Arisure® Closed Male Luer Mechanically Closed

Introduction

The Arisure Closed Male Luer (CML) is a single-use, swabbable, bi-directional valve intended for use as an accessory to an intravascular (IV) administration set. The CML provides access for the administration of fluids from a container to a patient's vascular system. The CML is designed to be mechanically and microbiologically closed, prohibiting the escape of hazardous drugs and vapor concentrations, as well as eliminating the risk of microbial contamination when used properly. The purpose of this paper is to present an overview of methods and testing used to demonstrate the mechanically closed features of the Closed Male Luer.

Procedure

To demonstrate that the CML is mechanically closed, 153 samples were tested for liquid and air leakage at time points of 0 years, 1 year accelerated-aging, and 3 years accelerated-aging. Liquid leakage was tested by attaching the CML to a water filled test system, flushing the sample with water and then subjecting it to a pressure of 60 psi for 30 seconds. To test air leakage, the CML was attached to a syringe, filled with water, and then a vacuum was applied per the ISO 594 test standard. The syringe was then observed for potential air bubbles.

Results

All samples met the testing requirements and passed for all time points.

Table 1. Liquid and air leakage testing results.

Time point	T=0 YR	T=1 YR AA	T=3 YR AA
Liquid leakage	Passed	Passed	Passed
Air leakage	Passed	Passed	Passed

Conclusions

All the CML samples subjected to mechanically closed tests demonstrated no leakage. There were no air bubbles observed in the syringe as well. The results demonstrate that the Arisure Closed Male Luer is mechanically closed and prohibits the escape of hazardous drugs and vapors into the environment.

Data on file at Yukon Medical. Arisure Closed Male Luer Mechanically Microbiologicaly Closed Whitepaper TSD 017.01.

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Arisure® Closed Male Luer Microbiologically Closed

Introduction

The Arisure Closed Male Luer (CML) is a single-use, swabbable, bi-directional valve intended for use as an accessory to an IV administration set. The CML provides access for the administration of fluids from a container to a patient's vascular system. The CML is designed to be mechanically and microbiologically closed, prohibiting the escape of hazardous drugs and vapor concentrations, as well as eliminating the risk of microbial ingress. The purpose of this paper is to present an overview of methods and testing used to demonstrate the microbiologically closed performance of the Closed Male Luer.

Procedure

When the CML is used for IV therapy, the maximum expected number of daily connections and disconnections is 8. The silicone valve surface of the CML was inoculated with *Staphylococcus aureus*, then disinfected. To simulate clinical conditions, this was repeated for each valve for a total of 8 times per day for 4 days. After each disinfection, the CML valves were flushed using a 0.9% isotonic saline flush from a pre-filled, sterile luer lock saline syringe. The resultant fluid was filtered and collected, and the filter plated to quantify the presence of the challenge bacteria. *S. aureus,* a single Gram-positive bacterium, was used specially due to its relevancy to hospital-acquired catheter-related blood stream infections. One positive control and one negative control were also evaluated. 15 CFU's of bacteria grown as a culture was set as the threshold for a positive diagnosis of infection.

Results

All positive controls were positive for the presence of bacteria. All negative controls were negative for the presence of bacteria. The test samples demonstrated no microbial ingresses beyond the 15 CFU threshold.

Table 1. Microbial ingress testing results, >15 CFU

Sample	Day 1	Day 2	Day 3	Day 4
1	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0
2	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0
3	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0
4	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0
5	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0
6	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,1,0

Conclusions

The positive controls demonstrate that the bacteria application methods are adequate to contaminate the valve. All of the CML samples subjected to microbial challenge test samples demonstrated growth beneath the threshold for causing catheter-related blood stream infections. The microbial ingress results are adequate to demonstrate the CML's resistance to microbial ingress and validate the DFU's disinfection methodology in a worst-case, clinically relevant, in-vitro study.

Data on file at Yukon Medical. Arisure Closed Male Luer Mechanically Microbiologicaly Closed Whitepaper TSD 017.01.

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Arisure® Closed Male Luer Microbial Ingress

Introduction

The Arisure Closed Male Luer (CML) is a single-use, swabable, bi-directional valve intended for use as an accessory to the IV administration set. The CML provides access for the administration of fluids from a container to a patient's vascular system. The purpose of this study is to evaluatethe resistance of the CML to microbial ingress.

