IV Accessories

Safeflow Needleless Connector

Clinical Evidence Summary

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SHARING EXPERTISE

Content Overview
Safeflow Needleless Connector

Laboratory Publication

Internal Laboraty Tests

Features & Benefits

1. Microbial tightness of the Safeflow valve

Gebel J; Kuriakose, S; Grüter, B; Exner, M. In vitro study validating the microbial barrier function by means of touch contamination. University of Bonn Hospital, Institute for Hygiene and Public Health, 2015.

1.1 Design

The aim of this study was to evaluate the microbial tightness of the Safeflow valve against touch and airborne contamination.

Safeflow is a needle-free closed injection port which is used for preparation and administration of intravenous therapies.

1.2 Method

The touch contamination analysis was carried out using Staphylococcus aureus.

Staphylococcus aureus was prepared and purified according to DIN EN 12353. An Intrafix® SafeSet administration set was inserted into an Ecoflac® plus IV solution container with 500 ml of 0.9 % sodium chloride solution, and the line was filled. An extension line ("Heidelberger" type) was connected to a single Safeflow valve, and the end of the line was placed into a sterile graduated cylinder.

A suspension of 10^7 cfu/ml of Staphylococcus aureus was used to contaminate the Safeflow valve. The volume of suspension applied per valve was 10 µl. This corresponds to 10^5 cfu of Staphylococcus aureus for each valve. After a drying period of one hour, the membrane of the Safeflow valve was then disinfected and let to air-dry.

Next, it was connected to the Luer lock of an Intrafix® SafeSet administration set. The roller clamp of the Intrafix® was opened, and 80 ml of the sodium chloride solution were transferred from the Ecoflac® plus into the sterile glass.

The entire procedure starting with the contamination of the valve was repeated four times. The collected infusate was filtered and incubated (Figure 1). Nine Safeflow devices were tested.

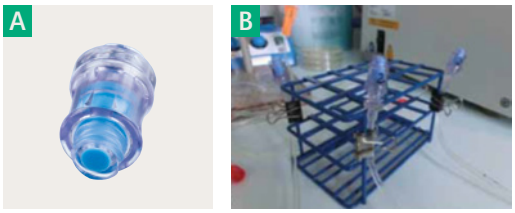
1.3 Results

Table 1: Evaluation of the microbial barrier of the Safeflow valve

	Documentation cfu/400ml of 0.9% NaCl		
Day 1	0	0	0
Day 2	0	0	0
Day 3	0	0	0

No transmission of Staphylococcus aureus through the needle-free access valve after contamination was detected in any of the Safeflow devices tested (Table 1).

Figure 1: Experimental setup



(A) Safeflow valve; **(B)** Experimental setup

1.5 Key Findings

Safeflow is a closed system according to the NIOSH definition. In general, the contamination on the fingertips of physician's dominant hands reaches on average 18.7 cfu/cm^2 of aerobic bacteria. According to Pittet et al. intact areas of some patients' skin can carry 10^0 – 10^6 cfu/cm^2, which can serve as a source for microbial transmission onto the healthcare worker's hands.

This study was carried out with touch contamination of 10^5-times higher concentrations of Staphylococcus aureus. The evaluation of Safeflow demonstrated highly effective microbial tightness based on touch contamination.
The results were also found for airborne contamination.

2. 7-Day Challenge

7-Day Microbial Barrier Performance (2007) - Engineering data on file.

2.1 Design

The study was conducted to demonstrate the integrity of the Safeflow (valve) microbial barrier properties after seven days (168 hours) of simulated worst-case clinical use (140 activations) using a common nosocomial infection organism, Staphylococcus aureus.

2.2 Method

The study included two positive, two negative and three sterility control samples. Each of the test samples and positive controls were challenged using the simulated clinical use model. They were swabbed and accessed 20 times each day. Inoculation and CFU determinations were done after the last activation for the day, as well as the first activation on Day 1.

Prior to each access: the injection site of each valve was swabbed with a fresh sterile 70 % isopropyl alcohol (IPA) pad folded once for 25 – 30 seconds followed by drying for a minimum of one (1) minute. After drying, each valve was accessed using a new, sterile syringe and flushed with 10 ml of sterile saline.

