B BRAUN
SHARING EXPERTISE

IV Accessories

CARESITE®
LUER ACCESS DEVICE

CLINICAL EVIDENCE SUMMARY

Content Overview
Caresite® Luer Access Device

INTERNAL LABORATORY TESTS

LABORATORY PUBLICATION

FEATURES & BENEFITS

1. Caresite® Luer Access Device can be effectively cleared of blood

Blood Clearance Test of the Needleless Connector (2010) - Engineering data on file.

1.1 DESIGN

The laboratory test was conducted in order to assess the capability of Caresite® Luer Access Device (LAD) to be cleared of blood with flushing procedures. This was determined by the measurement of hemoglobin, the oxygen-carrying protein attached to red blood cells.

1.2 METHOD

15 of Caresite® LADs were tested by attaching them to a catheter while a 5 ml syringe was attached to the opposite side of the Caresite®. The rabbit blood sample was drawn through the catheter and Caresite® into the syringe.

This process was followed by flushing each Caresite® with 5 ml of sterile saline, which was later collected in a sterile tube and tested. This procedure was repeated three more times for each of the 15 Caresite® LADs.

1.3 RESULTS

More than 98 % of the hemoglobin was removed during the first flush in 14 of the 15 Caresite® LADs tested. Of these 14 devices, 2 Caresite® LADs were completely cleared during the first 5 ml flush while the remaining 12 totally cleared with the second flush.

No hemoglobin was present in the third or fourth flushes in these 14 test devices. The 15th needleless connector had 92.3 % of the hemoglobin cleared on the first flush and complete clearance with the third flush.

1.4 KEY FINDINGS

The laboratory test results showed that 14 of the 15 Caresite® Luer Access Devices (LADs) can **be cleared of virtually all hemoglobin** with two 5 ml flushes of normal saline.

2. Caresite® Luer Access Device helps to prevent microbiological contamination.

7-Day Microbial Barrier Performance Test (2017) - Engineering data on file.

2.1 DESIGN

The laboratory test was conducted in order to quantify the risk of transfer of organisms through the Caresite® Luer Access Device (LAD).

2.2 METHOD

24 test samples of Caresite®, along with positive and negative controls, were studied. All the samples were twice sterilized before the test, by using ethylene oxide. The Caresite® devices and the positive control devices were challenged with four species of organisms:

- Staphylococcus aureus
- Staphylococcus epidermidis
- Pseudomonas aeruginosa
- Escherichia coli

After contaminating the needleless connectors, they were disinfected, flushed and activated. The negative controls were also run concurrently. This procedure was repeated in the same manner over a 7-day period.

2.3 RESULTS

The table below lists the results of the tested Caresite® LAD for the 7-day period. Devices growing greater than 15 colony forming units (CFU) are reported as this is a primary criterion for diagnosing catheter colonization. The results of the laboratory test show that each Caresite® LAD met the criteria for all bacteria challenges over the 7-day test period.

Devices growing greater than 15 cfu

Organism	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Staphylococcus aureaus	0	0	0	0	0	0	0
Staphylococcus epidermidis	0	0	0	0	0	0	0
Pseudomonas aeruginosa	0	0	0	0	0	0	0
Escherichia coli	0	0	0	0	0	0	0

2.4 KEY FINDINGS

The laboratory study shows that Caresite® Luer Access Device **prevents passage of tested organisms** through the needleless connector. The cleaning and disinfection methods performed in this study are the manufacturer's recommendation for **best practice to ensure proper surface maintenance** of the Luer Access Device.

3. Caresite® Luer Access Device demonstrates that blood samples can be obtained through this Luer Access Device.

Mechanical Hemolysis Test of the Needleless Connector (2010) - Engineering data on file.

3.1 DESIGN

The Caresite® Luer Access Device was tested in order to determine the percent of hemolysis produced.

3.2 METHOD

15 of Caresite® LADs were compared to 15 Ultrasite LADs. Both groups were tested for aspiration or drawing blood from the device and injecting blood through the device.

3.3 RESULTS

The positive controls (100 % hemolysis) produced high absorbance values while the negative controls (0 % hemolysis) produces low absorbance values. The average hemolysis for the Caresite® group was 0.4 % for blood aspiration and 0.2 % for injection.

