



Product Dossier

Large Vessel catheterization Catheters and Kits



Product characteristics

Large vessel catheterization catheters and kits

Class III



Product Dossier

Large Vessel catheterization Catheters and Kits

1. PRODUCT SPECIFICATION

1.1. Product description

Large vessels catheterization catheters and kits.

The elements of the Balton Large vessel catheterization kits are inserted into veins which are in the direct contact with the central circulatory system, i.e. vena cava superior and vena cava inferior, and in certain situations (a long guidewire or patient's anatomy) the Balton device can have the direct contact with central circulatory system itself. Also, drugs and other substances given via the Balton Large Vessel Catheters can have the direct effect on the components of the central circulatory system (including the heart).

Large vessel catheterization catheter is placed into a large vein in the neck (internal jugular vein), chest (subclavian vein or axillary vein) or groin (femoral vein).

Kits for large vessels cannulation consists of single-, double-, triple- and quadruple channel catheter made of the highest class polyurethane of TECOTHANE type containing 20 % Barium sulfate. Catheter from distal side is ended by a phased cone with central hole. Proximal part of the catheter is ended by an opposite ("female") luer-lock cap. Trough size code is marked on the catheter. This system of catheter production enables easy vessel cannulation and ensures maximum long period of keeping it in a vessel. Depending on the type kits contains: catheter, needle, split cannula, guide wire, dilators, scalpel, syringes.

Additionally, it is possible to configure the kit by adding the selected or all the additional components:

Y hub, Guiding syringe 5 ml, TEGO connector, Blocking switch, One way valve cap, ECG flex, Injection cap, Catheter introducer, V needle.

1.2. European directive medical devices classification

Classification was carried out accordance with Annex IX, Council Directive 93/42/EEC concerning medical devices.

Large vessels catheterization catheters and kits are classified in class Class III, Rule 7a:

Life time: Large vessels catheterization catheters and kits are intended for short term time contact, normally intended for continuous use for not more than 30 days it is in Class III.

1.3. The type and series of the products.

1.2.1 Large vessel catheterization catheter and kit single lumen, pediatric, with split cannula

KKDN1.2F^{a*} IR;

ZKDN1.2F^{a*} IR;

KKDN2F^{a*} IR;

ZKDN2F^{a*} IR;

KKDN1.2F^{a*} IRH;

ZKDN1.2F^{a*} IRH;

KKDN2F^{a*} IRH;

ZKDN2F^{a*} IRH.

Where

^{a*} = length from 5 to 32 cm

IR = split cannula

H = hydrophilic coating



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1.2.2 Large vessel catheterization catheter and kit single lumen, pediatric

KKDN2F^{b*}
ZKDN2F^{b*}
KKDN3F^{c*}
ZKDN 3F^{c*}
KKDN4F^{c*}
ZKDN 4F^{c*}
KKDN4.5F^{c*}
ZKDN4.5F^{c*}

KKDN2F^{b*}H
ZKDN2F^{b*}H
KKDN3F^{c*}H
ZKDN 3F^{c*}H
KKDN4F^{c*}H
ZKDN 4F^{c*}H
KKDN4.5F^{c*}H
ZKDN4.5F^{c*}H

Where:

^{b*} = length from 5 to 20 cm

^{c*} = length from 5 to 45 cm

H = hydrophilic coating

1.2.3 Large vessel catheterization catheter and kit single lumen

KKDN5F^{d*}
ZKDN5F^{d*}
KKDN5.5F^{d*}
ZKDN5.5F^{d*}
KKDN6F^{d*}
ZKDN6F^{d*}
KKDN7F^{d*}
ZKDN7F^{d*}
KKDN7.5F^{d*}
ZKDN7.5F^{d*}
KKDN8F^{d*}
ZKDN8F^{d*}
KKDN9F^{d*}
ZKDN9F^{d*}
KKDN10F^{d*}
ZKDN10F^{d*}
KKDN11F^{d*}
ZKDN11F^{d*}

KKDN5F^{d*}H
ZKDN5F^{d*}H
KKDN5.5F^{d*}H
ZKDN5.5F^{d*}H
KKDN6F^{d*}H
ZKDN6F^{d*}H
KKDN7F^{d*}H
ZKDN7F^{d*}H



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KKDN7.5F^{d*}H
ZKDN7.5F^{d*}H
KKDN8F^{d*}H
ZKDN8F^{d*}H
KKDN9F^{d*}H
ZKDN9F^{d*}H
KKDN10F^{d*}H
ZKDN10F^{d*}H
KKDN11F^{d*}H
ZKDN11F^{d*}H

Where:

^{d*} = length from 5 to 60 cm

H = hydrophilic coating

1.2.4 Large vessel catheterization catheter and kit double lumen

KKDND3F^{h*}
ZKDND3F^{h*}
KKDND4F^{h*}
ZKDND4F^{h*}
KKDND4.5F^{h*}
ZKDND4.5F^{h*}
KKDND5F^{h*}
ZKDND5F^{h*}
KKDND5.5F^{h*}
ZKDND5.5F^{h*}
KKDND6F^{h*}
ZKDND6F^{h*}
KKDND7F^{h*}
ZKDND7F^{h*}
KKDND7.5F^{h*}
ZKDND7.5F^{h*}
KKDND8F^{h*}
ZKDND8F^{h*}
KKDND8.5F^{h*}
ZKDND8.5F^{h*}
KKDND9F^{h*}
ZKDND9F^{h*}
KKDND10F^{h*}
ZKDND10F^{h*}
KKDND11F^{h*}
ZKDND11F^{h*}

KKDND3F^{h*}H
ZKDND3F^{h*}H
KKDND4F^{h*}H
ZKDND4F^{h*}H
KKDND4.5F^{h*}H
ZKDND4.5F^{h*}H
KKDND5F^{h*}H
ZKDND5F^{h*}H
KKDND5.5F^{h*}H



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Large Vessel catheterization Catheters and Kits

ZKDND5.5F^{h*}H
KKDND6F^{h*}H
ZKDND6F^{h*}H
KKDND7F^{h*}H
ZKDND7F^{h*}H
KKDND7.5F^{h*}H
ZKDND7.5F^{h*}H
KKDND8F^{h*}H
ZKDND8F^{h*}H
KKDND8.5F^{h*}H
ZKDND8.5F^{h*}H
KKDND9F^{h*}H
ZKDND9F^{h*}H
KKDND10F^{h*}H
ZKDND10F^{h*}H
KKDND11F^{h*}H
ZKDND11F^{h*}H

Where:

^{h*} = length from 5 to 30 cm

H = hydrophilic coating

1.2.5 Large vessel catheterization catheter and kit triple lumen

KKDNT4F^{h*}
ZKDNT4F^{h*}
KKDNT4.5F^{h*}
ZKDNT4.5F^{h*}
KKDNT5F^{h*}
ZKDNT5F^{h*}
KKDNT5.5F^{h*}
ZKDNT5.5F^{h*}
KKDNT6F^{h*}
ZKDNT6F^{h*}
KKDNT7F^{h*}
ZKDNT7F^{h*}
KKDNT7.5F^{h*}
ZKDNT7.5F^{h*}
KKDNT8F^{h*}
ZKDNT8F^{h*}
KKDNT8.5F^{h*}
ZKDNT8.5F^{h*}
KKDNT9F^{h*}
ZKDNT9F^{h*}
KKDNT11F^{h*}
ZKDNT11F^{h*}

