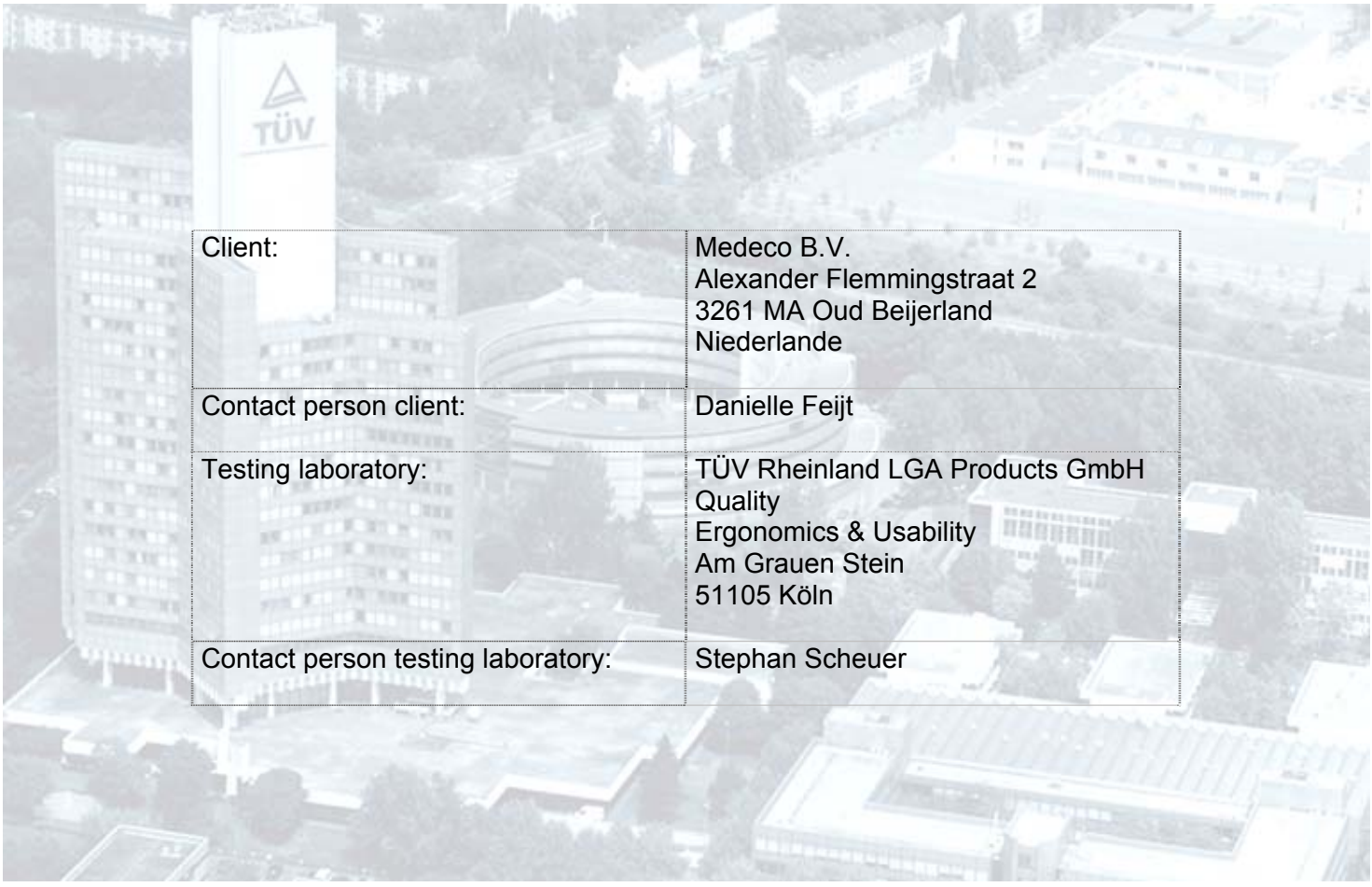
TÜV Rheinland LGA Products GmbH
Quality - Ergonomics & Usability
Am Grauen Stein
51105 Cologne, Germany

Benchmarktest

Pen-Needles



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1 Introduction

This test report contains the results of a comparative laboratory test of different pen-needles of two different manufactures. The criteria described in the scope have been considered in the test.

2 Scope of testing

The comparative laboratory test was performed on two pen needles of the type KLINION soft fine plus and the type BD Micro-Fine + each in two sizes:

- KLINION soft fine plus (0.33 mm (29G) x 12 mm) in the following **KLINION_29G**,
- BD Micro-Fine + (0.33 mm (29G) x 12,7 mm in the following **BD_29G**.
- KLINION soft fine plus (0.25 mm (31G) x 8 mm) in the following **KLINION_31G**,
- BD Micro-Fine + (0.25 mm (31G) x 8 mm) in the following **BD_31G**.

The following criteria were part of the laboratory test:

- **Manufacturing quality and finish**
  The manufacturing quality (Tipp, cutting edge, opening) and finish (burring and coating) are examined. The geometry is evaluated before penetration force test and after penetration force test.

- **Penetration characteristics (force)**
  The penetration characteristics are recorded as load/penetration length diagrammes while the cannula is piercing the polyurethane foil according to DIN 13097.

- **Flow resistance**
  The application resistance created by the cannula when applying the testing fluid is measured in a pen simulator. The analyses is in accordance to ISO 11608-3.

- **Cohesiveness of connection needle/hub**
  The chesiveness of the connection between needle and hub (screw part) is loaded by a pull force. The results are evaluated according to ISO 7864.

- **Wall thickness**
  The wall thickness is determined with the help of metallographic grindings.

- **Kingking test**
  The kinking test indicates the bearable kinking load (axial load) of the needle.

3 Product description

3.1 KLINION soft fine plus (29G)

Brand	Description	Size	Lot	Exp.-Date	PZN
KLINION	soft fine plus	0.33 mm (**29G**) x 12 mm	943000	09-2014	9166274

Figure 3-1: KLINION soft fine plus, 0.33 mm (29G) x 12 mm

3.2 BD Micro-Fine + (29G)

Brand	Description	Size	Lot	Exp.-Date	PZN
BD	Micro Fine +	0.33 mm **(29G)** x12,7 mm	9139815	2014-05	2757233

Figure 3-2: BD Micro-Fine + 0.33 mm (29G) x12,7 mm

3.3 KLINION soft fine plus (31G)

Brand	Description	Size	Lot	Exp.-Date	PZN
KLINION	soft fine plus	0.25 mm **(31G)** x 8 mm	947000	09-2014	9166251

Figure 3-3: KLINION soft fine plus, 0.25 mm (31G) x 8 mm

3.4 BD Micro-Fine + (31G)

Brand	Description	Size	Lot	Exp.-Date	PZN
BD	Micro Fine +	0.25 mm **(31G)** x 8 mm	9125266	2014-05	2757256

Figure 3-4: BD Micro-Fine + 0.25 mm (31G) x 8 mm

4 Tests

4.1 Manufacturing quality and finish

The manufacturing quality (Tipp, cutting edge, opening) and finish (burring and coating) are examined. The geometry is evaluated before penetration force test and after penetration force test.

The following geometrical measures are tested

- D_a - Outside diameter
- D_i - Inside diameter
- A - Point length)
- C - Secondary Bevel Length
- α - Primary Bevel Angle
- γ - Combined Secondary Bevel Angle

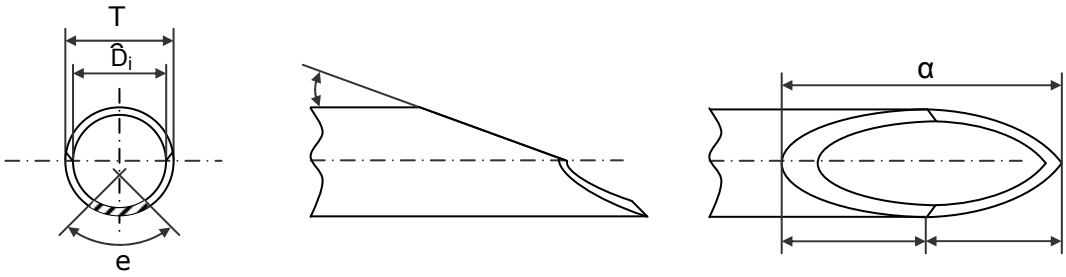


Figure 4-1 Nomenclature for geometric measures

Conspicuous needles are inspected under the microscope to determine the type and size of the deviation. Significant deviations are documented.

Measuring equipment: Facet Angle Measurings Station FACET
Stereomicroscope Olympus SZH
Profileprojector Werth
Micrometer Mitutoyo

4.2 Penetration characteristics (force)

4.2.1 Testing methods

The penetration force tests are performed according to the Standard DIN 13097. The penetration characteristics are recorded as load/penetration length diagrammes while the cannula is piercing the polyurethane foil. The testing material polyurethane is also described in the Standard DIN 13097. It is sensitive for the

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

Measuring equipment: Penetrometer DEKA 9, load cell +/- 50 N

Parameter:		
	Testing Medium:	Polyurethan Foil PU 0.4
	Testing Speed:	100 mm /min
	Testing Length:	8 mm (29G) und 6 mm (31G)
	Testing Direction:	perpendicular

4.2.2 Testing procedure

- Pick samples from sample boxes
- Peel seal
- Fix needle on Pen-Simulator
- Replace needle shields
- Insert the assembly in the testing station (position)
- Fix a new foil area in the foil holder
- Start Test; the needle penetrates the foil
- Record the load / testing length diagrams
- Print the statistical protocol

4.3 Application Force Measurement (Flow resistance)

4.3.1 Test Method

The force measurement is carried out according to ISO 7886 and ISO 11608-3. To determine the application resistance created by the cannula when applying the testing fluid the pen needles are screwed on the pen simulator and the cartridges are inserted. The testing arrangement is depicted in the sketch below.

