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DeltaVen® Technical Data Sheet

Dual Port with Dual Needleless Connectors

DEVICE CLASSIFICATION

Class llb

DEVICE DESCRIPTION

Closed system safety I.V. Catheter in polyurethane (PUR) with accessories.

GMDN

40601

CE MARK

CE 0123

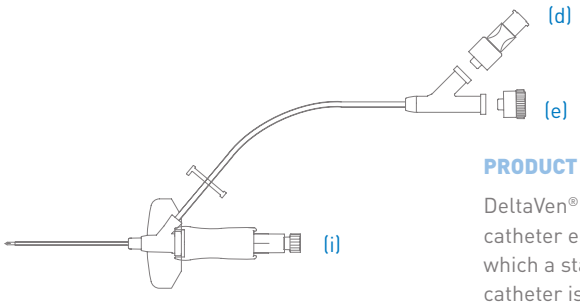
COUNTRY OF ORIGIN

Italy

ANIMAL ORIGIN

The devices listed on this product family are free from animal origin or have undergone inactivation of TSE/BSE agent's process.

DIAGRAM



STERILIZATION METHOD

Ethylene Oxide

MANUFACTURING SITE NAME AND ADDRESS

Delta Med SpA
Via G. Rossa, 20-46019
Viadana (Mn) – Italy
0375 785915

PRODUCT DESCRIPTION

DeltaVen® is a radio-opaque polyurethane catheter equipped with a rubber septum inside which a stainless steel needle is inserted. The catheter is connected to a lateral extension equipped with a clamp (i) whose end section is connected to a double port Luer-lock fitting. The straight port is complete with an air vent plug (d), on which a Luer-lock cap (e) is assembled; the side port is connected to a needleless connector (d).

The catheter is also equipped with a passive safety system designed to prevent needlestick injuries.

A loose extra needleless connector is included into the unit blister.

PRECAUTIONS

Use of the device is for medical or paramedical competence.

- Read the instructions before use.
- Use protective gloves.
- Do not use if the individual packaging is damaged or open or if the product is past the "use by" date.
- Do not use if the device is incomplete or has been tampered with.
- The product must be used immediately after the packaging has been opened.
- Do not attempt to reinsert the entry needle in the rubber septum it was extracted from.
- Do not reinsert the needle while the catheter is located wholly or partly on site. It could break the catheter.
- Do not insert needles, sharp objects or faulty connectors in the needleless connector. It could cause leakages from the device. In case of an attempted insertion of a needle or a blunt cannula, replace the needleless connector.
- Replace stopcock within a maximum time of 3 days or 24 hours if concentrated glucose, lipidic or blood-derived solutions are being used. Needleless connector must be replaced after 200 activations.
- Do not use needleless connector access with an operating pressure exceeding 2 bar.
- Disposable device: Do not sterilise and/or reuse in order to avoid compromising functionality or aid possible cross contamination with other patients.
- After use, dispose of as hospital waste.
- In case of incorrect transport and/or manipulation, the device or packaging could be subject to structural and/or functional damage.
- Do not use scissors at or near the insertion site.
- Do not remove the security system from the catheter prior to use.
- Use only Luer-lock connectors and caps (ISO 594-2).

If the device is used at a high pressure or with injectors:

- Connect directly to the pressure infusion system with the end Luer-lock connector of the device.
- Remove the stopcock connected to the device.
- Always check the patency of the device before use.
- Never exceed the maximum pressure of 23 bar (330 psi).
- Consider the internal residual volume of the device in the case of administration of small volumes of medicines.
- If pain, swelling around the catheter insertion area or the occurrence of edema/erythema or other local complications are experienced, replace the device and insert a new one in another site.
- Clean the device immediately after the administration of medicines or biological fluids.
- Immediately remove any needle that has no coating, always keeping the tip away from your body and fingers.
- Do not expose to heat or direct sunlight.
- If the catheter is incorrectly inserted under the skin, remove it and never try to re-insert the needle into the catheter when it was extracted partially or totally.
- If during insertion under the skin blood appears in the needle mounting unit or in the catheter after withdrawing the needle, discard the device and insert in another place.
- If you want to administer a drug bolus different from what is being administered subcutaneously in a continuous mode, you must insert a new catheter to avoid incompatibilities between drugs.

INDICATIONS

DeltaVen® is a catheter for peripheral venous and subcutaneous access that, in combination with other peripheral devices, allows the collection of blood samples and the administration of fluids. DeltaVen® is intended to be used for less than 30 days.

DeltaVen® is equipped with a passive system for the prevention of accidental needlestick injuries. During the initial insertion phase, the blood remains in the device facilitating the prevention of exposure to blood. The catheter can be used on any patient population while taking into account the vascular anatomy of the patient and of the adequacy of the procedure.

DeltaVen® catheters are suitable for use with pressure injectors (max. 330 psi) only if all accessories are removed. The recommended measurements for subcutaneous use are 26G, 24G and 22G with a 19 mm catheter length. DeltaVen® 26G: DO NOT USE FOR HIGH PRESSURE TREATMENTS.

PRODUCT COMPONENTS

Non-pyrogenic, sterile, single-use device. The device is not made of natural latex and phthalates.

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COMPONENT COMPOSITION

Polyurethane catheter with three radio-opaque strips enclosed in the wall containing $BaSO_4$.

- AISI304 stainless steel needle.
- Polycarbonate catheter hub.
- Silicone rubber septum needle seal.
- Butterfly with polypropylene body and thermoplastic synthetic rubber wings.
- Polyurethane extension line DEHP free.
- Polypropylene colored Luer-lock connection.
- Styrene butadiene copolymer air vent with high density polyethylene hydrophobic filter.
- Polypropylene Luer-lock cap.
- Needless connector with polyester / polycarbonate hub and silicone rubber core.

LABELLING AND PACKAGING

Container Type	Length	Width	Height	Weight
Unit Pack (1 unit)	140 mm	60 mm	22 mm	0.011 kg
Shelf Pack (20 units)	295 mm	140 mm	95 mm	0.35 kg
Case Pack (80 units)	395 mm	305 mm	160 mm	1.7 kg

PRODUCT(S) DESCRIBED MAY NOT BE LICENSED OR AVAILABLE FOR SALE IN CANADA AND OTHER COUNTRIES

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