IV THERAPY

Closed Needleless Connectors

bionector®

Clinical Performance Studies

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bionector® Clinical Performance Studies

The following five Clinical Performance Studies are summaries only. The full protocols and results are available in the Bionector Electronic Handbook. Please contact us or request a copy of the Bionector Electronic Handbook directly from your local Sales Executive.

When deciding which needleless connector to choose for your hospital, it is important to ensure that your choice meets the current 'global standards' for these devices. The global opinion leaders make a number of recommendations in terms of the essential features you should demand when choosing a needleless connector.[1,2,3,4]

We have designed Bionector to meet these standards and furthermore, our clinical performance studies provide the evidence to support our claim that Bionector meets these standards.

What do the global opinion leaders recommend?

- A needleless connector that is supported by microbial ingress testing data.[1]
- A split septum needleless connector device is associated with a lower incidence of CRBSI compared to a mechanical valve needleless connector device.[2,4]
- A needleless connector with a smooth external septum surface with few, if any gaps, that can be more thoroughly disinfected.[3]
- A tight seal between the septum and the needleless connector housing to reduce or eliminate space for contamination to occur and biofilm to develop.[3]
- A needleless connector with a direct, that is, straight fluid pathway that facilitates adequate flushing and reduces the internal surface for biofilm development.[3,4]
- A needleless connector with the most direct and least tortuous fluid pathway, with preferably no moving parts to reduce the potential risk of CRBSI.[3]
- A needleless connector with little or no dead space in the fluid pathway minimises the surfaces that infusates can contaminate and where biofilm can develop.[3]
- A needleless connector that does not require a clamping sequence.[3]
- A luer access mechanical valve needleless connector with little or no blood reflux.[3,4]

bionector® Clinical Performance Study 1[5]

Can Bionector be effectively disinfected?

Background

As more and more needleless devices are brought to market, some manufacturers/suppliers have made claims regarding hypothetical superior 'cleanability' of their device due to the design and construction of the 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 UK in May 2009.

Objective

To demonstrate that the Bionector membrane can be effectively disinfected.

Test summary & results

Ten Bionectors were assessed to check whether they prevent microorganisms entering the patients bloodstream. 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 Bionectors were 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 needleless device is more 'cleanable' than Bionector to show you a comparative microbiological report that proves it.

bionector® Clinical Performance Study 2[6]

Is Bionector a neutral pressure/displacement needleless device, and how does it compare to other needleless devices?

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 needleless 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 connected to 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 needleless device.

Test summary & results

In 2007 we asked Nelson Laboratories in the USA to test Bionector along with a number of other needleless access devices currently available on the global market.

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:

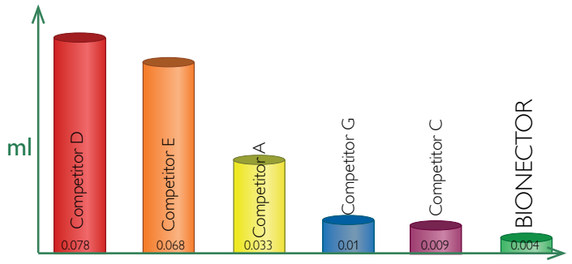
With the tubing primed to the distal end, the syringe was detached from the IV connector. The amount of fluid movement at the distal tip was measured with a ruler. The line was re-primed for the next sample. The IV line connector detachment phase was performed on eight different samples at five replicates 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 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 our competitors. The results concluded that our best performing competitor demonstrated 125% more reflux and our worst performing competitor demonstrated 1,950% more reflux.



bionector® Clinical Performance Study 3[7]

Is it possible to clear blood from Bionector following blood administration or blood sampling?

Background

More and more emphasis is being put on the ability to prove that blood can successfully be flushed/eliminated from needleless devices. This is due to the risk of biofilm formation which can increase the risk of catheter colonisation and thus catheter related blood-stream infection. Some needleless devices have a clear housing so the fluid pathway can be visualised post-flush. Of course having a transparent housing does allow the user to determine when macroscopic blood is present. However, can they conclude at what point microscopic blood has also been eliminated?

Objective

In April 2013, we tested Bionector at Nelson Laboratories, Salt Lake City, Utah, USA, to demonstrate whether the device can be successfully flushed and to conclude experimentally what volume of flush is required to eliminate blood from the device.

