TECHNICAL PAPER

Sure-Lok™ Needle-Free Luer Lock Performance Testing

Abstract

This study was performed to evaluate ease of connection, flow rate, reflux volume and priming volume of the new needle-free luer lock connector Sure-Lok, available through Amsino International, Inc.

Needle-free products have been widely used in the US for intravenous therapy since 1990 to reduce infection rates by avoiding needle-stick injuries and bloodstream infections.[1] In response to numerous clinical research studies related to the needle-free systems, Amsino developed the Sure-Lok.

About the Sure-Lok

The Sure-Lok is a male luer activated mechanical valve that provides a high flow rate, low connection resistance, tight septum seal, smooth flat septum surface, clear fluid pathway and is metal free. The valve remains closed until activated with a male luer. This allows fluid to flow in both directions for infusion and aspiration. The Sure-Lok provides a negative fluid displacement.

Methods of Measure

Test	Factors	Method	Result
1	Flow Rate	9g/L saline water at 1m head height	244 mL/minute
2	Resistance to Luer Connection	Force testing device	5.1N
3	Reflux Volume	Reflux volume when disconnected	0.1 mL
4	Priming Volume	Fluid Required for Priming Measured	0.5 mL
5	Leakage	200KPa @15min, 300KPa @30S, ±20KPa\50KPa@15s	Pass
6	Connection	ISO594-1, ISO594-2	Pass
7	Luer Activation	Connected and disconnected 200 times	Pass
8	Valve Kept Open	Test for 24h continue luer engaged connection	Pass
9	Others	Meets ISO594	Pass

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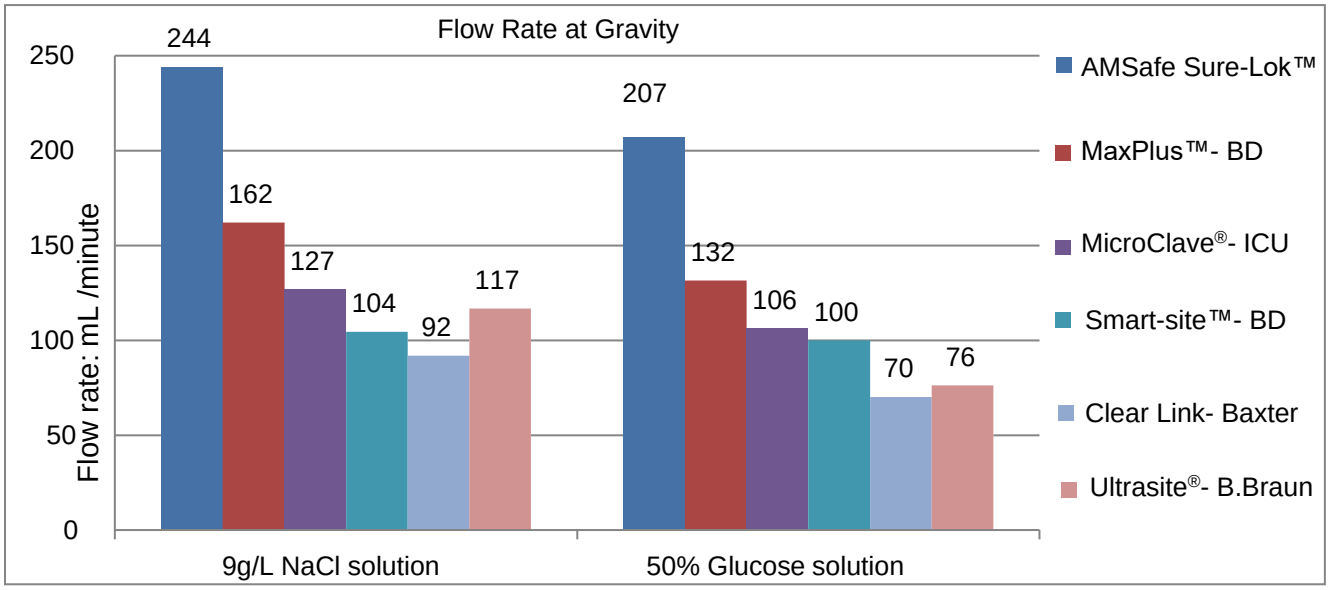
Comparison Performance Tests

