Bionector Clinical Performance Study: No. 2.

Is Bionector a neutral pressure/displacement needle-free device, and how does it compare to other needle-free devices currently available in the UK?

Background
Catheter occlusion is a major problem in terms of the management of vascular access devices. A number of papers currently recommend the use of neutral pressure needle-free devices to help combat the problem. As part of our ongoing programme of product development, we tested the effect on blood movement at the tip of a vascular access device when a syringe or administration set is removed from Bionector.

Objective
To demonstrate that Bionector creates the least movement of blood at the distal tip of a vascular access device when compared to our competitors, and thus can be confirmed as a neutral pressure needle-free device.

Test summary & results
In 2007 we asked Nelson Laboratories in the USA to test Bionector along with a number of other needle-free access devices currently marketed in the UK.

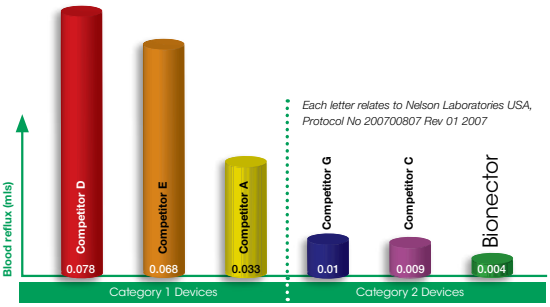
Test set-up:
2ml of red colouring was added to one litre of saline. The IV connector sample was attached to the 2Fr PICC tubing. A syringe was connected to the sample. Coloured saline was flushed through the IV connector and the tubing to prime the set-up.

IV line connector detachment:
With tubing primed to the distal end, the syringe was detached from the IV connector. The amount of fluid movement at the distal tip was measured with a balance or ruler. The line was re-primed for the next sample. The IV line connector detachment phase was performed on eight different samples at five replicates per sample.

IV line connector attachment:
After the tubing was primed, the syringe was connected to the IV connector. The amount of fluid movement was measured with a balance or ruler. The line was re-primed for the next sample. The IV line connector attachment phase was performed on eight different samples at five replicates per sample.

Conclusion
Due to the unique way in which Bionector functions, under test conditions the device displayed the least blood reflux into the tip of a VAD compared to all our competitors. The results concluded that our best performing competitor demonstrated 125% more reflux and our worst performing competitor demonstrated 1,950% more reflux.

Full Nelson Laboratories blood reflux testing study comparing Bionector to other needle-free devices currently available in the UK is available on request.



Graham Milward
Head of Technical Services & Regulatory Affairs
Vygon (UK) Ltd

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