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KD Medical GmbH Hospital Products · Charlottenstrasse 65 · 10117 Berlin · Germany

**Summary Essential Technical Data - KD-FINE sterile spinal needles for single-use**

<b><u>Manufacturer:</u></b>	KD Medical GmbH Hospital Products Charlottenstraße 65 10117 Berlin GERMANY
<b><u>Product:</u></b>	Spinal needles (Sterile spinal needles for single-use)
<b><u>Brand:</u></b>	KD-FINE
<b><u>UMDNS code:</u></b>	12-733
<b><u>Risk Class:</u></b>	Ila according to Annex IX, rule 6 of Council Directive 93/42/EEC
<b><u>Conformity assessment procedure:</u></b>	according to Annex II, section 3 of Council Directive 93/42/EEC
<b><u>Notified Body:</u></b>	TUEV Süd Product Service GmbH Ridlerstraße 65 80339 Munich, Germany Identification no 0123

**Brief description of the product**

Sterile spinal needles for single use are medical devices intended for both withdrawal of cerebro-spinal fluid and injection of medicine into the cerebro-spinal fluid.

The following types are available:

***Spinal needles Quincke:***

This type is characterized by the bevel grinding and by a high stability.

***Spinal needles Pencil Point:***

This type is characterized by its particular tip which is pointed with an edge-gated aperture. Thanks to this special grinding, the fibres of the meninges are not dissected but pushed apart which is less traumatizing.

Both types are also available with introducer needles. Introducer needles provide stabilization of shape and orientation of the spinal needles.

For details refer to item "Variants".

Sterilized by Ethylene Oxide, KD-FINE spinal needles are non-toxic, pyrogen-free and easy to use.

Bank	Deutsche Bank AG, Berlin	Commerzbank AG, Berlin	Registered Office: Berlin
Bank Code	100 700 00	100 800 00	Managing Director: Jörg Bartz
Account No.	605 24 50 00	905 94 65 00	Commercial Registry: Berlin-Charlottenburg HRB 64320
IBAN	DE77 1007 0000 0605 2450 00	DE50 1008 0000 0905 9465 00	VAT-No. DE 812 328 107
SWIFT	DEUT DE 33	DRES DE 33 100	

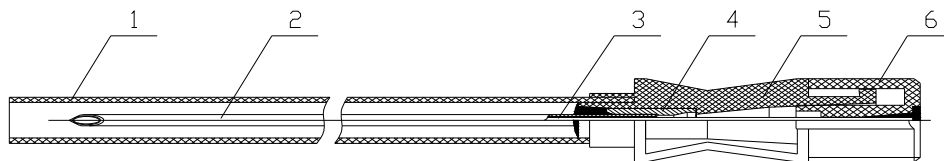
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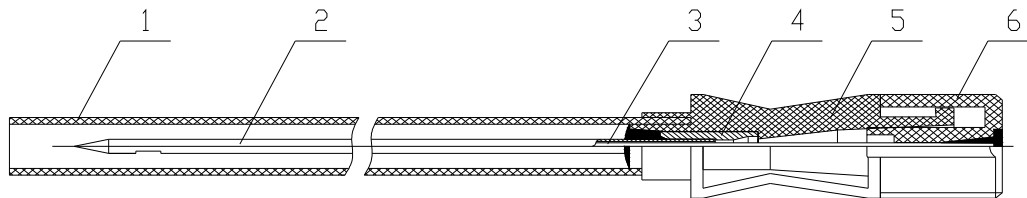
**Drawings:**

A. representative drawing of KD-FINE spinal needle, Quincke



- 1 Protective cap
- 2 Needle tube (outer)
- 3 Needle tube (inner)
- 4,5 Needle hub embedded parts
- 6 Needle hub

B. representative drawing of KD-FINE spinal needle, Pencil point



- 1 Protective cap
- 2 Needle tube (outer)
- 3 Needle tube (inner)
- 4,5 Needle hub embedded parts
- 6 Needle hub

**Material specifications:**

Component	Raw material
Protective cap, needle hub (embedded parts)	Ethylene Polypropylene Copolymer
Needle tube	Stainless Steel SUS 304
Needle hub	ABS (Acrylonitrile Butadiene Styrene)
Core line needle hub	PC (Polycarbonate)
Lubricant	Silicone



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## Packing data

### A. Quincke and pencil point **without** introducer:

	pieces per	dimensions (m)
<b>Blister (film / paper)</b>	1	0,170 x 0,0255
<b>inner box</b>	50	0,175 x 0,14 x 0,05
<b>export carton</b>	2000	0,53 x 0,37 x 0,31

### B. Quincke and pencil point **with** introducer:

	pieces per	dimensions (m)
<b>Blister (film / paper)</b>	1	0,193 x 0,06
<b>inner box</b>	50	0,21 x 0,193 x 0,06
<b>export carton</b>	2000	0,44 x 0,405 x 0,33

### Sterilization:

by Ethylene Oxide (ETO)

### Latex:

KD-FINE spinal needles are latex-free.

