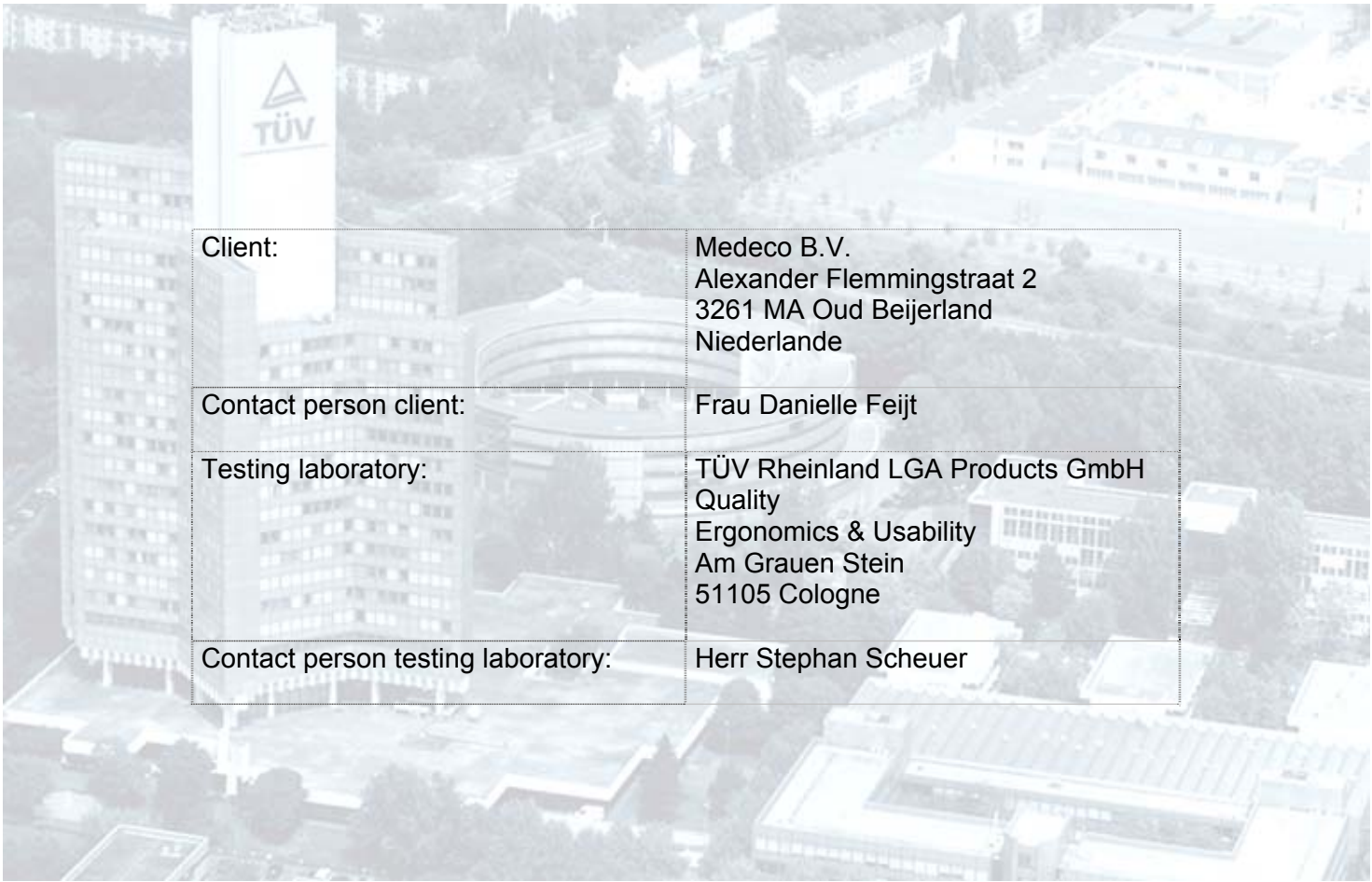
TÜV Rheinland LGA Products GmbH
Quality - Ergonomics & Usability
Am Grauen Stein
51105 Cologne

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 Novo Nordisk novofine each in two sizes:

- KLINION soft fine plus 6 mm (0.25 mm (31G) x 6 mm)
  in the following **soft fine 6 mm**,
- KLINION soft fine plus 8 mm (0.25 mm (31G) x 8 mm)
  in the following **soft fine 8 mm**,
- Novo Nordisk novofine 31G (0.25 mm (31G) x 6 mm,
  in the following **novofine 6 mm**,
- Novo Nordisk novofine 30G (0.3 mm (30G) x 8 mm,
  in the following **novofine 8 mm**.

