IV THERAPY

Closed Needleless Connectors

# vadsite®
## Clinical Performance Studies

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# vad**site**® Clinical Performance Studies

The following four Clinical Performance Studies are summaries/abstracts, the full protocols and results are available in the Vadsite Handbook. Please contact us directly or request the Handbook directly from your local Sales Executive.

When deciding which needleless connector to choose for your hospital, it is important that you ensure that your choice meets the current 'global standards' for these types of devices. The global opinion leaders make a number of recommendations in terms of the essential features you should look for when choosing a needleless connector[1,2,3].
We have designed Vadsite to meet these requirements and furthermore, our Clinical Performance Studies provide the evidence to support our claim that Vadsite meets this criteria.

## What do the global opinion leaders recommend?

- A needleless connector that is supported by microbial ingress testing data.[(1)]
- A split septum needleless connector is associated with a lower incidence of CRBSI compared to a mechanical valve needleless connector.[(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. Or, alternatively, use only one needleless connector type that requires a specific clamp-disconnection sequence (e.g., all negative pressure, all positive pressure or all neutral pressure) throughout the healthcare facility or system and insure that all Healthcare Workers understand and are well trained in this clamp-disconnection sequence.[(3)]
- A transparent needleless connector is preferable to one that is opaque. [(3)]



# vad**site**® Clinical Performance Study 1[(5)]



Can we conclude that Vadsite is truly a closed needleless device and it can resist bacterial ingress into the patient's fluid pathway?

## Background

The Food and Drug Administration Agency (FDA) has detailed a number of standards which the manufacturers of needleless connectors must ensure their devices reach in terms of microbial testing. A needleless device that facilitates bi-directional fluid flow may increase the patient's risk of infection because these features allow the entry of microorganisms into the sterile fluid path. We recommend that you (the manufacturer) conduct microbial ingress testing of these devices.

We recommend that you provide results from a simulated use test for microbial ingress in your device. Testing should simulate the use of the device in a clinical setting, i.e., the number of microbial challenges in the study should approximate the number of user interactions with the access site that would be expected clinically. The testing should demonstrate that the disinfection procedures you use are effective. We recommend that you provide an analysis of the study results and a summary of the results and conclusions.

## Objective

We tested 54 Vadsites to confirm whether the device allows bacteria to enter the fluid pathway whilst the device is connected at both the male and female luers (connections)?
The test is designed to simulate the connection between a vascular access device, Vadsite and a fluid administration set/extension line.

## Test summary & results

Each Vadsite was connected at the female luer with an extension line with integrated 3-way tap, and on the male luer with a straight fluid administration extension line. A syringe containing sterile thioglycolate broth was then injected into the 3-way tap, thus priming the entire assembly from the 3-way tap, through the Vadsite and into the straight fluid administration line. The entire primed assembly was then immersed in a highly concentrated bacterial broth for 8 days at body temperature. After 8 days the thioglycolate broth in the assembly was flushed into a test tube and this fluid incubated for a further 7 days at body temperature. Following the 7 day incubation, the fluid in the test tube was tested to determine whether or not any bacteria from the highly concentrated bacterial broth had entered the assembly.

## Conclusion

Every Vadsite sample showed no bacterial growth. Thus a Vadsite that has been connected at both ends and then immersed in a highly concentrated bacterial broth for 8 days can resist the ingress of bacteria into the fluid pathway.

# vadsite® Clinical Performance Study 2[6]

## Can we conclude that Vadsite can be effectively cleaned using standard hospital disinfectants?

## Background

The Centre for Disease Control[1], the Infusion Nurses Society[2] and William Jarvis[3] have all confirmed the need to be able to adequately disinfect the membrane/septum of needleless connectors to inhibit the passage of microorganisms into the patient's vasculature. It is common sense to conclude, that a needleless connector, that is easy to clean and has a microbiological study, is essential in terms of reducing the risk of CRBSI.

## Objective

A 2 part study to conclude that the Vadsite septum can be effectively cleaned using standard hospital disinfectants (2% chlorhexidine + 70% isopropyl alcohol) and that no bacteria is transferred to the fluid pathway and the patient's vasculature.

## Test summary & results

**Part 1:Validation of septum disinfection.**

1. The devices were registered on arrival and delivered to the laboratory in their packaging.
2. Two (2) connectors remained un-inoculated as negative control samples.
3. Seven (7) connector septums were inoculated using a suspension of S.epidermidis at a final concentration of $10^6$ and allowed to dry for 30 minutes. Once inoculated, two samples were maintained as positive controls and as such did not undergo disinfection. The remaining five (5) were disinfected as described below.
4. The disinfection process was conducted using 2% w/v chlorhexidine + 70% v/v isopropyl alcohol wipes (Briemarpak: Product code CW1000: Exp 11/15). Each of the five (5) test devices was disinfected by cleaning in a circular motion for 5 seconds using a wipe.
5. Each device was placed into 100mL of 0.1% peptone water (PW) and rinsed by physical agitation for 2 minutes.
6. The devices were then aseptically removed and serial dilutions from this first wash made in peptone water and plate counts made on Baird Parker agar (BPA).
7. The plates were incubated at 37°C for 48h and typical Staphylococcus epidermidis colonies counted to represent the total number of viable microorganisms. This count represented the number of viable microorganisms on the connectors.

