INSTRUCTIONS FOR USE

FlowArt Extension Set with Needle-Free Split Septum Valve, One Directional

Product No.s:

A2010CV	AUL1010L17CV	AU1010TYWOR-PH
A2010CV-PH	A2010TY	A2010TYWOR
A3010CV	A2010TY-PH	A2010TYWOR-PH
A3010CV-PH	A3010TY	A3010TYWOR
A2010CVWOR	A3010TY-PH	A3010TYWOR-PH
A2010CVWOR-PH	AU1010TY	A20TY10Y
A3010CVWOR	AU1010TY-PH	A20TY10Y-PH
A3010CVWOR-PH	AULB1010TY	ATU3010TY
A20CV10Y	AULB1010TY-PH	AUL1010L10TY
A20CV10Y-PH	AUWB1010TY	AYWB4010CV
AUL1010L10CV	AUWB1010TY-PH	AYWB7010CV
AWB2010CV	AU1010TYWOR	AYWB4010TY
		AYWB7010TY

<u>Caution</u>: Federal law restricts this device to sale by or on the order of a licensed practitioner.

INDICATIONS FOR USE

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

Stopcocks are intended for use to change the direction of flow of fluids through a tubing set.

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

INSTRUCTIONS & FEATURES

- Swab the FlowArt Needle-free valve port with 70/30 IPA wipes before connecting any syringe or IV set according to your hospitals infection control protocol.
- 2. Prime the set with saline.
- 3. Connect the male luer of FlowArt Needle-free valve Port to female luer of I.V. cannula or catheter hub.
- 4. Flush after each fluid intervention per facility protocol.
- Rotate male luer of the administration set or the syringe 90-180° clockwise whilst inserting into FlowArt Needle-free valve.
- 6. May be used with TPN solutions containing lipid emulsions, blood transfusion and high flow-rate infusion.
- 7. May be used over 300 times up to 7 days if swabbing protocols of seal are fully implemented.
- When FlowArt Needle-free valve is used in combination with I.V cannula and infusion set, use infusion set or I.V cannula replacement time as reference.
- 9. Fully compatible with emergency glass syringe infusions.
- 10. Not made with PVC or NR latex and metals.
- 11. Fluid pathway is STERILE and NON-PYROGENIC.

CAUTIONS

- 1. Discard if packaging is damaged.
- 2. Product expiration date is <u>5</u> years.
- 3. DO NOT use after expiration date.
- 4. DO NOT use a needle or blunt cannula.
- DO NOT use in patients with known hypersensitivity to any of the materials used.
- 6. DO NOT overtighten connections.
- 7. The FlowArt 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 in the MR environment is

unknown. Scanning a patient who has this medical device may result in patient injury.

- 8. Replace if the silicone part of the needle-free valve is damaged after multiple accesses. This may cause leakage.
- 9. Replace if the seal is found to be leaking.
- 10. Replace if the silicone part of the needle-free valve does not return to its original position after removal of luer.
- 11. Replace if any part of the extension set detaches.
- 12. FlowArt extension 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 straight while held at the body not at the collar/ring.
- 13. Make sure that luer slip connectors to be inserted to the FlowArt needle-free valve of the extension set are compliant with ISO 80369-7. Non-compliant luers may not connect to FlowArt extension set properly. This may cause cracking during connection. In such cases, replace the product with a new one.
- 14. After infusion or transfusion, flush saline solution.
- 15. Keep the unused lumen clamp closed.
- 16. Close the clamp of valve extension before removing the syringe or infusion set luer.
- 17. The product is for single use only. DO NOT resterilize.
- 18. DO NOT leave luer slip syringes or luer slip infusion sets unattended.
- 19. If you observe a drug or fluid degrading any part of FlowArt extension set, replace the valve with a new one and inform our company by giving the name of the drug.
- 20. Arterial usage is not recommended.
- 21. Replace tubing per hospital policy or CDC guidelines.

STORAGE CONDITIONS

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	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		
STERILE EO STERILE EO Sterilized using ethylene oxide	Medical Device		
Does not contain DEHP	Single Sterile Barrier System		

ASSET MEDIKAL TASARIM SAN. VE TIC. A.S Ikitelli OSB Mah., 17. Cd., No:17, Basaksehir, Istanbul TURKEY Tel: +902124942727, www.assetmedical.com

