

NeutralSite™

DESCRIPTION

m|devices NeutralSite™ Valve 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.

FEATURES & BENEFITS

- Flat swabable pre-slit septum
- Straight internal fluid pathway
- Low priming volume
- Neutral pressure displacement with very minimal reflux volume
- Compatible with luer lock and luer slip connectors
- Gap-less space between the septum and housing mechanically providing an effective microbial barrier against bacterial contamination
- Transparent housing for clear visibility when flushing

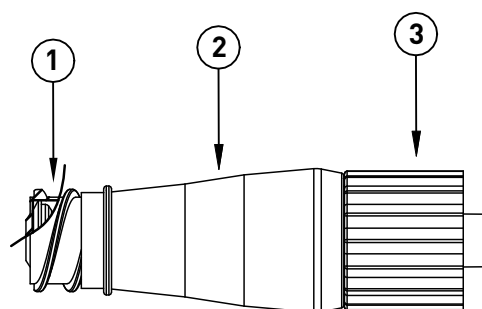
PRODUCT DATA

- Maximum flow rate at 350psi: 10mL/second
- Number of accesses: over 200 times
- Priming volume: 0.08mL
- Reflux volume: 0.0059mL
- PSI rating: 350psi
- Lipid resistant
- MRI compatible: Yes
- Not Made with DEHP
- Not Made with Natural Rubber Latex
- Recommended use of up to 7 days*
- Material: PP, ABS and silicone
- Shelf life: 3 years
- ARTG number: 355439

ISO STANDARDS

- EN ISO 8536-4:2013 Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed
- EN ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- EN ISO 10993-10:2013 Biological Evaluation of medical devices – Part 10: Tests for irritation and skin sensitisation

PRODUCT DIAGRAM



ITEM	DESCRIPTION
1	Plug
2	Upper Cover
3	Lower cover

NeutralSite™

STERILE

RE-ORDER	DESCRIPTION
IV200005	NeutralSite™

CARTON/QTY
100