Test summary & results

The procedure was designed to determine the effectiveness of 0.9% saline in flushing the test article after blood exposure. The design involved injecting human citrated blood through the test article, flushing 0.9% saline through the device and collecting the flushed solution. The flushed solutions were then analised to determine the amount of haemoglobin present. Multiple flushes were conducted to determine the residual amount of haemoglobin present after each flush.

Conclusion

The test results demonstrate that blood can effectively be flushed from Bionector using normal saline. 99.697% of the blood challenged was cleared with the first 5ml flush.

Results

The result below contains the average optical density reading, the average amount of haemoglobin present and the percentage for the first saline flush only.

Device	Average OD (optical density)	Haemoglobin Present (mg/ml)	Percent Recovery
Bionector	**0.591**	**85.489**	**99.697%**

bionector® Clinical Performance Study 4[8]

Can we conclude that Bionector is truly a closed system?

Background

More and more emphasis is being put on how needleless devices function and the impact that this has on the transmission of bacteria into the patient's vascular access device and thus infection. Many manufacturers suggest that transparent needleless devices are the way forward for helping to identify when the device either needs to be replaced or when flushing has been effective (see section 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 transmitted to 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 UK.

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 30°C ± 2°C 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 30°C ± 2°C 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.

bionector® Clinical Performance Study 5

How does Bionector function?

Background

Following the publication of the CDC guidelines[2], there has been a great deal of discussion regarding the design of needleless connectors and their functionality. Our Clinical Performance Studies regarding microbial ingress and membrane/septum disinfection conclude that Bionector can be cleaned effectively and resists the entry of bacteria to the patients' vasculature. However, according to the CDC classification, is Bionector a split septum or mechanical valve needleless connector?

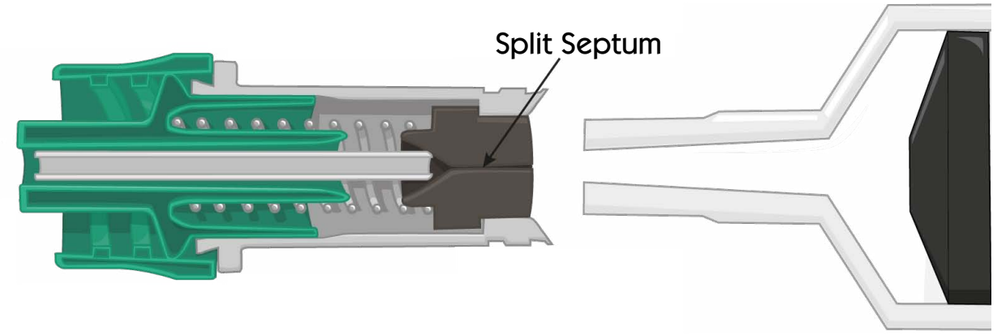
Objective

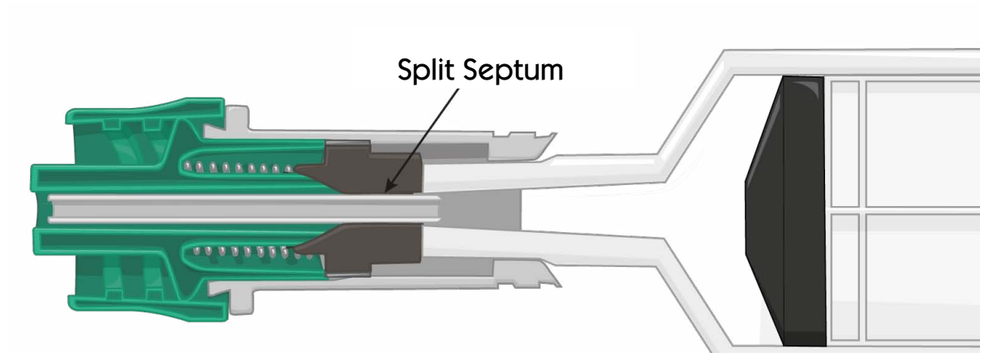
To define which of the above categories defines the functionality of Bionector.

Summary

Bionector has an internal pin which interfaces with the split in the septum of the membrane from below as the tip of a syringe or infusion set depresses the membrane during connection.

Bionector is best defined as a split septum needleless connector in terms of its functionality.





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