

m|devices®

IV020010 Transfusion Set

2 NeutralSite™ and 2 Non-Return Valve
6cm Side Arm

INSTRUCTION FOR USE

DESCRIPTION

m|devices Transfusion Sets are used to administer fluids, blood/blood products from a bag/bottle to the patient's vascular system through an intravenous catheter inserted into a vein.

This Transfusion Set consists of a tubing length of 251cm with a 6cm side arm, 200 µm filter, vented chamber and two NeutralSite™ and two non-return valves.

FOR USE BY A QUALIFIED CLINICIAN. THE BELOW IS ONLY A SUGGESTION AND FACILITY PROTOCOL MUST BE FOLLOWED FOR ALL CLINICAL PROCEDURES WHERE THIS PRODUCT IS USED.

CAUTION

- The integrity of the NeutralSite™ should be confirmed by the clinician before and immediately after each use.
- Glass syringes are NOT compatible with the NeutralSite™.
- Gravity use only.
- Single use only.
- DO NOT re-sterilise.
- DO NOT store at extreme temperatures and humidity, avoid direct sunlight. Handle with care.
- STERILE (EO), DO NOT use if the package or product has been damaged or contaminated.
- EU Notice: any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and /or patient is established.

STEPS

Ensure aseptic technique is followed at all times.

1. Close roller regulator.
2. Remove protective cap from spike and insert into fluid container (in case of rigid container, open vent on spike).
3. Suspend container.
4. Squeeze lower half of the drip chamber until half full.
5. To prime the line, open the roller regulator and invert the NeutralSite™ until all air is expelled from the line to male luer connector.
6. If air is still apparent in the NeutralSite™ after priming, use a sterile syringe to aspirate the air before proceeding to the next step.
7. Close roller regulator.
8. Remove protective cap from male luer lock connector and secure by inserting into access device and engaging rotating collar.
9. Control flow rate with roller regulator.
10. To access NeutralSite™, insert syringe with a straight motion, push and twist using a clockwise motion.

USING THE NEUTRALSITE™

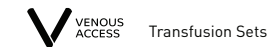
1. Using your regulatory approved disinfectant, thoroughly disinfect the entire surface of the NeutralSite™ using mechanical friction, for at least 30 seconds. Allow the NeutralSite™ to completely dry.
2. Holding the NeutralSite™, insert the luer lock syringe with a straight motion, push and twist to the right until locked. If using a luer slip syringe, insert with a straight motion and twist 1/4 turn to the right.
3. To disconnect; hold the NeutralSite™ firmly and with a twisting motion, turn the luer to the left to unlock and pull out the luer connector.
4. Flush the NeutralSite™ with a syringe filled with N/Saline after every use or as per facility protocol.
5. Repeat the above steps for every instance the NeutralSite™ is accessed.


PRECAUTIONS


- Do not use a needle or blunt cannula with the NeutralSite™.
- The security of all connections should be checked once the circuit is established and monitored during use to prevent disconnection.
- Priming slowly can assist in reducing turbulence that can form air bubbles.
- If applicable, when inverting the NeutralSite™ during priming, gentle tapping whilst the fluid is passing the Y-site to the NeutralSite™ can assist with removing any trapped air.
- The risk of contamination can be reduced when using mechanical friction. The surface of the NeutralSite™ must be cleaned before and after each access, using an approved disinfectant. This step will ensure that any residual medication/blood remnants are immediately and effectively removed from the surface of the NeutralSite™ after use.

m|devices

27 Llewellyn Avenue
Villawood NSW 2163
Australia
T +61(0)2 8718 2800
F +61(0)2 8718 2801



 **BQ Plus Medical Co., Ltd.**
No. 18, Che Ye Road
Che Dun Town, Songjiang
201611 Shanghai, China

 **Prolinx GmbH**
Brehmstr. 56
40239 Duesseldorf
Germany

