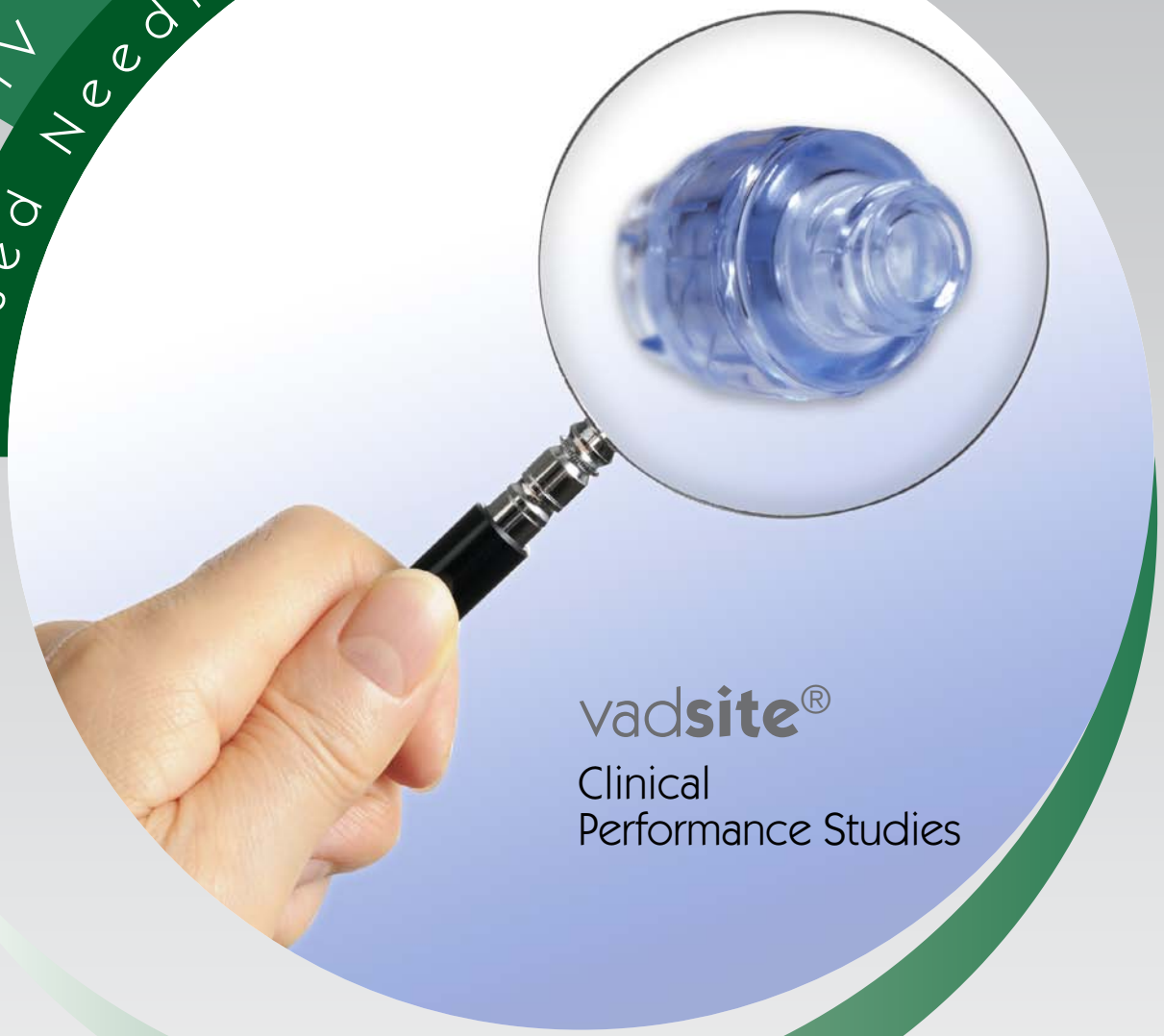
IV THERAPY

Closed Needleless Connectors



vadsite®

Clinical Performance Studies

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vadsite® 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]

vadsite® 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 ahighly 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

To conclude that Vadsite can be effectively cleaned using standard hospital disinfectants.

Test summary

60 Vadsites were contaminated with Staphylococcus Aureus of approximately 108 Colony Forming Units (CFU) per ml. 6 contaminated samples were retained to test the level of bio-burden (control).

Each Vadsite was then placed in a sterile container containing 10ml of Tryptone salt with Tween and then mixed using a vortex shaker for 30 seconds. Serial dilutions were made from each extracted liquid then incubated for 2 days at 36°C. Each Vadsite was then cleaned for 5 seconds with gauze soaked in Hibisprint and allowed to dry for 30 seconds.

5ml of sterile Tryptic soy broth was then injected through each Vadsite via a syringe. This broth was then collected and incubated for a further 3 days at 36°C and then examined for bacterial growth (Staphylococcus Aureus).

Conclusion

According to this test, we can conclude that Vadsite can be effectively cleaned using standard hospital disinfectants.

vadsite® 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%**

vadsite® Clinical Performance Study 4

How does Vadsite function?

Background

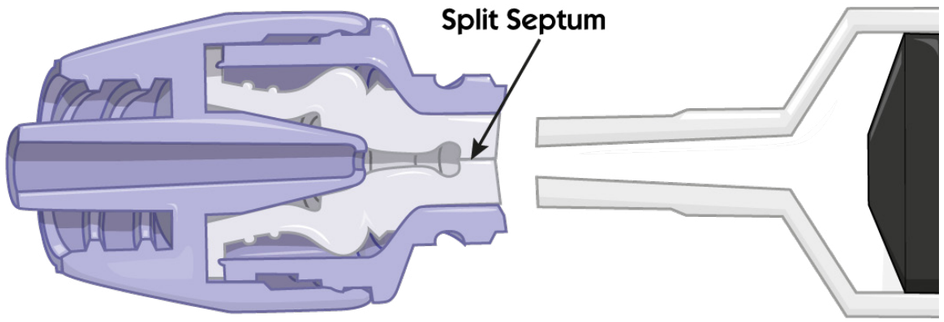
Following the publication of the CDC guidelines[2], there has been a great deal of discussion regarding the design of needleless connectors and their functionality. Our Clinical Performance Studies regarding microbial ingress and membrane/septum disinfection conclude that Vadsite can be cleaned effectively 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?

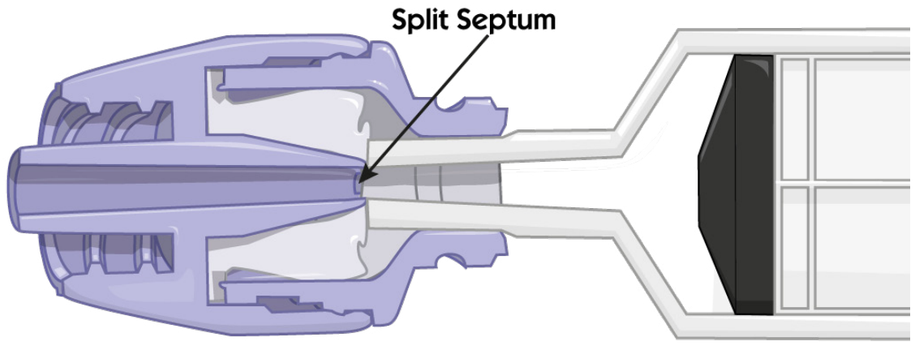
Objective

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.





References

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