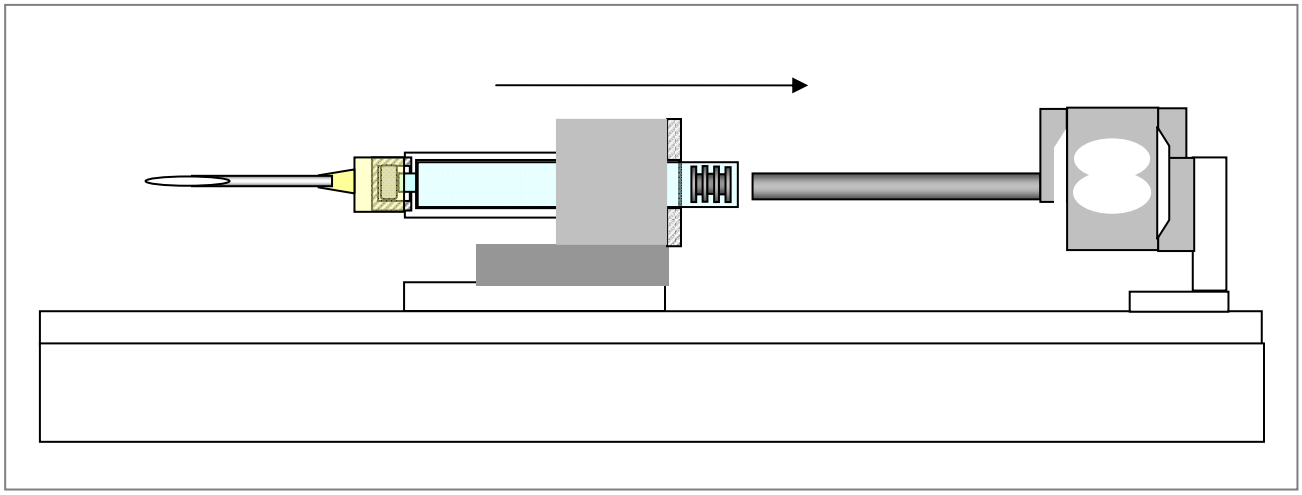


Figure 4-2: Testing Arrangement of plunger force tests (Application Forces, ISO 11608)

The slider moves towards the plunger pusher during the test, thus pressing out the fluid through the needle.

Measuring equipment: Penetrometer DEKA 9

Parameter: Testing medium: 3 ml cartridges
(different manufacturer and testing fluids)
Testing Speed: 100 mm /min (ISO 7886)
Testing Length: 20 mm
Testing Direction: axial

Manufacturer	Description	Size	Lot	Exp.-Date
Lilly	Saline Solution	**3 ml**	A574848A	12-2011
Novo	Test medium	**3 ml**	SW 50652	10-2007
Sanofi Aventis	Water	**3 ml**	41N156	-

Table 4-1: Testing fluids

4.3.2 Testing procedure

- Pick samples from sample boxes
- Peel seal
- Fix needle on pen simulator (screw)
- Insert cartridge
- Replace needle shields
- Insert assembly in the testing station (position)
- Start measurement (the plunger pusher forwards the plunger so the fluid in the cartridges is pressed through the needle)
- Record force/length diagrams
- Print Statistical protocol

4.4 Cohesiveness of connection needle/hub

4.4.1 Testing method

The glue connection between needle and hub (screw part) is loaded by a pull force until it separates. The results are evaluated according to ISO 7864. The standard defines minimum separation forces correlated with the outside diameter of the needle (ISO 7864, Table 2).

Measuring equipment: Penetrometer DEKA 9

Parameter: Testing Speed: -15 mm/min
Testing Length: 5 mm
Testing Direction: axial

4.4.2 Test procedure

- Pick testing samples from sample boxes
- Peel seal
- Fix the needle on pen simulator
- Replace needle shields
- Insert the assembly in the counter bearing
- Fix needle on pull tool
- Start Test; The needle is pulled regarding the hub
- Record the load / testing length diagrammes
- Print the statistical protocol

4.5 Wall thickness

To determine wall thickness, metallographic grindings are produced from every sample. While doing this, right-angled and plane-parallel preparation is especially important.
Subsequently, the wall thickness is measured on a scale of 500:1 with the Zeiss “AXIO Imager M2m” optical microscope. The wall thickness is offset in 4 measurements each time at a 90° angle and also determined in two grinding levels.

For analysis of the microstructure, the samples are then etched and documented.

4.6 Kinking test

4.6.1 Test methode

The kinking test indicates the bearable kinking load (axial load) of the needle. Within the test the needle tip runs against a non pierceable material and starts bending and sub-sequentially kinks with further forwarding. This test is performed following the Euler Kinking Cases 1 resp. 2. The recorded characteristics indicate the elastical area and the plastical area of the kinking.

Measuring equipment:	Penetrometer DEKA 9 Stereo Microscope SZH	
Parameter:	Testing speed:	20 mm / min
	Testing length:	2 mm
	Testing direction:	axial

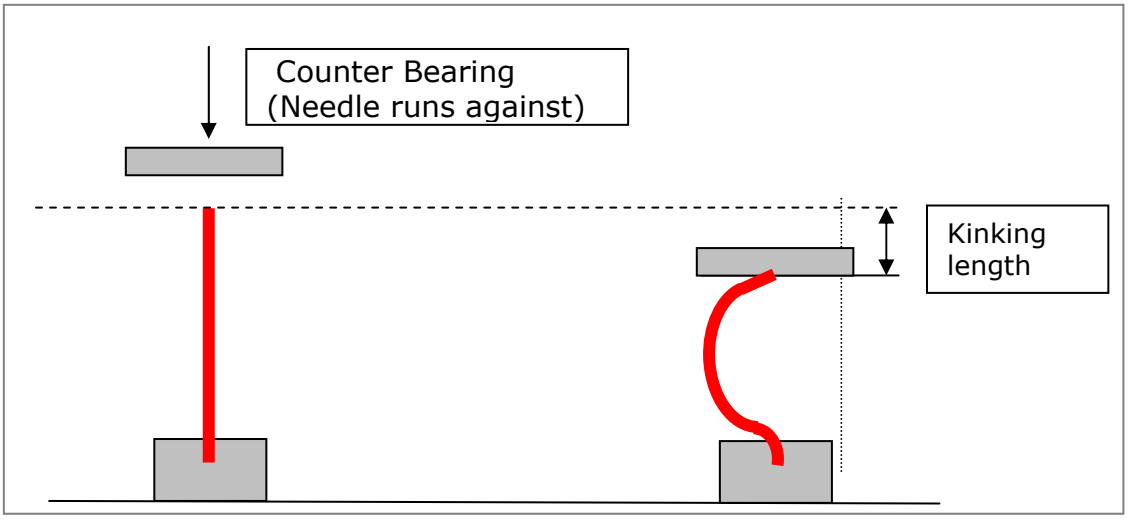


Figure 4-3: Arrangement of the kinking test

4.6.2 Test procedure

- Pick Samples from samples boxes
- Peel seal
- Fix needle on pen simulator
- Replace needle shields
- Insert assembly in the testing station
- Start Test; the needle runs agains the counter bearing
- Record the load / testing length diagrams
- Print statistical protocol

5 Test results

5.1 Manufacturing quality and finish

5.1.1 Geometry

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

D_a - outside diameter
D_i - inside diameter
A- Point length
C - Secondary Bevel Length
α - Primary Bevel Angle
γ - Combined Secondary Bevel Angle

NW - normal walled
TW- thin walled
UTW- ultra thin walled

	D_a mean mm	D_i mean mm	A mean min-max mm	B = A-C mm	C mean min-max mm	α mean min-max degree	γ mean min-max degree
*Specification ISO 9626 **29G***	*0.324-0.351*	*NW: 0.143-0.190*					
KLINION_29G	**0.340**	**0.181**	**1.23** 1.21-1.26	0.69	**0.54** 0.52-0.58	**11.7** 11.5-12.5	**112.2** 110-114
BD_29G	**0.340**	**0.188**	**1.50** 1.42-1.55	0.86	**0.64** 0.61-0.67	**8.8** 8.5-9.0	**116.6** 113-125
*Specification ISO 9626 **31G***	*0.254-0.267*	*TW: > 0.125*					
KLINION_31G	**0.265**	**0.154**	**1.18** 1.15-1.22	0.66	**0.52** 0.48-0.56	**9.1** 8.5-9.6	**106.6** 103-110
BD_31G	**0.261**	**0.149**	**1.17** 1.08-1.31	0.76	**0.41** 0.29-0.48	**8.9** 8.5-9.2	**110.1** 104-115

Table 5-1: Geometry

The geometrical measures of the tested needles are market usual. The BD_31G needles have slightly bigger deviations for the geometrical bevel measures, such as bevel length, secondary bevel length and the combined secondary bevel angle.

5.1.2 Results of the optical inspections

Tip defects are:

- 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

The following sketch shows the visible tip defects. Tips polished to blunt and tiny hooks with a great inclination angle are optically – if any – hardly visible but they affect the penetration characteristics significantly.