The average hemolysis for the Ultrasite® LAD was 0 % for blood aspiration and 0 % for injection. The samples from the syringe alone without the addition of an LAD produced 0.8 % hemolysis for aspiration and injection.

3.4 KEY FINDINGS

Caresite and Ultrasite Luer Access Device demonstrates that blood samples can be obtained through the device, **reducing the risk for hemolysis.**

4. The positive displacement needleless connectors were associated with ingress of significantly fewer microorganisms compared with several of the other devices tested.

Casey, A; Karpanen, T; Nightingale, P; Elliott, T. A Laboratory Comparison of Microbial Ingress into Eight Different Needleless IV Access Devices. J Infus Nurs. Jan-Feb 2015;38(1):18-25. DOI: 10.1097/NAN.0000000000000082.

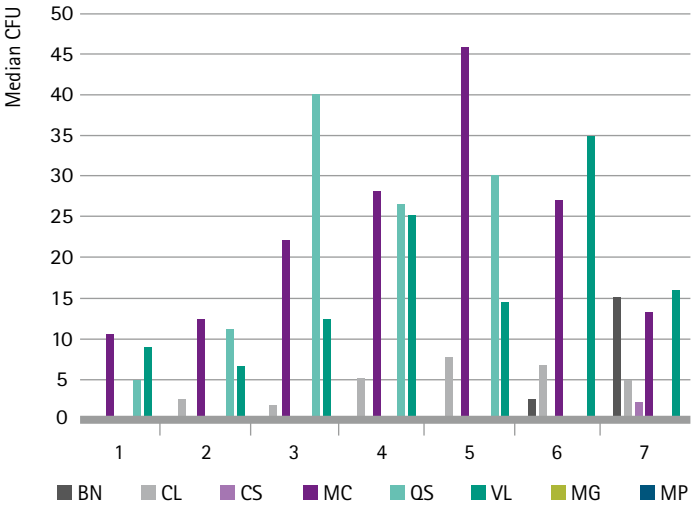
4.1 DESIGN

Identification of differences between the rates of microbial ingress into 8 different needleless IV access devices after contamination. 24 of each needleless connector were subjected to a simulation of microbial contamination of the injection site and decontamination followed by saline flushes through repeated procedure over the 7-day period.

4.2 METHOD

The simulation of clinical use involved consecutivley innoculating the needleless connector with Staphylococcus aureus, followed by decontamination of the needleless connector with isopropyl alcohol wipe (70%), flushing, and finally, connecting a male luer to the needleless connector.

4.3 RESULTS



Median CFU of Staphylococcus aureus recovered from each daily saline eluate of 8 different needleless IV access devices over 7 days of simulated clinical use with a 5-second cleaning regimen (n = 12). Abbreviations: BN, Bionector; CFU, colony-forming unit; CL, Clave; CS, CareSite; IV, intravenous; MC, MicroClave Clear; MG, MaxGuard; MP, MaxPlus Clear; QS, Q-Syte; VL, V-Link.

The graphic shows differences of eight different needleless connectors in the number of CFU (colony-forming units) of Staphylococcus aureus over the 7-day period. The positive displacement needleless connectors, including Caresite®, were associated with ingress of significantly fewer microorganisms compared with several of the other devices tested.

4.4 KEY FINDINGS

Caresite®, as a positive displacement needleless connector tested in the study, was **associated with ingress of significantly fewer microorganisms.** This result may has been related to the product design and mainly to the injection site of the tested positive displacement needleless connectors, which may have influenced the efficacy of the decontamination process.

5. Caresite® Luer Access Device forms a closed system as it is designed to prevent microbial ingress and the escape of contaminants.

