Microbial Challenge of nSyte™ Needle-free Connector after 7 Day Use Case

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PREFACE: FDA recommends that manufacturers of needle-free connectors provide results from a simulated use test for proving resistance to microbial ingress[1]. The nSyte™ Needle-free Connector successfully passed simulated use testing[2] in accordance with FDA guidance, which targets use that would be expected clinically (i.e. microbial challenges over 4 days). A study that examines the effectiveness of the microbial barrier after extended use is also of interest.

nSyte™ Needle-free Connector

OBJECTIVE: Toxikon Corporation (Bedford, MA, USA) conducted a study of the nSyte™ Connector to demonstrate that microorganisms deposited upon its split septum following an extended use case do not enter the fluid path of the connector after proper disinfection with an alcohol prep pad[3]. Over the course of a seven (7) day use case, each day the nSyte™ Connector was subjected to:

- Connection to an ISO Luer device for 8 consecutive hours per day
- Multiple activations per day (7+) with an ISO Luer device
- Repeated daily exposure to chemical stress via 70% concentration isopropyl alcohol

METHOD SUMMARY: A total of twenty-five (25) nSyte™ Needle-free Connector test articles (20 test samples, 3 positive control samples and 2 negative control samples) underwent the following procedure as part of the microbial challenge study:

- 7 day extended use conditioning of nSyte™ with ISO Luer syringes.
- *Staphylococcus aureus* inoculation upon the nSyte™ septum of approximately 41,000 CFU (> 40x FDA guidance[1]).
- Brief incubation followed by wiping of the septum with an alcohol prep pad for 10 seconds and allowing septum to dry.
- nSyte™ connection to a 0.9% sodium chloride prefilled syringe and flushing of 10 mL through nSyte™ 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 5 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 summary table below, the assays for each of the twenty (20) nSyte™ test samples and the two (2) negative control samples showed no growth of *Staphylococcus aureus*. Moreover, the three (3) positive control samples showed microorganism growth that was too numerous to count (TNTC), confirming the viability of the route of administration. Inoculation verification yielded an average of 41,000 CFU per microbial challenge, which is more than 40 times the FDA guidance of ≥1000 CFU per microbial challenge[1].

Summary of Microbial Ingress Results for nSyte™			
Study Parameter		Organism Level	
		Assay Requirement	Study Result
Controls	Inoculum	≥1000 CFU/sample	41,000 CFU/sample
	Positive Control Samples (n=3)	Growth	TNTC
	Negative Control Samples (n=2)	No Growth	0 CFU/sample
Test	Test Samples (n=20)	No Growth	0 CFU/sample

In addition to demonstrating microbial resistance, the nSyte™ samples that were subjected to seven (7) day extended use conditioning successfully met their performance requirements associated with back pressure (30 psi leak resistance) and flow rate[4].

CONCLUSION: The nSyte™ Needle-free Connector, following seven (7) days of use, demonstrated an effective microbial barrier to bacteria and maintained essential functionality, specifically flow rate and back pressure performance. Additionally, ten (10) second swabbing of the septum with a 70% concentration isopropyl alcohol prep pad has been shown to effectively disinfect nSyte™.

1. Guidance for Industry and FDA Staff - Intravascular Administration Sets Premarket Notification Submissions [510(k)]; Section 8, Microbial Ingress Testing. Issued on July 11, 2008. http://www.fda.gov/regulatoryinformation/guidances/ucm070844.htm
2. Data on file at Nelson Laboratories; #847107 (Salt Lake City, Utah, USA).
3. Data on file at Toxikon Corporation; #16-02371-N1 (Bedford, MA, USA).
4. Data on file at NP Medical, Inc.; #SR20160061 (Clinton, MA, USA).