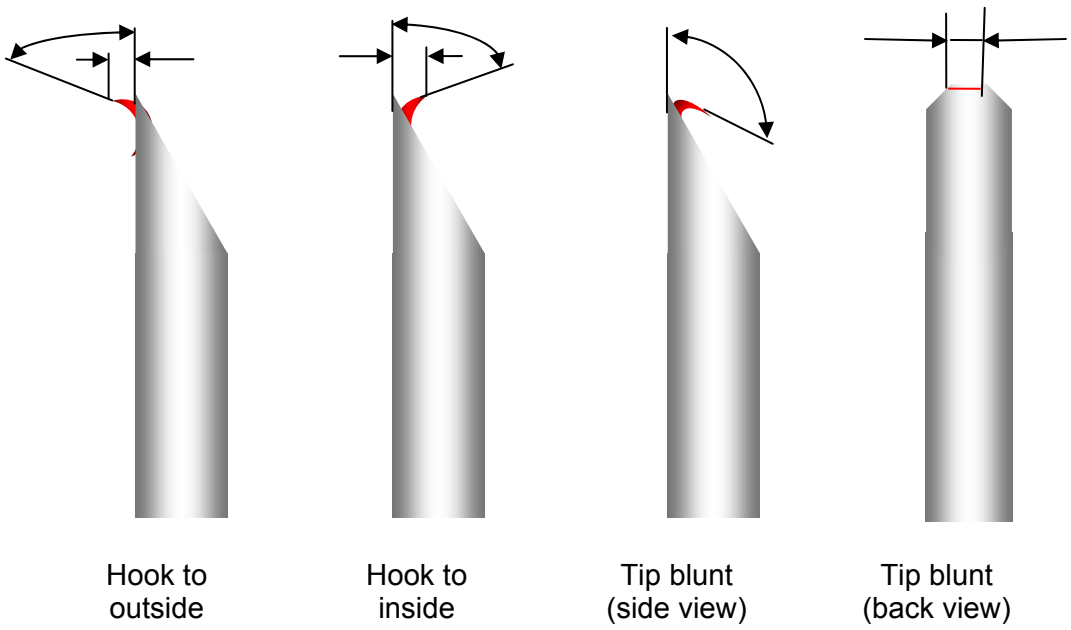


Figure 5-1: Tip defects

None of the tested needles shows remarkable tip defects. This confirms the good manufacturing quality.

Some needles have differences in the length of the facets (left to right). These differences are rather common with the very small sized needles than with bigger ones. The penetration force is not affected detrimental by this.

No differences can be determined regarding states of the tip and the bevel 'prior' and 'after' the penetration force test. With the BD needles there is partially silicone visible in the tip area which is pushed back to the return position after the penetration.

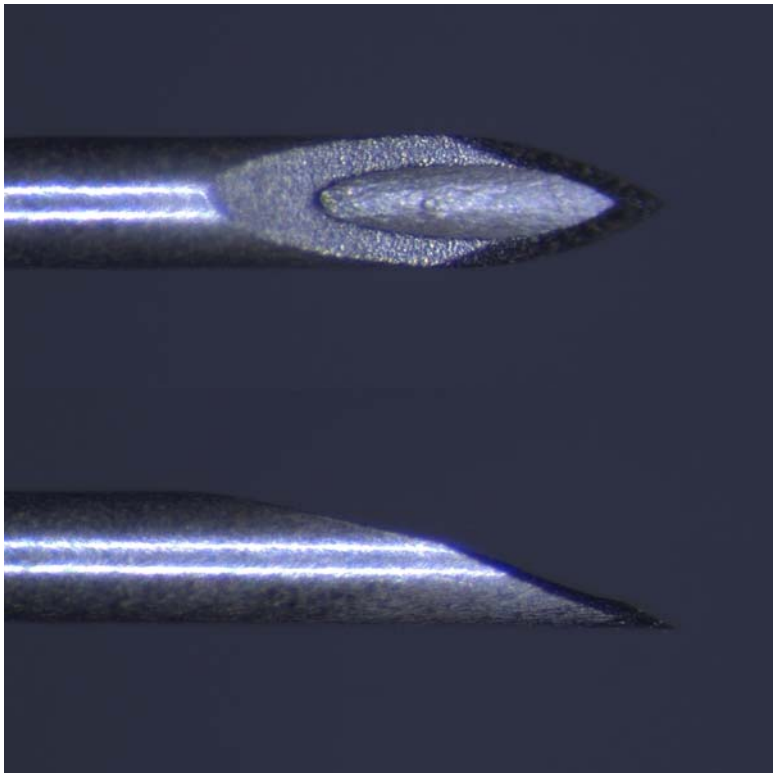


Figure 5-2: KLINION_29G

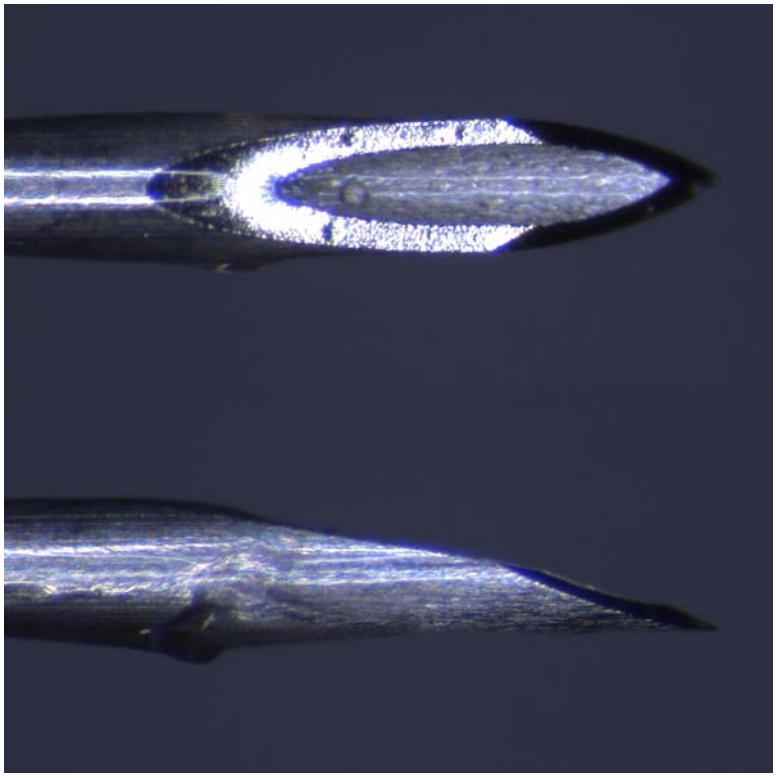


Figure 5-3: BD_29G

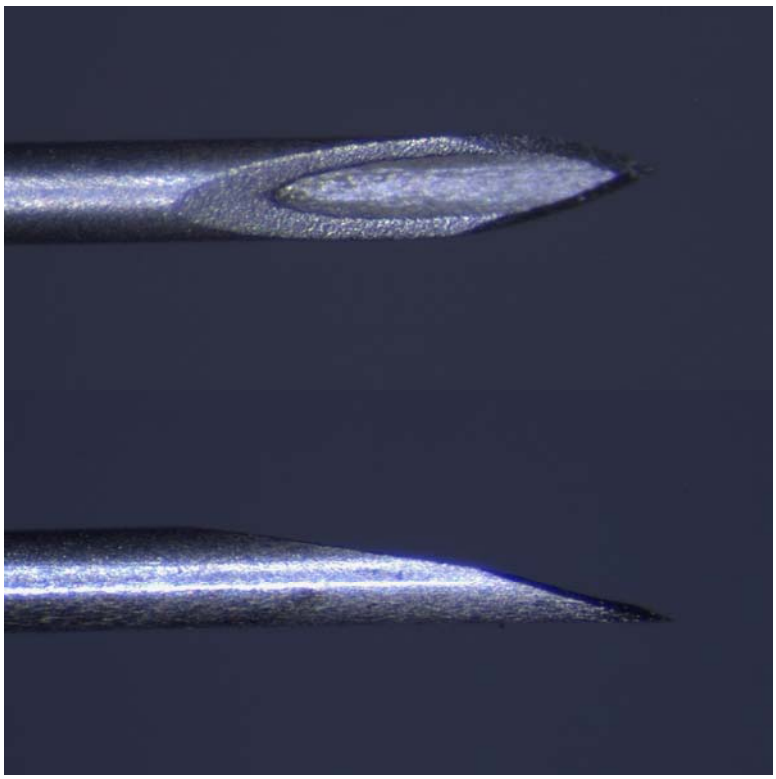


Figure 5-4: KLINION_31G

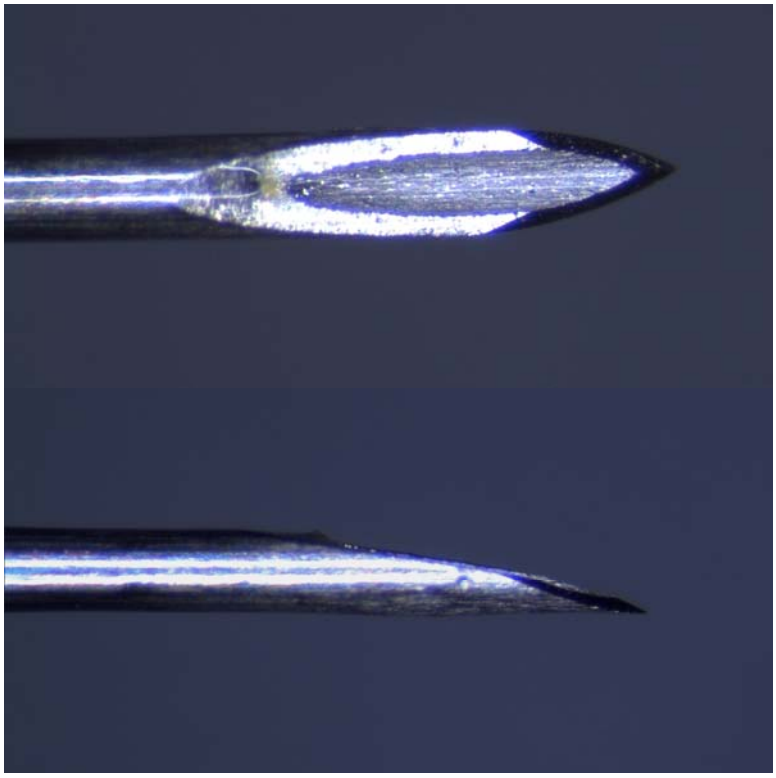


Figure 5-5: BD_31G

5.2 Penetration characteristics (force)

The testing results are listed in the table below as minimum-, maximum- and mean values of the significant measures:

F0 – Maximum of the piercing phase
F1 – Maximum of the cutting phase
F2 – Maximum of the dilatation phase
FR – Mean Value of the Friction Phase (55% to 95% of the testing length)

	Size	No. tested	**F0** mean min-max in N	**F1** mean min-max in N	**F2** mean min-max in N	**FR** mean min-max in N
KLINION_29G	0.33 x 12 (29G)	32	**0.54** 0.5-0.59	**0.54** 0.5-0.58	**0.76** 0.64-0.87	**0.08** 0.06-0.12
BD_29G	0.33 x 12.7 (29G)	32	**0.34** 0.29-0.41	**0.39** 0.33-0.48	**0.70** 0.63-0.86	**0.03** 0.03-0.04
KLINION_31G	0.25 x 8 (31G)	32	**0.42** 0.36-0.44	**0.43** 0.35-0.57	**0.63** 0.46-0.81	**0.11** 0.04-0.15
BD_31G	0.25 x 8 (31 G	32	**0.39** 0.35-0.61	**0.45** 0.34-0.61	**0.73** 0.63-0.84	**0.03** 0.01-0.06

Table 5-2: Results of the penetration test

The piercing and the cutting forces of the tested needles are at a low level. That means the tips and the cutting edges are good. Also the friction forces are very low.

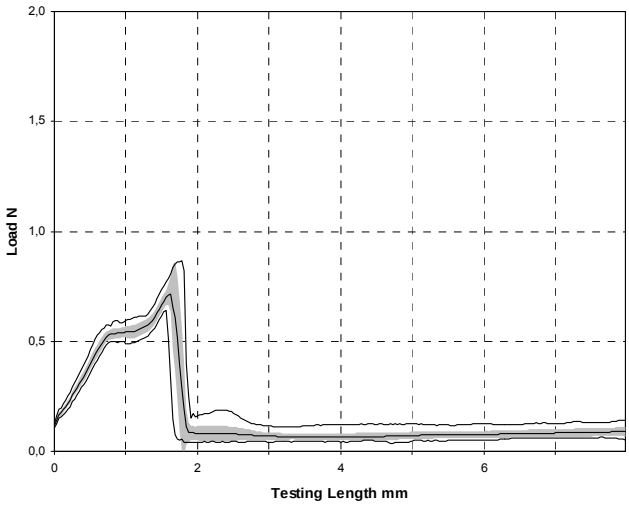


Figure 5-6: Penetration diagram KLINION_29G

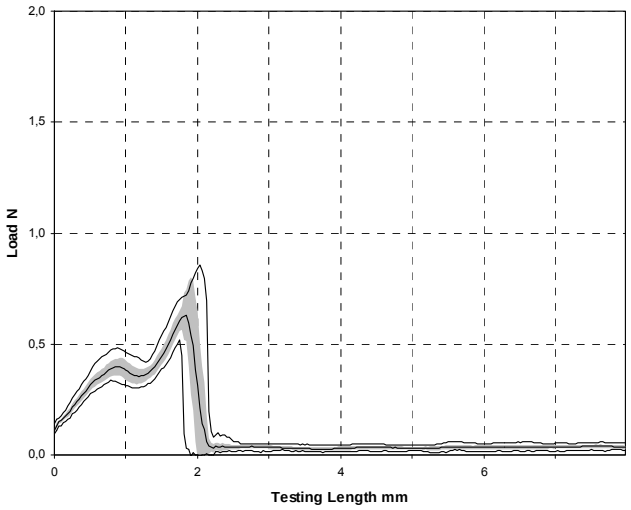


Figure 5-7: Penetration diagram BD_29G

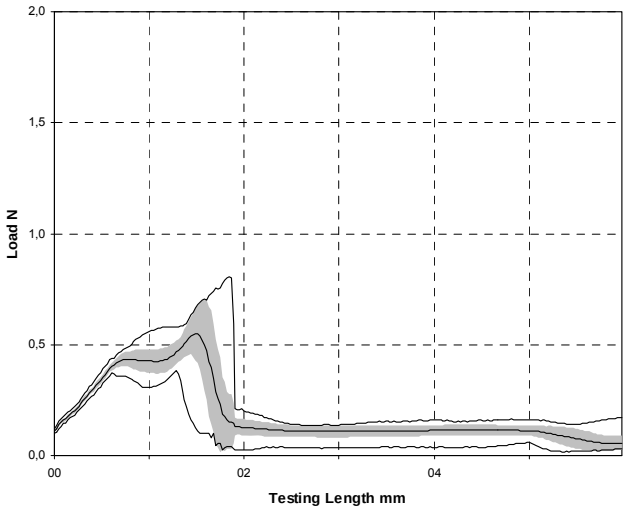


Figure 5-8: Penetration diagram KLINION_31G

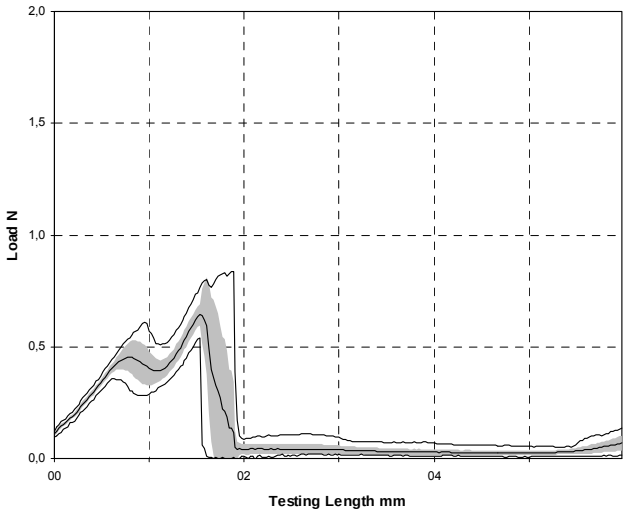


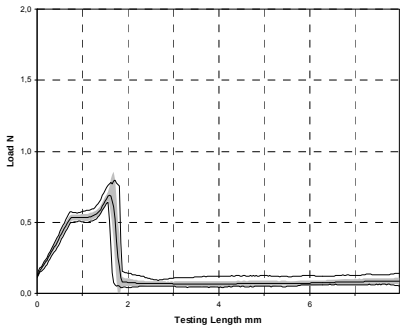
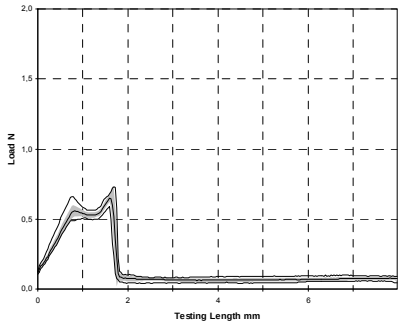
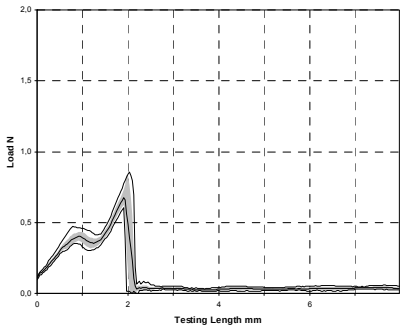
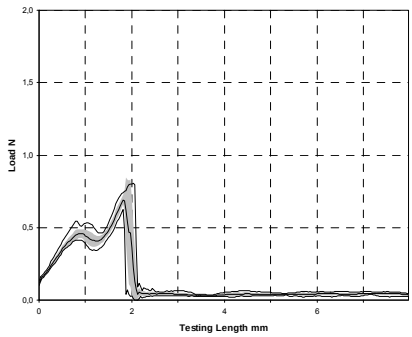
Figure 5-9: Penetration diagram BD_31G

The needles KLINION_29G show very consistent penetration characteristics with a slim band for the standard deviation (grey shaded area). Also the needles BD-29G have a slim standard deviation. Slightly bigger are the deviations for the 31G needles of both manufacturers.

Note: For the first 12 samples the penetration load tests were repeated to document that there is also no remarkable change in the penetration characteristics due to the penetration test as documented in the images of table 5-4. Due to the fact that solely 12 samples were evaluated only the mean values are listed in the table below.

