Bionector Clinical Performance Study: No. 4.

Can we conclude that Bionector is truly a closed system?

Background

More and more emphasis is being put on how needle-free devices function and the impact that this has on the transmission of bacteria to the patient's vascular access device and thus infection. Many manufacturers suggest that transparent needle-free devices are the way forward for helping to identify when the device either needs to be replaced or when flushing has been effective (see study 3 for Bionector flushing evaluations). In terms of the device needing to be replaced, being able to see inside the device is not a very conclusive way to ensure that bacteria has not colonised the space, because bacteria is of course microscopic.

Objective

As part of our ongoing programme of product development, we deliberately contaminated the internal mechanism of Bionector with bacteria. We then tested the device to see if any of this bacteria could be to transmitted the patient's vascular access device.

Test summary & results

In 2007 we tested Bionector at the respected Health Protection Agencies (HPA) Porton Down Laboratory in Wiltshire.

Five Bionectors (male/female luer-lock connector), pre-damaged to simulate a crack in the female luer of the casing, were individually connected upstream via tubing to a sterile saline bag and downstream to a sterile collection vessel.

The five Bionectors were then immersed in a suspension of more than 108cfu/ml Brevundimonas diminuta over a 24 hour period. The saline was run through the Bionector and tubing, and held for a 24 hour period.

After this time, the remaining fluid in the five bags was emptied via the Bionector and tubing into the five downstream collection vessels over a one hour period. The saline collected in each of the downstream vessels was filtered through a 0.2µm polycarbonate filter. The filters were then placed onto agar plates and incubated at 30ºC ± 2ºC for 48 hours.

The five filters showed no growth of Brevundimonas diminuta. Therefore, under these test conditions, even with a crack in the female luer, there was no evidence of penetration of micro-organisms into the sterile line.

Conclusion

No growth occurred after 48 hours incubation at 30ºC ± 2ºC in 500ml of sterile saline (x 5) travelling through five sterile Bionectors (male/female luer-lock connector), pre-damaged to simulate a crack in the female luer of the casing. The Bionectors had been immersed in a high concentration suspension (>108cfu/ml) of Brevundimonas diminuta for over 24 hours to create a worst-case scenario. Under these rigorous test conditions, there is no evidence of bacteria entering the sterile line.

Complete HPA test data including the full protocol and results are available on request.

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

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