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..

- **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.

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

- **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.

3 Product description

3.1 KLINION soft fine plus 6 mm

Brand	Description	Size	Lot	Exp.-Date	PZN
KLINION	soft fine plus 6 mm	0.25 mm **(31G)** x 6 mm	046119	05-2015	9166245

Figure 3-1: KLINION soft fine plus 6 mm

3.2 KLINION soft fine plus 8 mm

Brand	Description	Size	Lot	Exp.-Date	PZN
KLINION	soft fine plus 8 mm	0.25 mm (**31G)** x 8 mm	047025	02-2015	9166251

Figure 3-2: KLINION soft fine plus 8 mm

3.3 Novo Nordisk novofine 31G

Brand	Description	Size	Lot	Exp.-Date	PZN
Novo Nordisk	novofine 31G	0.25 mm **(31G)** x 6 mm	10B02M	01-2015	-

Figure 3-3: Novo Nordisk novofine 31G

3.4 Novo Nordisk novofine 30G

Brand	Description	Size	Lot	Exp.-Date	PZN
Novo Nordisk	novofine 30G	0.3 mm **(30G)** x 8 mm	09J11K	08-2014	-

Figure 3-4: Novo Nordisk novofine 30G

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. Optical inspections are conducted 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

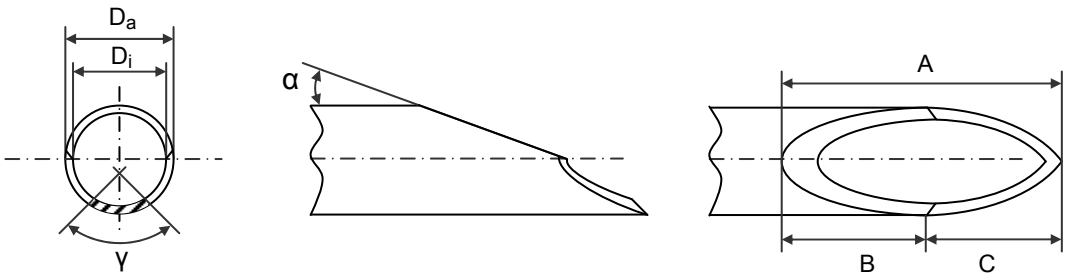

Figure 4-1 Nomenclature for geometric measures

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:	6 mm (31G, 8 mm) und 4 mm (31G, 6 mm)
	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 Kinking test

