EN

Fig. 1: Peripheral venous catheter with closed system (Single and Two-way) before removing the needle and the accessories.
Fig. 2: Peripheral venous catheter with closed system (Single and Two-way) after removing the needle and the accessories.
Fig. 3: Needle protection device after activation.

Indications for use.
Deltaven Fast Flash Closed I.V. Catheter systems are catheters for short-term peripheral venous access that allow the collection of blood samples and administration of fluids intravascularly.
Deltaven Fast Flash Closed I.V. Catheter systems are equipped with a passive system for the prevention of accidental needlestick injuries.
Blood is contained within the device during the catheter insertion process, aiding the prevention of blood exposure.
The device can be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.
Deltaven Fast Flash Closed I.V. Catheter systems 16-24 gauge catheters are suitable for use with pressure injectors rated for a maximum of 330 psi when the access ports and stopcocks are removed and a direct connection is made with the proximal luer lock connector.
Deltaven Fast Flash Closed I.V. Catheter systems 26 gauge are not suitable for the administration at high pressure.

Description of the device.
Non-pyrogenic, sterile, single use only. The device is not made from natural latex and phthalates. Deltaven Fast Flash Closed I.V. Catheter systems are radio-opaque polyurethane catheters equipped with a silicone septum inside in which a stainless steel needle, is inserted. The catheters are connected to a lateral extension equipped with a clamp (i) whose section is connected with a fitting with a single or double luer-lock together with an air vent connection (f). The end connections can be equipped with a luer-lock cap (e), with a needleless connector (d), with a three-way stopcock (g) which is also equipped with a needleless connector (h). The catheters are also equipped with a passive safety system to prevent needlestick injuries. (Fig.III)

INSTRUCTIONS FOR USE.
1. Choose the correct IV cannula gauge and length.
2. Follow a strict aseptic procedure and prepare the venipuncture site according to facility policy and guidelines.
3. Open the device packaging at the corner marked "PEEL".
4. Check to ensure all connections are secured and check that the clamp is in the "open" position
5. Hold the white grip pads to remove the protective sheath and inspect the device.
   Separate the catheter from the introducer needle for no more than 3mm. Subsequently reseat the catheter hub back to initial position
6. Verify that the push-off tab and the needle bevel are in the "up" position
7. Anchor the vein with gentle skin traction.
8. Insert the catheter needle at the appropriate angle for the vein you are accessing.
9. Confirm vessel entry by looking for flashback through the notched needle at the distal tip of catheter (Fast Flash ™) and flash chamber
10. Decrease angle and insert the device slightly to assure catheter entry into the vein.
11. Hold the grip pads stable and advance the push-off tab to carefully thread the catheter hub to the patient 's skin.
12. Keep your finger behind the push-off tab to stabilize the device then pull back on the grip pads to retract the needle in a continuous movement, keeping the needle aligned with the catheter body. An audible click indicates the safety has been activated.
13. Observe blood filling the extension tubing, indicating patency
14. Dispose of the safety needle in a suitable sharps container.
15. Apply IV dressing per istitutional policy ensuring the catheter septum is covered to prevent access.
16. Close the clamp.
17. Remove the 2-piece vent plug and cap from the system, apply slight distal pressure to sides of the hub while pulling back and twisting the vent plug, avoiding downward pressure. To aid grip, consider removing the dead-end cap from vent plug first.
18. Open the clamp on the extesion tubing to administer fluid or medication.
19. Apply a primed needle free connector, or sterile end cap or make a direct connection to an IV Line to start desired fluid or medication. Follow local policy and guidelines for saline flushing and preparation of IV device prior to use. When using needleless connectors disinfect prior each entry in to the device.
20. Perform a routine check of the venipuncture site. Continue to observe the site to ensure there are no complications.
21. If the device is used to withdraw blood sample, flush carefully with saline solution to remove all visible blood from the device, to reduce the risk of clot formation.

We recommend using the Deltaven Fast Flash Closed I.V. Catheter systems according to the protocols of the institution and the CDC guidelines.

Warnings. (PRECAUTIONS.)
- Use of this device is restricted to trained medical professionals only.
- 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 silicone 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 bend the needle prior or during insertion, threading, or removal of the catheter assembly.
- Do not insert needles, sharp objects or faulty connectors into the needleless connector, if present. 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 the needleless connector within a maximum time of 7 days or after exceeding 200 activations.
- If the device is equipped with a stopcock it is recommended that it be replaced after 72 hours or 24 hours if using concentrated solutions of glucose, lipids or blood products.
- If the catheter is in place and you want to replace the accessories, close the clamp on the extension tubing.
- Do not use needleless connectors with an operating pressure exceeding 2 bar (29 psi).
- 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 the catheter as biohazardous 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 needle safety 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 all the accessories connected to the device and replace them with a luer-lock cap where necessary.
  - 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.
- Do not administer incompatible medications simultaneously through the same device.
- 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.
- Flush 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.
- Always use Universal Precautions and dispose of the needles in appropriate sharps container.
- Follow current institutional policies and procedure for catheter insertion , maintenance and removal.
- Ensure fluid administration/hub connection is secure in order to prevent leaking.
- Ensure stabilization of the catheter to the patient. Improper stabilization may lead to loss of vascular access.

