# **INSTRUCTIONS FOR USE**

# FlowArt® Filter Set with Needle-Free Split Septum Valve, 0.2 Micron

## Product No.s:

AF6002B	AF6302-PH	AF6102B
AF6002B-PH	AF6202	AF6102B-PH
AF6002	AF6202-PH	AF6102
AF6002-PH	AFY6302B	AF6102-PH
AF6002ET	AFY6302B-PH	A2F6002B
AF6002ET-PH	AFY6202B	A2F6002B-PH
AF6302B	AFY6202B-PH	A3F6002B
AF6302B-PH	AFY6302	A3F6002B-PH
AF6202B	AFY6302-PH	A2F30106002B
AF6202B-PH	AFY6202	
AF6302	AFY6202-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 (>0.2  $\mu$ m) 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.
- 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. **NOT** suitable for use with TPN solutions containing lipid emulsions and blood transfusion.
- 2. Needle-free valve may be used over 300 times up to 7 days if swabbing protocols of seal are fully implemented.
- 3. Compatible with emergency glass syringe infusions.
- 4. Not made with PVC or NR latex and metals.
- 5. 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 is 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.
- Arterial usage is not recommended.
  Replace per hospital policy. CDC guidelines or after 96 hospital policy.
- 20. Replace per hospital policy, CDC guidelines or after 96 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	LOT Batch code		
Keep away from sunlight	R 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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