4.3.1 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

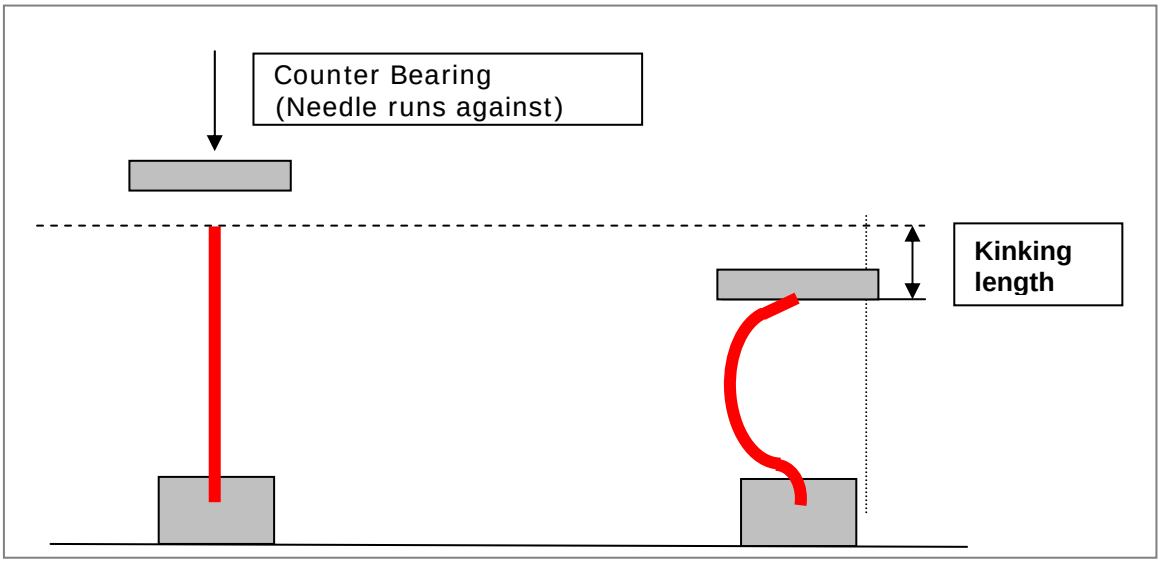

Figure 4-2: Arrangement of the kinking test

4.3.2 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

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

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
Specificationen ISO 9626 ***31G***	*0.254-0.267*	*TW: > 0.125*					
soft fine 6 mm	**0.260**	**0.153**	**1.26** 1.21-1.35	0.70	**0.56** 0.52-0.60	**8.4** 7.5-9.0	**110.6** 107-117
soft fine 8 mm	**0.261**	**0.150**	**1.28** 1.25-1.33	0.63	**0.65** 0.57-0.70	**9.1** 8.5-10.0	**109.9** 103-114
novofine 6 mm	**0.256**	**0.152**	**1.15** 1.12-1.18	0.55	**0.60** 0.57-0.63	**9.7** 8.5-10.5	**110.8** 108-114
Specificationen ISO 9626 ***30G***	*0.298-0.320*	*TW: > 0.165*					
novofine 8 mm	**0.308**	**0.176**	**1.42** 1.37-1.46	0.69	**0.73** 0.70-0.75	**9.75** 9.0-10	**108.5** 107-111

Table 5-1: Geometry

The needles fulfil the requirements of ISO 9626 concerning the diameters. The geometrical measures of the tested needles are market usual. The deviations are small.

5.1.2 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.

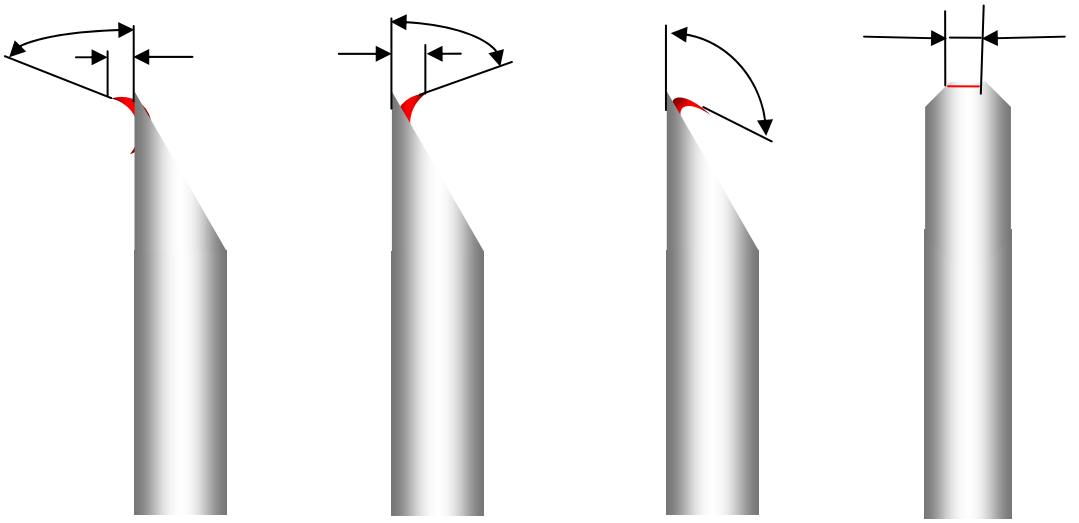

Figure 5-1: Tip defects

Soft fine 6 mm: None of the tested needles shows remarkable tip defects.

