Fluid Displacement Study

Laboratory No. 301988

Intraluminal Protection System

InVision-Plus®

with Neutral Advantage Technology

TABLE 1	I.V. Line Detachment for RyMed Sample						
Sample	Replicate #1	Replicate #2	Replicate #3	Replicate #4	Replicate #5	Mean (mL)	
1	0.003 mL	0.003 mL	0.002 mL	0.001 mL	0.000 mL	0.0019	
2	0.001 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0001	
3	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	
4	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	
5	0.000 mL	0.001 mL	0.000 mL	0.000 mL	0.000 mL	0.0002	
6	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	
7	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	
8	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	
9	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	
10	0.000 mL	0.000 mL	0.000 mL	0.002 mL	0.000 mL	0.0003	
11	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	
				OVERALL		0.0002	

TABLE 2	I.V. Line Attachment for RyMed Sample						
Sample	Replicate #1	Replicate #2	Replicate #3	Replicate #4	Replicate #5	Mean (mL)	
1	0.006 mL	0.000 mL	0.001 mL	0.000 mL	0.000 mL	0.0014	
2	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	
3	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	
4	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	
5	0.011 mL	0.010 mL	0.000 mL	0.003 mL	0.000 mL	0.0048	
6	0.000 mL	0.007 mL	0.003 mL	0.000 mL	0.022 mL	0.0064	
7	0.011 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0022	
8	0.000 mL	0.000 mL	0.000 mL	0.006 mL	0.013 mL	0.0038	
9	0.006 mL	0.009 mL	0.000 mL	0.010 mL	0.002 mL	0.0054	
10	0.000 mL	0.000 mL	0.000 mL	0.003 mL	0.000 mL	0.0006	
11	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.000 mL	0.0000	
				OVERALL		0.0022	

TABLE 3	Summary of Results	
Sample	ATTACHMENT	DETACHMENT (AVG.)
InVision-Plus®	0.0022 mL (+)	0.0002 mL (-)

(-) Negative fluid movement (+) Positive fluid movement

Testing performed by Nelson Laboratories, Inc., Salt Lake City, UT Sept 2005

RyMed Technologies, LLC

Fluid Displacement Study for the InVision-Plus® with Neutral Advantage Technology

Nelson Laboratories, Inc. (Salt Lake City, UT), an independent laboratory facility, was contracted to determine the positive and negative movement of fluid through a catheter upon connection and disconnection to the **InVision-Plus® with Neutral Advantage Technology,** manufactured by RyMed Technologies, LLC.

OBJECTIVE: Fluid displacement caused by connection to and disconnection from needlefree I.V. connectors is an area of concern. Repeated fluid displacement, or blood reflux, through a catheter during routine I.V. connector access is known to condition the intraluminal catheter surface with blood fibrin which increases the potential for intraluminal thrombotic occlusion, affects catheter patency, delays therapy, and adds costs. Traditional I.V. connectors, including positive-push mechanical valves, exhibit negative fluid displacement immediately upon connection or disconnection and must be used in accordance with clamping instructions. This test procedure was designed to demonstrate that the **InVision-Plus® with Neutral Advantage Technology** exhibits *neutral fluid displacement* upon connection and disconnection and requires no special clamping instructions.

PROCEDURE: Test Set Up – A 250 mL bag of 0.9% normal saline was hung above the I.V. line and test sample. Two (2) mL of red coloring per bag of saline was injected into the bag. The I.V. line was attached to the bag of saline. The drip chamber on the I.V. line was squeezed to fill the chamber half full of red saline fluid. The roller clamp was opened to completely prime the I.V. set, and then the clamp was closed. The **InVision-Plus®** sample was attached to the 0.013" I.D. ultra-microbore PVC I.V. tubing (inside diameter is equivalent to a 2.0Fr PICC catheter). The I.V. set was connected to the **InVision-Plus®**. The roller clamp was opened to prime the **InVision-Plus®** sample and ultra-microbore tubing. The roller clamp was left opened as the I.V. line was disconnected from the **InVision-Plus®** sample. This action fully primed the ultra-microbore tubing to the distal end.

I.V. Line Connector Attachment: After the tubing was primed, the I.V. line was connected to the test **InVision-Plus®** sample. The amount of fluid movement was measured with a balance. The I.V. line was re-primed for the next sample. The I.V. line connector attachment phase was performed on 11 different samples at five replicates per sample

I.V. Line Connector Detachment: With the I.V. line attached to the test sample, the ultra-microbore I.V. tubing was primed to the distal end. The I.V. line was detached from the **InVision-Plus®** sample. The amount of fluid movement was measured with a balance. The line was re-primed for the next sample. The I.V. line connector detachment phase was performed on 11 different samples at five replicates per sample.

RESULTS: The results are presented in Tables 1 and 2. The results are summarized in Table 3.

CONCLUSION: Upon detachment, 48 out of 55 device replicates showed 0.000 mL fluid movement. The overall mean fluid displacement for all device replicates was -0.0002 mL. Upon attachment, 39 out of 55 device replicates showed 0.000 mL fluid movement. The overall mean fluid displacement for all device replicates was +0.0022 mL.

The complete study protocols and final reports on file at RyMed Technologies, LLC.

InVision-Plus® is a registered trademark of RyMed Technologies, LLC.
U.S. Patent Numbers: 6,113,068; 6,299,131; 6,994,315; 7,530,546B2; 8,096,525B2 and other U.S. and foreign patents pending.
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