### Shelflife:

5 years from the date of manufacture  
*dates of manufacture and expiry as well as the batch number are embossed / printed on both individual packages and inner boxes*

### Storage:

Do not store at extreme temperature and humidity.

### Precautions for use:

Use is restricted to qualified medical staff.  
Check the integrity of the individual package before use.  
Do not use if the package is damaged.  
To be used immediately after the package has been opened.  
For single use only. Discard after single use to avoid risk of infection.

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**Variants:**

**KD-FINE Spinal needles, Quincke**

Article no	Size of needle	
900840	18 G x 3"	1,30 x 75 mm
900857	18 G x 3 1/2"	1,30 x 88 mm
900871	19 G x 1 1/2"	1,10 x 40 mm
900864	19 G x 3 1/2"	1,10 x 88 mm
900888	20 G x 3"	0,90 x 75 mm
900895	20 G x 3 1/2"	0,90 x 88 mm
901199	20 G x 3 1/2"	0,90 x 90 mm
901069	21 G x 3 1/2"	0,80 x 88 mm
900918	22 G x 1 1/2"	0,70 x 40 mm
901021	22 G x 3"	0,70 x 75 mm
900901	22 G x 3 1/2"	0,70 x 88 mm
901212	22 G x 3 1/2"	0,70 x 90 mm
901083	23 G x 3 1/2"	0,60 x 88 mm
901045	24 G x 3 1/2"	0,55 x 88 mm
900925	25 G x 3 1/2"	0,50 x 88 mm
901106	26 G x 3 1/2"	0,45 x 88 mm
901120	27 G x 3 1/2"	0,40 x 88 mm

**KD-FINE Spinal needles, Pencil Point**

Article no	Size of needle	
901472	18 G x 3 1/2"	1,30 x 88 mm
901489	19 G x 3 1/2"	1,10 x 88 mm
901496	20 G x 3 1/2"	0,90 x 88 mm
901502	21 G x 3 1/2"	0,80 x 88 mm
901519	22 G x 3 1/2"	0,70 x 88 mm
901526	23 G x 3 1/2"	0,60 x 88 mm
901533	24 G x 3 1/2"	0,55 x 88 mm
901540	25 G x 3 1/2"	0,50 x 88 mm
901632	26 G x 3 1/2"	0,45 x 88 mm
901649	27 G x 3 1/2"	0,40 x 88 mm

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### Variants:

#### **KD-FINE Spinal needles, Quincke, with introducer (guided needle)**

Article no	Size of needle		Size of introducer needle
<b>901236</b>	22 G x 3 1/2"	0,70 x 90 mm	19G x 1 1/4" (1,10 x 30 mm)
<b>910672</b>	22 G x 4 1/8"	0,70 x 105 mm	19G x 1 1/4" (1,10 x 30 mm)
<b>901205</b>	22 G x 4 4/5"	0,70 x 120 mm	19G x 1 1/2" (1,10 x 38 mm)
<b>901243</b>	24 G x 3 1/2"	0,55 x 90 mm	20G x 1 1/4" (0,90 x 30 mm)
<b>901458</b>	24 G	0,55 x 105 mm	20G x 1 1/4" (0,90 x 30 mm)
<b>901212</b>	24 G x 4 4/5"	0,55 x 120 mm	20G x 1 1/2" (0,90 x 38 mm)
<b>901144</b>	25 G x 3 1/2"	0,50 x 90 mm	21G x 1 1/2" (0,80 x 38 mm)
<b>901458</b>	25 G	0,50 x 105 mm	21G x 1 1/2" (0,80 x 38 mm)
<b>901212</b>	25 G x 4 4/5"	0,50 x 120 mm	21G x 1 1/2" (0,80 x 38 mm)
<b>901151</b>	26 G x 3 1/2"	0,45 x 90 mm	21 G x 1 1/2" (0,80 x 38 mm)
<b>901229</b>	26 G	0,45 x 105 mm	21 G x 1 1/2" (0,80 x 38 mm)
<b>901168</b>	27 G x 3 1/2"	0,40 x 90 mm	22 G x 1 1/2" (0,70 x 38 mm)

#### **KD-FINE Spinal needles, Pencil Point, with introducer (guided needle)**

Article no	Size of needle		Size of introducer needle
<b>901175</b>	25 G x 3 1/2"	0,50 x 90 mm	21G x 1 1/2" (0,80 x 38 mm)
<b>901182</b>	26 G x 3 1/2"	0,45 x 90 mm	21 G x 1 1/2" (0,80 x 38 mm)
<b>901441</b>	27 G x 3 1/2"	0,40 x 90 mm	22 G x 1 1/2" (0,70 x 38 mm)

Issue:	26.07.2011
Revision:	2

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