

INSTRUCTIONS FOR USE

FlowArt® Filter Set with Needle-Free Split Septum Valve, 1.2 Micron

Product No.s:

AF6012	AF6312	AF6112B
AF6012-PH	AF6312-PH	AF6112B-PH
AF6012B	AF6312B	AF6112
AF6012B-PH	AF6312B-PH	AF6112-PH
AF6212	AFY6312	A2F6012B
AF6212-PH	AFY6312-PH	A2F6012B-PH
AF6212B	AFY6312B	A3F6012B
AF6212B-PH	AFY6312B-PH	A3F6012B-PH
AFY6212B	AFY6212	
AFY6212B-PH	AFY6212-PH	

INDICATIONS FOR USE

For administering fluids from container to a patient's vascular system through a vascular access device. Used for the removal of particulate matter (>1.2 µm) from infusion fluids while administering.

Allows the user to add medication into the primary line without the use of a needle.

INSTRUCTIONS

1. Remove the FlowArt® set out of its package using aseptic technique
2. Prime to remove any entrapped air.
3. Connect the male luer of the set to female luer of I.V. cannula or catheter hub.
4. Insert male luer of the IV administration set or the syringe into FlowArt® needle-free valve by rotating 90-180° clockwise.
5. Flush after each fluid intervention per facility protocol.
6. Disconnect the luer-lock or luer-slip syringe or IV administration set from the FlowArt® needle-free valve carefully while twisting the luer counter clockwise. Wipe the port surface dry by swabbing surface if any fluid escapes.
7. Prior to access, disinfect the FlowArt® needle-free valve according to your hospital's infection control protocol.
8. Change in accordance with current, recognized guidelines of IV therapy or to facility protocol.




















FEATURES


1. May be used with TPN solutions containing lipid emulsions.
2. **NOT** suitable for blood transfusion.
3. Needle-free valve may be used over 300 times up to 7 days if swabbing protocols of seal are fully implemented.
4. Compatible with emergency glass syringe infusions.
5. Not made with PVC or NR latex and metals.
6. Fluid pathway is STERILE and NON-PYROGENIC.

CAUTIONS

1. Federal law restricts this device to sale by or on the order of a licensed practitioner.
2. Discard if packaging is damaged.
3. Product expiration date is 5 years. DO NOT use after expiration date.
4. DO NOT use needles or blunt cannula.
5. DO NOT use in patients with known hypersensitivity to any of the materials used.
6. DO NOT overtighten luer connections.
7. The FlowArt® set has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of FlowArt® valve in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.
8. Replace if the seal of the needle-free valve is found to be leaking.

9. Replace if the silicone part is damaged after multiple accesses. This may cause leakage.
10. Replace if the silicone part does not return to its original position after removal of luer.
11. Replace the product if any part of the extension set detaches.
12. FlowArt® set is suitable for all luer lock syringes and lines but when using rotating collar male luer lock (MLL) connectors ensure that the luer is inserted fully while held at the body not at the collar/ring before tightening.
13. Make sure that luer slip connectors to be inserted to the FlowArt® Needle-free valve are compliant with ISO 80369-7. Non-compliant luers may not connect to FlowArt® Needle-free valve properly. This may cause cracking during connection. In such cases, replace FlowArt® set with a new one.
14. Keep the unused lumen clamp closed.
15. Close the clamp of valve extension before removing the syringe or infusion set luer.
16. The product is for single use only. DO NOT resterilize.
17. DO NOT leave luer slip connections unattended.
18. If you observe a drug or fluid degrading the set, replace with a new one and inform our company by giving the name of the drug.
19. Arterial usage is not recommended.
20. Replace per hospital policy, CDC guidelines or after 24 hours of continuous filtration (whichever comes first).
21. Do not store above 40°C temperature or in humid conditions. Do not expose to direct sunlight or water.

Symbol Glossary	
 Temperature limit	 Catalog Number
 Keep dry	 Batch code
 Keep away from sunlight	 Prescription only
 Not made with natural rubber latex	 Manufacturer
 Does not contain PVC	 Date of manufacture
 Use-by date	 Consult instructions for use
 Do not re-use	 Non- pyrogenic
 Do not Resterilize	 Do not use if package is damaged
 Sterilized using ethylene oxide	 Medical Device
 Does not contain DEHP	

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