Using the Corvida Halo® CSTD for the prevention of microbial ingress

OBJECTIVE:

Demonstrate with a high degree of confidence that the Halo® CSTD acts as an effective tool in preventing microbial ingress into access sites of patients' IV sets. Demonstrate that even through repeated accesses of the same site with the same components, microbial ingress is prevented.

TEST METHOD:

The Halo® dry-to-dry seal connections have been designed to allow for repeated connections while preventing microbial ingress through these seals. Furthermore, FDA guidance requires that needless devices that facilitate bi-direction flow must not allow the entry of micro-organisms into the sterile fluid path[1]. Testing was performed by Nelson Laboratories Inc, an independent lab with extensive experience in biological testing.

The Halo® devices were challenged using two Gram-positive and two Gram-negative clinically relevant organisms: Staphylococcus aureus American Type Culture Collection, Staphylococcus epidermidis, Klebsiella pneumoniae, and Pseudomonas aeruginosa. A total of 60 sets of Halo® test articles were used for the test, fifteen (15) for each organism. In addition, negative and positive control devices were tested. Negative control devices were tested to demonstrate that the samples and flush fluid are sterile. Positive control devices were tested to demonstrate that the seals of the test articles were inoculated with the appropriate concentration of viable organisms. The test procedure for each set of test articles was as follows:

1. Attach Halo® Closed Vial Adaptor to sterile vial
2. Inoculate seal of Halo® Closed Syringe Adaptor and Closed Vial Adaptor with challenge organisms with a minimum of 10^3 CFU/test article; allow inoculum to dry on the seal for at least one minute
3. Thoroughly disinfect the contaminated surface of each device with 70% IPA following standard aseptic practices
4. Attach the Closed Syringe Adaptor to a 10mL sterile saline syringe, connect to the Closed Vial Adaptor, flush 10mL of saline through the device into the vial, disconnect Closed Syringe Adaptor from Closed Vial Adaptor
5. Repeat steps 2-4 a total of eight (8) cycles on day 1 and six (6) cycles on day 2
6. The flush from all cycles performed for the day is pooled for each device
7. Filter collected fluids from each set, rinse filter with at least 10mL of peptone Tween™, 0.1%, remove filter and place onto soybean casein digest agar (SDCA) plate, incubate for 2-4 days at 30-35°C
8. Plates analyzed for recover of study organisms

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RESULTS:

- Recovery of 10^4 CFU/inoculated device/organism for each positive controls
- Recovery of zero CFUs for negative controls
- Recovery of zero CFUs for each of the 60 test articles (15 per organism)

CONCLUSION:

Even after severe challenge conditions of fourteen connections, the Halo® dry-to-dry seal connections can effectively prevent microbial ingress when used with aseptic swabbing techniques. All seals in the Halo device feature a raised design to facilitate swabbing.

Reference:

1. FDA guidance document "Instravascular Administration Sets Premarket Notification Submissions [510(k)]" issued July 11, 2008.
2. Nelson Laboratories Inc. test report#784128