



KD MEDICAL GMBH HOSPITAL PRODUCTS®

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

### Summary essential technical data - KD-FIX - IV Cannula

**Manufacturer:** KD Medical GmbH Hospital Products  
Charlottenstraße 65  
10117 Berlin  
GERMANY

**Product:** IV Cannula

**Brand:** KD-FIX, KD-FIX MONO, KD-FIX SOLO  
KD-FIX QUICK, KD-FIX QUICK MONO, KD-FIX QUICK SOLO

**UMDNS code:** 10-727

**Risk Class:** IIa according to Annex IX, rule 7 of Council Directive 93/42/EEC,  
amended by Council Directive 2007/47EC

**Conformity  
assessment  
procedure:** according to Annex II, section 3 of Council Directive 93/42/EEC,  
amended by Council Directive 2007/47EC

**Standards applied:** EN ISO 13485:2003 / AC:2009  
EN ISO 14971:2009  
EN ISO 10555-1, ISO 10555-5  
EN 980, EN 1041

**Notified Body:** TUEV Süd Product Service GmbH  
Ridlerstraße 65  
80339 Munich, Germany  
Identification no 0123

### **Brief description of the product**

KD-FIX IV Cannulae are sterile medical devices for single use.

IV Cannulae are over-needle peripheral catheters for short-term use intended to be inserted into a peripheral vein in order to provide access to the human circulatory system. Once inserted, they allow both provision of fluids or medicine and withdrawal of blood samples.

IV Cannulae consist of a short flexible plastic tube (catheter) which is inserted over a hollow introducer needle. After insertion into the vein, the needle is withdrawn and discarded.

Successful venipuncture is visualized by the transparent flash-back chamber.  
KD-FIX QUICK variants are equipped with an advanced needle technology:  
the needle has an opening on its upper side - once the vein is punctured, blood flows through this additional opening inside the catheter so that an instant visual confirmation of successful venipuncture is being ensured.

KD-FIX IV Cannula are available with FEP and PUR catheters. Different types are available, please refer to section "Variants".

IV Cannulae are to be used in an aseptic environment. Usage is restricted to qualified medical staff.

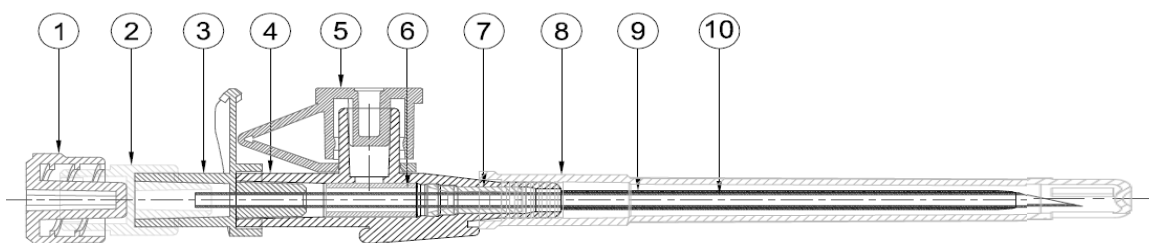
Bank	Deutsche Bank AG, Berlin	Commerzbank AG, Berlin	Registered Office: Berlin
Bank Code	100 700 00	100 800 00	Managing Director: Jörg Bartz
Account No.	605 24 50 00	905 94 65 00	Commercial Registry: Berlin-
IBAN	DE77 1007 0000 0605 2450 00	DE50 1008 0000 0905 9465 00	Charlottenburg HRB 64320
SWIFT	DEUT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

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**Drawing of a representative product and material specifications:**



No	Component	Raw material
1	Threaded stopper:	High-density polyethylene (HDPE)
2	Flash back chamber	Polypropylene
3	Needle hub:	Polypropylene
4	Body (wing housing):	Polypropylene
5	Port cap:	High-density polyethylene (HDPE) + low-density polyethylene (LDPE)
6	Silicone tube:	Silicone
7	Slip ring:	Polyacetal (Polyoxymethylene, POM)
8	Needle cover:	low-density polyethylene (LDPE)
9	Catheter:	FEP or Polyurethane (PUR)
10	Needle:	stainless steel

**Features:**

- sterile, non pyrogenic, non toxic
- back-cut grinded beveled needle for smooth venipuncture
- minimum clearance between catheter and needle to prevent peel back - less traumatic and convenient
- double-tapered kink-resistant catheters
- radio-opaque catheters
- transparent flash-back chamber for easy visual confirmation of venipuncture (except KD-FIX QUICK variants)
- colour-coded according to ISO 10555-5 for easy size identification

**Latex:** all variants are latex-free

**Sterilization:** by ethylene oxide (EO)

**Shelf life:** 5 years from the date of manufacture  
*manufacturing and expiry dates are printed on each individual package*

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**Precautions for use:** Check the integrity of the individual package before use.

