CARESITE MICRO™ LUER ACCESS DEVICE (LAD) :

7-Day Microbial Barrier Study

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Abstract

Numerous factors may contribute to the risk of bloodstream infection such as the design of the connection surface, internal mechanism of the device, and extreme variations in clinical technique for cleaning the device.

CARESITE MICRO is a needleless connector with a split-septum and straight fluid path. An independent laboratory tested the CARESITE MICRO LAD to quantify the risk of transfer of organisms through the device.

This study demonstrates over the course of seven (7) days, that the CARESITE MICRO LAD prevents passage of tested organisms through the needleless connector following thorough, well-defined cleaning before each use.

Methods

Following the recommendation for microbial ingress testing from the United States Food and Drug Administration (FDA) Guidance for Industry and FDA Staff, Intravascular Administration Sets Premarket Notification Submissions [510(k)], July 2008, thirty-two (32) test samples of CARESITE MICRO, including positive and negative controls, were studied. All needleless connector samples were sterilized twice using ethylene oxide and accelerated aged for the equivalent of 5 years prior to testing.

The CARESITE MICRO test devices and the positive control devices were challenged with four (4) species of organisms, two gram positive and two gram negative, including Staphylococcus aureus, Staphylococcus epidermidis, Pseudomonas aeruginosa, and Escherichia coli. All species were supplied by ATCC, a major provider of microorganisms for scientific testing purposes. All species were prepared using the same process. To ensure adequate viability of the organism, fresh solution was prepared daily using the same procedure. The challenge organism was incubated for 24-48 hours at 30-35° C. A suspension for each organism was prepared and the concentration of the bacterial culture was adjusted to 10^8 CFU/mL utilizing a spectrophotometer and diluted in sterile saline to a concentration greater than 2 x 10^5 CFU/mL.

Each valve was disinfected by swabbing the valve inlet surface vigorously with a 70% Isopropyl alcohol (IPA) pad for 15 seconds and allowed to air dry. The inlet or connection surface of the test devices were then inoculated with 5 uL of the challenge organism solution and allowed to set for 60 seconds. After inoculation and the set period, the connection surface was again disinfected by swabbing the top of the LAD vigorously with a new 70% Isopropyl alcohol pad for 15 seconds. The alcohol pad was discarded, and the connection surface allowed to air-dry.

Microbial recovery was performed by flushing each sample, and the effluent from simulated administrations was collected, passed over a 0.45 µm filter, and transferred to Trypticase Soy Ager (TSA) plates for incubation at 30-35° C for four (4) days.

On each of the 7 days, the test articles were activated fifteen (15) times a day, making sure to use a new sterile syringe each time and disinfecting the valve prior to each syringe access, allowing the valve to air dry after each swabbing. The challenge was performed at the beginning of Day 1 and the end of Day 2 through 7.

For each challenge organism, two (2) samples were used as positive controls (challenged and not disinfected), and two (2) samples were used as negative controls (not challenged but disinfected). The controls were run concurrently with the test articles, and all devices were kept in ambient temperature under the laminar flow hood until the next day procedure.

Results

The table below lists the results of the tested CARESITE MICRO LAD for all seven (7) days. The test criteria applied was "No observable colonies" (NOC). Each CARESITE MICRO device met these criteria for all bacteria challenges over the seven (7)-day test period.

These results show no microbial ingress.

Test Results for Caresite Micro Test Articles

Devices Exhibiting Observable Colonies							
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

For all challenge strains, the devices were challenged with greater than 10^3 CFU/article and the appropriate indicator strain was recovered from positive control samples. No microorganisms were recovered from the negative control and media controls, satisfying the assay validity requirements.

Conclusion

This study demonstrates that the CARESITE MICRO LAD satisfies the acceptance criteria for microbial ingress and demonstrates that swabbing with fifteen (15) seconds with 70% IPA is an effective sanitization procedure after multiple microbial contamination events over the course of a seven (7) day simulated access protocol.

Discussion

Introduction of organisms is possible with each manipulation of the catheter hub including administration of fluids and medications, changing I.V. administration sets and needleless connectors, flushing catheters to assess functionality and reduce lumen occlusion, and drawing blood samples. It is important that hospitals emphasize the need for aseptic technique when performing these luer connection hub manipulations.

The cleaning methods performed in this study are the manufacturer's recommendation for best practice to ensure proper surface maintenance of the LAD. Detailed evidence-based procedures for cleaning luer connection surfaces have not been established as industry standards. The details of such a procedure should include the best agent to use, the length of cleaning time, the cleaning technique, and the length of drying time.