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

Summary Essential Technical Data - KD-LINE - Sterile extension tube for single use

<u>Manufacturer:</u>	KD Medical GmbH Hospital Products Charlottenstraße 65 10117 Berlin GERMANY
<u>Product:</u>	Extension Tubing (Sterile extension tubes for single use)
<u>Brand:</u>	KD-LINE, KD-FLEXOLINE
<u>UMDNS code:</u>	12-170 16-621 for high-pressure extension tubing
<u>Risk Class:</u>	Ila according to rule 2 of Annex IX of Council Directive 93/42/EEC, amended by Council Directive 2007/47/EC
<u>Conformity assessment procedure:</u>	according to Annex II, section 3 of Council Directive 93/42/EEC, amended by Council Directive 2007/47/EC
<u>Notified Body:</u>	TUEV Süd Product Service GmbH Ridlerstraße 65 80339 Munich, Germany Identification no 0123

Brief description of the product

Extension tubes for single use are widely used in the infusion and transfusion therapy. They can be incorporated between infusion line and indwelling venipuncture device and can be connected to infusion lines, to infusion pumps and to other medical devices.

They are used for the extension of infusion and transfusion lines and can be divided into the following types:

A. Normal Extension tubing

this type is mainly used for the extension of infusion and transfusion lines in order to minimize the forces exerted on the venipuncture device.

B. Extension Tubing with Three-Way-Stopcock

this type is used for the extension of infusion lines and provides the opportunity to administer additional fluid / drugs controlled by the stopcock.

C. High Pressure Extension tubing:

this type is used when high-pressure infusion is performed. It is used for the extension of high-pressure resistant infusion lines. PVC tubes of variable lengths and a minimal diameter facilitate high pressure infusion and monitoring of the arterial blood pressure up to 40 kg/cm².

Usage of disposable medical devices can avoid cross-infections between patients.

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IBAN	DE77 1007 0000 0605 2450 00	DE50 1008 0000 0905 9465 00	Charlottenburg HRB 64320
SWIFT	DEUT DE 33	DRES DE 33 100	VAT-No. DE 812 328 107

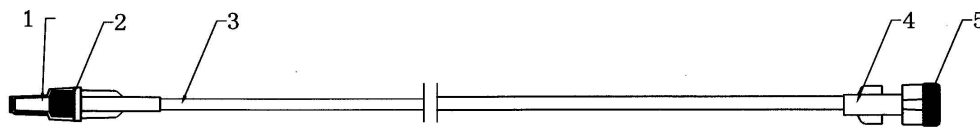
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Variants: drawings and material specification:

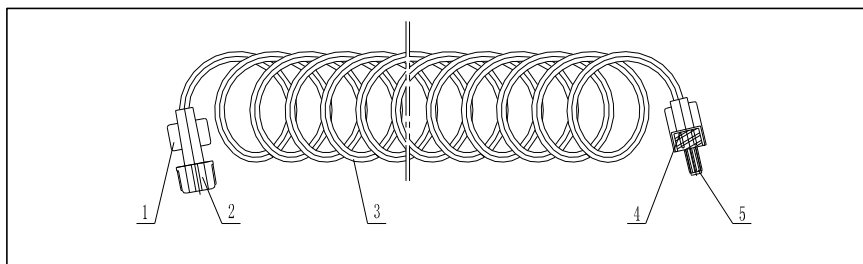
A.1 Normal Extension Tubing



1	Protective cap	PE (polyethylene)
2	male (6 %) luer conical lock fitting	ABS (Acrylonitrile Butadiene Styrene)
3	Tube	PVC (Polyvinyl chloride polymer)
4	female (6%) luer conical lock fitting	ABS (Acrylonitrile Butadiene Styrene)
5	Protective cap	PE (polyethylene)

plasticizer DOP

A.2 Spiral Extension tubing



1	male (6 %) luer conical lock fitting	ABS (Acrylonitrile Butadiene Styrene)
2	Protective cap	PE (polyethylene)
3	Tube	polyurethane
4	female (6%) luer conical lock fitting	ABS (Acrylonitrile Butadiene Styrene)
5	Protective cap	PE (polyethylene)

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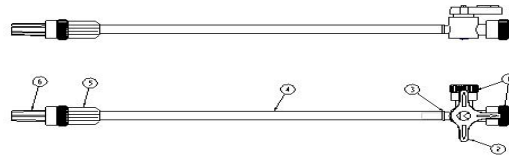
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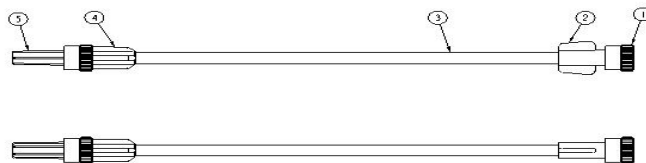
B. Extension Tubing with Three-Way-Stopcock



1	Protective cap	PE (polyethylene)
2	Stopcock tap	PE (polyethylene)
3	Stopcock body	Polycarbonate
4	Tube	PVC (Polyvinyl chloride polymer)
5	male (6 %) luer conical lock fitting	ABS (Acrylonitrile Butadiene Styrene)
6	Protective cap	PE (polyethylene)

plasticizer DOP (DEHP) or DINCH (DEHP-free)

C. High pressure Extension Tubing



1	Protective cap	PE (polyethylene)
2	female (6%) luer conical lock fitting	ABS (Acrylonitrile Butadiene Styrene)
3	Tube	PVC (Polyvinyl chloride polymer)
5	male (6 %) luer conical lock fitting	ABS (Acrylonitrile Butadiene Styrene)
6	Protective cap	PE (polyethylene)

plasticizer DOP (DEHP) or DINCH (DEHP-free)

