

m|devices

IV072001

Closed System Transfer Set

 INSTRUCTION FOR USE

DESCRIPTION

The m|devices Closed System Transfer Set is a needle free device with multi-lumen extensions designed for efficient fluid transfer.

The configuration of the set is as below:

- 3 x Spikes
- 1 x 3-Way Stopcock
- 1 x NeutralSite™
- 4 x Female Luer Connectors
- Length 43cm

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™.
- 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. Remove product from packaging, maintaining aseptic technique.
2. Close all click clamps and close the 3-Way tap off so that the line is closed off to the distal and side port. Remove spike caps and insert into fluid bags.
3. Open the three click clamps on the spike perforator tubing lines to allow sterile fluid to flow through the tubing to the 3-Way tap.
4. Open the click clamp to the line with the NeutralSite™ and prime the tubing to the NeutralSite™. Once primed, close the click clamp.
5. Turn the 3-Way tap to open the line to the side port (first outlet of the 3-Way tap) to allow fluid to drip out to expel air. Once air has been removed, turn the 3-Way tap to indicate the flow towards the distal end of the set.
6. Open each of the remaining click clamps on the four distal tubing lines and allow fluid to flow through each lumen to the female luer connectors until all air has been expelled. Close click clamps.
7. If air is still visible in tubing lines, continue to prime until all air has been expelled.

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.

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