7 Day Extreme Use Microbial Challenge of nPulse™ Needle-free Connector

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PREFACE: A flat, smooth septum surface maintained throughout the useful life of a needle-free connector will facilitate the clinician's disinfection routine. Any gaps or openings create spaces that may not be reached during the disinfection step, which can result in the infusion of potentially contaminating pathogens into the patient's bloodstream.[1]

Toxikon Corporation (Bedford, MA, USA) conducted a study to demonstrate that microorganisms deposited upon the split septum of the nPulse™ Needle-free Connector, which had been subjected to a seven (7) day extreme use clinical simulation, do not enter the fluid path of the connector prior to or subsequent to wiping the top of the septum with an alcohol prep pad.

Septum end of nPulse™ Needle-free Connector

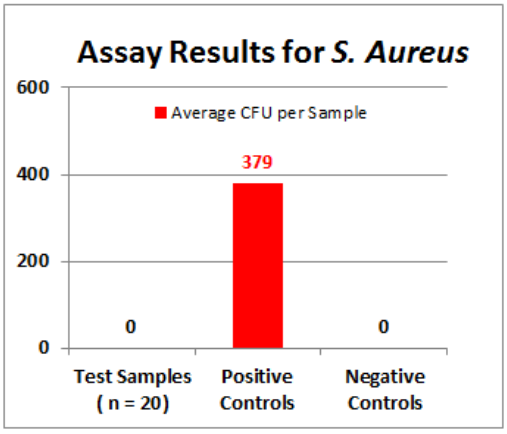
OBJECTIVE: Evaluate the microbial barrier performance of the nPulse™ Connector after subjecting it to both of the following extreme use conditions:

- Multiple activation cycles: 168 (equates to 1 per hour for 7 days)
- Extended activation period: 7 days (168 consecutive hours)

METHOD SUMMARY: A total of twenty-five (25) nPulse™ test articles (20 test samples, 3 positive control samples, and 2 negative control samples) underwent the following microbial challenge:

- 7 day extreme use conditioning via 168 activation cycles and a 168 hour activation period (with ISO Luer syringes).
- *Staphylococcus aureus* inoculation upon the device septum at a clinically high level of approximately 500 CFU[2].
- Brief incubation followed by wiping of the septum with an alcohol prep pad in accordance with Instructions For Use.
- Device connection to a 0.9% sodium chloride prefilled syringe and flushing of 10 mL through device for collection.
- Membrane (0.45 micron) filtration of collected volume and aseptic membrane transfer to the surface of a TSA plate.
- Incubation of TSA plate (inverted, 30 to 35°C for 3 days) followed by colony count determination.
- Positive controls were not wiped w/ alcohol pads after inoculation; negative controls were inoculated w/ PBS-peptone.

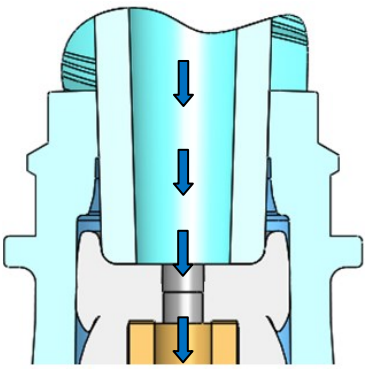
RESULTS[3]:



As shown in the adjacent table, the assay of each of the twenty (20) nPulse™ test samples showed no growth of *Staphylococcus aureus*. Moreover, the three (3) positive control samples had positive assays of 398, 372, and 366 CFU, confirming the viability of the route of administration. The two (2) negative control samples had negative assays, confirming the absence of the test organism within the system. Inoculation verification was also performed and yielded an average of 527 CFU per challenge.

CONCLUSION: The absence of *Staphylococcus aureus* in the assays of all test samples demonstrates the effectiveness of the nPulse™ Connector's microbial barrier when subjected to the noted seven (7) day extreme use challenge and used according to the Instructions For Use.

The microbial barrier performance of the nPulse™ Needle-free Connector benefits from the unique means by which the septum is opened while making a connection with an ISO male Luer connector. As depicted in the image to the right, the nPulse™ Needle-free Connector has the advantage of a self-opening split septum (SOSS™) design that avoids forcing the male Luer tip through the septum and eliminates the need for an internal cannula that drags against the critical septum seal surface.



1. Jarvis W., MD. Choosing the Best Design for Intravenous Needleless Connectors to Prevent Bloodstream Infections. Infection Control Today, July 2010, http://www.infectioncontroltoday.com/articles/2010/07/choosing-the-best-design-for-intravenous-needleless-connectors-to-prevent-bloodstream-infections.aspx
2. Larson EL, Cronquist AB, Whittier S, Lai L, Lyle CT, Della Latta P. Differences in skin flora between inpatients and chronically ill patients. *Heart Lung* 2000; **29:** 298–305. http://www.ncbi.nlm.nih.gov/pubmed/10900068
3. Data on file at Toxikon Corporation (Bedford, MA, USA).