

EVALUATION OF THE FLUID PATH CONTAMINATION POTENTIAL OF THE BD POSIFLOW™ IV ACCESS SYSTEM

INTRODUCTION

Needlestick injuries have become a major issue with healthcare workers due to the potential of acquiring bloodborne infections such as Hepatitis B, Hepatitis C and AIDS. One approach to minimizing this risk has been to develop new medical devices that do not require a sharp needle to access an intravenous (I.V.) line. However, the introduction of needleless connectors to access I.V. lines has caused concerns that these devices may increase the risk of introducing bacteria into the fluid path of the device. For that reason, the BD Posiflow™ valve has been tested for microbial barrier properties.

Microbial Contamination Study of NIMA™ Needleless Adapter

The BD Posiflow™ valve design and manufacturing rights were purchased from a company that called the product NIMA™. This company tested the valve for fluid path contamination resulting from the placement of approximately 1,000 colony forming units of *Staphylococcus epidermidis* onto the top of the valve element. After drying, the connecting surfaces were wiped with alcohol and the valve was actuated in the same manner that would be used in the clinical setting. On each of eight days, sterile water was injected through the devices and cultured for bacteria. The conclusion of that study was “The study results confirm that the NIMA™ needleless adapter did not demonstrate increased rates of infection during 96 hours of use. The NIMA™ needleless adapter is a safe and effective device.”

Evaluation of the Fluid Path Contamination Potential as a Result of Introducing Bacteria into the Internal Spaces of the BD Posiflow™ Valve

The purpose of these studies was to determine whether the fluid path of needleless connectors could become contaminated with bacteria in the unlikely event that bacteria were inoculated into the internal (not fluid path) space of these devices.

Study #1

Working under aseptic conditions, a hole was drilled into the side of each of 10 BD Posiflow™ devices with a sterile drill bit. Care was exercised to avoid damaging the internal components of these devices. The internal space of each device was inoculated with a known volume of a suspension of *Staphylococcus epidermidis* containing 10^4 CFU's/ml. Immediately after inoculation, the holes were sealed with a quick-curing, 2-part Epoxy resin.

A bottle of culture medium was attached to the fluid path of these devices by their male Luer connectors. Each device was then repeatedly sampled during the study. This medium provided an amplification system to promote the growth of a small number of viable bacteria if they had contaminated the fluid path of a device.

Each device was activated 50 times per day for 3 consecutive days. All devices were wiped once across the connecting surface of the device using a new isopropyl alcohol (IPA)-saturated pad for each device and with thumb pressure. After wiping the Luer connections with an IPA-saturated pad, a three cc syringe was connected to the device. The connection and disconnection cycle was accomplished for each device before repeating the process on the next device. A sterile syringe was employed for each actuation. Every tenth activation was cultured by drawing approximately 0.5 ml of medium into the syringe. All but approximately 0.1 ml was reinjected into the bottle. The syringe was then disconnected and 1 or 2 drops of the medium were expressed onto the surface of sterile culture medium in a disposable Petri plate.

The plates were then inverted and incubated at 35°C ± 2°C for 48 to 72 hours and checked for growth.

Results

The results of this study are shown in Table I. None of the BD Posiflow™ valves had any growth through 150 actuations.

Table I. Results of Study #1 evaluating the BD Posiflow™ needleless I.V. access system for the potential for fluid path contamination as a result of inoculating the internal space of each device with *S. epidermidis*. The reported numbers are the number of test set-ups growing/number subcultured.

Actuation Numbers	0-50	51-100	101-150
BD Posiflow™	0/10	0/10	0/10

Study #2

Sixty-six BD Posiflow™ valves were connected to separate bottles of sterile bacterial culture medium by the male Luer connector. The valves were accessed 40 times each with sterile, disposable 3 ml syringes. Prior to each actuation, each valve was wiped with an IPA-saturated pad. A new, sterile syringe was used for each activation. After the 40th activation, a hole was drilled into the side of each valve. Then, a suspension of *S. epidermidis* containing approximately 5 X 10³ CFU's/ml was inoculated into each device. The hole was sealed with epoxy resin, and an additional 10 cycles of wiping with an IPA-soaked pad and connection to a syringe were completed. The test sets were then incubated at 37C for 72 hours and observed for growth. Three of the devices were not incubated with the 63 other valves. To check for viability of the inoculum throughout the final 10 actuation cycles, these devices were opened and cultures were obtained from the internal space.

Results

None of the 63 incubated set ups had growth, thus indicating that the fluid paths of these devices remained sterile throughout the study. The three devices that were opened and cultured grew *S. epidermidis*. This demonstrated that the microorganisms remained viable during the study.

CONCLUSION

The summaries of the laboratory studies in this document indicate that the needleless BD Posiflow™ I.V. access system, when used in conjunction with adequate disinfection procedures, is a barrier to microbial contamination of an I.V.-access device to which it would be connected. These tests also demonstrate that, in the unlikely event that fluid contaminated with bacteria entered into the internal space of a BD Posiflow™ valve, there is little potential for the fluid pathway to be contaminated.