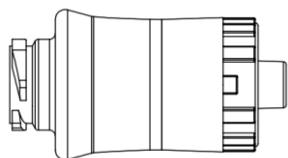


FlowArt

Needle-Free Split Septum Valve, Hemodialysis



INDICATIONS FOR USE:

Needle-free valve is intended for use as an accessory to a vascular access device used in hemodialysis or as an accessory to an intravascular administration set for the administration or withdraw of fluids to a patient through a cannula or needle placed in the vein.

DESCRIPTION & FEATURES

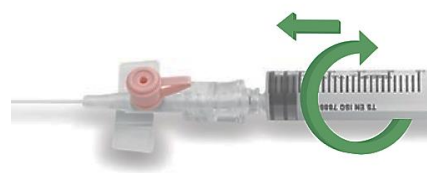
- FlowArt valve has an unobstructed transparent housing with an integrated flat silicone seal and internal fluid pathway. It protects the patient and nursing staff from exposures to needlestick injuries, chemicals and microorganism causing infection during IV therapy. It acts as a barrier to protect the fluid path by use of a mechanically actuated silicone septum. Insertion of an ISO male luer from admin sets and syringes compresses the solid silicone seal, forcing it against a rigid column, spreading open the top of the seal. Fluid enters chamber through the split-opened silicone seal, achieving flow.
- FlowArt valve can be easily disinfected in less than 1 minute due to easy to swab feature of the seal.
- May be used with TPN solutions containing lipid emulsions, blood transfusion and high flow-rate infusion procedures to a pressure of 400 psi at a flow rate of 10 mL per second (Flowrates >600 ml/min).
- May be used over 300 times up to 7 days if swabbing protocols of seal are fully implemented.
- Compatible with emergency glass syringe infusions.
- Not made with PVC or NR latex and metals.
- Fluid pathway is STERILE and NON-PYROGENIC.

INTENDED USER AND TARGET POPULATION

Intended to be used by health care professionals for patient populations including neonate, infant, child, adolescent, and adult populations in all patient care settings where vascular access devices are utilized such as medical, surgical, and critical care specialties, pre-hospital, hospital, long-term care, and home-care settings.

INSTRUCTIONS

1. Remove the FlowArt needle-free valve out of its package using aseptic technique.
2. Prime to remove any entrapped air.
3. Connect the male luer of the needle-free valve to female luer of I.V. cannula or catheter hub.
4. Insert male luer of the IV 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 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 port according to your hospital's infection control protocol.
8. Change in accordance with current, recognized guidelines of IV therapy or to facility protocol.

CAUTIONS

- Federal law restricts this device to sale by or on the order of a licensed practitioner.
- Discard if packaging is damaged.
- Product expiration date is 5 years. DO NOT use after expiration date.
- DO NOT use needles or blunt cannula.
- DO NOT use in patients with known hypersensitivity to any of the materials used.
- DO NOT overtighten luer connections.

- The FlowArt valve 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.
- Replace if the seal is found to be leaking.
- Replace if the silicone part is damaged after multiple accesses. This may cause leakage.
- Replace if the silicone part does not return to its original position after removal of luer.
- FlowArt Needle-free valve 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.
- 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 Needle-free valve with a new one.
- The product is for single use only. DO NOT resterilize.
- DO NOT leave luer slip connections unattended.
- If you observe a drug or fluid degrading FlowArt valve, replace with a new one and inform our company by giving the name of the drug.
- Arterial usage is not recommended.
- When used with power injector, secure all connections with a luer lock and unused lumens with a clamp. Do not use if split-septum valve is not protected from back-pressure.
- Replace tubing per hospital policy or CDC guidelines.
- Do not store above 40°C temperature or in humid conditions. Do not expose to direct sunlight or water.

Symbol Glossary			
	Temperature limit	REF	Catalog Number
	Keep dry	LOT	Batch code
	Keep away from sunlight	Rx	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
STERILE EO	Sterilized using ethylene oxide	MD	Medical Device
	Does not contain DEHP		Single Sterile Barrier System



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