



## *Facilitating Aseptic Storage of Intravenous Sets in Patient Care Areas: An innovative new device for IV therapy*

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### **Abstract**

Healthcare-associated infections are a staggering cause of increased provider costs and morbidity in the United States. Intravenous therapy complications are a major contributor to bloodstream infections. Among the many root causes of infection through IV therapy is the simple issue of contamination caused when the system is not kept closed. While ordinary syringe tip caps have been one solution, Baxa Corporation has developed a unique new device, the PadLock® Set Saver that acts as an aseptic docking station for open tubing ends, and facilitates best practice. Significant laboratory testing has been completed that shows the PadLock to be an easy and effective method to store open tube set ends and prevent the opportunity for infection.

### **Background**

The incidence of healthcare-associated infections (also referred to as hospital-acquired or nosocomial infections) is a significant issue for US healthcare providers. One shocking statistic is that the Centers for Disease Control and Prevention (CDC) consider healthcare-associated infections (HAIs) in the top ten leading causes of death in the US. Estimates indicate these infections account for a staggering 1.7 million hospital infections per year, leading to 99,000 associated deaths and an additional \$4.5 to \$11 billion or more in patient care costs.<sup>1-4</sup> For the US, this means that as many as one hospital patient in ten acquires an HAI.<sup>4</sup>

There are many causes for HAIs, but complications from intravenous (IV) therapy are among the most common and complicated. Risks from vascular access procedures have been studied and tracked for decades. A comprehensive study by Maki et. al. systematically reviewed 200 prospective studies completed between 1966 and 2005 to determine numbers and trends.<sup>5</sup>

Dr. Maki determined many ratios for bloodstream infections (BSIs) depending on variables such as catheter type, length of insertion, medical condition, location etc. A basic finding is the universal agreement that intravenous devices are associated with increased hospital length of stay. Among Maki's financial conclusions is that these costs increased length of stay, on average, from 10 to 20 days at a cost of \$4,000 to \$56,000 per episode.<sup>6-10</sup>

Further, Maki observed that until recently, most of the emphasis on intravascular device-related infection had focused on central venous catheters used in intensive care units. The final simple conclusion of his article is that infection control programs must do a better job at consistently applying essential control measures and preventative technologies to *all* types of intravascular devices.

### **The Problem: Preventing catheter-related infections**

Common sense indicates that catheter-related infections are extremely preventable.<sup>11-12</sup> Studies in multi-center and single institution locations have demonstrated catheter-associated bloodstream infection reductions greater than 65% by using simple fundamental infection control procedures.<sup>13</sup>

One of the most basic ways to prevent infection is not to allow the end of an IV tubeset to become contaminated by leaving the closed system open. Hadaway determined in a survey of current intravenous administration set practices that IV sets were being left hanging and open to room air for a significant amount of time.<sup>16</sup> Sixty-two percent of nurses surveyed reported that they disconnect primary infusions from the catheter hub for periods ranging from a few minutes

to unlimited times. Surprisingly, the survey found that only a few nurses felt that this practice should never be done.

The obvious solution to the risks posed by not consistently keeping closed systems closed would be relevant written policies and procedures to promote good practice. Unfortunately, Hadaway found that 76.2% of survey respondents did not believe that their institution even had a policy on handling open set ends. Probably the best news in this situation is that nurses were almost unanimous in agreeing that an uncapped and disconnected set should be discarded and replaced with a new set.

Absorbing the cost of a new set is certainly preferable to using a potentially contaminated IV set and risking the type of issues so well documented by Dr. Maki in the study cited above. Still, the problem remains that open sets do increase healthcare costs, one way or another.

The Institute for Safe Medication Practices sought to spotlight the problem of uncapped IV tubing in a July 26, 2007 *Medication Safety Alert* entitled, "Failure to cap IV tubing and disinfect IV ports place patients at risk for infections."<sup>17</sup> Once again, the solution to a severe problem is quite simple. Exposed tube set ends need to be covered with some sort of cap between uses. The Alert further suggests that the port needs to be disinfected prior to connecting a tubing or syringe to the port.