	Size	No. tested	**F0** mean min-max in N	**F1** mean min-max in N	**F2** mean min-max in N	**FR** mean min-max in N
KLINION_29G	0.33 x 12 (29G)	12	**0.55**	**0.54**	**0.67**	**0.07**
BD_29G	0.33 x 12.7 (29G)	12	**0.38**	**0.45**	**0.75**	**0.04**
KLINION_31G	0.25 x 8 (31G)	12	**0.41**	**0.42**	**0.58**	**0.09**
BD_31G	0.25 x 8 (31 G	12	**0.43**	**0.47**	**0.72**	**0.04**

Table 5-3: Results of the repeated penetration test

	1. Penetraton – Needle-No. 1-12	2. Penetraton – Needle-No. 1-12
KLINION_29G		
BD_29G		

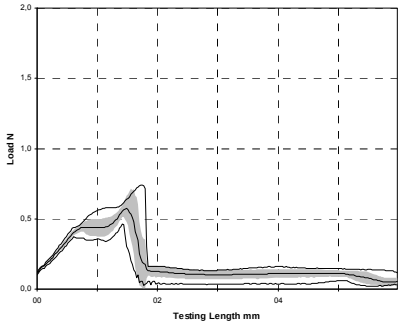
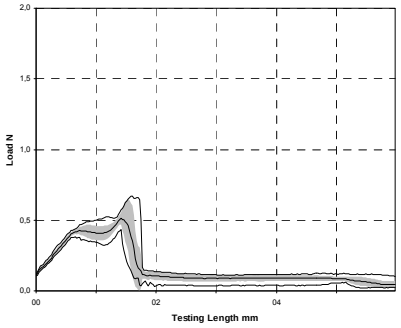
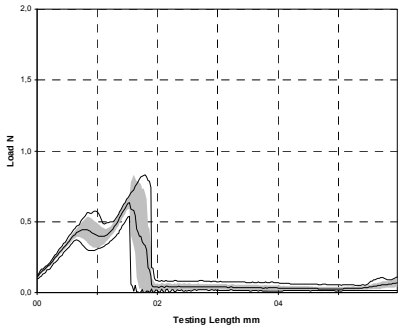
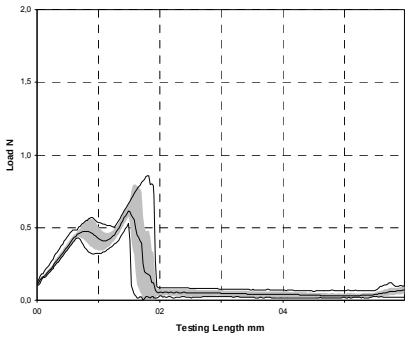
	1. Penetraton – Needle-No. 1-12	2. Penetraton – Needle-No. 1-12
KLINION_31G		
BD_31G		

Table 5-4: Comparison of the penetration forces of the 1st and the 2nd penetration

5.3 Application Force Measurement (Flow resistance)

The results of the application force measurements are listed in the table below as minimum-, maximum and mean values of

FIni - **Ini**tial Force (force needed to start the plunger)
Fsust - **sust**aining Force (force needed to run the plunger)

5.3.1 Application force measurements Saline Sol./Lilly

	Size (needle)	No. tested	**FIni** mean min-max in N	**Fsust** mean min-max in N	Size (cartridge)	Fluid/ Manufacturer
Requirements according to ISO 11608			***≤40***	***≤20***		
KLINION_29G	0.33 x 12 (29 G)	6	**20.4** 25.9-18.2	**14.0** 12.3-15.4	3 ml	Saline Sol. /Lilly
BD_29G	0.33 x 12.7 (29G)	6	**17.3** 16.5-18.6	**12.7** 11.6-13.4	3 ml	Saline Sol. /Lilly
KLINION_31G	0.25 x 8 (31G)	6	**22.6** 21.3-24.6	**20.3** 18.7-21.4	3 ml	Saline Sol. /Lilly
BD_31G	0.25 x 8 (31G)	6	**24.0** 22.0-26.7	**22.6** 21.8-24.8	3 ml	Saline Sol. /Lilly

Table 5-5: Results of the application force measurements

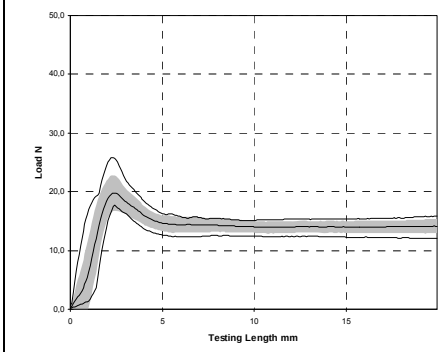
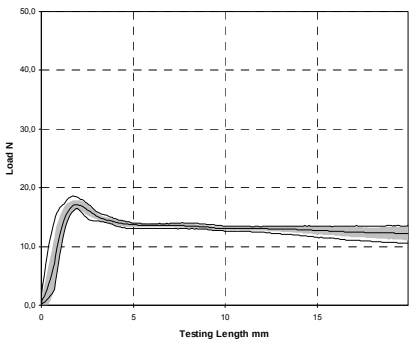
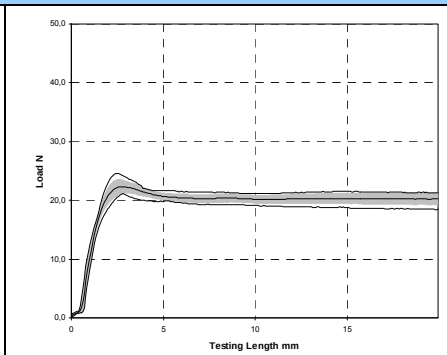
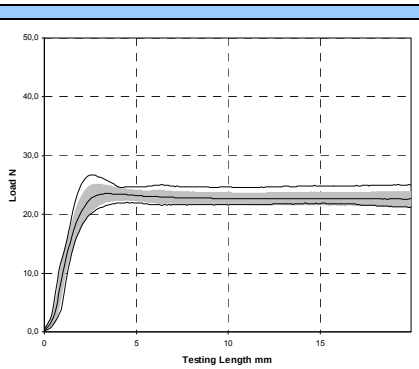
	KLINION	**BD**
29G		
31G		

Table 5-6: Application force diagrams – Saline Sol./Lilly

5.3.2 Application force measurements Testmedium/Novo

	Size (needle)	No. tested	**FIni** mean min-max in N	**Fsust** mean min-max in N	Size (cartridge)	Fluid/ Manufacturer
Requirements according to ISO 11608			***≤40***	***≤20***		
KLINION_29G	0.33 x 12 (29 G)	6	**10.5** 9.2-12.1	**8.7** 8.1-9.7	3 ml	Testmedium /Novo
BD_29G	0.33 x 12.7 (29G)	6	**10.6** 9.6-11.7	**8.7** 8.0-9.2	3 ml	Testmedium /Novo
KLINION_31G	0.25 x 8 (31G)	6	**10.2** 8.0-11.6	**10.0** 7.5-11.5	3 ml	Testmedium /Novo
BD_31G	0.25 x 8 (31G)	6	**17.4** 16.5-18.7	**17.2** 16.4-17.7	3 ml	Testmedium /Novo

Table 5-7: Results of the application force measurements

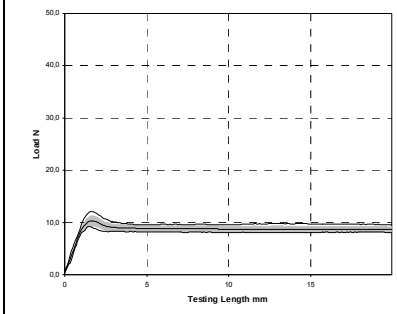
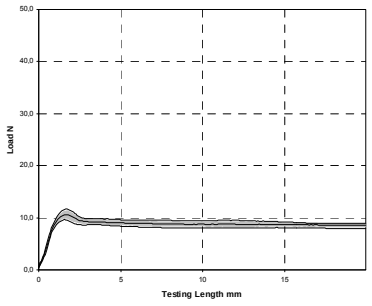
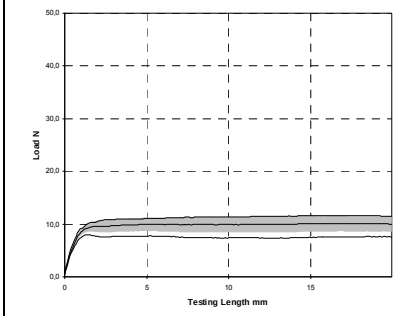
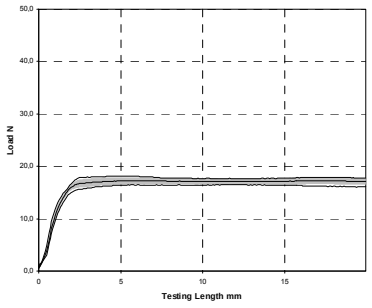
	KLINION	**BD**
29G		
31G		

Table 5-8: Application force diagrams – Testmedium/Novo

5.3.3 Application force measurements Water /Sanofi

	Size (needle)	No. tested	**FIni** mean min-max in N	**Fsust** mean min-max in N	Size (cartridge)	Fluid/ Manufacturer
Requirements according to ISO 11608			***≤ 40***	***≤ 20***		
KLINION_29G	0.33 x 12 (29 G)	6	**17.8** 15.0-20.8	**11.4** 9.4-13.8	3 ml	Water /Sanofi
BD_29G	0.33 x 12.7 (29G)	6	**16.7** 15.4-18.3	**10.7** 9.7-12.5	3 ml	Water /Sanofi
KLINION_31G	0.25 x 8 (31G)	6	**20.4** 18.4-21.5	**16.4** 15.2-17.6	3 ml	Water /Sanofi
BD_31G	0.25 x 8 (31G)	6	**23.5** 22.0-24.3	**19.2** 18.1-20.1	3 ml	Water /Sanofi