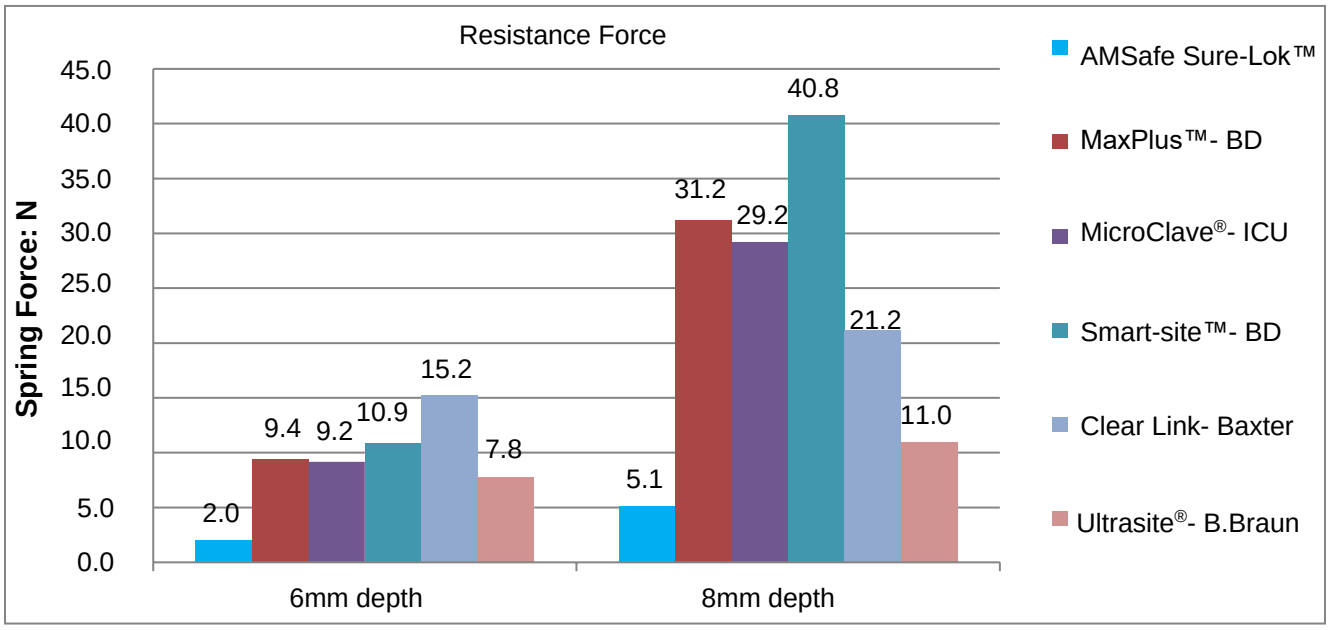
When testing the flow rate and resistance to luer connections the Sure-Lok was compared to top competitive brands that provide needle-free valves for infusion.

Flow rate was measured at regular intervals using both 9g/L NaCl Solution and 50% Glucose solution and an average test result is detailed for each valve.

Graph 1: Comparative brand valve average flow rate test



Graph 2: Comparative brand valve resistance force test



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Bacterial Ingress Testing

A bacterial ingress study was performed to test the ability of the Sure-Lok Needle-Free Luer Lock feature's ability to support infection control procedures during intravenous infusion. The Sure-Lok was tested by inoculating 0.01 mL bacterial suspension on the needle-free connector's septum, allowed to dry, then disinfected using 75% alcohol for at least 30 seconds and allowed to dry. This study was simulated by adding medication from 0 hour to 72 hours, and tested simulated extended infusion from 72 hours to 76 hours. The counting of test group for all strains was 0 cfu, both the negative and positive control groups showed normally.