Procedure

Testing was completed using a total of six CML devices. The valve surface was inoculated with *Staphlylococcus aureus*, a pathogen relevant to hospital-acquired catheter-related blood stream infections as a result of IV infusion therapy. The valves were then disinfected, and this was repreated for each valve for a total of 8 times per day for 4 days, to simulate worse-case scenario. After each disinfection, the CML valves were flushed using 0.9% isotonic saline flush from a pre-filled, sterile luer lock saline syringe. The resultant fluid was filtered and collected, and the filter plated to quantify the presence of the challenge bacteria. One positive control and one negative control were also evaluated. Functional performance testing was completed with the Arisure Neutral Valve, a standard female needle-free valve. Both the CML and ANV were sterilized prior to testing. 15 CFUs of bacteria grown as a culture was set as the threshold for a positive diagnosis of infection[1].

Results

All positive controls were positive for the presence of bacteria, all negative controls were negative for the presence of bacteria. The test samples demonstrated no microbial ingresses beyond the 15 CFU threshold.

Sample	Day 1	Day 2	Day 3	Day 4
1	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0
2	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0
3	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0
4	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0
5	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0
6	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0	0,0,0,0,0,0,0,0

Conclusions

The results of this study demonstrate that there was no microbial ingress beyond 15 CFUs with the CML.

References

1. "Clinical Guidelines for the Diagnosis and Management of Intravascular Catheter-Related Infection: 2009 Update by the Infections Diseases Society of America." *Clinical Infectious Diseases.* (2009).

Data on file at Yukon Medical. Arisure Closed Male Luer Microbial Ingress Whitepaper TSD 014.02.

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Arisure® Closed Male Luer Chemical Compatibility

Introduction

In addition to presenting health risks for healthcare workers, many common infusion drugs contain chemicals which can cause damage to infusion and compounding devices. Damage to devices has the potential to expose healthcare workers to spills and compromise their safety. One or more elements in common drug formulations increase the risk of damage to plastic devices. These elements include: drug preservatives (Benzyl Alcohol), excipients (Cremophor EL), infusate chemistries (low pH), or other formulation chemistries known to cause damage to plastics.

The Arisure Closed Male Luer (CML) is a single use, non-pyrogenic valve intended for use as an accessory to an intravascular administration set. To demonstrate that the CML is compatible with these types of drugs, several tests were conducted on a valve having the same geometry and materials as the CML. These tests challenged the devices with prolonged, continuous, fluid path exposure to drugs which present a range of these formulation elements.

Procedure

A chemical compatibility test was administered on sterilized and 3 year real time aged devices to evaluate compatibility with Isopropanol (immersed in solution), Intralipid 20, and Taxol Analogue (luers filled via syringe). After 168 hours of exposure, devices were flushed with water and tested according to Table 1.

Results

Table 1 (aged T=3 Real Time Aged)

Drug	Requirement	Result	
Isopropanol (IMX-7)	Multiple Activations (224) + Extended Activation (7 day)		Pass
	Flow Rate 6L/hr	32/32	Pass
	Liquid/Air Leakage	80/80	Pass
	Power Injector Use	80/80	Pass
	Ultrasonic weld must withstand a separation force of 50lbs	80/80	Pass
Intralipid 20 (LMX-7)	Multiple Activations (224) + Extended Activation (7 day)		Pass
	Flow Rate 6L/hr	32/32	Pass
	Liquid/Air Leakage	80/80	Pass
	Power Injector Use	80/80	Pass
	Ultrasonic weld must withstand a separation force of 50lbs	80/80	Pass
Taxol Analogue (TMX-7)	Multiple Activations (224) + Extended Activation (7 day)		Pass
	Flow Rate 6L/hr	32/32	Pass
	Liquid/Air Leakage	80/80	Pass
	Power Injector Use	80/80	Pass
	Ultrasonic weld must withstand a separation force of 50lbs	80/80	Pass

Conclusions

Testing and evaluation has demonstrated that the plastic and elastomeric materials used are resistant to stress cracking, swelling, or degradation after clinically relevant disinfectants and infusates. It is concluded the Closed Male Luer is chemcially compatible with common infusion drugs.

Data on file at Yukon Medical. Chemical Compatibility CML White Paper TSD 005.01.

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