



# Bionector Clinical Performance Study: No. 1.

Can Bionector be effectively disinfected with 2% chlorhexidine in 70% alcohol?

## Background

As more and more needle-free devices are brought to market in the UK, some manufacturers/suppliers have made claims regarding hypothetical superior 'cleanability' of their device due to the design and construction of device's membrane. Some customers tell us that they have been shown a test using ultraviolet light to demonstrate that their device glows less than Bionector after it is cleaned. Another manufacturer/supplier will tell you that even if you don't clean their device it will transmit fewer bacteria to the patient's vascular access device than Bionector.

As part of our ongoing programme of product development, we tested the 'cleanability' of the Bionector membrane using the latest cleaning agent at the respected Health Protection Agencies (HPA) Porton Down Laboratory in Wiltshire in May 2009.

## Objective

To demonstrate that the Bionector membrane can be effectively cleaned using 2% chlorhexidine in 70% alcohol solution.

## Test summary & results

Ten Bionectors were assessed to check whether they prevent microorganisms entering the bloodstream of patients. Prior to the test a sterile 100mm extension line was connected to the male luer of the Bionector. A sterile 5ml syringe filled with Phosphate-Buffered Saline (PBS) was luer-locked onto the female end of the Bionector, and 2ml of the saline solution was passed through the device. Each Bionector was then deliberately contaminated on the external surfaces of the female luer using a microbial culture, staphylococcus epidermidis NCIMB 12721. The inoculated Bionector was allowed to dry at room temperature for 30 minutes.

The contaminated surface was swabbed for approximately 5 seconds using sterile 2% chlorhexidine in 70% alcohol wipes (Sanicloth). After the cleaning process, a sterile 5ml syringe was filled with sterile nutrient broth, and 2ml of broth was passed through the inoculated and swabbed Bionector into a culture tube containing culture broth. The culture tube was incubated at 37°C for 72 hours and observed daily for any growth. The culture tubes showed no growth of staphylococcus epidermidis. Therefore, under these test conditions there was no evidence of penetration of microorganisms into the sterile line when the Bionector was swabbed with a sterile disinfectant.

## Conclusion

If Bionector is cleaned using an appropriate disinfectant, no bacteria is transmitted to the patient's vascular access device. We would urge you to ask any manufacturer who makes a claim that their needle-free device is more 'cleanable' than Bionector to show you a comparative microbiological report that proves it.

*Complete HPA test data comparing the cleanability of MicroClave to Bionector and Maxguard to Bionector are available on request.*

## Graham Milward

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