Soft fine 8 mm: On four of the tested needles small tip deformities were discovered (sample no. 5 hook-in 14µm, sample no. 11 hook-out 33 µm, sample no. 14 hook-out 12 µm and sample no. 27 hook-in 28 µm).

novofine 6 mm: Small tip deformities were discovered (sample no. 5 hook-in 27 µm, sample no. 8 hook-out 8 µm, sample no. 11 hook-out 26 µm).

novofine 8 mm: On one of the tested needles small tip deformities were discovered (sample no. 2 hook-out 9 µm).

No differences between the first optical inspection prior to the penetration force test and after were found.

The silicone coating of the KLINION and the Novo Nordisk needles is uniform and moderate.

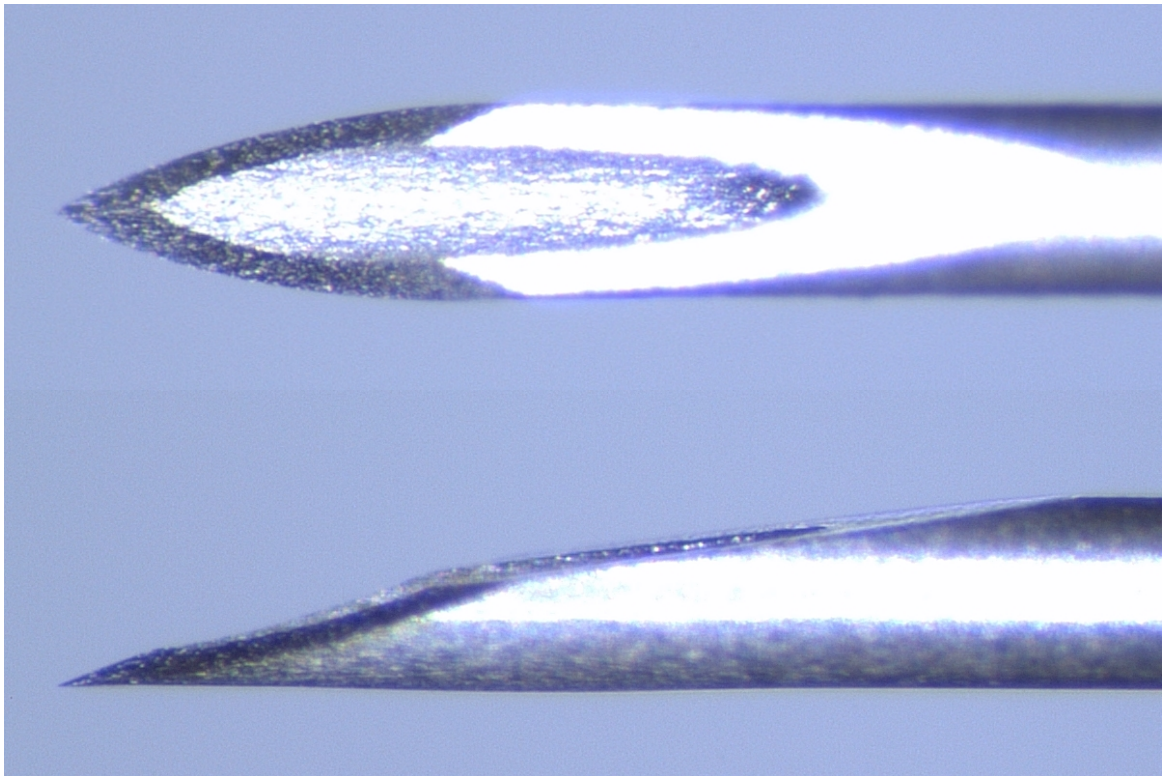