Brünke, J. Closed infusion systems prevent microbial contamination. (2017)

5.1 DESIGN

The aim of the laboratory study was to prove the microbial barrier function of the connections of a typical infusion system that are exposed to microbial contamination. The study was performed under controlled conditions and two test scenarios were investigated:

- Touch contamination
- Airborne contamination

The contamination was carried out with three different, but clinically relevant pathogens:

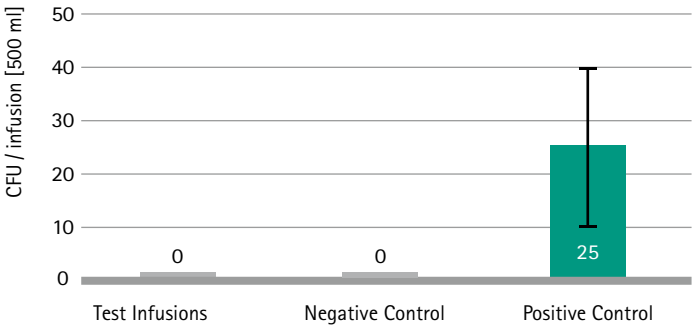
- Staphylococcus epidermidis
- Escherichia coli
- Candida albicans

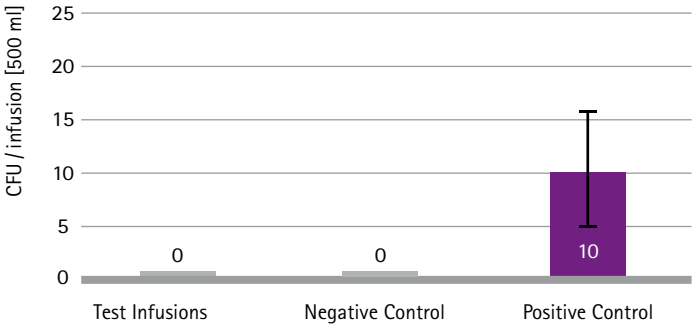
5.2 METHOD

Touch / microbial contamination:
The products were contaminated with the pathogens and afterwards disinfected with Softa® Cloth. Afterwards they were connected to each other to collect, centrifuge and analyze infusion solution for bacterial contamination.

Airborne contamination:
All materials were placed inside the aerosol chamber. An aerosol was generated and then the connection sites were disinfected with a Softa® Cloth. The infusion setup was then connected to ensure collection, centrifugal coating and analysis of the infusion solution for bacterial contamination.

5.3 RESULTS





The results showed that no microbial contamination was detected in any of the five Caresite® extension sets tested, in the both touch and airborne contamination.

5.4 KEY FINDINGS

The results showed that the tested infusion system components **act as a microbial barrier**, providing they are applied according to instructions for use and guidelines. Presented data confirmed that not only individual parts of an infusion system, but also a complete infusion system, can be classified as a closed system according to the guidelines for hand and airborne microbial contamination.

Caresite® Luer Access Device
Positive Displacement Needleless Connectors

CARESITE® LUER ACCESS DEVICE

CARESITE® IS DESIGNED TO MAKE ACCESS CLEAR AND EASY.

Caresite® Luer Access Device with positive displacement feature is designed to help reduce catheter occlusions while preventing healthcare workers from accidental needlestick injuries. Input from clinicians provided the basis for the Caresite® design. The result is a device designed to help improve outcomes and efficiency.[1,2,3,4]

DESIGNED TO MINIMIZE SLIPS AND TOUCH CONTAMINATION

Ergonomic design provides easy access by allowing a good grip and easy connection.

ONLY FOR LUER ACCESS DEVICE (NEEDLELESS CONNECTOR):

- **Flow rate:** 208 ml/min
- **Pressure resistance** Up to 400 psi @ 15 ml/sec
- **Low priming volume*** 0.22 ml
- **Low retained volume*** 0.20 ml

*compared to other positive Luer Access Devices

CONNECT

Requires low insertion force when connecting.

VISUALLY INSPECT

Clear design helps verify proper flush.

CLEAN

Smooth surface permits easy cleaning.

Literature: 1. Infusion Therapy Standards of Practice, Journal of Infusion Nursing (Jan/Feb 2016, Volume 39, Number 1S, Page 152). | 2. Silverstein S. Efficacy of a "saline only" flush protocol utilizing the Ultrasite® positive displacement device. Nurse Consultant, Omnicare Infusion Services of Northern Illinois, January 2003. | 3. Berger L. The effects of positive pressure devices on catheter occlusions. Journal of Vascular Access Devices, Volume 5, Issue 4, 2000, Page 31-33. | 4. Leone M. Dillon R. Catheter outcomes in home infusion. JIN March/April 2008 Vol 31, No2.

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