

MICROBIOLOGICAL CHALLENGE FOR THE BUTTON ASSEMBLY OF THE 1o2® VALVE

Introduction

The 1o2 valve by ICU Medical, Inc. is a novel drug delivery system which permits both infusion and aspiration. The technology combines one-way or no-reflux valve infusion, yet can also provide aspiration through a push button feature. Such devices may be used in clinical areas such as anesthesia or critical care where multiple drug infusions and delivery sites are necessary.

The most widely used method for such delivery is done through a stopcock or also known as a three way tap. The stopcock provides versatile drug delivery and aspiration but requires a significant amount of manipulations to operate. This is accomplished through a directional turn handle. It has been shown in literature that multiple manipulations might lead to an increase in line sepsis as a result of the manipulations of the stopcock (Danzig et al. JAMA 1995).

The 1o2 was designed to reduce the number of manipulations required to administer and aspirate IV fluids. The button componentry of the 1o2 is used solely for aspiration, infusion is completed through the one-way valve automatically. The significant difference between the operational features of the stopcock turn handle and the 1o2 button is that the turn handle of the stopcock is an open friction fit assembly. The 1o2, has a closed welded seal assembly around the button component in order to protect the internal fluid path.

This microbiological challenge demonstrates that with repeated manipulations, the 1o2 valve maintained a closed physical barrier to bacteria for a three day use model.



Protocol

To validate the ability of the 1o2 to prevent microbial ingress, an independent research facility, Laboratory Services of Monrovia, CA was contracted to perform a rigorous in-vitro test model. Samples of the 1o2 were artificially contaminated with *Staphylococcus epidermidis* surrounding the button component and then subjected to the use model of repeat activations. *Staph. epidermidis*, in a 5.0×10^9 /mL population, was selected as the challenge organism dilution to demonstrate a worst case contamination model. Twenty samples of the 1o2 were selected as required by the US Pharmacopoeia (USP) for

sterility testing including a negative control sample and population verification samples.

The samples were setup and primed using a 5cc syringe of sterile PBS solution on the proximal luer of the 1o2. A ten inch tubing extension was used to attach the distal luer to a sterile filter funnel unit. The end cap was removed from the sideport and the 5cc syringe was transferred to the sideport to prime the port. A sterile end cap was used to protect the proximal luer.

The button component was inoculated with 10^3 colony forming units (cfu) and allowed to settle for one to four minutes. A 5cc syringe of sterile PBS was attached to the sideport. The 5cc of PBS was infused through the sideport while simultaneously pressing the button two complete intervals. The PBS wash was then passed through the filter and into the funnel unit.

This procedure was completed on each of the 20 individual samples and then repeated an additional 15 times per sample for a total of 32 activations or 16 complete cycles for each sample. The negative control was processed with the elimination of the inoculation procedure. The study cycles were repeated two additional days for a total of three days and 96 activations or 48 complete cycles per sample. The filter membrane was then incubated in SCDA for five days at 32-35°C. Any microbiological contaminant were identified and characterized.

Results

The study indicated no microbiological contamination of the 1o2 button assembly for three days or a 72 hour use life. Initial contamination of the 1o2 was verified to average 1990 cfu's per sample. The ability of the 1o2 to maintain its integrity when microbiologically challenged under a worst case model is demonstrated in the following table.

Time	Number samples positive for <i>Staph. epi</i>	Negative Control
24h	0/20	0/1
48h	0/20	0/1
72h	0/20	0/1

Conclusion

In all cases, the 1o2 maintained a physical barrier at the button assembly for three days, while administering 32 repeat activations per day. The study results indicate that the 1o2, did not result in increased contamination rates under a worst case in-vitro model.