Figure 5-2: soft fine 6 mm

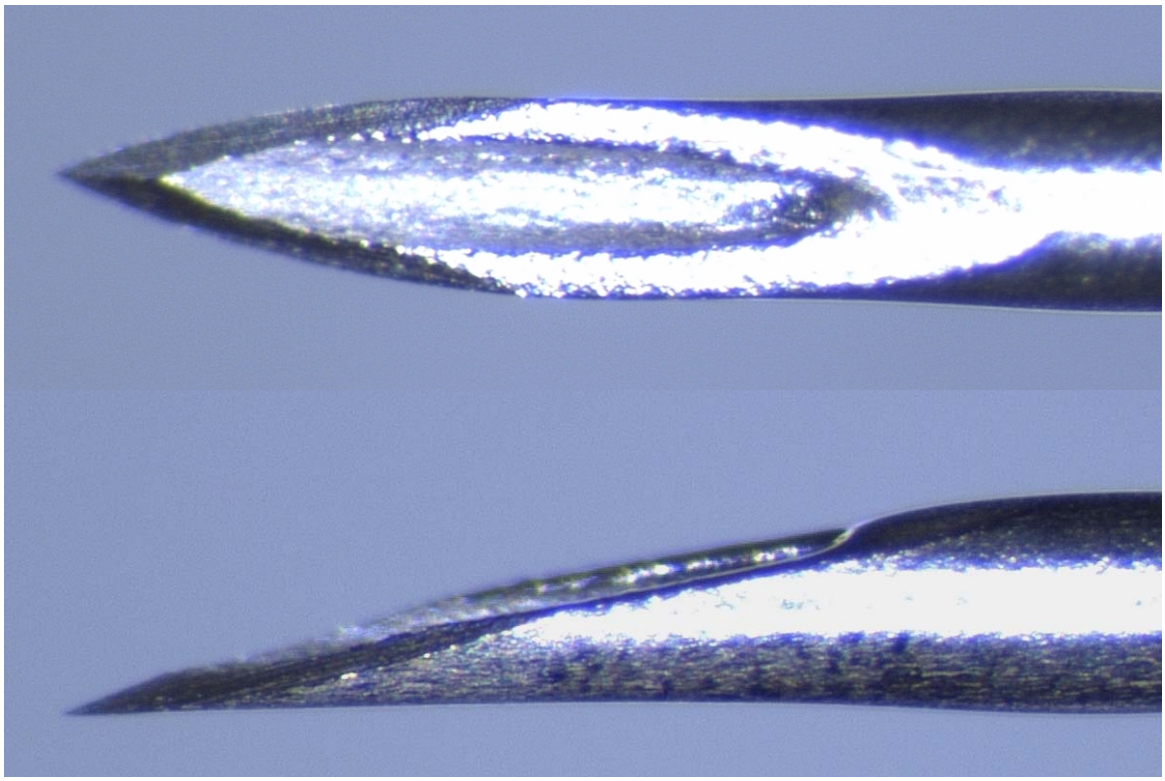

Figure 5-3: soft fine 8 mm

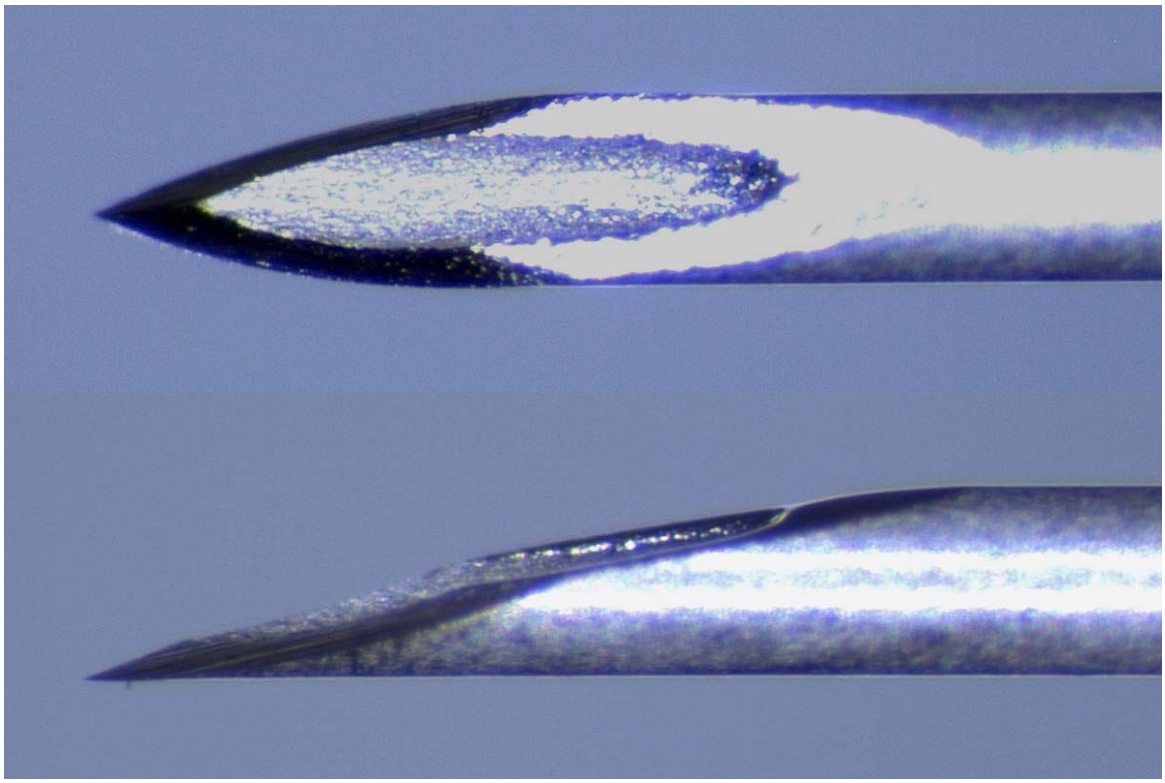

Figure 5-4: novofine 6 mm

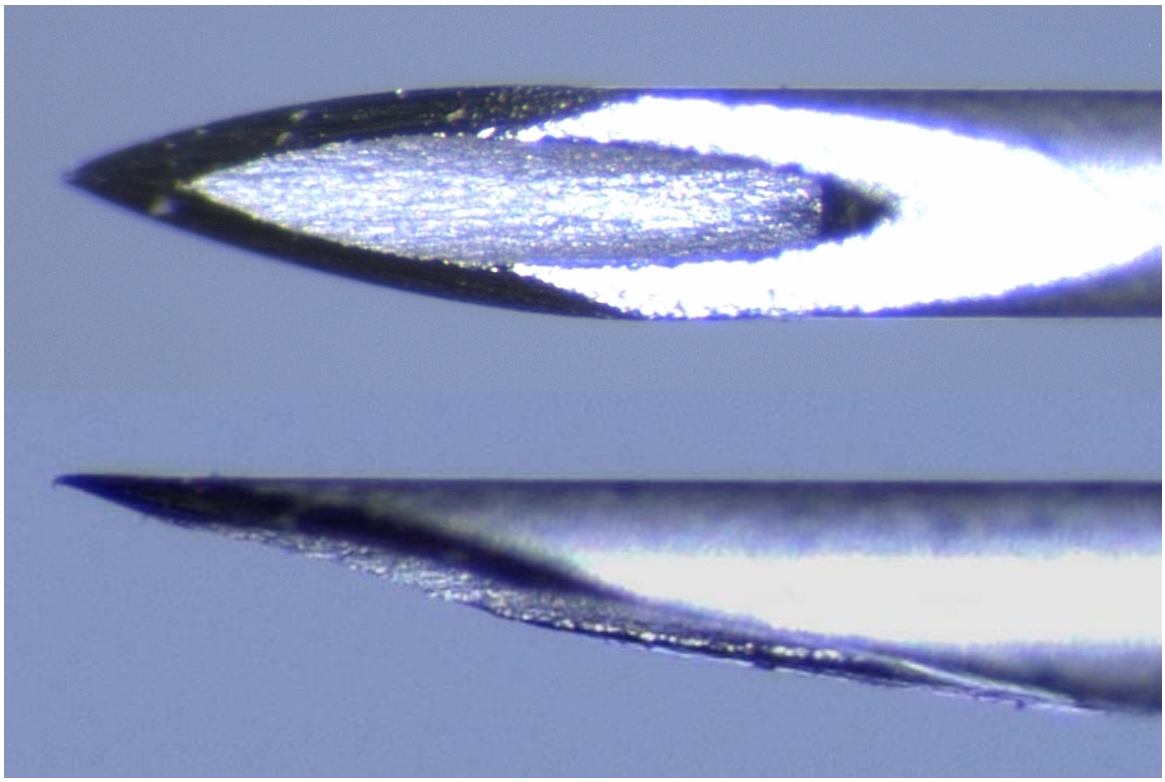

Figure 5-5: novofine 8 mm

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
soft fine 6 mm	0.25x6 (31G)	32	**0.44** 0.4-0.53	**0.48** 0.42-0.55	**0.60** 0.46-0.75	**0.12** 0.06-0.25
soft fine 8 mm	0.25x8 (31G)	32	**0.33** 0.30-0.57	**0.40** 0.34-0.45	**0.40** 0.35-0.67	**0.08** 0.06-0.10
novofine 6 mm	0.25 x 6 (31G)	32	**0.32** 0.30-0.50	**0.38** 0.34-0.53	**0.50** 0.42-0.57	**0.05** 0.04-0.06
novofine 8 mm	0.30x8 (30G)	32	**0.34** 0.32-0.38	**0.42** 0.38-0.46	**0.56** 0.48-0.64	**0.07** 0.06-0.08

Table 5-2: Results of the penetration test

soft fine 6 mm:
The penetration forces are low. The tips and the cutting edges are good. The friction forces are slightly higher compared with the other 3 needle types. Sample no. 22 and no. 25 have enlarged friction forces up to 0.25 N.

soft fine 8 mm:
The mean penetration forces are very low. Also the friction forces are low. Sample no. 27 has a hook-in (28 µm) at the tip and thus enlarged piercing forces but still at a low level.

novofine 6 mm:
The mean penetration forces are very low. Also the friction forces are very low.

novofine 8 mm:
The mean penetration forces are very low. Also the friction forces are very low.

