Nexus TKO®
Anti-Reflux Device

Nexus **TKO**®-6P:
96-Activation Microbial Barrier Performance Study

Introduction

The use of a needle-free device can increase the risk of bloodstream infections as it provides a potential site for the ingress of bacteria. Therefore, the design of the needle-free device plays a critical role in bloodstream infection prevention as stated by Dr. Jarvis in his published article found in *"Infection Control Today"*.[1] Following Dr. Jarvis' recommendations in that article, the Nexus TKO®-6P was designed with a smooth external septum surface and 360° compression seal between the septum and housing when the septum is at rest to aid in disinfection. Additionally, that compression seal forces the slit to remain sealed while the septum is unactivated, preventing the ingress of microorganisms that can cause bloodstream infections.

In order to demonstrate the efficacy of the design features of the Nexus TKO®-6P in preventing ingress of microorganisms during simulated use, the microbial ingress test was conducted per the 2008 FDA guidance, "Intravascular Administration Sets Premarket Notification Submission [510(k)]"[2]. Specifically, the study was designed to demonstrate the ease of disinfection of TKO-6P using a standard IPA prep pad and manual scrubbing technique prior to each access.

Methods

Following the recommendation for microbial ingress testing from the FDA, Nexus commissioned Nelson Laboratories of Salt Lake City Utah to execute a GLP study on the TKO-6P. A total of 24 TKO-6P devices were challenged along with positive and negative controls. Based on the FDA recommendations, 2 Gram positive (*S. aureus & S. epidermis*) and 2 Gram negative (*E. coli & P. aeruginosa*) were chosen as the challenge organisms and were sourced from ATCC. The concentration of the microbial suspensions was adjusted to 10^5-10^6 CFU/mL to create an appropriate challenge level in order to meet the FDA recommendation, which is a minimum of 10^3 CFU/mL. New inoculum suspensions were prepared each test day.

Additionally, the FDA guidance states the microbial ingress test should simulate repeated access. Typical usage of the device would yield 1 to 8 activations a day over the course of 1 to 7 days. Nexus chose to perform the test using a total of 96 activations to simulate a more extreme usage condition. The 96 activations equate to an hourly activation over the course of 4 days (96 hours) in an extreme case or approximately 14 activations a day over 7 day period. As performing the ingress test 24 hours a day for four days is not easily accomplished Nexus chose to pre-activate the test devices. Prior to the initial microbial challenge, each test device and negative control was activated a total of 72 times using a sterile saline syringe. A new syringe was used for each sample device.

At the beginning of the test and each subsequent test day, each sample was disinfected using a 10 second circular swab technique with a standard individually packaged Becton Dickinson 70% IPA prep pad. The device was then allowed to dry for at least 1 minute. Each sample was then inoculated with 0.01mL of the challenge organism and the inoculum was allowed to remain on the septum for a minimum of 1 minute but not longer than 5 minutes. Each challenge device was then disinfected following the same swabbing procedure as listed above. Following the disinfection, the test devices were then flushed using a Pre-filled BD 10mL sterile saline syringe. The cycle of inoculation, disinfection and flushing was performed a total of 6 times on each test device for four days. See the table below showing the breakdown of activations. The last flush of

the day was collected on a 0.45µ filter media and placed on Soybean-Casein Digest Agar (also known as Trypticase Soy Agar) plates. The plates were then incubated at 30-35°C for 2-4 days prior to counting.

Day	# Activations per day	# of Total Activations
0 – prior to start of test	72 (pre-activations)	72
1	6	78
2	6	84
3	6	90
4	6	96

Positive and negative controls were run concurrently with the study. The negative controls were not inoculated and the positive controls were inoculated, but not disinfected. Additionally, a daily positive monitor for each of the challenge organisms was used to ensure the minimum requirement of 10^3 CFU/mL was met.

Results

The positive monitor devices demonstrated that the test devices were inoculated with the minimum of 10^3 CFU/mL. The results ranged from 5.5×10^3 CFU/mL to 3.7×10^4 CFU/mL.

All positive controls showed growth and all negative controls had no growth.

The following table shows the results for the TKO-6P devices following the full 96 activations:

Identification		CFU Recovered
S. aureus **ATCC #6538**	Replicate 1	0
	Replicate 2	1
	Replicate 3	0
	Replicate 4	0
	Replicate 5	0
	Replicate 6	0
S. epidermidis **ATCC #12228**	Replicate 1	0
	Replicate 2	0
	Replicate 3	0
	Replicate 4	0
	Replicate 5	0
	Replicate 6	0
E. coli **ATCC #8739**	Replicate 1	0
	Replicate 2	0
	Replicate 3	0
	Replicate 4	0
	Replicate 5	0
	Replicate 6	0
P. aeruginosa **ATCC #9027**	Replicate 1	0
	Replicate 2	0
	Replicate 3	0
	Replicate 4	0
	Replicate 5	0
	Replicate 6	0

Conclusions

The results demonstrate the Nexus TKO®-6P was effective at preventing the ingress of microorganisms when subjected to a rigorous simulated use model.

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Discussion

Cather-related bloodstream infections (CRBSIs) create both clinical and financial risks for a facility and are a major complication that impacts the patient's health. As the needle-free device connected to the catheter may contribute to these infections, using infection-prevention strategies as key factors in design is vital. The device design must be effectively disinfected using standard techniques and prevent the ingress of microorganisms.

The Nexus TKO®-6P was designed to be easily disinfected and prevent the ingress of microorganisms with its smooth external septum surface and 360° compression seal. Overall, the data demonstrates the TKO-6P, after 96 activations, prevents the passage of most organisms through the septum following a disinfection procedure using a standard IPA prep pad prior to each use.

[1] Jarvis,W. Choosing the best design for the Intravenous needleless connection to prevent HA-BSI's. *Infection Control Today*, 2010 Aug

[2] Guidance for Industry and FDA Staff – Intravascular Administration Sets Premarket Notification Submissions [510(k)], July 11, 2008.