Table 5-9: Results of the application force measurements

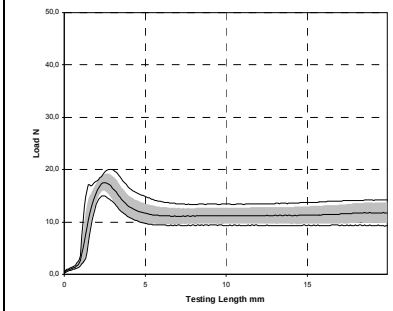
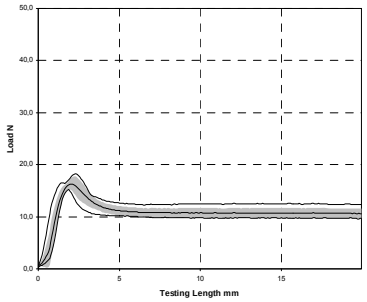
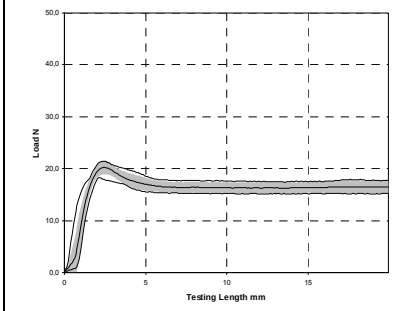
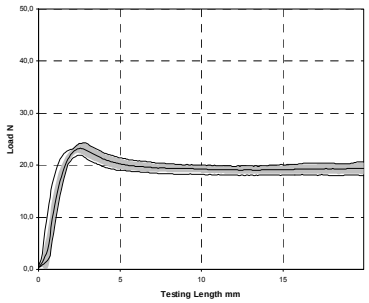
	Klinion	BD
29G		
31G		

Table 5-10: Application force diagrams – Water/Sanofi

Note: The specified (listed) thresholds are valid for the medicine to be administered with an application speed of 6 ml/min (ISO 11608-3).
The various testing fluids have very different viscosities.

The measured values are meant to compare the properties of the needles regarding the application resistance. The results indicate obviously that the inside diameter of the needle as well as the viscosity of the fluid have an immense influence on the application forces. The measured forces for the 31G needles reach or even exceed partially the threshold but with a testing speed of 100 mm/min (ISO 7886).

Due to the fact that the needles BD_31G and KLINION_31G exceed the threshold with the ‚Saline-Solution of Lilly' additional tests were performed with an application speed of 6 ml/min.

Inside diameter of the 3 ml cartridges is 9.65 mm

The testing speed is calculated as follows:

$s = 6000\ mm^3/(\pi \times D(inside)^2/4)$ with $D(inside) = 9.65\ mm$ (1)
$s = 82\ mm$

$V = s/t = 82\ mm/min$ (2)

Measuring equipment: Penetrometer DEKA 9,

Parameter:
Testing Medium: 3 ml cartridge (Saline Solution Lilly)
Testing Speed: 82 mm /min (ISO 11608-3)
Testing Length: 20 mm
Testing Direction: axial

	Size (needle)	No. tested	**FIni** mean min-max in N	**Fsust** mean min-max in N	Size (cartridge)	Fluid/ Manufacturer
Anforderungen nach ISO 11608			***≤ 40***	***≤ 20***		
KLINION_31G	0.25 x 8 (31G)	6	**18.5** 16.2-23.4	**15.3** 14.6-16.5	3 ml	Saline Sol. /Lilly
BD_31G	0.25 x 8 (31G)	6	**21.3** 18.3-24.1	**17.75** 16.3-20.1	3 ml	Saline Sol. /Lilly

Table 5-11: Application force of the 31G BD and Klinion needles with v = 6ml/min

The application force (resistance) is with the testing speed of 6 ml/min below the threshold of the standard. That means both needle types comply with the requirements of ISO 10608-3 for the used testing fluids.

5.4 Cohesiveness of connection needle/hub

The results of the separation force tests are listed in the table below as minimum-, maximum- and mean values.

A remarkable number of glue connections withstood the pull test. In this cases the cannula tube was deformed (over-strained) and ruptured. The number of ruptured cannulae is also listed in the result table.

Note: The testing arrangement allows to hold the front side of the hub. Thus only the connection cannula / hub is pulled but not the connection thread / Pen-simulator. Also this connection could fail (separate), so the cannula remains e.g. in the patient's skin. This is possible, if the needle is not screwed on the PEN properly or the thread is not formed correctly.

	Size (needle)	No. tested	**Fmax** mean min-max in N	Number of needles ruptured
Requirements according ISO 7864			***≥ 22N***	
KLINION_29G	0.33 x 12 (29G)	32	**78.5** 62.4-92.6	**19**
BD_29G	0.33 x 12.7 (29G)	32	**42.7** 28.7-79.0	**4**
KLINION_31G	0.25 x 8 (31G)	32	**50.8** 43.7-55.0	**32**
BD_31G	0.25 x 8 (31G)	32	**59.6** 38.4-66.2	**27**

Table 5-12: Results of the Separation Force Tests

All needles tested comply with the minimum-requirements of the standard ISO 7864 regarding the stability of the glue connection between the cannulae and the hubs.

5.5 Wall thickness

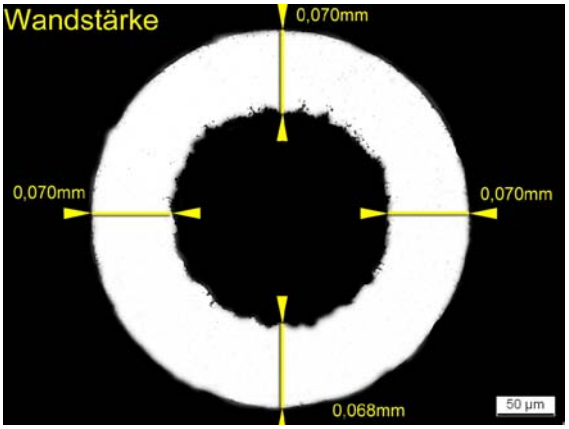
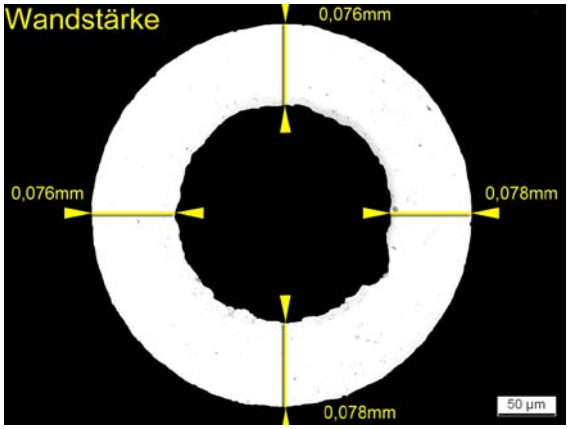
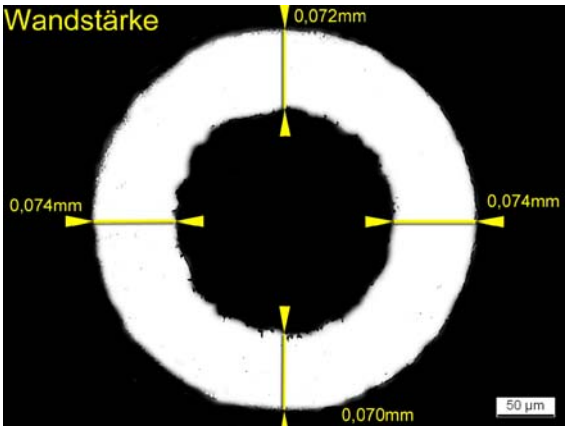
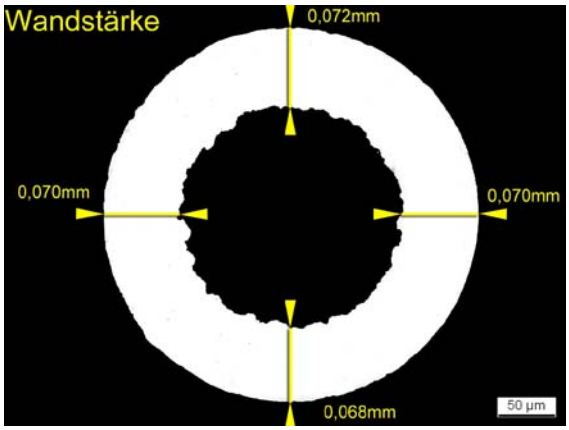
5.5.1 Results

	Size (needle)	Wall thickness in mm 1st level	Wall thickness in mm 2nd level
KLINION_29G	0.33 x 12 (29G)	**0.070**	**0.077**
BD_29G	0.33 x 12.7 (29G)	**0.073**	**0.070**
KLINION_31G	0.25 x 8 (31G)	**0.047**	**0.057**
BD_31G	0.25 x 8	**0.057**	**0.058**

Table 5-13: Wall thickness - average of 4 measurements

Individual measuring values and location of measurements are documented in the following chapter.