PREPARATION

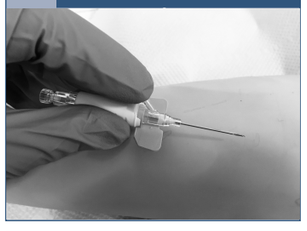
1 Ref.2: Follow a strict aseptic procedure and prepare the venipuncture site
Ref.3: check that the connections and /or accessories are secured correctly

2 Ref.4: Check that the clamp on the extension or stopcock switch is in the open position

INSERTION

1 Ref. 5: Open the primary packaging following the indication (peel)
Ref.6: While holding the coloured part of the catheter, remove the protector.

2 Ref. 7: Take hold of the device with one hand
Ref. 8: Avoid touching the catheter tip.
Ref.9: Insert the cannula in the vein from a low angle.

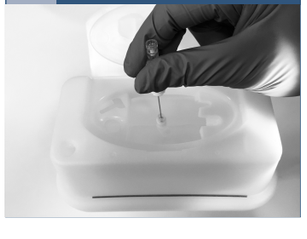


3 Ref. 10: Check that the blood flows into catheter tube and along the extension

4 Ref. 11: Partially extract the needle and in the meantime carefully insert the cannula
Ref. 12: The needle extraction should be done in a continuous movement while keeping the needle aligned with the axis of the catheter body.

5 Ref.13: Extract the needle completely until the safety device activates, as can be confirmed by a "click" sound, keeping the catheter fixed on the patient's skin.

6 Ref.14: Dispose of the needle in a suitable sharps container, avoiding contact with the tip.



CONTRAST MEDIA: IOMERON 400 AT 20°C	MAX FLOW RATE (ml/sec)
GAUGE	
24G x 19mm	4
22G x 19mm	5
22G x 25mm	5
20G x 25mm	8
20G x 32mm	8
20G x 45mm	7
18G x 25mm	>10
18G x 32mm	>10
18G x 45mm	>10
16G x 32mm	>10

Injection pressure: 325 PSI

Catheter Gauge and length	Priming Volume Dual entry (ml)	Priming Volume Single entry (ml)
26G 19mm	0.25	0.20
24G 19mm	0.30	0.25
22G 19mm	0.30	0.26
22G 25mm	0.31	0.26
20G 25mm	0.41	0.36
20G 32mm	0.41	0.36
20G 45mm	0.42	0.38
18G 25mm	0.44	0.39
18G 32mm	0.44	0.39
18G 45mm	0.45	0.41
16G 32mm	0.47	0.42
Accessories:	Stopcock: 0.12ml	Needleless connector: 0.04ml

SYMBOL GLOSSARY

Do not reuse. Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. Ref. 5.4.2 in ISO 15223-1:2016		Do not resterilize. Indicates a medical device that is not to be resterilized. Ref. 5.2.6 in ISO 15223-1:2016	STERILIZE
Caution. Consult instructions for use Ref. 5.4.3 in ISO 15223-1:2016		Do not use if package is damaged. Indicates a medical device that should not be used if the package has been damaged or opened. Ref. 5.2.8 in ISO 15223-1:2016	
Sterilized using ethylene oxide. Indicates a medical device that has been sterilized using ethylene oxide. Ref. 5.2.3 in ISO 15223-1:2016	STERILE EO	Fragile, handle with care. Indicates a medical device that can be broken or damaged if not handled carefully. Ref. 5.3.1 in ISO 15223-1:2016	
Keep dry. Indicates a medical device that needs to be protected from moisture. Ref. 5.3.4 in ISO 15223-1:2016		Keep away from sunlight. Indicates a medical device that needs protection from light sources. Ref. 5.3.2 in ISO 15223-1:2016	
Non-pyrogenic. Ref. 5.6.3 in ISO 15223-1:2016			

Rx Only Caution: Federal law (USA) restricts this device sale by or on the order of a physician.

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DELTA MED MEDICAL DEVICES

DELTAVEN FASTFLASH

EN - Safety I.V. catheter of PUR with closed system

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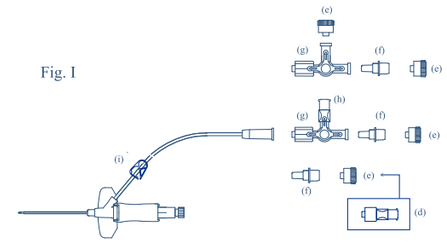
Fig. I



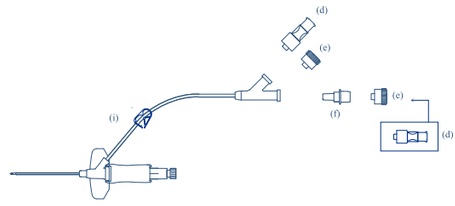
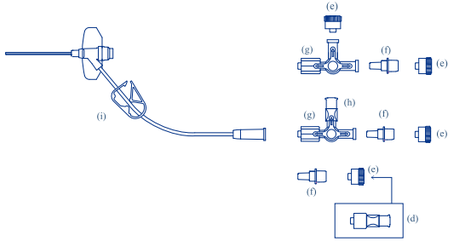


Fig. II



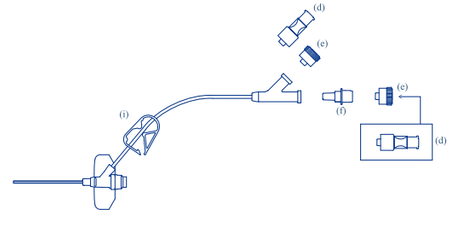


Fig. III