4 Day Microbial Barrier Performance Study

Laboratory No. 458652

(n = 20 samples)

Intraluminal Protection System

InVision-Plus®

with Neutral Advantage Technology

	S. epidermidis	*S. aureus*	*E. coli*	*P. aeruginosa*
Day 1				
Total CFUs per device	45,000	140,000	330,000	110,000
Avg. CFUs collected per device	1	1	0	0
% Effectiveness*	100.00%	100.00%	100.00%	100.00%
Day 2				
Total CFUs per device	85,000	180,000	140,000	98,000
Avg. CFUs collected per device	1	2	1	0
% Effectiveness*	100.00%	100.00%	100.00%	100.00%
Day 3				
Total CFUs per device	120,000	220,000	170,000	190,000
Avg. CFUs collected per device	0	1	1	0
% Effectiveness*	100.00%	100.00%	100.00%	100.00%
Day 4				
Total CFUs per device	120,000	250,000	280,000	230,000
Avg. CFUs collected per device	0	2	0	0
% Effectiveness*	100.00%	100.00%	100.00%	100.00%

Swabbing Protocol: 3 rotations (clockwise/counter-clockwise) with 70% IPA

***% Effectiveness represents the ability of the device to prevent microorganism ingress**

RyMed Technologies, LLC

Microbial Barrier Performance Study for the InVision-Plus® with Neutral Advantage Technology

Nelson Laboratories, Inc. (Salt Lake City, UT), an independent laboratory facility, was contracted to conduct an evaluation of the microbial barrier performance of the **InVision-Plus® with Neutral Advantage Technology,** manufactured by RyMed Technologies, LLC.

OBJECTIVE: While minimizing the risk of needle stick injuries, needleless I.V. connectors have been associated with an increase in a patient's risk for catheter-related bloodstream infection (CR-BSI). Several manufacturers offer many different I.V. connectors with design variations in microbial barrier or seal designs, septum seal integrity, negative fluid displacement, and overall function. The safety and efficacy performance of these devices has not been extensively studied to compare efficacy at preventing downstream contamination which may lead to CR-BSI. This *in-vitro* study details a method for the evaluation of the microbial barrier performance of the **InVision-Plus® with Neutral Advantage Technology** which incorporates a smooth, swabbable septum and septum seal integrity with a double microbial barrier. The test conditions simulate real-use conditions over the anticipated period of time the devices will be used in a typical patient combining septum contamination and biofilm adhesion, development, and colonization potential.

METHODS: The **InVision-Plus®** was contaminated with four challenge organisms, disinfected, aspirated with bovine blood, flushed, and then re-contaminated with a pooled suspension of the challenge organisms which included *S. epidermidis, S. aureus, E. coli, and P. aeruginosa*.

TEST PROCEDURES: The test was performed on 20 samples, 3 positive controls, 3 positive monitors and 3 negative controls. The test consisted of the following time points: 0, 6, 12, 24, 30, 36, 48, 54, 60, 72, 78, 84 and 96 hours.

Each infusion consisted of the following:

1. Attaching a 10 mL sterile 0.9% normal saline filled syringe to the device;
2. Aspirating Bovine blood through the device until blood is seen in the syringe;
3. Flushing the entire 10 mL of saline through the device;
4. Swabbing the septum surface with 70% IPA with 3 clockwise/counter-clockwise rotations;
5. Administration step of flushing 1.0 mL of saline through the devices;
6. Contaminating the septum with a pooled suspension containing a minimum of 10^5 CFU of each of the challenge organisms;

The flushed solution was collected, filtered, plated, and incubated at time points 12, 36, 60 and 84 hours, in order to detect the presence of microorganisms that might be introduced into the fluid pathway and subsequently into the bloodstream leading to a potential CR-BSI.

RESULTS: The chart summarizes the inoculum levels per device and demonstrates the percentage effectiveness of the **InVision-Plus®** at preventing microbial ingress through its **Neutral Advantage Technology** design.

The complete study protocol and final report on file at RyMed Technologies, LLC.

RyMed TECHNOLOGIES, LLC