5.5.2 Individual measurement values

Wall thickness 1st level	Wall thickness 2nd level
KLINION_29G 0.070 mm / 0.070 mm / 0.068 mm / 0.070 mm	0.076 mm / 0.078 mm / 0.078 mm / 0.076 mm
	
BD_29G 0.072 mm / 0.074 mm / 0.070 mm / 0.074 mm	0.072 mm / 0.070 mm / 0.068 mm / 0.070 mm
	

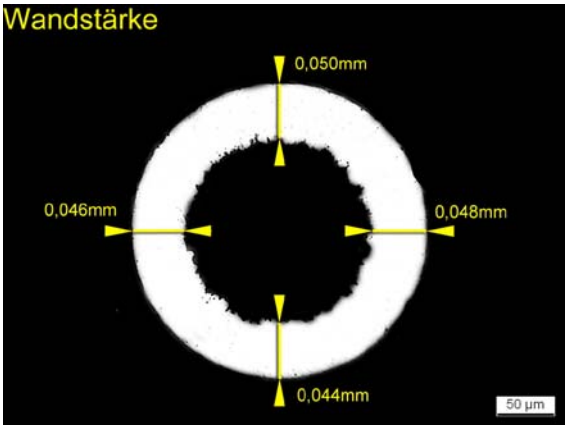
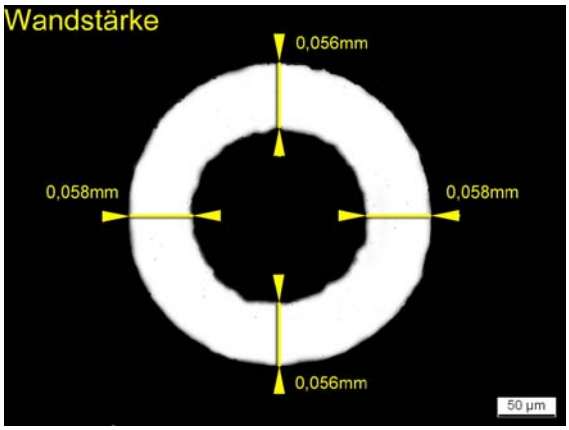
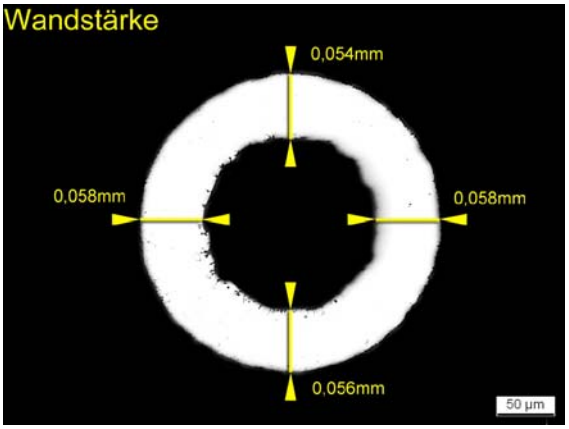
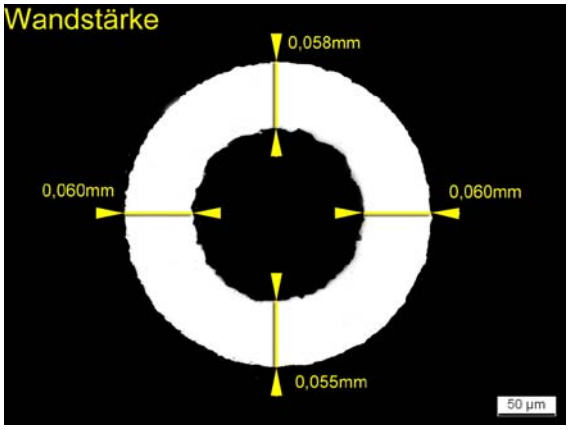
Wall thickness 1st level	Wall thickness 2nd level
KLINION_31G 0.050 mm / 0.048 mm / 0.044 mm / 0.046 mm	0.056 mm / 0.058 mm / 0.056 mm / 0.058 mm
	
BD_31G 0.054 mm / 0.058 mm / 0.056 mm / 0.058 mm	0.058 mm / 0.060 mm / 0.055 mm / 0.060 mm
	