KKDNT4F^{h*}H
ZKDNT4F^{h*}H
KKDNT4.5F^{h*}H
ZKDNT4.5F^{h*}H



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KKDNT5F^{h*}H
ZKDNT5F^{h*}H
KKDNT5.5F^{h*}H
ZKDNT5.5F^{h*}H
KKDNT6F^{h*}H
ZKDNT6F^{h*}H
KKDNT7F^{h*}H
ZKDNT7F^{h*}H
KKDNT7.5F^{h*}H
ZKDNT7.5F^{h*}H
KKDNT8F^{h*}H
ZKDNT8F^{h*}H
KKDNT8.5F^{h*}H
ZKDNT8.5F^{h*}H
KKDNT9F^{h*}H
ZKDNT9F^{h*}H
KKDNT11F^{h*}H
ZKDNT11F^{h*}H

Where:

^{h*} = length from 5 to 30 cm

H = hydrophilic coating

1.2.6 Large vessel catheterization catheter and kit quadruple lumen

KKDNIV7F^{g*}
ZKDNI7F^{g*}
KKDNIV8F^{g*}
ZKDNI8F^{g*}
KKDNIV8.5F^{g*}
ZKDNI8.5F^{g*}

KKDNIV7F^{g*}H
ZKDNI7F^{g*}H
KKDNIV8F^{g*}H
ZKDNI8F^{g*}H
KKDNIV8.5F^{g*}H
ZKDNI8.5F^{g*}H

Where:

^{g*} = length from 15cm to 30 cm

H = hydrophilic coating

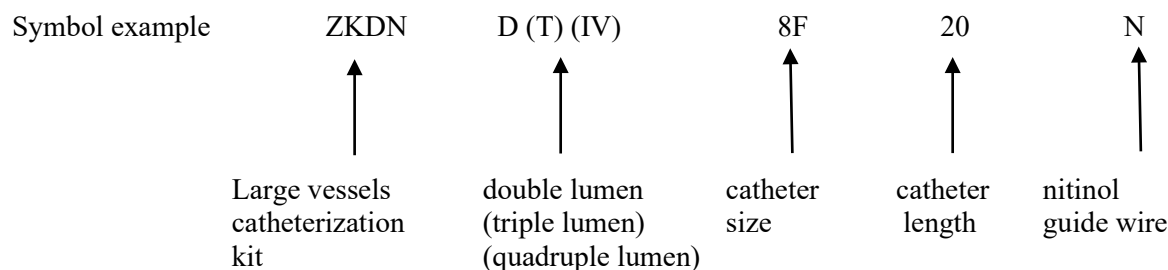


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Large Vessel catheterization Catheters and Kits

Additionally:

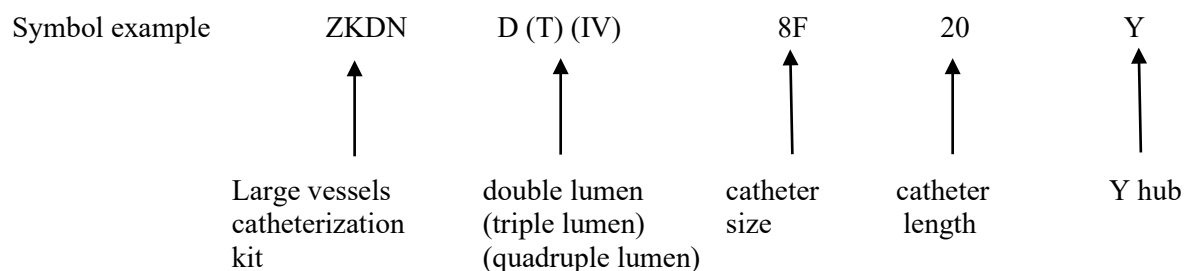
There is possibility to add Nitinol guide wire to the kit.



Codes according to the table:

ZKDN2F b * H *N ZKDN3F c * H *N ZKDN4F c * H *N ZKDN4.5F c * H *N ZKDN5F d * H *N ZKDN5.5F d * H *N ZKDN6F d * H *N ZKDN7F d * H *N ZKDN7.5F d * H *N ZKDN8F d * H *N ZKDN9F d * H *N ZKDN10F d * H *N ZKDN11F d * H *N Where: b * = length from 5 to 20 cm c * = length from 5 to 45 cm d * = length from 5 to 60 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h * H *N ZKDND4F h * H *N ZKDND4.5F h * H *N ZKDND5F h * H *N ZKDND5.5F h * H *N ZKDND6F h * H *N ZKDND7F h * H *N ZKDND7.5F h * H *N ZKDND8F h * H *N ZKDND8.5F h * H *N ZKDND9F h * H *N ZKDND10F h * H *N ZKDND11F h * H *N Where: h * = length from 5 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h * H *N ZKDNT4.5F h * H *N ZKDNT5F h * H *N ZKDNT5.5F h * H *N ZKDNT6F h * H *N ZKDNT7F h * H *N ZKDNT7.5F h * H *N ZKDNT8F h * H *N ZKDNT8.5F h * H *N ZKDNT9F h * H *N ZKDNT11F h * H *N Where: h * = length from 5 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g * H *N ZKDNIV8F g * H *N ZKDNIV8.5F g * H *N Where: g * = length from 15 cm to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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There is possibility to add Y hub to the kit.



Large Vessel catheterization Catheters and Kits

Codes according to the table:

ZKDN2F b [*] H [*] Y ZKDN3F c [*] H [*] Y ZKDN4F c [*] H [*] Y ZKDN4.5F c [*] H [*] Y ZKDN5F d [*] H [*] Y ZKDN5.5F d [*] H [*] Y ZKDN6F d [*] H [*] Y ZKDN7F d [*] H [*] Y ZKDN7.5F d [*] H [*] Y ZKDN8F d [*] H [*] Y ZKDN9F d [*] H [*] Y ZKDN10F d [*] H [*] Y ZKDN11F d [*] H [*] Y Where: b [*] = length from 5 to 20 cm c [*] = length from 5 to 45 cm d [*] = length from 5 to 60 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h [*] H [*] Y ZKDND4F h [*] H [*] Y ZKDND4.5F h [*] H [*] Y ZKDND5F h [*] H [*] Y ZKDND5.5F h [*] H [*] Y ZKDND6F h [*] H [*] Y ZKDND7F h [*] H [*] Y ZKDND7.5F h [*] H [*] Y ZKDND8F h [*] H [*] Y ZKDND8.5F h [*] H [*] Y ZKDND9F h [*] H [*] Y ZKDND10F h [*] H [*] Y ZKDND11F h [*] H [*] Y Where: h [*] = length from 5 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h [*] H [*] Y ZKDNT4.5F h [*] H [*] Y ZKDNT5F h [*] H [*] Y ZKDNT5.5F h [*] H [*] Y ZKDNT6F h [*] H [*] Y ZKDNT7F h [*] H [*] Y ZKDNT7.5F h [*] H [*] Y ZKDNT8F h [*] H [*] Y ZKDNT8.5F h [*] H [*] Y ZKDNT9F h [*] H [*] Y ZKDNT11F h [*] H [*] Y Where: h [*] = length from 5 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g [*] H [*] Y ZKDNIV8F g [*] H [*] Y ZKDNIV8.5F g [*] H [*] Y Where: g [*] = length from 15 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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There is possibility to add Guiding syringe 5 ml to the kit

Symbol example	ZKDN	D (T) (IV)	8F	20	SR
	↑	↑	↑	↑	↑
	Large vessels catheterization kit	double lumen (triple lumen) (quadruple lumen)	catheter size	catheter length	Guiding syringe 5ml

Large Vessel catheterization Catheters and Kits

Codes according to the table:

