

Instructions for Use



Product Name

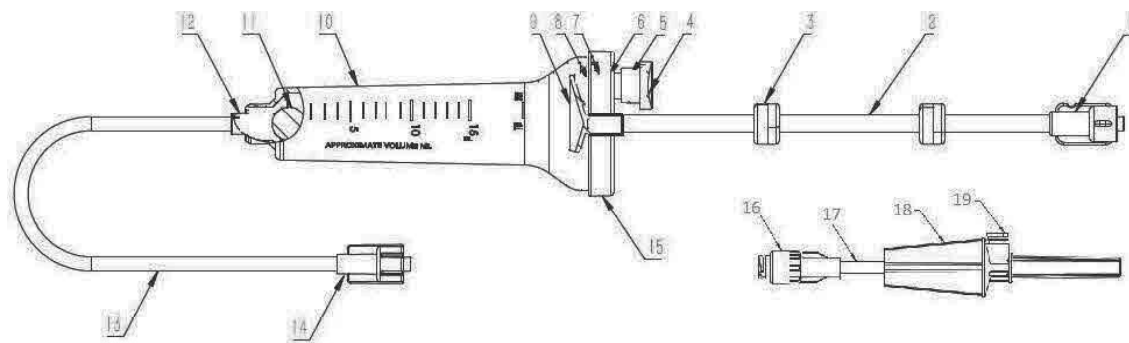
Burette Infusion Sets Without Needle - Burette CMS, integrated valves, 150cm large bore tubing, vented spike

Product Type

XDP0101A

Brief Product Description

The Burette CMS, integrated valves, 150cm large bore tubing, vented spike consists of 2 check valves, drip chamber with safety ball and large bore tubing. All components are made from medical-grade materials and are non-toxic, , and non-pyrogenic after sterilisation with ethylene oxide (EO) gas. The product is designed for safe and easy use.



1. Male Luer Lock; 2. PU Tubing; 3. Check Valve (x 2); 4. Vent Button; 5. Spring; 6. Sealing Ring; 7. Vent valve stem;
8. Air Filter Membrane; 9. Flow guide; 10. Drip Chamber; 11. Float; 12. Drip chamber base; 13. PU Tube;
14. Male Luer Lock 15. Drip chamber cover; 16. Female Needle Free Valve; 17. PVC Tube; 18. Spike; 19. Vent

Intended Purpose

This passive Burette CMS, integrated valves, 150cm large bore tubing, vented spike is intended for single use and does not come into direct contact with the skin.

Body Contact

Indirect contact with blood.

Scope of Application

Suitable for adult patients.

Cautions

1. Use proper aseptic techniques when handling.
2. This product is for single use only. Do not reuse.
3. Read these instructions carefully before use. Check that the packaging is intact. Do not use if damaged.
4. Store away from sunlight, high temperatures, humidity, ultraviolet radiation, and corrosive environments.
5. Avoid kinking or breaking the tubing during use.
6. Use only by trained personnel or qualified medical professionals.
7. Do not use under high pressure.
8. Use immediately after opening the package
9. Ensure all connections are tight, the presence of air in the system may lead to embolism and in rare instances to death.
10. Once connected, verify there is no leakage.

Instructions for Use:

Burette CMS, integrated valves, 150cm large bore tubing, vented

1. Inspect prior to use to ensure no damage has occurred during the shipping process.
2. If caps are present, remove the caps from the Burette CMS System assembly.
3. Connect the male luer of the delivery tubing on the Burette CMS to the manifold.
4. Ensure that the valve on the manifold is "OFF" to the Burette CMS assembly.
5. Connect the Contrast media spike to the inlet tube of the Burette CMS.
6. Using proper sterile techniques, connect the media spike to the container of the contrast media container.

7. Open the media connection and verify that the fluid flows toward the manifold.
8. While pressing and holding in the white button, squeeze the chamber. For optimal results squeeze the chamber firmly to evacuate air from the system.
9. Release the Chamber. Continue holding the white button until the chamber is filled to the recommended fill level.
10. If the yellow ball is seated in the base of the chamber, squeeze the base of the chamber to dislodge the ball. The ball will float freely to the surface.
NOTE: IF the ball does not float freely to the surface, open the stopcock on the manifold and push fluid back towards the Burette CMS assembly. This will ensure that the ball floats to the surface.
11. Aspirate contrast media through the tubing assembly. Debubble the system. The tubing assembly is now ready to use.
NOTE: The vacuum created by the “automatic filling” will facilitate a constant fluid level in the reservoir during the course of the procedure.
NOTE: The system includes an automatic shut-off at the bottom of the reservoir. The ball will seat when the reservoir is drained to decrease the potential of air embolus to the patient.

Validity

Shelf life: Five years. The production lot number and expiry date are indicated on the packaging.

Manufacturer and Registrant

Zhuhai DR Medical Instruments Co., Ltd.

Address: No. 352, Dingwansan Road, Jinwan District, Zhuhai, Guangdong Province, P.R. China Telephone: +86-0756-6802188

Fax: +86-0756-6802188

SRN: CN-MF-000021135

Authorised Representative

Shanghai International Holding Corp. GmbH(Europe)

Address: Eiffestraße, 80 20537 Hamburg

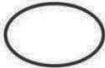
Telephone: +49-40-2513175

SRN: DE-AR-000000001

Symbol and instruction

On the product package "⊗" indicates for single use . "STERILE EO" indicates Ethylene oxide sterilization.

Definitions of Signs:

Symbol	Definitions of symbol
	Batch code
	Catalogue number
	Date of Manufacture
	Use-by date
	Do not re-use
	Do not use if the package is damaged
	Consult instructions for use
	Sterilized using ethylene oxide
	Single sterile barrier system
	Do not re-sterilize
	This Way UP

Symbol	Definitions of symbol
	Fragile, handle with care
	Caution
	Keep away from sunlight
	Keep dry
	Unique Device Identifier
	Country of manufacture
	Manufacturer
	Medical device
	Authorized representative in the European Community
	CE marking of conformity, and Notified Body Code
	Manufacturer Logo