

Baxa Corporation

PadLock™ Microbial Testing

Technical Paper

An evaluation of fluid path sterility for IV administration sets connected to the PadLock Set Saver.


Baxa Corporation
14445 Grasslands Drive
Englewood, CO 80112

tel: 303-690-4204
fax: 303-690-4804
www.baxa.com

Introduction

The PadLock Set Saver is a reusable device that provides a secure seal for the tip of an IV (intravenous) administration set, preventing line contamination when the set is not being used for infusion. Effective for multiple uses, PadLock clamps onto an IV administration set and is designed to be swabbed and reused. When used as directed, the PadLock Set Saver replaces the need for sterile, single-use caps and facilitates best practice for aseptic closure of IV administration sets.



To prevent inadvertent contamination, IV administration sets should be manipulated using aseptic technique. However, in a busy clinical setting, IV administration sets may be left open to the air or closed in a suboptimal way. The PadLock Set Saver is the first and only aseptic storage solution for an IV administration set that can be swabbed and re-used. The Set Saver attaches to the IV administration set, so it is always available at the bedside for safe, quick, convenient storage of the IV administration set between infusions.

Since the PadLock Set Saver is designed to replace multiple sterile, single-use caps, the product was challenged to show that its microbial barrier properties are equivalent to a sterile, single-use cap, when used as directed.

Method

The PadLock Set Saver was tested under worst-case and extreme microbial contamination conditions to demonstrate that the design prevents ingress of microorganisms into the fluid path of a mating IV administration set. This testing consisted of three separate protocols:

Simulated Clinical Use

The PadLock septum was inoculated with *Staphylococcus aureus* in a concentration approximating 1.0×10^5 organisms per 1 mL of solution. It was then swabbed with a 70% isopropyl alcohol pad for five seconds and allowed to dry. The IV administration set's male luer was connected to the PadLock. After disconnection from the PadLock, fluid was collected from the IV administration set for culture. For comparison, another IV administration set was capped with a single-use, sterile cap, then disconnected and fluid was collected from the IV administration set for culture.

This protocol was repeated for sixty fluid samples collected from IV administration sets connected to the Padlock. An additional sixty samples were collected from IV administration sets connected to a single-use, sterile cap.

Submersion Test

The PadLock was submerged into a solution of *Staphylococcus aureus* in a concentration approximating 1.0×10^5 organisms per 1 mL of solution. The entire luer feature and septum were completely immersed in the microbial solution. The septum then was swabbed with a 70% isopropyl alcohol pad for 5 seconds and allowed to dry. The IV administration set was connected to the PadLock. After disconnection from the PadLock, fluid was collected from the IV administration set for culture. Sixty fluid samples were collected in this way from IV administration sets connected to the PadLock.

Spray Test

A suspension was created with approximately three microliters of a four-organism cocktail suspension of *Staphylococcus aureus*, *Enterococcus faecalis*, *Pseudomonas aeruginosa* and *Escherichia coli* in a concentration of 1.0×10^6 of each organism per 1 mL of solution. The front of the PadLock septum and its surrounding surfaces were sprayed with this organism cocktail. A syringe was connected to the PadLock twice to simulate potential misuse through septum manipulation. The Set Saver septum was swabbed with a 70% isopropyl alcohol pad for five seconds and allowed to dry. The IV administration set was connected to it. After the IV administration set was disconnected from the PadLock, fluid was collected from the IV administration set for culture. Sixty fluid samples were collected in this way from IV administration sets connected to the Padlock.

Results

The acceptance criterion for the microbial challenge testing was that no microbial growth of the challenge organisms would be found in cultures of the collected fluid. The collected fluid from the IV administration sets connected to the PadLock demonstrated no growth of the challenge organism over the entire test period. The test findings were identical to the results from the sterile, single-use syringe tip cap test samples, both exhibiting no growth.

Table 1: Summary of Results

	No Bacterial Growth	Bacterial Growth
Simulated Use		
PadLock	60	0
Sterile Cap	60	0
Positive Controls	0	2
Negative Controls	1	0
Submersion Test		
PadLock	59	0
Positive Controls	0	3
Negative Controls	1	0
Spray Test		
PadLock	59	0
Positive Controls	0	12
Negative Controls	1	0

Conclusion

The PadLock Set Saver is intended to prevent IV administration set contamination and promote proper aseptic technique for set closure, when used as directed. PadLock replaces the use of multiple sterile, single-use caps for closing an IV administration set. In testing, the PadLock performed equivalent to sterile, single use caps in protecting an IV administration set from contamination.

For more information see www.baxa.com/padlock.