To be used immediately after the individual package has been opened

Do not use if the package is damaged.

For single use only.

Re-use of single-use devices creates a potential risk of patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

**Never try to reinsert a partially or completely withdrawn needle.**

Discard after single use to avoid risk of infection.

**Storage:** Store in a cool and dry place.

Do not expose to heat and / or direct sunlight.

**Packing data:**

	pieces per	dimensions (m)
individual package (Tyvek)	1	
Inner box	50	0.135 x 0.170 x 0.083
Export carton	1000	0.430 x 0.350 x 0.290

**Variants:**

KD-FIX - IV Cannula with wings, with port, FEP, 2 radio-opaque stripes					
Article no	Size / Gauge	Length of catheter (mm)	ID (mm)	OD (mm)	Average flow rate (ml / min)
766057	14	45	1.74	2.0	305
766064	16	45	1.37	1.7	200
766071	17	45	1.13	1.5	142
766088	18	45	1.00	1.3	95
766095	20	32	0.80	1.1	65
766101	22	25	0.65	0.9	36
766118	24	19	0.50	0.7	23
766125	26	19	0.44	0.6	17

KD-FIX PUR - IV Cannula with wings, with port, PUR, 3 radio-opaque stripes					
Article no	Size / Gauge	Length of catheter (mm)	ID (mm)	OD (mm)	Average flow rate (ml / min)
766217	14	45	1.74	2.0	305
766224	16	45	1.37	1.7	200
766231	17	45	1.13	1.5	142
766248	18	45	1.00	1.3	95
766255	20	32	0.80	1.1	65
766262	22	25	0.65	0.9	36
766279	24	19	0.50	0.7	23
766286	26	19	0.44	0.6	17

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**KD-FIX MONO - IV Cannula with wings, without port, FEP, 2 radio-opaque stripes**

Article no	Size / Gauge	Length of catheter (mm)	ID (mm)	OD (mm)	Average flow rate (ml / min)
766378	14	45	1.74	2.0	305
766385	16	45	1.37	1.7	200
766392	17	45	1.13	1.5	142
766408	18	45	1.00	1.3	95
766415	20	32	0.80	1.1	65
766422	22	25	0.65	0.9	36
766439	24	19	0.50	0.7	23
766446	26	19	0.44	0.6	17

**KD-FIX MONO PUR - IV Cannula with wings, without port, PUR, 3 radio-opaque stripes**

Article no	Size / Gauge	Length of catheter (mm)	ID (mm)	OD (mm)	Average flow rate (ml / min)
766538	14	45	1.74	2.0	305
766545	16	45	1.37	1.7	200
766552	17	45	1.13	1.5	142
766569	18	45	1.00	1.3	95
766576	20	32	0.80	1.1	65
766583	22	25	0.65	0.9	36
766590	24	19	0.50	0.7	23
766606	26	19	0.44	0.6	17

**KD-FIX SOLO - IV Cannula without wings, without port, FEP, 2 radio-opaque stripes**

Article no	Size / Gauge	Length of catheter (mm)	ID (mm)	OD (mm)	Average flow rate (ml / min)
766699	14	45	1.74	2.0	305
766705	16	45	1.37	1.7	200
766712	17	45	1.13	1.5	142
766729	18	45	1.00	1.3	95
766736	20	32	0.80	1.1	65
766743	22	25	0.65	0.9	36
766750	24	19	0.50	0.7	23
766767	26	19	0.44	0.6	17

**KD-FIX SOLO PUR - IV Cannula without wings, without port, PUR, 3 radio-opaque stripes**

Article no	Size / Gauge	Length of catheter (mm)	ID (mm)	OD (mm)	Average flow rate (ml / min)
766859	14	45	1.74	2.0	305
766866	16	45	1.37	1.7	200
766873	17	45	1.13	1.5	142
766880	18	45	1.00	1.3	95
766897	20	32	0.80	1.1	65
766903	22	25	0.65	0.9	36
766910	24	19	0.50	0.7	23
766927	26	19	0.44	0.6	17

**KD-FIX QUICK - IV Cannula with wings, without port, FEP, quick flashback, advanced needle technology, radio-opaque**

Article no	Size / Gauge	Length of catheter (mm)	ID (mm)	OD (mm)	Average flow rate (ml / min)
767979	14	45	1.74	2.0	305
767986	16	45	1.37	1.7	200
767993	17	45	1.13	1.5	142
768006	18	45	1.00	1.3	95
768013	20	32	0.80	1.1	65
768020	22	25	0.65	0.9	36
768037	24	19	0.50	0.7	23
768044	26	19	0.44	0.6	17

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