### **One Solution: A new way to promote best practice**

An IV tip cap is the most common way to keep IV sets closed between uses. Needles are no longer an appropriate choice for IV sets, due to the many documented dangers for healthcare workers and the mandate for needleless connections in US healthcare. Tip caps are relatively inexpensive, but the volumes needed in a major healthcare setting can be significant. Of great importance, however is that a sterile cap may not be available at the bedside at the time the caregiver needs the device. Too often, the result is that the line end is then left open, creating an opportunity for contamination and ultimately a bloodstream infection.

So while tip caps fulfill the function, the process has limitations. Extra costs and procedural steps for the care giver have been introduced that could be reduced. There is now another innovative device to the age old problem of what to do with an open end of a tubing that will need to be used later.

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. See the picture below for a better idea of the concept.

To prevent inadvertent contamination, IV administration sets should be manipulated using aseptic technique. In a busy clinical setting, the reality is that 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 between infusions.

### **Performance Testing**

Since the PadLock Set Saver is designed to replace multiple sterile, single-use caps, the product was challenged to demonstrate that its microbial barrier properties are equivalent to a sterile, single-use cap, when used as directed. These tests are described in more detail in the following section.

The PadLock Set Saver was tested under worst-case and extreme microbial contamination conditions to demonstrate that its 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  $1.0 \times 10^5$  organisms per 1 mL of solution. The septum 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 Set Saver. 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 in a solution of *Staphylococcus aureus* in a concentration approximating  $1.0 \times 10^5$  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 Set Saver.

### *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  $1.0 \times 10^6$  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. An 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 collected fluid from any of the IV administration sets connected to the PadLock demonstrated no growth of the challenge organism over the entire test period in any of the three test scenarios. These results met the microbial challenge testing acceptance criterion of having no microbial growth in any cultures of the collected fluid. The test findings were identical to the results from the sterile, single-use syringe tip cap test samples. There was no growth in any of the samples tested using the PadLock Set Saver.

### **Discussion**

There are many ways for intravenous therapy to cause bloodstream infections that have nothing to do with uncapped IV sets. Still, keeping IV systems closed is a real-life issue that demands a safe and cost effective solution. The PadLock Set Saver has undergone extensive testing and regulatory scrutiny that indicates that it is a safe alternative for this basic function in the pressing mandate for the US healthcare system to do a better job of reducing unnecessary healthcare infections.

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### **About the Author**

Michael Hurst, RPh, MBA is the Clinical Pharmacy/IV Specialist for Baxa Corporation. A national expert on syringe pump intermittent IV infusion technology, Mike Hurst successfully managed the Swedish Medical Center pharmacy in Seattle and has ten years experience as a pharmaceutical industry consultant. He developed dilution, compounding, drug solution expiration tables and IV pharmacy operational recommendations that set the standard for the most common intermittent syringe infusers.

At Baxa, Mike developed the Rapid Rate Infuser – the standard for Adenoscan infusion for cardiac stress monitoring. Currently, he supports business development and pharmacy process improvement activities.

Mike holds a BS in Pharmacy from the University of Washington and an MBA from City University (Bellevue).

### **About Baxa Corporation**

Baxa, a customer-focused medical device company, provides innovative, solution-based technologies for medication handling and delivery. Its systems and devices promote the safe and efficient preparation, handling, packaging, and administration of medications. Key products include the PadLock<sup>®</sup> Set Saver, Rapid-Fill<sup>™</sup> □ Automated Syringe Fillers, Exacta-Med<sup>®</sup> Oral Dispensers, MicroFuse<sup>®</sup> Syringe Infusers, Repeater<sup>™</sup> Pharmacy Pumps, and Exacta-Mix<sup>™</sup> and MicroMacro<sup>™</sup> Multi-Source Automated Compounders; used worldwide in hospitals and healthcare facilities. Privately held, Baxa Corporation has subsidiaries and sales offices in Canada and the United Kingdom; direct representation in Austria, Belgium, Finland, France, Germany, Luxembourg, The Netherlands and Switzerland; and distribution partners worldwide. Further information is available at [www.baxa.com](http://www.baxa.com).

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