ZKDN2F b * H *SR ZKDN 3F c * H *SR ZKDN4F c * H *SR ZKDN4.5F c * H *SR ZKDN5F d * H *SR ZKDN5.5F d * H *SR ZKDN6F d * H *SR ZKDN7F d * H *SR ZKDN7.5F d * H *SR ZKDN8F d * H *SR ZKDN9F d * H *SR ZKDN10F d * H *SR ZKDN11F d * H *SR Where: b * = length from 5 to 20 cm c * = length from 5 to 45 cm d * = length from 5 to 60 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h * H *SR ZKDND4F h * H *SR ZKDND4.5F h * H *SR ZKDND5F h * H *SR ZKDND5.5F h * H *SR ZKDND6F h * H *SR ZKDND7F h * H *SR ZKDND7.5F h * H *SR ZKDND8F h * H *SR ZKDND8.5F h * H *SR ZKDND9F h * H *SR ZKDND10F h * H *SR ZKDND11F h * H *SR Where: h * = length from 5 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h * H *SR ZKDNT4.5F h * H *SR ZKDNT5F h * H *SR ZKDNT5.5F h * H *SR ZKDNT6F h * H *SR ZKDNT7F h * H *SR ZKDNT7.5F h * H *SR ZKDNT8F h * H *SR ZKDNT8.5F h * H *SR ZKDNT9F h * H *SR ZKDNT11F h * H *SR Where: h * = length from 5 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g * H *SR ZKDNIV8F g * H *SR ZKDNIV8.5F g * H *SR Where: g * = length from 15 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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There is possibility to add TEGO connector to the kit

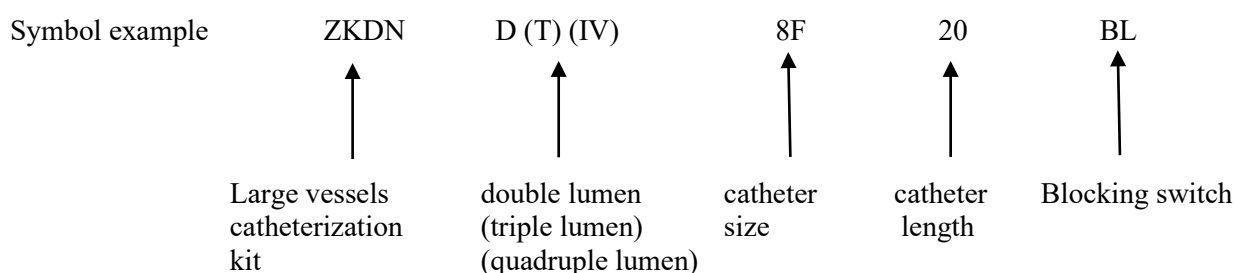
Symbol example	ZKDN	D (T) (IV)	8F	20	KLLT
	↑	↑	↑	↑	↑
	Large vessels catheterization kit	double lumen (triple lumen) (quadruple lumen)	catheter size	catheter length	TEGO connector

Large Vessel catheterization Catheters and Kits

Codes according to the table:

ZKDN2F b * H *KLLT ZKDN3F c * H *KLLT ZKDN4F c * H *KLLT ZKDN4.5F c * H *KLLT ZKDN5F d * H *KLLT ZKDN5.5F d * H *KLLT ZKDN6F d * H *KLLT ZKDN7F d * H *KLLT ZKDN7.5F d * H *KLLT ZKDN8F d * H *KLLT ZKDN9F d * H *KLLT ZKDN10F d * H *KLLT ZKDN11F d * H *KLLT Where: b * = length from 5 to 20 cm c * = length from 5 to 45 cm d * = length from 5 to 60 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h * H *KLLT ZKDND4F h * H *KLLT ZKDND4.5F h * H *KLLT ZKDND5F h * H *KLLT ZKDND5.5F h * H *KLLT ZKDND6F h * H *KLLT ZKDND7F h * H *KLLT ZKDND7.5F h * H *KLLT ZKDND8F h * H *KLLT ZKDND8.5F h * H *KLLT ZKDND9F h * H *KLLT ZKDND10F h * H *KLLT ZKDND11F h * H *KLLT Where: h * = length from 5 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h * H *KLLT ZKDNT4.5F h * H *KLLT ZKDNT5F h * H *KLLT ZKDNT5.5F h * H *KLLT ZKDNT6F h * H *KLLT ZKDNT7F h * H *KLLT ZKDNT7.5F h * H *KLLT ZKDNT8F h * H *KLLT ZKDNT8.5F h * H *KLLT ZKDNT9F h * H *KLLT ZKDNT11F h * H *KLLT Where: h * = length from 5 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g * H *KLLT ZKDNIV8F g * H *KLLT ZKDNIV8.5F g * H *KLLT Where: g * = length from 15 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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There is possibility to add Blocking switch to the kit



Large Vessel catheterization Catheters and Kits

Codes according to the table:

ZKDN2F b* H* BL ZKDN3F c* H* BL ZKDN4F c* H* BL ZKDN4.5F c* H* BL ZKDN5F d* H* BL ZKDN5.5F d* H* BL ZKDN6F d* H* BL ZKDN7F d* H* BL ZKDN7.5F d* H* BL ZKDN8F d* H* BL ZKDN9F d* H* BL ZKDN10F d* H* BL ZKDN11F d* H* BL Where: b* = length from 5 to 20 cm c* = length from 5 to 45 cm d* = length from 5 to 60 cm H* = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h* H* BL ZKDND4F h* H* BL ZKDND4.5F h* H* BL ZKDND5F h* H* BL ZKDND5.5F h* H* BL ZKDND6F h* H* BL ZKDND7F h* H* BL ZKDND7.5F h* H* BL ZKDND8F h* H* BL ZKDND8.5F h* H* BL ZKDND9F h* H* BL ZKDND10F h* H* BL ZKDND11F h* H* BL Where: h* = length from 5 to 30 cm H* = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h* H* BL ZKDNT4.5F h* H* BL ZKDNT5F h* H* BL ZKDNT5.5F h* H* BL ZKDNT6F h* H* BL ZKDNT7F h* H* BL ZKDNT7.5F h* H* BL ZKDNT8F h* H* BL ZKDNT8.5F h* H* BL ZKDNT9F h* H* BL ZKDNT11F h* H* BL Where: h* = length from 5 to 30 cm H* = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g* H* BL ZKDNIV8F g* H* BL ZKDNIV8.5F g* H* BL Where: g* = length from 15 to 30 cm H* = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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There is possibility to add One way valve cap to the kit

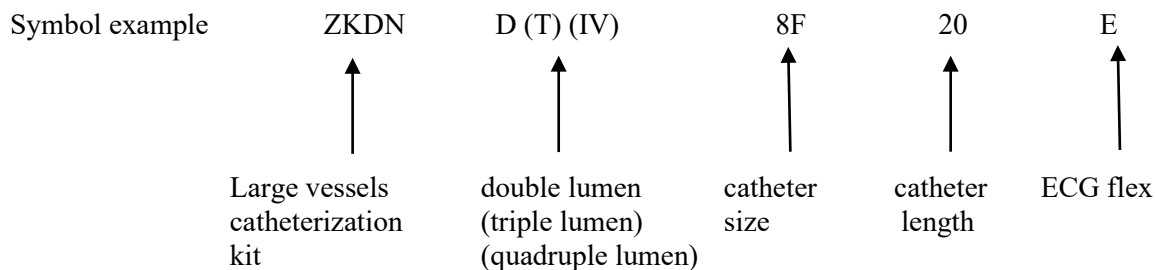
Symbol example	ZKDN	D (T) (IV)	8F	20	V
	↑	↑	↑	↑	↑
	Large vessels catheterization kit	double lumen (triple lumen) (quadruple lumen)	catheter size	catheter length	One way valve cap

Large Vessel catheterization Catheters and Kits

Codes according to the table:

ZKDN2F b * H *V ZKDN3F c * H *V ZKDN4F c * H *V ZKDN4.5F c * H *V ZKDN5F d * H *V ZKDN5.5F d * H *V ZKDN6F d * H *V ZKDN7F d * H *V ZKDN7.5F d * H *V ZKDN8F d * H *V ZKDN9F d * H *V ZKDN10F d * H *V ZKDN11F d * H *V Where: b * = length from 5 to 20 cm c * = length from 5 to 45 cm d * = length from 5 to 60 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h * H *V ZKDND4F h * H *V ZKDND4.5F h * H *V ZKDND5F h * H *V ZKDND5.5F h * H *V ZKDND6F h * H *V ZKDND7F h * H *V ZKDND7.5F h * H *V ZKDND8F h * H *V ZKDND8.5F h * H *V ZKDND9F h * H *V ZKDND10F h * H *V ZKDND11F h * H *V Where: h * = length from 5 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h * H *V ZKDNT4.5F h * H *V ZKDNT5F h * H *V ZKDNT5.5F h * H *V ZKDNT6F h * H *V ZKDNT7F h * H *V ZKDNT7.5F h * H *V ZKDNT8F h * H *V ZKDNT8.5F h * H *V ZKDNT9F h * H *V ZKDNT11F h * H *V Where: h * = length from 5 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g * H *V ZKDNIV8F g * H *V ZKDNIV8.5F g * H *V Where: g * = length from 15 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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There is possibility to add ECG flex to the kit

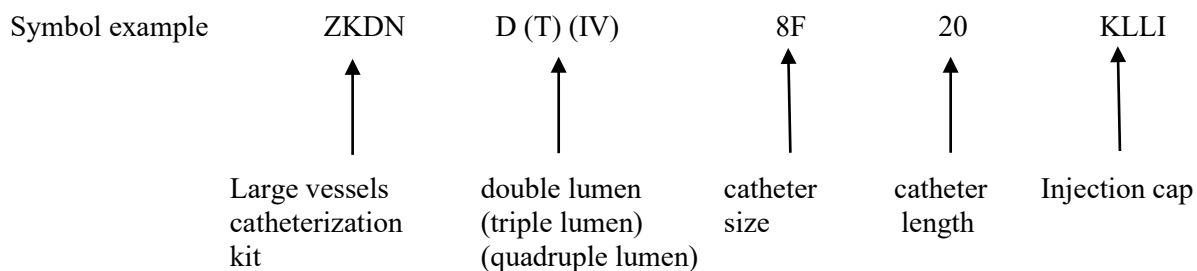


Large Vessel catheterization Catheters and Kits

Codes according to the table:

ZKDN2F b [*] H [*] E ZKDN3F c [*] H [*] E ZKDN4F c [*] H [*] E ZKDN4.5F c [*] H [*] E ZKDN5F d [*] H [*] E ZKDN5.5F d [*] H [*] E ZKDN6F d [*] H [*] E ZKDN7F d [*] H [*] E ZKDN7.5F d [*] H [*] E ZKDN8F d [*] H [*] E ZKDN9F d [*] H [*] E ZKDN10F d [*] H [*] E ZKDN11F d [*] H [*] E Where: b [*] = length from 5 to 20 cm c [*] = length from 5 to 45 cm d [*] = length from 5 to 60 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h [*] H [*] E ZKDND4F h [*] H [*] E ZKDND4.5F h [*] H [*] E ZKDND5F h [*] H [*] E ZKDND5.5F h [*] H [*] E ZKDND6F h [*] H [*] E ZKDND7F h [*] H [*] E ZKDND7.5F h [*] H [*] E ZKDND8F h [*] H [*] E ZKDND8.5F h [*] H [*] E ZKDND9F h [*] H [*] E ZKDND10F h [*] H [*] E ZKDND11F h [*] H [*] E Where: h [*] = length from 5 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h [*] H [*] E ZKDNT4.5F h [*] H [*] E ZKDNT5F h [*] H [*] E ZKDNT5.5F h [*] H [*] E ZKDNT6F h [*] H [*] E ZKDNT7F h [*] H [*] E ZKDNT7.5F h [*] H [*] E ZKDNT8F h [*] H [*] E ZKDNT8.5F h [*] H [*] E ZKDNT9F h [*] H [*] E ZKDNT11F h [*] H [*] E Where: h [*] = length from 5 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g [*] H [*] E ZKDNIV8F g [*] H [*] E ZKDNIV8.5F g [*] H [*] E Where: g [*] = length from 15 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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There is possibility to add Injection cap to the kit



Large Vessel catheterization Catheters and Kits

Codes according to the table:

ZKDN2F b * H *KLLI ZKDN3F c * H *KLLI ZKDN4F c * H *KLLI ZKDN4.5F c * H *KLLI ZKDN5F d * H *KLLI ZKDN5.5F d * H *KLLI ZKDN6F d * H *KLLI ZKDN7F d * H *KLLI ZKDN7.5F d * H *KLLI ZKDN8F d * H *KLLI ZKDN9F d * H *KLLI ZKDN10F d * H *KLLI ZKDN11F d * H *KLLI Where: b * = length from 5 to 20 cm c * = length from 5 to 45 cm d * = length from 5 to 60 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h * H *KLLI ZKDND4F h * H *KLLI ZKDND4.5F h * H *KLLI ZKDND5F h * H *KLLI ZKDND5.5F h * H *KLLI ZKDND6F h * H *KLLI ZKDND7F h * H *KLLI ZKDND7.5F h * H *KLLI ZKDND8F h * H *KLLI ZKDND8.5F h * H *KLLI ZKDND9F h * H *KLLI ZKDND10F h * H *KLLI ZKDND11F h * H *KLLI Where: h * = length from 5 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h * H *KLLI ZKDNT4.5F h * H *KLLI ZKDNT5F h * H *KLLI ZKDNT5.5F h * H *KLLI ZKDNT6F h * H *KLLI ZKDNT7F h * H *KLLI ZKDNT7.5F h * H *KLLI ZKDNT8F h * H *KLLI ZKDNT8.5F h * H *KLLI ZKDNT9F h * H *KLLI ZKDNT11F h * H *KLLI Where: h * = length from 5 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g * H *KLLI ZKDNIV8F g * H *KLLI ZKDNIV8.5F g * H *KLLI Where: g * = length from 15 to 30 cm H * = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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There is possibility to add Catheter introducer to the kit

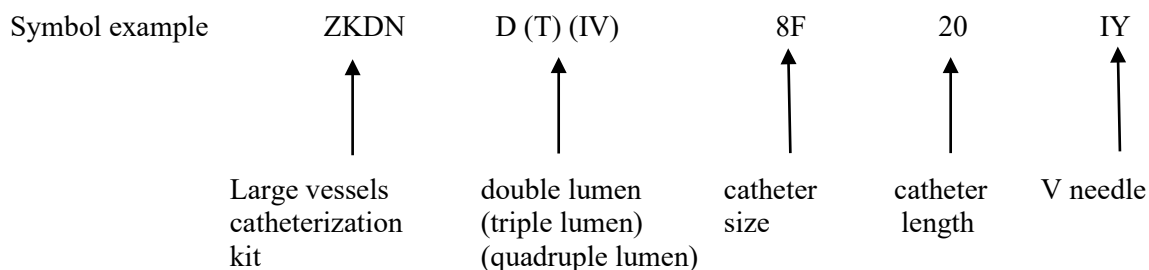
Symbol example	ZKDN	D (T) (IV)	8F	20	IZK
	↑	↑	↑	↑	↑
	Large vessels catheterization kit	double lumen (triple lumen) (quadruple lumen)	catheter size	catheter length	Catheter introducer

Large Vessel catheterization Catheters and Kits

Codes according to the table:

ZKDN2F b [*] H [*] IZK ZKDN3F c [*] H [*] IZK ZKDN4F c [*] H [*] IZK ZKDN4.5F c [*] H [*] IZK ZKDN5F d [*] H [*] IZK ZKDN5.5F d [*] H [*] IZK ZKDN6F d [*] H [*] IZK ZKDN6.5F d [*] H [*] IZK ZKDN7F d [*] H [*] IZK ZKDN7.5F d [*] H [*] IZK ZKDN8F d [*] H [*] IZK ZKDN8.5F d [*] H [*] IZK ZKDN9F d [*] H [*] IZK ZKDN10F d [*] H [*] IZK ZKDN11F d [*] H [*] IZK Where: b [*] = length from 5 to 20 cm c [*] = length from 5 to 45 cm d [*] = length from 5 to 60 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F h [*] H [*] IZK ZKDND4F h [*] H [*] IZK ZKDND4.5F h [*] H [*] IZK ZKDND5F h [*] H [*] IZK ZKDND5.5F h [*] H [*] IZK ZKDND6F h [*] H [*] IZK ZKDND6.5F h [*] H [*] IZK ZKDND7F h [*] H [*] IZK ZKDND7.5F h [*] H [*] IZK ZKDND8F h [*] H [*] IZK ZKDND8.5F h [*] H [*] IZK ZKDND9F h [*] H [*] IZK ZKDND10F h [*] H [*] IZK ZKDND11F h [*] H [*] IZK Where: h [*] = length from 5 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F h [*] H [*] IZK ZKDNT4.5F h [*] H [*] IZK ZKDNT5F h [*] H [*] IZK ZKDNT5.5F h [*] H [*] IZK ZKDNT6F h [*] H [*] IZK ZKDNT7F h [*] H [*] IZK ZKDNT7.5F h [*] H [*] IZK ZKDNT8F h [*] H [*] IZK ZKDNT8.5F h [*] H [*] IZK ZKDNT9F h [*] H [*] IZK ZKDNT11F h [*] H [*] IZK Where: h [*] = length from 5 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F g [*] H [*] ZK ZKDNIV8F g [*] H [*] IZK ZKDNIV8.5F g [*] H [*] ZK Where: g [*] = length from 15 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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There is possibility to add V needle to the kit



Large Vessel catheterization Catheters and Kits

Codes according to the table:

ZKDN5F \mathbf{d}^* \mathbf{H}^* Y ZKDN5.5F \mathbf{d}^* \mathbf{H}^* Y ZKDN6F \mathbf{d}^* \mathbf{H}^* Y ZKDN7F \mathbf{d}^* \mathbf{H}^* Y ZKDN7.5F \mathbf{d}^* \mathbf{H}^* Y ZKDN8F \mathbf{d}^* \mathbf{H}^* Y ZKDN9F \mathbf{d}^* \mathbf{H}^* Y ZKDN10F \mathbf{d}^* \mathbf{H}^* Y ZKDN11F \mathbf{d}^* \mathbf{H}^* Y Where: \mathbf{d}^* = length from 5 to 60 cm \mathbf{H}^* = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDND3F \mathbf{h}^* \mathbf{H}^* Y ZKDND4F \mathbf{h}^* \mathbf{H}^* Y ZKDND4.5F \mathbf{h}^* \mathbf{H}^* Y ZKDND5F \mathbf{h}^* \mathbf{H}^* Y ZKDND5.5F \mathbf{h}^* \mathbf{H}^* Y ZKDND6F \mathbf{h}^* \mathbf{H}^* Y ZKDND7F \mathbf{h}^* \mathbf{H}^* Y ZKDND7.5F \mathbf{h}^* \mathbf{H}^* Y ZKDND8F \mathbf{h}^* \mathbf{H}^* Y ZKDND8.5F \mathbf{h}^* \mathbf{H}^* Y ZKDND9F \mathbf{h}^* \mathbf{H}^* Y ZKDND10F \mathbf{h}^* \mathbf{H}^* Y ZKDND11F \mathbf{h}^* \mathbf{H}^* Y Where: \mathbf{h}^* = length from 5 to 30 cm \mathbf{H}^* = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNT4F \mathbf{h}^* \mathbf{H}^* Y ZKDNT4.5F \mathbf{h}^* \mathbf{H}^* Y ZKDNT5F \mathbf{h}^* \mathbf{H}^* Y ZKDNT5.5F \mathbf{h}^* \mathbf{H}^* Y ZKDNT6F \mathbf{h}^* \mathbf{H}^* Y ZKDNT7F \mathbf{h}^* \mathbf{H}^* Y ZKDNT7.5F \mathbf{h}^* \mathbf{H}^* Y ZKDNT8F \mathbf{h}^* \mathbf{H}^* Y ZKDNT8.5F \mathbf{h}^* \mathbf{H}^* Y ZKDNT9F \mathbf{h}^* \mathbf{H}^* Y ZKDNT11F \mathbf{h}^* \mathbf{H}^* Y Where: \mathbf{h}^* = length from 5 to 30 cm \mathbf{H}^* = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number	ZKDNIV7F \mathbf{g}^* \mathbf{H}^* Y ZKDNIV8F \mathbf{g}^* \mathbf{H}^* Y ZKDNIV8.5F \mathbf{g}^* \mathbf{H}^* Y Where: \mathbf{g}^* = length from 15 to 30 cm \mathbf{H}^* = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number
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It is possible to configure the kit by adding the selected or all the additional components:

- **Y** -Y hub
- **SR** - Guiding syringe 5 ml
- **KLLT** - TEGO connector
- **BL** - Blocking switch
- **V** - One way valve cap
- **E** - ECG flex
- **KLLI** - Injection cap
- **IZK** - Catheter introducer
- **IY** - V needle
- **N** - Nitinol guide wire

Large Vessel catheterization Catheters and Kits

Codes according to the table:

ZKDN2F b [*] H [*] i [*] ZKDN3F c [*] H [*] i [*] ZKDN4F c [*] H [*] i [*] ZKDN4.5F c [*] H [*] i [*] ZKDN5F d [*] H [*] i [*] ZKDN5.5F d [*] H [*] i [*] ZKDN6F d [*] H [*] i [*] ZKDN7F d [*] H [*] i [*] ZKDN7.5F d [*] H [*] i [*] ZKDN8F d [*] H [*] i [*] ZKDN9F d [*] H [*] i [*] ZKDN10F d [*] H [*] i [*] ZKDN11F d [*] H [*] i [*] Where: b [*] = length from 5 to 20 cm c [*] = length from 5 to 45 cm d [*] = length from 5 to 60 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number i [*] = Y or/and SR or/and KLLT or/and BL or/and V or/and E or/and KLLI or/and IZK or/and N or/and IY (IY – it is possible adding only ZKDN5F)	ZKDND3F h [*] H [*] i [*] ZKDND4F h [*] H [*] i [*] ZKDND4.5F h [*] H [*] i [*] ZKDND5F h [*] H [*] i [*] ZKDND5.5F h [*] H [*] i [*] ZKDND6F h [*] H [*] i [*] ZKDND7F h [*] H [*] i [*] ZKDND7.5F h [*] H [*] i [*] ZKDND8F h [*] H [*] i [*] ZKDND8.5F h [*] H [*] i [*] ZKDND9F h [*] H [*] i [*] ZKDND10F h [*] H [*] i [*] ZKDND11F h [*] H [*] i [*] Where: h [*] = length from 5 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number i [*] = Y or/and SR or/and KLLT or/and BL or/and V or/and E or/and KLLI or/and IZK or/and IY or/and N	ZKDNT4F h [*] H [*] i [*] ZKDNT4.5F h [*] H [*] i [*] ZKDNT5F h [*] H [*] i [*] ZKDNT5.5F h [*] H [*] i [*] ZKDNT6F h [*] H [*] i [*] ZKDNT7F h [*] H [*] i [*] ZKDNT7.5F h [*] H [*] i [*] ZKDNT8F h [*] H [*] i [*] ZKDNT8.5F h [*] H [*] i [*] ZKDNT9F h [*] H [*] i [*] ZKDNT11F h [*] H [*] i [*] Where: h [*] = length from 5 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number i [*] = Y or/and SR or/and KLLT or/and BL or/and V or/and E or/and KLLI or/and IZK or/and IY or/and N	ZKDNIV7F g [*] H [*] i [*] ZKDNIV8F g [*] H [*] i [*] ZKDNIV8.5F g [*] H [*] i [*] Where: g [*] = length from 15 to 30 cm H [*] = there is possibility to add catheter with a hydrophilic coating to the kit, then you should add H in the catalog number i [*] = Y or/and SR or/and KLLT or/and BL or/and V or/and E or/and KLLI or/and IZK or/and IY or/and N
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1.4. Packaging conditions

Large Vessel Catheterization Kits –are packed in sterile single-use packing. Each Kit is placed respectively in polyvinyl chloride form made of hard foil. Then the hard foil is welded with medical paper with inscriptions and then every single set is placed into cardboard box with the instruction for use. The unit packs are placed into white boxes and then into a collecting pack made of cardboard resistant to mechanical damage and stuck with tape that makes it impossible to open the box without damaging it. An individual unit packaging is then put in a bulk packaging – a collecting cardboard. The labels are affixed to the single use packaging, cardboard box and collecting cardboard.



