FlowArt® Extension Set With Needle-Free Split Septum Valve

Product No.s:

A2010*	A3010-PH*	AU1010*
A2010L11*	A3010WOR*	AU1010-PH*
A2010L15*	A3010WOR-PH*	AU1010WOR*
A2010L23*	A3010Y	AU1010WOR-PH*
A2010-PH*	A3010YL11*	AUL1010*
A2010WOR*	A3010YL11-PH*	AUL1010L10*
A2010WOR-PH*	A3010YL15*	AUL1010L11*
A2010Y	A3010YL15-PH*	AUL1010L11-PH*
A2010YL11*	A3010YL21*	AUL1010L15*
A2010YL11-PH*	A3010YL21-PH*	AUL1010-PH*
A2010YL15*	A3010Y-PH	AUL1010WOR*
A2010YL15-PH*	A4010*	AUL1010WOR-PH*
A2010YL18*	A4010-PH*	AULB1010*
A2010YL23*	A4010Y	AULB1010-PH*
A2010YL23-PH*	A4010Y-PH	AUU1010L40*
A2010Y-PH	A5010Y	AUWB1010L10*
A3010*	A5010Y-PH	AUWB1010T
A3010L11*	A6010Y	AWB2010*
A3010L15*	A6010Y-PH	AWB2010RMLL*
A3010L21*	ATU3010	AWB2010YL18*

INDICATIONS FOR USE

For administering fluids from container to a patient's vascular system through a vascular access device.

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

*Power injection with injection rating of maximum 400 psi and flowrate of 10 mL/sec (also noted on the package label of the product).

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.
- 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 and for blood transfusion.
- 2. 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.
- 19. Arterial usage is not recommended.
- 20. 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.
- 21. Replace tubing per hospital policy or CDC guidelines.
- 22. Do not store above 40°C temperature or in humid conditions. Do not expose to direct sunlight or water.

Symbol Glossary				
-40°C	Temperature limit	REF	Catalog Number	
Ť	Keep dry	LOT	Batch code	
*	Keep away from sunlight	R	Prescription only	
	Not made with natural rubber latex		Manufacturer	
RVC	Does not contain PVC		Date of manufacture	
	Use-by date		Consult instructions for use	
\otimes	Do not re-use	X	Non- pyrogenic	
STER	Do not Resterilize		Do not use if package is damaged	
STERILE	EO Sterilized using ethylene oxide	MD	Medical Device	
Does not contain DEHP				

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