Table 5-14: Wall thickness – Individual measuring values

5.5.3 Metallographic evaluation of the surface

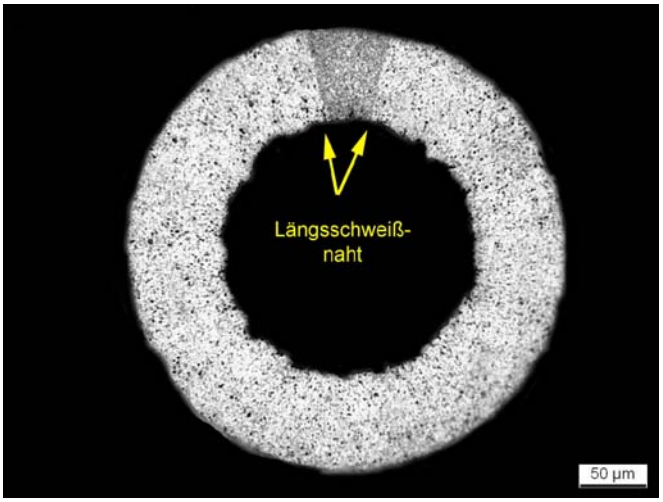


Figure 5-10: KLINON_29G - Overview, etched, longitudinal weld

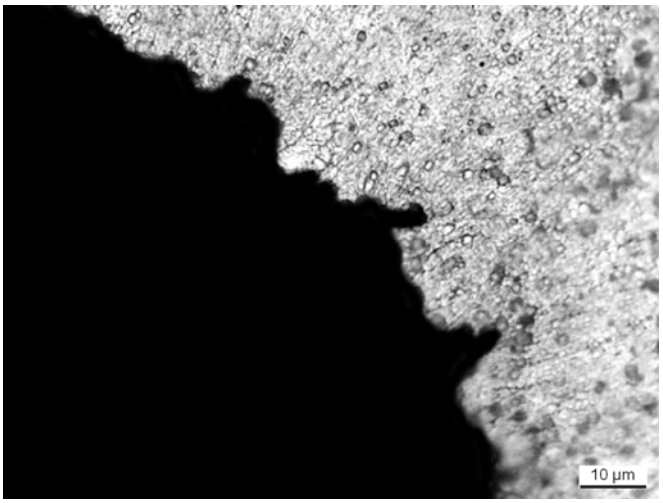


Figure 5-11: KLINON_29G – Internal surface, wide die marks up to 12 µm depth

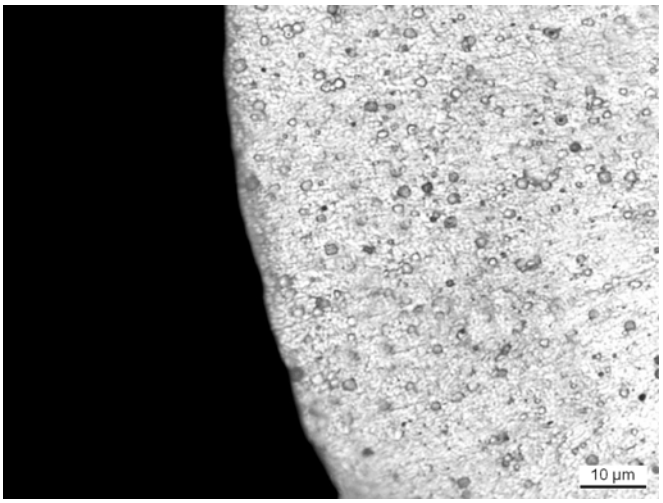


Figure 5-12: : KLINON_29G – Outer surface

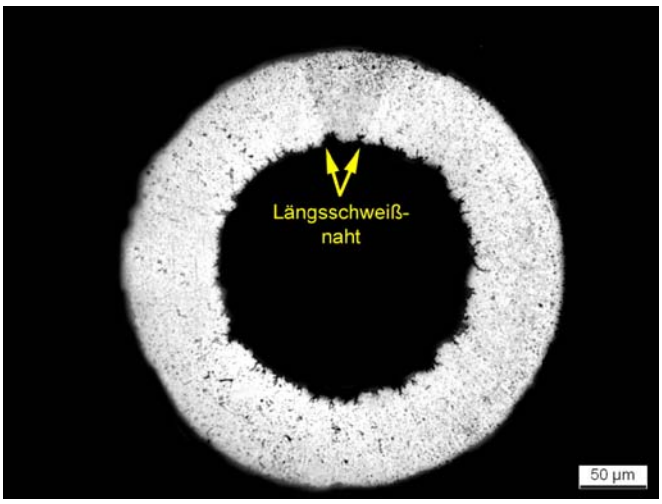


Figure 5-13: BD_29G - Overview, etched, longitudinal weld

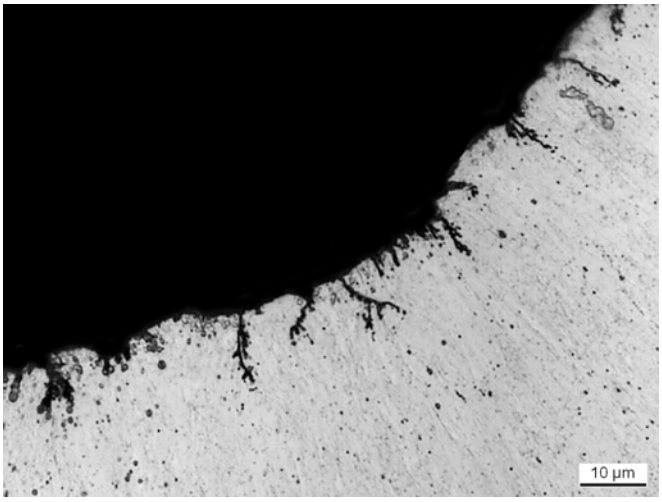


Figure 5-14 BD_29G - Internal surface, folds up to 12 µm depth

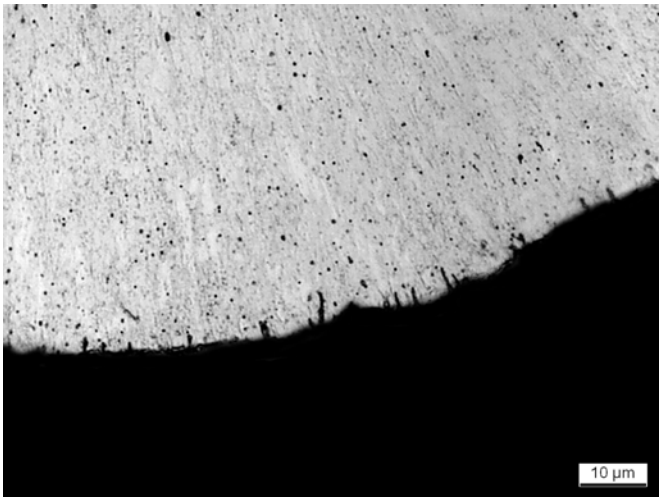


Figure 5-15: BD_29G – Outer surface, die marks up to 5 µm depth

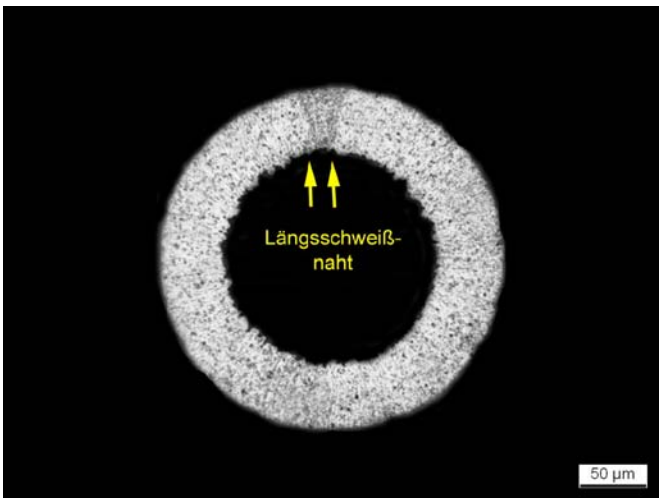


Figure 5-16: KLINON_31G - Overview, etched, longitudinal weld

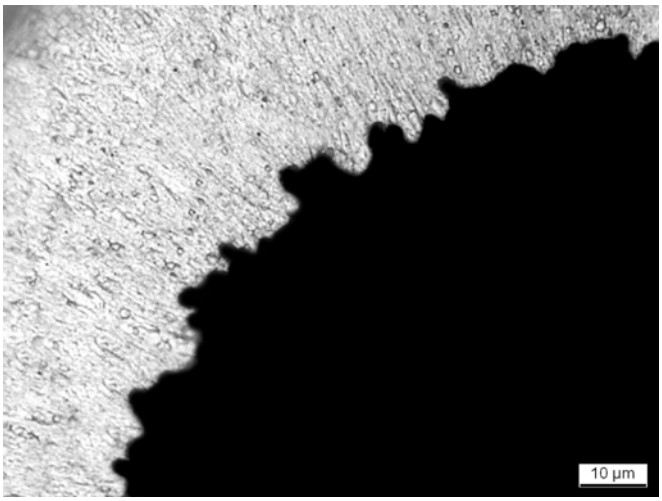


Figure 5-17: KLINON_31G - Internal surface, wide die marks up to 7 µm depth

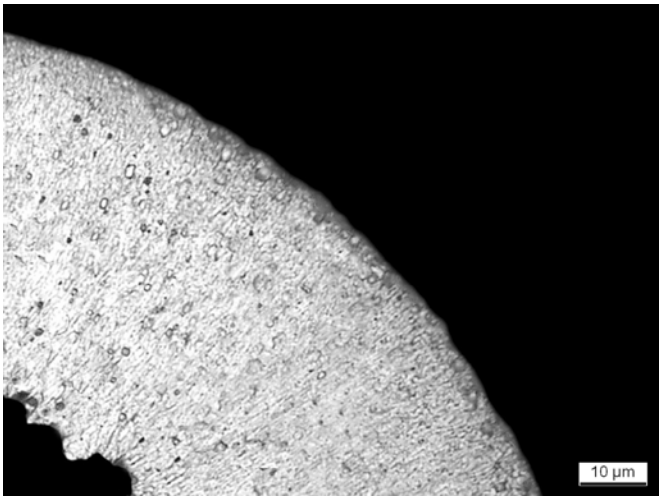


Figure 5-18: KLINON_31G - Outer surface

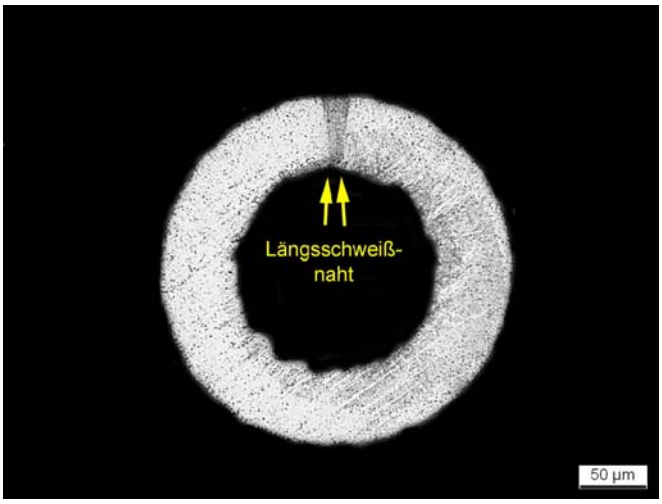


Figure 5-19: BD_31G - Overview, etched, longitudinal weld

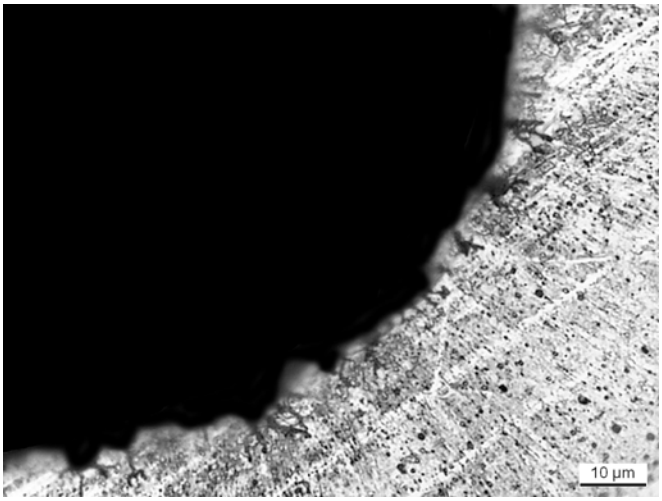


Figure 5-20: BD_31G - Internal surface, folds up to 8 µm depth

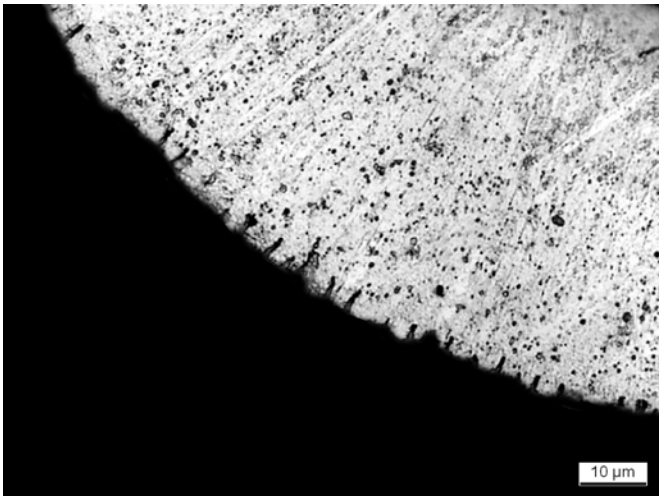


Figure 5-21: BD_31G - Outer surface, die marks up to 7 µm depth

5.6 Kinking test

The results of the Kinking Tests are listed in the table below as mean values of

Felast - Fmax (threshold elastical/plastical)
Fplast - Mean value of the falling curve (plastical area)

	Size (needle)	Lot-No.	No. tested	**F(elast)** mean in N	**F(plast)** mean in N
KLINION_29G	0.33 x 12 (29G)	943000	6	**10.5**	**7.7**
BD_29G	0.33 x 12.7 (29G)	9139815	6	**10.7**	**8.8**
KLINION_31G	0.25 x 8 (31G)	947000	6	**7.7**	**4.8**
BD_31G	0.25 x 8	9125266	6	**8.7**	**5.3**

Table 5-15: Results of the Kinking Tests

The kinking resistance of the needles BD_29G and Klinion_29G are on the same level. Small differences are indicated with the 31 G Needles.

6 Resume

The piercing and the cutting forces of the tested KLINION and BD needles are on a low level. Also the friction forces are low. All products stand out due to low penetration forces combined with small standard deviations.

No tip defects or irregularities on the bevel were determined on all products within the visual inspections under the microscope. The BD Needles show silicone cluster under the microscope. This silicone is pushed back during the penetration but it means that there is more silicone than necessary. The silicone coating of the KLINION needles is uniform and moderate.

The Klinion Needles have a common 3-bevel facet grinding with a usual facet length. Also the BD needle tips are 3-bevel facet grindings but mostly with short facets. The deviation of the facet lengths of the BD needles is greater than of the KLINION needles. These differences are not detectable in the practical use.

All tested needles comply with the requirements of ISO 11608-3 regarding the application forces with the used testing fluids. As expected, the application forces of the 31G needles are significant higher than those recorded with the 29G needles.

The kinking resistance of the 29G needles is on the same level for both Brands. The same is true for the 31 G Needles

The connection needle/hub complies with the requirements of ISO 7864 for both brands and needle sizes. The glue connections are fast fitted.

Köln, 2010-02-11
TÜV Rheinland LGA Products GmbH

Matthias Koldehoff (SV) Martina Adler (SV)

Unsigned report due to this is a translation from the German original version to English. In the case of any inconsistencies the German version is valid!