Product Dossier

Large Vessel catheterization Catheters and Kits

Large Vessel Catheterization catheters are packed in sterile single use packing. Each Catheter is placed on pouch composed of medical paper and foil. Next, each single set is placed into cardboard box with the instruction for use. The unit packs are placed into white boxes and then into a collecting pack made of cardboard resistant to mechanical damage and stuck with tape that makes it impossible to open the box without damaging it. An individual unit packaging is then put in a bulk packaging – a collecting cardboard. The labels are affixed to the single use packaging, cardboard box and collecting cardboard.

The packing is providing according with EN ISO 11607-1 and EN ISO 11607-2 Standards.

1.5. Directions for use

Large vessel catheterization catheters and kits are intended for:

- Need for intravenous therapy when peripheral venous access is impossible (frequent blood draws, rehydration, drugs administration)
- Administration of noxious drugs (chemotherapy, amiodarone, vasopressors, hypertonic saline, potassium chloride, calcium chloride, long-term intravenous antibiotics, long-term pain medications)
- Parenteral nutrition especially in chronically ill patients
- Hemodynamic monitoring of the central venous pressure
- Peripheral blood stem cell collections

1.6. Contraindications.

Contraindications to large vessel catheterization are relative and depend upon the urgency and alternatives for venous access.

- sites with anatomic distortion or other indwelling intravascular hardware, such as a pacemaker, or already inserted hemodialysis catheter.
- coagulopathy and/or thrombocytopenia.
- infection at the puncture site.
- lack of patient's informed consent.
- dehydration with preserved peripheral venous access.

1.7. Complications

Adverse events are presented in the alphabetic order:

- Air embolism
- Allergic reactions or reactions caused by oversensitivity to polyamide/polyurethane or xylocaine
- Arterial puncture/cannulation
- Bleeding or hemorrhage requiring blood transfusion
- Catheter migration/fracture
- Death
- Extravasation of liquids or drugs
- Fistula formation
- Heart rhythm disturbances of atrial or ventricular origin
- Hematoma
- Hemothorax
- Hypertension or hypotension
- Infection at the puncture site or systemic
- Loss of the guide wire (guide wire lost inside the vessel)
- Nerve injury
- Pneumothorax
- Pseudoaneurysm
- Pulmonary embolism
- Systemic migration
- Thoracic duct injury
- Venous thrombosis

1.7 Precautions

- The procedure should be performed only by physicians who have received appropriate training.
- The device is designed for single use only.
- The device is not suitable to be re-sterilized.
- Do not expose the catheter on the action of organic solvents like alcohol.
- One should remember about EtO residues.



Product Dossier

Large Vessel catheterization Catheters and Kits

- Do not use if the package is damaged.
- Do not use after the expiry date stated on the label.
- Keep in dry place at temperature 10 – 30 °C.

1.8 Instruction for Use

Product should be used according to description. Instruction is attached to each kit.

2. PRODUCT SPECIFICATION

2.1. Product composition

2.1.1 Large vessel catheterization catheter and kit single lumen, pediatric, with split cannula

Semi product	Materials
Single channel tube	Polyurethane
Cuff tube	Polyurethane
Transparent tube	Polyurethane
Mandryn	Stainless steel
Luer cap	Polystyrene
Cap connector	Polyurethane
Female luer-lock cap	Copolyester
Female luer-lock cap under the butterfly	Copolyester
Butterfly for the Female luer-lock cap	Polyvinyl chloride
Clamp 0,5	Polyethylene
Fixing tube	Polyamide
Catheter casing	Polyethylene
Split cannula	Finished product
Syringe	Finished product
Hydrophilic coating	According to QI 8.2.6.30.

2.1.2 Large vessel catheterization catheter and kit with single lumen cannula, pediatric

Semi product	Materials
Single channel tube	Polyurethane
Cuff tube	Polyurethane
Transparent tube	Polyurethane
Cap connector	Polyurethane
Female luer-lock cap	Copolyester
Butterfly	Thermoplastic Elastomer
Clamp for the butterfly	Polyethylene
Clamp 0,5	Polyethylene

Large Vessel catheterization Catheters and Kits

Dilatator tube	Polypropylene, Bismuth/ or Polyethylene, Bismuth
Dilator cap	Polyethylene
Guide wire	Finished product
Guide wire casing	Polyethylene
Guide wire casing	Polyvinyl chloride
Catheter casing	Polyethylene
Guide wire tip casing	Polypropylene
Double connector	Polypropylene
Triple connector	Polypropylene
Straightener big	Polyethylene
Straightener small	Polypropylene
Luer-lock cap	Polyethylene
Straight needle	Finished product
Scalpel	Finished product
Syringe	Finished product
Y hub	Finished product
Syringe under the guide wire	Finished product
TEGO connector	Finished product
Blocking switch	Finished product
One way valve cap	Finished product
ECG flex	Finished product
Injection cap	Finished product
Catheter introducer	Finished product
NiTi Guide Wire	Finished product
Hydrophilic coating	According to QI 8.2.6.30.

2.1.3 Large vessel catheterization catheter and kit with single lumen cannula

Semi product	Materials
Single channel tube	Polyurethane
Soft tube	Polyurethane
Cuff tube	Polyurethane
Transparent tube	Polyurethane
Cap connector	Polyurethane
Female luer-lock cap	Copolyester
Butterfly	Thermoplastic Elastomer
Butterfly	Polyvinyl chloride
Butterfly clamp	Polyethylene
Butterfly clamp	Polypropylene
Clamp 0,7	Polyethylene
Dilatator tube	Polyethylene, Bismuth
Dilator cap	Polyethylene
Guide wire	Finished product
Guide wire casing	Polyethylene
Catheter casing	Polyethylene
Guide wire tip casing	Polypropylene
Double connector	Polypropylene



Product Dossier

Large Vessel catheterization Catheters and Kits

Triple connector	Polypropylene
Straightener big	Polyethylene
Straightener small	Polypropylene
Luer-lock cap	Polyethylene
Straight needle	Finished product
Scalpel	Finished product
Syringe	Finished product
Y hub	Finished products
Syringe under the guide wire	Finished product
TEGO connector	Finished product
Injection cap	Finished product
Blocking switch	Finished product
One way valve cap	Finished product
ECG flex	Finished product
Catheter introducer	Finished product
Syringe	Finished product
V needle	Finished product
NiTi Guide Wire	Finished product
Hydrophilic coating	According to QI 8.2.6.30.