**Part 2: Validation of the sterile fluid delivery post disinfection.**

1. The devices were registered on arrival and delivered to the laboratory in their packaging.
2. Five (5) connectors remained un-inoculated as negative control samples.
3. Fifteen (15) connectors were inoculated using the suspension of S.epidermidis as described in part 1. Once inoculated, five samples were maintained as positive controls and as such did not undergo disinfection.The remaining ten (10) inoculated samples were disinfected as described below.
4. The disinfection process was conducted using 2% w/v chlorhexidine + 70% v/v isopropyl alcohol wipes (Briemarpak: Product code CW1000: Exp 11/15). Each of the five (5) test devices was disinfected by cleaning in a circular motion for 5 seconds using a wipe.
5. Each device (inoculated, negative controls, positive controls) was analyzed using the procedure described as follows.

i. A 10mL syringe was filled with sterile 0.1% peptone water and luer locked onto the female end of the connector.
ii. 10ml of the sterile diluent was passed through the connector and collected into a sterile jar.
iii. Each collection fluid was analyzed by filtration using a 0.45µ filter using Advanced Analytical method 09-502 (mod).
iv. The filter was aseptically removed and placed onto the surface of a Baird Parker agar (BPA) plate.
v. All plates were incubated at 37°C for 48h.
vi. After incubation all plates were examined for typical growth of Staphylococcus epidermidis colonies.





## Results

**Part 1:Validation of disinfection**.
The results for all test samples analyzed post disinfection indicate that S.epidermidis was undetectable (<1cfu/device) for all samples. As such the results validate a 6-log reduction of S.epidermidis on the devices using the prescribed disinfection procedure.

**Part 2:Validation of the sterile fluid delivery post disinfection.**
The results indicate that the diluent passed through ten (10) inoculated and disinfected connectors remained sterile. There was no positive growth of the target organism identified in any of the filtered samples plated onto BPA. As such the disinfection procedure was able to eliminate S. epidermidis and ensure an aseptic transfer of sterile solution through the connector.

## Conclusion

Vadsite can be easily cleaned using 2% chlorhexidine + 70% isopropyl alcohol following a 5 second decontamination process.

# vad**site**® Clinical Performance Study 3[7]

## Is it possible to clear blood from Vadsite 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.

### Objective

In April 2013, we tested Vadsite 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 be flushed effectively from Vadsite using normal saline. 99.629% of the blood challenged was cleared with the first 5ml flush.

| Device | Average OD (optical density) | Haemoglobin Present (mg/ml) | Percent Recovery |
|---|---|---|---|
| **Vadsite** | **0.595** | **85.154** | **99.629%** |



# vad**site**® Clinical Performance Study 4



## How does Vadsite 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 Vadsite can be cleaned effectively and resists the entry of bacteria to the patient's vasculature. However, according to the CDC classification, is Vadsite a split septum or mechanical valve needleless connector?

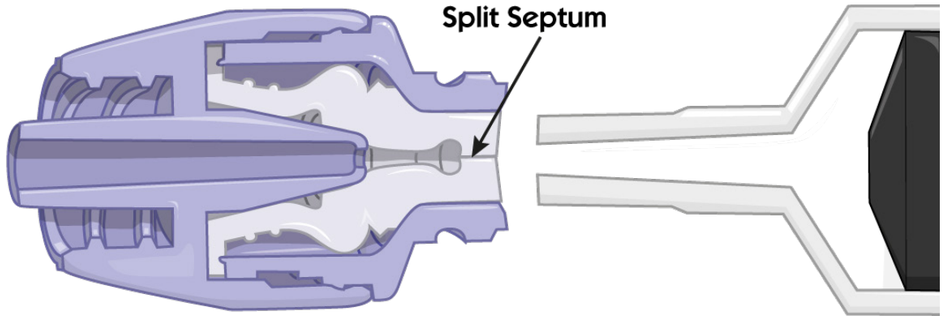
### Objective

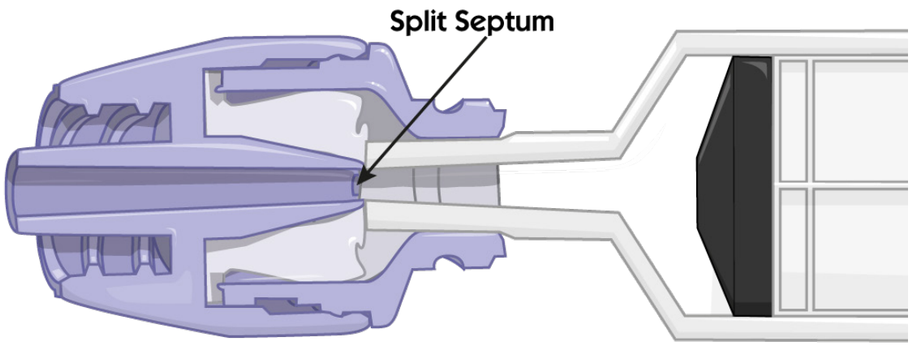
To define which of the above categories defines the functionality of Vadsite.

### Summary

Vadsite 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.

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



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