m|devices®

IV200005
NeutralSite™
Valve

INSTRUCTION FOR USE

DESCRIPTION

m|devices NeutralSite™ provides neutral pressure displacement and is specially designed not only to reduce blood reflux to avoid catheter occlusion, but also to decrease the risk of catheter related bloodstream infections (CRBSI) due to its swabable flat surface with pre-slit septum. In addition, the internal straight fluid pathway helps to minimise the priming volume and address dead space concerns.

The NeutralSite™ is recommended for use of up to 7 days as per independent laboratory test study following Guidance for Industry and FDA staff: Intravascular Administration Sets Premarket Notification Submissions [510(k)] and Standard: YY/T 0923-2014 Needleless access port for fluid lines and blood lines - Test method for microbial ingress.

The NeutralSite™ was challenged with four ATCC test microorganisms, selected in accordance with the FDA guideline. The NeutralSite™ was challenged with a high concentration of inoculum which was assessed to higher than that normally seen in a clinical setting. The mean results produced show that the valve does have an effective barrier with vigorous disinfection, achieving a bacterial log reduction of 7. The study was conducted over a 7-day period with 140 activations.

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.
- Aseptically replace the NeutralSite™, in any of the following circumstances: If there is residual blood within the NeutralSite™ or if there is drug particulate matter within the NeutralSite™.
- Glass syringes are NOT compatible with the NeutralSite™.
- 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

1. Using aseptic technique, open the packaging and remove the NeutralSite™.
2. According to facility protocol, using a syringe filled with N/Saline prime the NeutralSite™ to dispel air.
3. Remove the end protective cap and attach to the corresponding luer connection/ catheter hub.
4. 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.
5. 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.
6. 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.
7. Flush the NeutralSite™ and connecting catheter with a syringe filled with N/Saline after every use or as per facility protocol.
8. Repeat above steps (4-7) for every instance the NeutralSite™ is accessed.

ASPIRATION OF BLOOD

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. Using a syringe filled with N/Saline, flush the NeutralSite™ before withdrawal of blood to check for patency.
3. Pull back on the syringe and withdraw blood as per facility protocol. This blood is to be discarded and not used for specimen.
4. Detach the syringe and 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.
5. Attach the vacutainer holder to the NeutralSite™ and insert the blood tube into the holder to start the withdrawal of blood.
6. Once sufficient amount of blood has been collected, detach the vacutainer holder and using your regulatory approved disinfectant, thoroughly disinfect the entire surface of the NeutralSite™. Use mechanical friction, for at least 30 seconds. Allow the NeutralSite™ to completely dry.
7. Flush the NeutralSite™ and connecting catheter with a syringe filled with N/Saline after every use as per facility protocol.

PRECAUTIONS

- Only luer connectors are recommended when accessing the NeutralSite™.
- No sharp needles/instruments are to be used with the NeutralSite™.
- Ensure all connections are secure and monitored during use.
- When disconnecting, ensure the NeutralSite™ is held firmly and not held below on the catheter hub, as the NeutralSite™ may disconnect when twisting the corresponding luer connector.
- Ensure aseptic technique is maintained at all times when accessing the NeutralSite™ and corresponding luer connectors/catheter hubs. Once the NeutralSite™ has been disinfected, avoid contact with any non-sterile surfaces.
- 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

VENOUS ACCESS Needle Free Valves

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

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

STERILE EO MD CE 0197