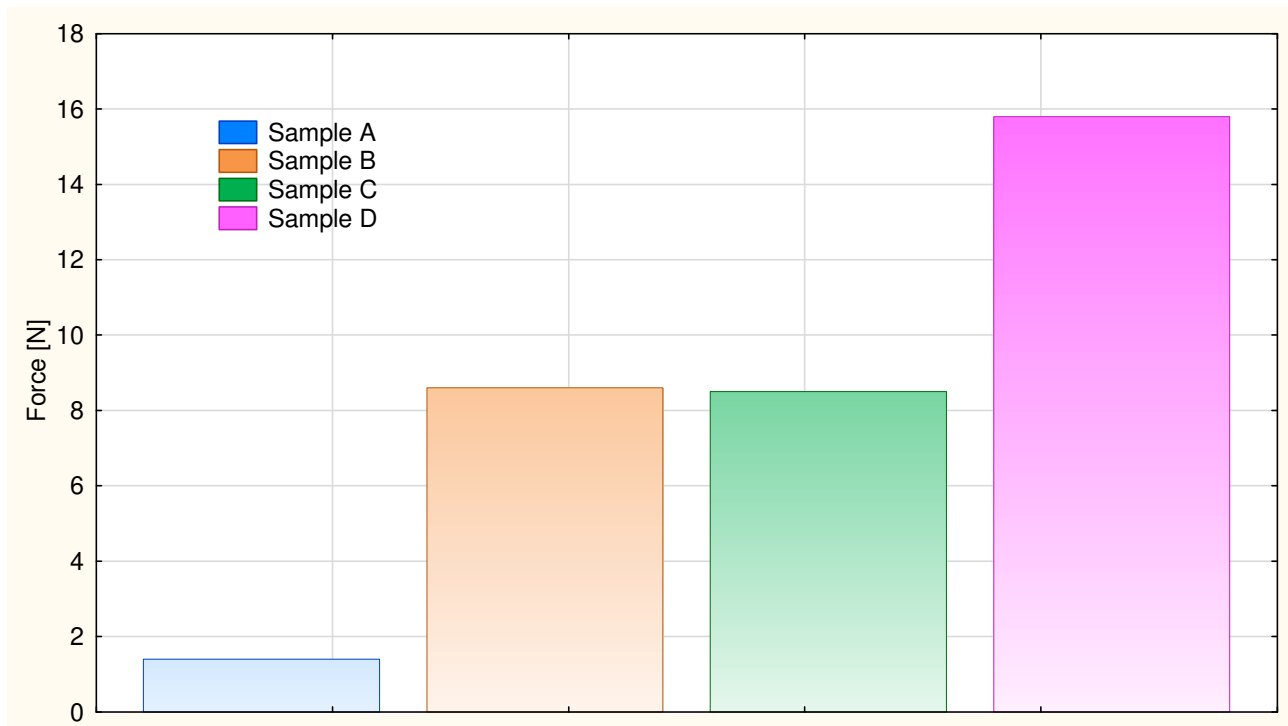
Sample	Description	Lot.No.
A	GBO Safety Blood Collection / Infusion Set, 21G x ¾", 19 cm tubing	15J17
B	Semi-automatic safety blood collection set, 30 cm tubing	4196944
C	Semi-automatic safety blood collection set, 19 cm tubing	4125957
D	Safety blood collection set with manually activated sliding mechanism, 30 cm tubing	6034602

### Testing procedure

The packaging of the products was attached to the Zwick and Roell tension and compression measuring device in a way that the flaps or parts of the packaging intended for opening were held by the clamping jaws. The tension test was carried out until the packaging opened completely, and the maximum force for opening the different products was recorded and compared.

### Results

Max. Opening Force [N]		Sample A	Sample B	Sample C	Sample D
	mean	1,4	8,6	8,5	15,8
	std	0,2	0,6	0,5	1,4
	min	1,1	7,9	8,0	14,7
	max	1,7	9,0	9,0	17,3
	range	0,6	1,1	1,1	2,6



### **Conclusion:**

The results show that the Greiner Bio-One SAFETY Blood Collection Sets have clearly the lowest opening forces for the single pouch packaging.