			Test Group					Positive Control Group		Negative Control Group	
Strains	Time	Strains counting (CFU)	#1	#2	#3	#4	#5	#6	#7	#8	#9
Staphylococcus Aureaus	1h	$1.2x10^3$	0	0	0	0	0	+	+	-	-
Staphylococcus Aureaus	2h	$1.2x10^3$	0	0	0	0	0	+	+	-	-
Staphylococcus Aureaus	24h	$1.3x10^3$	0	0	0	0	0	+	+	-	-
Staphylococcus Aureaus	48h	$1.2x10^3$	0	0	0	0	0	+	+	-	-
Staphylococcus Aureaus	72h	$1.1x10^3$	0	0	0	0	0	+	+	-	-
Staphylococcus Aureaus	76h	$1.1x10^3$	0	0	0	0	0	+	+	-	-
Candida Albicans	1h	$1.3x10^3$	0	0	0	0	0	+	+	-	-
Candida Albicans	2h	$1.3x10^3$	0	0	0	0	0	+	+	-	-
Candida Albicans	24h	$1.2x10^3$	0	0	0	0	0	+	+	-	-
Candida Albicans	48h	$1.2x10^3$	0	0	0	0	0	+	+	-	-
Candida Albicans	72h	$1.1x10^3$	0	0	0	0	0	+	+	-	-
Candida Albicans	76h	$1.1x10^3$	0	0	0	0	0	+	+	-	-
Pseudomonas Aeruginosa	1h	$1.0x10^3$	0	0	0	0	0	+	+	-	-
Pseudomonas Aeruginosa	2h	$1.0x10^3$	0	0	0	0	0	+	+	-	-
Pseudomonas Aeruginosa	24h	$1.0x10^3$	0	0	0	0	0	+	+	-	-
Pseudomonas Aeruginosa	48h	$1.1x10^3$	0	0	0	0	0	+	+	-	-
Pseudomonas Aeruginosa	72h	$1.0x10^3$	0	0	0	0	0	+	+	-	-
Pseudomonas Aeruginosa	76h	$1.0x10^3$	0	0	0	0	0	+	+	-	-
Escherichia Coli	1h	$1.1x10^3$	0	0	0	0	0	+	+	-	-
Escherichia Coli	2h	$1.1x10^3$	0	0	0	0	0	+	+	-	-
Escherichia Coli	24h	$1.2x10^3$	0	0	0	0	0	+	+	-	-
Escherichia Coli	48h	$1.2x10^3$	0	0	0	0	0	+	+	-	-
Escherichia Coli	72h	$1.0x10^3$	0	0	0	0	0	+	+	-	-
Escherichia Coli	76h	$1.1x10^3$	0	0	0	0	0	+	+	-	-

Conclusions

AMSafe Sure-Lok™ provided 103% increase in flow rate over the average flow rate of the competitive needle-free connectors tested using saline solution. In addition, the Sure-Lok required, on average, 81% less disconnection force when compared to other needle-free valves tested. Both high flow rates and low resistance to luer connection provide the clinician the ability to use the device easily and effectively. The results of the bacterial ingress testing study show no microorganisms invading into the sterile fluid path indicating that the Sure Lok can prevent microbial ingress, even during extended infusion, when proper disinfection techniques are applied.

Features	Benefits
Clear Housing and Septum	Allows for visual confirmation of fluid flush
Increased Flow Rate	Instant fluid delivery at a rate greater than 200 mL/minute
Low Resistance to Luer Connections <10N	Provides the clinician the ability to use the device easily and effectively
Smooth Flat Top	Easy swabbing and connection
Metal Free	MRI compatible
Priming Volume of 0.5 Ml	Minimal residual fluid
Tight Septum Seal	Reduces opportunity for bacteria growth

Patent Information

- China Invention Patent ZL2l01220432281.4

References

[1] Clinical use of disinfectable needle-free connectors Yébenes, Juan C. et al. American Journal of Infection Control , Volume 36 , Issue 10 , S175.e1 - S175.e4