Sterilization: by Ethylene oxide

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Latex: KD-LINE is latex free**Shelf life:** 5 years from the date of manufacture
*Note: dates of manufacture and expiry are printed on each individual package***Storage:** Do not store at extreme temperature and humidity.**Precautions for use:** The operators should be professionally trained medical staff.
Check the integrity of the individual package before use. Do not use if the package is damaged.
For single use only. To be used immediately when individual package is opened.
Discard after single use to avoid risk of infection.
Use within the validity period**Variants:****KD-LINE, PVC, Heidelberger Extensions (3,0 x 4,1 mm), luer lock, blister packing**

Article no	Length of tube	dimensions (I.D./O.D.)
770207	10 cm	3,0 / 4,1 mm
770221	50 cm	3,0 / 4,1 mm
770245	75 cm	3,0 / 4,1 mm
770269	150 cm	3,0 / 4,1 mm
770283	5 cm	3,0 / 4,1 mm
770306	7 cm	3,0 / 4,1 mm
770320	25 cm	3,0 / 4,1 mm
770344	100 cm	3,0 / 4,1 mm
770368	200 cm	3,0 / 4,1 mm
770382	250 cm	3,0 / 4,1 mm
770627	125 cm	3,0 / 4,1 mm
772256	30 cm	3,0 / 4,1 mm
772263	320 cm	3,0 / 4,1 mm

KD-LINE, Extension tubing/Extension line - LS-connectors, PVC, Blister

Article no	Length of tube	I.D. / priming volume	features
772294	15 cm	3,0 mm / 1,6 ml	two flexible connectors
772300	35 cm	3,0 mm / 4,5 ml	four flexible connectors, roller clamp
772317	35 cm	3,0 mm / 2,5 ml	five rigid connectors, IN-Stopper, roller clamp

KD-LINE, Extension tubing/Extension line with Y-Port, PVC, Luer lock, Blister

Article no	Length of tube	I.D.
770603	14 cm	3,0 mm

KD-LINE, Extension tubing/Extension line, PVC, Luer lock, Blister

Article no	Length of tube	dimensions (I.D./O.D.)	features
770641	150 cm	1,45 / 2,75 mm	for Infusion Syringes pumps only
770764	45 cm	1,45 / 2,75 mm	for Infusion Syringes pumps only
770771	150 cm	1,45 / 2,75 mm	for Infusion Syringes pumps only
770788	180 cm	1,45 / 2,75 mm	for Infusion Syringes pumps only
770825	30 cm	1,45 / 2,75 mm	for Infusion Syringes pumps only
770849	10 cm	1,45 / 2,75 mm	for Infusion Syringes pumps only
770863	25 cm	1,45 / 2,75 mm	for Infusion Syringes pumps only
770887	200 cm	1,45 / 2,75 mm	for Infusion Syringes pumps only

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KD-LINE, Extension tubing/Extension line, PVC, Luer lock, Blister

Article no	Length of tube	dimensions (I.D.) / priming volume	features
772355	50 cm	1,5 mm / 0,9 ml	
772362	75 cm	0,9 mm / 0,5 ml	
772379	150 cm	0,9 mm / 1,0 ml	
772386	150 cm	1,5 mm / 2,6 ml	
772393	150 cm	1,5 mm / 2,6 ml	opaque - light protected
772409	200 cm	1,5 mm / 3,5 ml	
772416	200 cm	1,5 mm / 3,8 ml	
772423	250 cm	1,5 mm / 4,4 ml	
772430	300 cm	1,5 mm / 5,3 ml	
772454	30 cm	1,2 mm / 0,3 ml	

KD-LINE, Extension tubing/Extension line, PVC, Luer slip, Blister

Article no	Length of tube	dimensions (I.D.)	priming volume
772447	30 cm	1,2 mm	0,3 ml

KD-LINE, Extension tubing/Extension line, PE, Latex-free, Luer lock, Blister

Article no	Length of tube	dimensions (I.D.) / priming volume	features
770900	150 cm	ID 1.45 - OD 2,75 mm	for Infusion Syringes pumps only
770481	50 cm	1,0 mm / 0,4 ml	
770504	100 cm	1,0 mm / 0,8 ml	
770528	150 cm	1,0 mm / 1,2 ml	
770542	150 cm	1,0 mm / 1,2 ml	opaque - light protected
770566	200 cm	1,0 mm / 1,6 ml	
770580	250 cm	1,0 mm / 2,0 ml	

KD-FLEXOLINE, PVC, Heidelberger Extension Tubing with Three Way Stop Cock, luer lock

Article no	Length of tube	dimensions (I.D./O.D.)
771204	10 cm	3,0 / 4,1 mm
771228	50 cm	3,0 / 4,1 mm
771242	75 cm	3,0 / 4,1 mm
771266	150 cm	3,0 / 4,1 mm
771280	5 cm	3,0 / 4,1 mm
771303	7 cm	3,0 / 4,1 mm
771327	25 cm	3,0 / 4,1 mm
771341	100 cm	3,0 / 4,1 mm
771365	200 cm	3,0 / 4,1 mm
771389	250 cm	3,0 / 4,1 mm
771624	125 cm	3,0 / 4,1 mm

KD-LINE, Extension tubing/Extension line, PUR, Spiral tubings, Luer lock, Blister

Article no	Length of tube	dimensions (I.D.)	priming volume
770405	150 cm	1,0 mm	1,2 ml
770429	150 cm	2,0 mm	4,7 ml
770443	300 cm	1,0 mm	1,2 ml
770467	300 cm	2,0 mm	4,7 ml

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