2.1.4 Large vessel catheterization catheter and kit with double lumen

Semi product	Materials
Double channel tube	Polyurethane
Soft tube	Polyurethane
Cuff tube	Polyurethane
Transparent tube	Polyurethane
Cap connector	Polyurethane
Female luer-lock cap	Copolyester
Butterfly	Thermoplastic Elastomer
Butterfly	Polyvinyl chloride
Butterfly on the cap connector	Polyvinyl chloride
Butterfly clamp	Polyethylene
Butterfly clamp	Polypropylene
Snap clamp	Polypropylene
Clamp 0,7	Polyethylene
Dilatator tube	Polypropylene, Bismuth/ or Polyethylene, Bismuth
Dilator cap	Polyethylene
Guide wire	Finished product
Guide wire casing	Polyethylene
Catheter casing	Polyethylene
Guide wire tip casing	Polypropylene
Double connector	Polypropylene
Triple connector	Polypropylene
Straightener big	Polyethylene
Straight needle	Finished product
Syringe	Finished product
Luer-lock cap	Polyethylene
Scalpel	Finished product



Product Dossier

Large Vessel catheterization Catheters and Kits

Y hub	Finished products
Syringe under the guide wire	Finished product
TEGO connector	Finished product
Blocking switch	Finished product
One way valve cap	Finished product
ECG flex	Finished product
Injection cap	Finished product
Syringe	Finished product
Catheter introducer	Finished product
V needle	Finished product
NiTi Guide Wire	Finished product
Hydrophilic coating	According to QI 8.2.6.30.

2.1.5 Large vessel catheterization catheter and kit with triple lumen

Semi product	Materials
Triple channel tube	Polyurethane
Soft tube	Polyurethane
Cuff tube	Polyurethane
Transparent tube	Polyurethane
Cap connector	Polyurethane
Female luer-lock cap	Copolyester
Butterfly	Thermoplastic Elastomer
Butterfly	Polyvinyl chloride
Butterfly on the cap connector	Polyvinyl chloride
Butterfly clamp	Polyethylene
Butterfly clamp	Polypropylene
Snap clamp	Polypropylene
Snap clamp	Polypropylene
Clamp 0,7	Polyethylene
Dilatator tube	Polypropylene, Bismuth/ or Polyethylene, Bismuth
Dilatator tube	Polyethylene, Bismuth
Dilator cap	Polyethylene
Guide wire	Finished product
Guide wire casing	Polyethylene
Catheter casing	Polyethylene
Guide wire tip casing	Polypropylene
Double connector	Polypropylene
Triple connector	Polypropylene
Straightener big	Polyethylene
Luer-lock cap	Polyethylene
Straight needle	Finished product
Scalpel	Finished product
Syringe	Finished product
Y hub	Finished products
Syringe under the guide wire	Finished product
TEGO connector	Finished product
Injection cap	Finished product



Product Dossier

Large Vessel catheterization Catheters and Kits

Blocking switch	Finished product
One way valve cap	Finished product
ECG flex	Finished product
Syringe	Finished product
Catheter introducer	Finished product
V needle	Finished product
NiTi Guide Wire	Finished product
Hydrophilic coating	According to QI 8.2.6.30.

2.1.6 Large vessel catheterization catheter and kit with quadruple lumen

Semi product	Materials
Four-Channel Tube	Polyurethane
Soft tube	Polyurethane
Transparent tube	Polyurethane
Cap connector	Polyurethane
Female luer-lock cap	Polyester
Butterfly	Thermoplastic Elastomer
Butterfly clamp	Polyethylene
Butterfly on the cap connector	Polyvinyl chloride
Clamp 0,7	Polyethylene
Dilatator tube	Polypropylene, Bismuth/ or Polyethylene, Bismuth
Dilator cap	Polyethylene
Guide wire	Finished product
Guide wire casing	Polyethylene
Catheter casing	Polyethylene
Guide wire tip casing	Polypropylene
Double connector	Polypropylene
Triple connector	Polypropylene
Straightener big	Polyethylene
Luer-lock cap	Polyethylene
Straight needle	Finished product
Scalpel	Finished product
Syringe	Finished product
Y hub	Finished products
Injection cap	Finished product
Blocking switch	Finished product
One way valve cap	Finished product
ECG flex	Finished product
TEGO connector	Finished product
Syringe under the guide wire	Finished product
Catheter introducer	Finished product
V needle	Finished product
NiTi Guide Wire	Finished product
Hydrophilic coating	According to QI 8.2.6.30.



Product Dossier

Large Vessel catheterization Catheters and Kits

2.2 Control characteristics.

Polyamide, Polyethylene, Polypropylene, Polyvinyl chloride, Polyester, Polystyrene, Copolyester, Polyurethane, Stainless steel, Thermoplastic Elastomer

Finished product is controlled based on the manufacturer's certificate.
Visual control, control of certificates.

2.3. Information concerning the supplier.

The suppliers have been qualified in accordance with the EN ISO 13485 Standard, according to the procedures QP 7.4.1.; QP 7.4.3.

3. SPECIFICATION OF PRODUCTION PROCESS

Individual production stages are conducted in air – conditioned rooms with the air control in accordance with the **ISO Class 8.**

3.1. Description of production process

The description of particular operations in the manufacturing process and measuring instruments used in the production is presented in the appropriate technical instructions for a given product. Productive operations are documented in the reports of product series.

Product name	Technological instruction No	Reference No Batch report
Large vessels catheterization kit single lumen with split cannula	No 226	BA 226
Large vessels catheterization kit single lumen, pediatric	No 227	BA 227
Large vessels catheterization kit single lumen	No 228	BA 228
Large vessels catheterization kit double lumen	No 229	BA 229
Large vessels catheterization kit triple lumen	No 230	BA 230
Large vessels catheterization kit quadruple lumen	No 231	BA 231

4. PACKAGING AND LABELLING SPECIFICATION

4.1. Packaging

Large Vessel Catheterization Kits –are packed in sterile single use packing. Each Kit is placed respectively in polyvinyl chloride form made of hard foil. Then the hard foil is

Large Vessel catheterization Catheters and Kits

welded with a medical paper with inscriptions and then each single set is placed into cardboard box with the instruction for use. The unit packs are placed into white boxes and then into a collecting pack made of cardboard resistant to mechanical damage and stuck with tape that makes it impossible to open the box without damaging it. An individual unit packaging is then put in a bulk packaging – a collecting cardboard. The labels are affixed to the single use packaging, cardboard box and collecting cardboard.

Large Vessel Catheterization catheters are packed in sterile single use packing. Each Catheter is placed on pouch composed of medical paper and foil. Next, each single set is placed into cardboard box with the instruction for use. The unit packs are placed into white boxes and then into a collecting pack made of cardboard resistant to mechanical damage and stuck with tape that makes it impossible to open the box without damaging it. An individual unit packaging is then put in a bulk packaging – a collecting cardboard. The labels are affixed to the single use packaging, cardboard box and collecting cardboard.

The packing is providing according with EN ISO 11607-1 and EN ISO 11607-2 Standards.

Mark	Packaging material	Norms and specifications
Blister foil	Foil PVC	FT/03/04
Paper	Medical paper	PM/02/04
Pouch	Medical paper - Foil	RPF/01/04
Box	Carton	HŽ/C/03002/09
Carton	Carton	ISO 4046-1-4:2002

4.2. Packaging units

For the Large vessels catheterization kits:

Welding foil blister with medical paper:

- WEBER BLISTER SENIOR; No 01-503-N
- ILLIG HSP35/3; No 01-140-N
- ILLIG HSP35/3; No 01-953-N
- ILLIG HSP35B; No 01-958-N
- ILLIG; No 01-264-N

For the Large vessels catheterization catheters:

- STERIKING RS120; No 01-515-N

4.3. Packaging process

Large Vessel catheterization Catheters and KitsPackaging process for the Large vessels catheterization kits

- preparation of finished products,
- placement of product products into foil blister,
- welding foil blister with medical paper,
- sticking labels on single units,
- single units packing into the boxes,
- sticking labels on boxes,
- boxes packing into the collective cardboard box,
- sticking labels onto the cardboard.