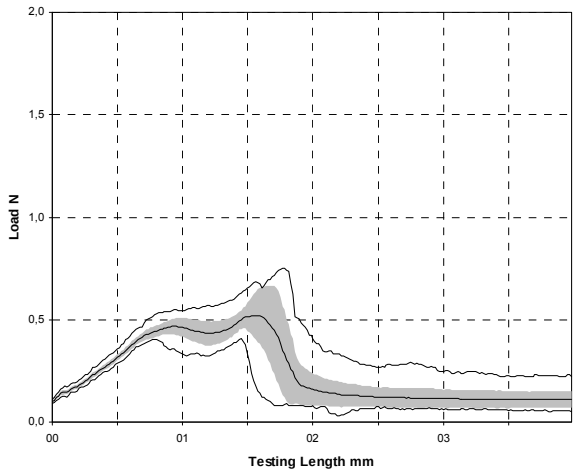

Figure 5-6: Penetration diagram soft fine 6 mm

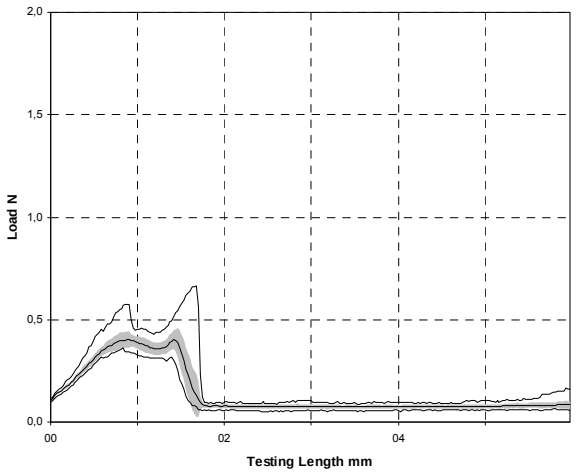

Figure 5-7: Penetration diagram soft fine 8 mm

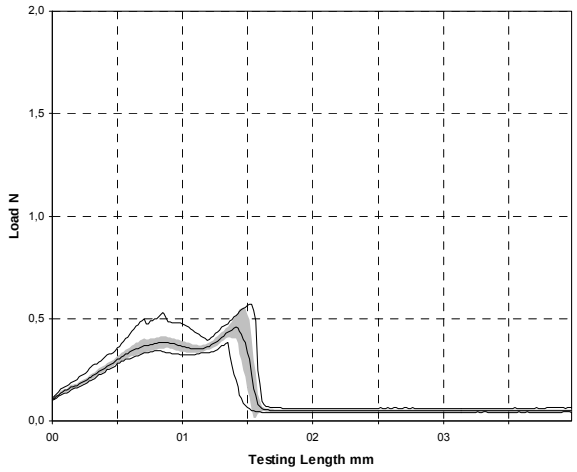

Figure 5-8: Penetration diagram novofine 6 mm

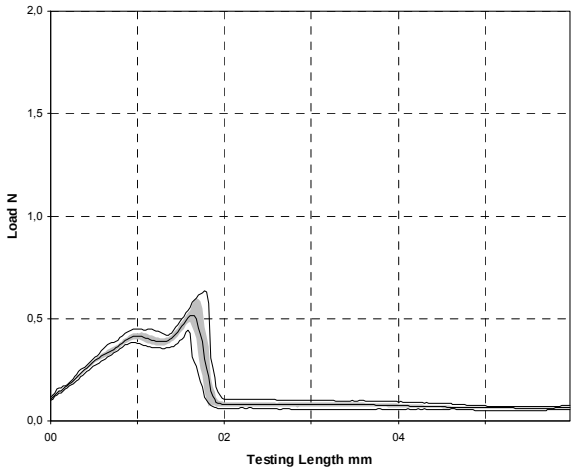

Figure 5-9: Penetration diagram novofine 8 mm

5.3 Kinking test

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

F(elast) - F_{max} (threshold elastical/plastical)
F(plast) - Mean value of the falling curve (plastical area)

	Size (needle)	Lot-No.	No. tested	**F(elast)** mean in N	**F(plast)** mean in N
soft fine 6 mm	0.25x6 (31G)	046119	6	**13.0**	**8.0**
soft fine 8 mm	0.25x8 (31G)	047025	6	**8.7**	**5.6**
novofine 6 mm	0.25 x 6 (31G)	10B02M	6	**11.1**	**7.0**
novofine 8 mm	0.30x8 (30G)	09J11K	6	**15.0**	**10.6**

Table 5-3: Results of the Kinking Tests

The kinking resistance of the short slim needles is relatively high as expected. The differences between novofine 6 mm and soft fine 6 mm are caused by small differences in the kinkable length.

The influence of the outside diameter on the kinking resistance is indicated obviously if comparing values recorded 8,7 N with soft fine 8 mm and 15,0N with novofine 8 mm.

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***	
soft fine 6 mm	0.25x6 (31G)	32	**43.8** 30.8-53.7	**2**
soft fine 8 mm	0.25x8 (31G)	32	**51.7** 27.8-61.7	**1**
novofine 6 mm	0.25 x 6 (31G)	32	**48.5** 30.5-57.2	**7**
novofine 8 mm	0.30x8 (30G)	32	**84.0** 67.1-90.0	**20**

Table 5-4: 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.

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6 Resume

The piercing and the cutting forces of the tested KLINION and Novo Nordisk needles are very low. Also the friction forces are low (smaller than 0,1 N) apart from KLINION 6 mm needle where the friction reaches 0,25 N. All products stand out due to low penetration forces combined with small standard deviations.

Very small tip deformities were determined. The needles are not conspicuous in practical use. The silicone coating of the KLINION and the Novo Nordisk needles is uniform and moderate.

The Klinion needles as well as the Novo Nordisk needles have a common 3-bevel facet grinding with a usual facet length. The deviations of the measures are small.

The kinking resistance of the KLINION 6 mm needles is a bit higher than that of the Novo Nordisk 6 mm needles . The kinkable length of the Novo Nordisk needles is slightly longer. The influence of the length is obvious if comparing the kinking resistance of the 31G needles

As expected the kinking resistance of the Novo Nordisk 30G needle (8 mm) is remarkable higher than that of the 31G (8 mm) Klinion needles.

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

Cologne, 2010-12-07
TÜV Rheinland LGA Products GmbH

Matthias Koldehoff (SV) Volker Meuser (SV)

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