*Nexus **TKO**®-5: 96-Activation Microbial Barrier Performance Study*

Methods

In 2006, Nexus commissioned Apptec Laboratory Services in St. Paul MN to execute a GLP study on the TKO-5. A total of 10 TKO-5 devices were challenged along with positive and negative controls. *S. epidermis* was chosen as the challenge organism as it is a common skin bacterium. The concentration of the microbial suspensions was adjusted to $5x10^5$ 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.

At the beginning of the test and each subsequent test day, each sample was disinfected using a 3 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 4 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 10mL of PBS. The cycle of inoculation, disinfection and flushing was performed a total of 12 times on each test device for eight days. See the table below showing the breakdown of activations. All 12 flushes were pooled and collected on a 0.45µ filter media and placed on SCDA plates. The plates were then incubated at 30-35°C for a minimum of 96 hours prior to counting.

Day	# Activations per day	# of Total Activations
1	12	12
2	12	24
3	12	36
4	12	48
5	12	60
6	12	72
7	12	84
8	12	96

A positive and negative control were run concurrently with the study. The negative control was not inoculated and the positive control was inoculated, but not disinfected.

Results

All positive controls showed growth and all negative controls had no growth. The TKO-5 had reported results of < 1 recovered CFU/device over the 8-day test.

The following table shows the results for the TKO-5 devices following the full 96 activations:

Identification		CFU Recovered
S. epidermidis **ATCC #12228**	Replicate 1	<1
	Replicate 2	<1
	Replicate 3	<1
	Replicate 4	<1
	Replicate 5	<1
	Replicate 6	<1
	Replicate 7	<1
	Replicate 8	<1
	Replicate 9	<1
	Replicate 10	<1

Conclusions

Overall, the data demonstrates the TKO-5 prevents passage of organisms through the septum following a disinfection procedure prior to each use.