Bionector vs. Caresite

Comparative matrix additional information

Flushing device of blood

When you aspirate an IV line using Caresite, blood fills the positive flush chamber of the Caresite. When the device is then flushed the membrane/piston compresses/distorts and comes into contact with the inside of the device housing and trapping the blood in certain areas. This means that when you flush the device the saline cannot access this area. This is why in their IFUs they advocate that NFD is flushed at least twice with a 5ml syringe, this gives the crushable piston an opportunity to readjust the second time and hopefully expose the previously trapped blood. Interestingly in their flush study, it required 3 or 4 attempts with a 5ml flush to completely clear the housing.

See video http://player.vimeo.com/video/57960955?autoplay=1?autoplay=0

Results:
More than 98% of the haemoglobin was removed during the first flush in 14 of the 15 Caresites tested. Of these 14 devices, two were completely cleared during the first 5ml flush with the remaining 12 totally cleared with the second flush. No haemoglobin was present in the third or fourth flushes in these 14 test devices. The 15th valve had 92.3% of the haemoglobin cleared on the first flush and complete clearance with the third flush.

Conclusion:
The laboratory test for the presence of haemoglobin provides measurable data about the ability of clearing Caresite LADs of virtually all haemoglobin with two 5ml flushes of normal saline. In clinical practice, 5 to 10ml of normal saline is the most common volume used in flushing central venous catheters after each use.

BBraun's line of argument

Flat, Smooth surface, free of nooks, crannies and slits
Bionector has independent microbiological tests to show it can be effectively disinfected with a five second clean and allowed to dry. This line of argument as we know with Curos is all about time and application as all needle-free devices can be cleaned effectively, just some take longer than others based on product instructions for use.

Transparent
Bionector is proven flushable due to its straight fluid pathway. We can prove that macro and microscopic particles, for example blood, can be successfully flushed from the device with only one 5ml flush. This point of argument should focus on the flushing protocol and volume required to clear a given device based on robust testing.

Positive displacement of fluid
Bionector is neutral split septum device not a mechanical valve.

«FDA has published information that raises concerns about the safety of positive displacement needleless connectors». This kind of device, according to the FDA, may be associated with increased rates of CRBSI.[1]

Larger to promote ANTT handling

Bionector has been successfully and independently reviewed by the 'ANTT product technical assessment team', and provides unique product features which support ANTT, by utilising the non-touch port for the single bung application to prevent touch contamination (0896.21/0896.01), and a luer taper guide to help ensure the syringe is guided onto the access septum (key part), rather than slip off and be at risk of contamination.

Octopus ARV are not required as a gravity set with ARV can be used instead

BBraun are offering Intrafix Gravity Set with integrated ARV and suggesting the trust remove all ARV's from needle-free as a cost saving. Do they explain the fluid dynamics and what the consequences are of moving away from ARV's on needle-free?

- To achieve the same clinical performance as the octopus with ARVs, hospitals will need to upgrade all gravity lines, syringe driver lines and volumetric pump lines with back check valves (ARV).

Risk of removing ARV's from Needle-less Octopus extensions running two pumped infusions:

- Backtracking reflux up the lower flow rate infusion line will still occur without an occluded catheter. This will delay drug delivery of the slower infusion.
- Drug delivery delay; patient not receiving what they should as the fluid flowing at the faster rate is pushing up the slower rate line and preventing or limiting delivery of that drug.
- Drug Overdose; this will occur when a Catheter is temporarily occluded and then reopens. The subsequent impact is drug overdose to the patient
- Consequences; back tracking would be potentially significant in ANY infusion to a neonate, lipid infusions are viscus fluids given at very low rates and back tracking is not uncommon. This is very serious as neonates need lipid for their nervous system development
- Other considerations for backtracking/drug underdelivery or overdelivery;
- Significant drugs would be any vaso-active drug/inotrope such as noradrenaline, dobutamine, dopamine, dopexamine, adrenaline; anti-arrythmic drug such as amiodarone; muscle relaxants such as atracurium or vecuronium; sedatives such as midazolam or propofol; opiates such as morphine or diamorphine
  - Possibly dangerous might be anti-convulsants or asthma therapies, depending on the severity of the patients condition. (Ref: Laura Savage Clinical Trainer)
  - BBraun offer a pump admin set with ARV but this is a premium priced product and would be a significant cost pressure having to change the Infusion set more often than 7 days as with an NFD.
- Change admin set every 24/48/72hrs vs a 7 day needle-free device Higher cost pressure. Are customers comparing unit for unit or do they take into consideration that for every Bionector/Vadsite many admin sets will be needed.

1. FDA Medical Device Safety Alert, July 28, 2010: Letter to Infection Control Practitioners Regarding Positive Displacement Needleless Connectors (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm220459.htm)

VYGON Value Life

Designed and printed by Vygon (UK) Ltd.
Vygon (UK) Ltd, The Pierre Simonet Building, V Park, Gateway North, Latham Road, Swindon, Wiltshire SN25 4DL
Tel: 01793 748800 Fax: 01793 748899 Web: www.vygon.co.uk Email: vygon@vygon.co.uk @vygonuk