Packaging process for the Large vessels catheterization catheter

- preparation of finished products
- placement of the product in a sleeve
- sealing of the sleeve
- labelling sleeve
- packing unit packs into the boxes
- sticking labels on boxes
- boxes packing into the collective cardboard box,
- sticking a label onto the cardboard

Single unit packing is performed in air-conditioned units with controlled air ISO Class 8.

Bulk packing is performed in packaging unit without controlled air.

4.4. Labels

The paper label stuck onto unit packs, unit boxes and cardboard contains the following information in comply with EN 15223-1, EN 1041 Standards:

- product name,
- manufacturer's name, address and trade-mark,
- UDI code,
- LOT number,
- listed elements included in the kit
- sterile, nontoxic, nonpyrogenic
- expiry date (year, month)
- sterilization date: (year, month)

- inscriptions:
 - store in room temperature, 10°-30°C
 - consult instruction for use,
 - do not use if package is damaged,
 - use only once,
 - sterilized with ethylene oxide.

5. SUBSEQUENT CONTROL SPECIFICATION.

5.1. Control of materials

Control of materials is lead according to procedure QP 7.4.3.; visual control and certificates control.

5.2. Interoperation production control

- visual,
- checking the quality of workmanship of the kit components
- checking dimensions and quality of the kit components (1, 2, 3, 4-lumen tubes, lateral opening, soft tube, transparent tube, dilatator tube, cuff tube, needle, guide wire)
- checking tightness and resistance of joints
- checking sealing and sticking-in quality
- the quality and correctness of marking,
- checking of completeness of kits elements.

Particular control stages have been presented in the Technological Instructions.

5.3. Control of impurities during the production process

The purity state of the products, at individual production stages before sterilisation, is controlled for individual product groups and is defined in the procedure QP 6.4. and the instruction

QI 6.4.1.

5.4. Control of packaging materials

Performed according to procedure QP 7.4.3.

5.5. Packaging control

The control of single packages.

The control of welding integrity.
According to instruction QI 8.2.6.16

5.6. Final product control

5.6.1. Physical control

Checking:

- checking the appearance and dimensions of set's elements
- checking the strength of catheters and their connections
- checking the catheters and dilator caps
- checking quality 1, 2, 3, 4-lumen tube marking correctness and quality,
- checking resistance to leaking under pressure
- checking quality of tube joint with connectors cap,
- checking the strength of guide wire components parts joints
- checking the resistance of guide wire on fracture
- checking the resistance of guide wire on damage
- checking the resistance of metal elements devices on corrosion
- checking physical-mechanical properties of the needle
- checking needle tube stiffness.

Physical control is providing in comply with ISO 2859-1, ISO 10555-1, ISO 10555-3, EN ISO 7864, EN ISO 9626, EN ISO 11070 Standards and QI 8.2.6.11.; QI 8.2.6.12.; QI 8.2.6.13.; QI 8.2.6.14.; QI 8.2.6.16., QI 8.2.6.17.; QI 8.2.6.18.; QI 8.2.6.21.; QI 8.2.6.22., QI 8.2.6.23.; QI 8.2.6.24, QI 8.2.6.30. Instructions.

5.6.2. **Pyrogens**

Test LAL is performed according to instruction QI 8.2.6.3. in microbiological laboratory of Balton company.

5.6.3. **Sterility**

Performed according to instruction QI 8.2.6.2. in microbiological laboratory of Balton company.

5.6.4. **Biocompatibility**

Performed by the National Medicines Institute, by the Toxicon Europe NV and by the CHSP Technochemia.

6. **OBSERVANCE OF ENVIRONMENT**

6.1. Controls of the room and air.

According to the procedure QP 6.4. and the instruction QI 6.4.1.

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- the control of overpressure in individual rooms,
- annual control or once the air particle filters have been changed, filter check,
- quarterly verification of the air supplying installation and air conditioning,
- bacteriological control of working rooms and air monitoring /instruction,
- quarterly control of water microbiological purity /instruction.

6.2. Personnel control.

According to the procedure QP 6.4. and the instruction QI 6.4.1.

- the control of personnel hygiene in the rooms with controlled atmosphere,
- periodic medical checkups,
- the control of working clothing in the clean zone.

6.3. Contents of microbiological contamination in the product before sterilization.

According to the instruction QI 8.2.6.6.

7. STORAGE, MAINTENANCE**7.1. Expiry date.**

Products sterilised with ethylene oxide. Expiry date for Large vessels catheterization catheter and kit is 4 years and 11 months from the day after sterilization. The expiry date of the devices with hydrophilic coating is 1 year and 11 months.

7.2. Storage conditions.

The products should be stored in a dry and cool place in the temperature of 10-30°C /the procedure QP 7.5.11./.

7.3. Sterilization.

It is carried out in accordance with the EN ISO 11135 Standard.
Sterilization with ethylene oxide is carried out in accordance with the instructions QP 7.5.1.2. and QI 7.5.1.3.

8. STERILIZATION

According to norm EN ISO 11135 Standard.
Sterilization by ethylene oxide is performed according to instructions QI 7.5.1.2 and QI 7.5.1.3

8.1. Sterilization conditions

Device type: the sterilizer of the Getinge GEE 14422 73 AR-2, sterilization conditions in accordance with the instruction QI 7.5.1.2.

Parameters:

- | | |
|--|--|
| a) Preliminary conditioning parameters: | |
| Final conditioning period temperature | $42 \pm 5^{\circ}\text{C}$ |
| Relative humidity | above 50 % |
| Conditioning time | min. 8 h |
| Pressure | 0,08-0,1 bar |
| b) Sterilization process parameters: | |
| Temperature in the chamber | $44 \pm 3^{\circ}\text{C}$ |
| Relative humidity | above 50% |
| Ethylene oxide concentration | $0,7-0,9 \text{ kg/m}^3$ |
| Allowed S-90 gas quantity | 17 kg-19 kg |
| S-90 gas quality | mixture of 90% ETO+10% CO ₂ |
| Sterilization time | $220 \pm 10\% \text{min}$ |
| Exposure time | $320 \pm 15\% \text{min}$ |
| Preliminary pressure | 0,08 bar |
| Pressure following introduction of ethylene oxide | min. 0,05 bar |
| Working pressure | min. $0,9 \pm 0,05 \text{ bar}$ |
| c) Sterilization material degasification process parameters: | |
| Pressure value in sterilization chamber | from 0,014 to 0,95 bar |
| Pressure value following gas evacuation | 0,95 bar |
| Final pressure value | 1 bar |
| Gas evacuation time | $100 \pm 10\% \text{min}$ |
| Number of run-purge | 5x |
| d) Quarantine process parameters: | |
| Desorption time | min. 7 days |
| Number of air exchange counts in quarantine | min. 8 |
| Desorption temperature | $20^{\circ} \pm 5^{\circ}$ in the room |

8.2. Control of sterilization efficacy

- printing of sterilization process parameters,
- a quality control certificate including a sterilization efficiency estimation with 20 tests containing bacillus atrophaeus – 1264 3M Health Care spores at the concentration 10^6 and 10 chemical test (PCD indicators). Following sterilization tests were incubated at the temperature 37°C for 2 days for culture growth,



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- a measurement of EtO residues in the product,
- a control measurement of microbiological contaminations before sterilization,
- placement of indicators according to the QI 7.5.1.3 Instruction.

Following sterilization the action is in compliance with the indicators and QI 7.5.1.4 Instruction.

8.3. Routine control

8.3.1. Microbiological purity on different production stages

Purity examination is performed before sterilization for respective groups of products according to instruction QI 8.2.6.6.

8.3.2. Process certificate

- sterilization parameters,
- the certificate of sterilization effectiveness