Inoculum: A fresh culture of Staphylococcus aureus was used each day. A suspension was prepared and diluted to approximately 1.0×10^3 Colony Forming Units (CFU) / 0.01 ml for use as an inoculant and stored at 2 - 8 °C. The inoculum population during the seven-day test period ranged from 9.3×10^2 to 5.4×10^3 CFU / 0.01 ml.

Prior to inoculation of test samples and positive controls, each seal was swabbed as described above and was allowed to dry for a minimum of one (1) minute. 0.01 ml of inoculum was placed directly on the top of each valve. The inoculated sites were allowed to sit undisturbed for thirty minutes. Valves were then swabbed as described above with 70 % IPA followed by drying for a minimum of one (1) minute. After drying, each valve was accessed using a new, sterile syringe and flushed with 10 ml of sterile saline. The saline was collected and filtered through a 0.45-micron membrane filter. The filter was placed on TSA and incubated at 30 – 35 °C for 48 hours. Following the incubation period, the CFU's for each valve filtrate were enumerated.

The negative controls were swabbed and accessed twenty times each day as described above. After the last access of the day, the saline was collected and filtered through a 0.45-micron membrane filter. The filter was placed on TSA and incubated at 30 – 35 °C for 48 hours. Following the incubation period, the CFU's for each valve were counted.

The sterility controls (sterilized devices) were placed in 30 ml tubes of tryptic soy broth and incubated at 30 – 35 °C for seven days.

2.3 Results

During the seven days and 140 accesses of the test study using the method described above, the Safeflow valve test samples and negative controls demonstrated no growth of the challenge organism. Positive controls exhibited growth typical of the challenge organism. The recovery ranged from 5×10^0 to 9.4×10^2 CFU with a mean count of 1.86×10^2 CFU. Sterility controls demonstrated absence of growth after seven days of incubation.

2.4 Key Findings

The Safeflow, when used with an adequate disinfection procedure, maintains its microbial barrier properties after 140 activations over a 7-day period. The study was conducted using a higher concentration of challenge organism than typically found in a hospital environment and a non-typical extended time period.

3. Flushing study

Flushing study (2006) - Engineering data on file.

3.1 Design

The aim of this study was to demonstrate the flushing efficiency of B. Braun "Swabable Straight Valves". Tested samples were the B. Braun Safeflow swabable valve. AppTec Laboratory Services, St. Paul, MN, performed all laboratory testing. Three (3) B. Braun Safeflow "Swabable Straight Valves" were tested. 5 mL of human blood was aspirated through each valve.

The valves were exposed to the blood for 10 minutes at room temperature. The blood was removed by the attached syringe immediately prior to initiation of flushing. Each valve was flushed with 1 mL deionized water. The flushing was repeated five times. The eluates were collected into sample tubes and analyzed for total hemoglobin concentration and flushing efficiency (% clearance).

3.2 Method

The study included positive and negative controls. The positive controls were filled with a solution of 5.0 mL of sterile water mixed with 0.35 mL of whole blood. The negative controls were filled with water only.

Test samples: 5 mL of blood was aspirated through each sample valve and left for 10 minutes at room temperature. The syringe was then removed immediately prior to flushing. The valve tip was blotted, and a new syringe with flushing fluid was attached. Each valve was flushed with 1 mL of deionized water and the flush was collected into labeled tubes. The flush was repeated five times. The hemoglobin concentration in the samples was determined using Drabkin's reagent at 1:1 ratio. After a 15-minute incubation at room temperature, the absorbance of each sample was read using a spectrophotometer at a wavelength of 545 nm. Controls were tested concurrently. The total hemoglobin concentration and % clearance was determined for each flush separately.

3.3 Results

Safeflow can be effectively flushed. 100 % clearance was achieved by the 3rd flush for the B. Braun Safeflow "Swabable Straight Valve".

3.4 Key Findings

The Safeflow valve has demonstrated that it can be effectively flushed using the methods performed in this study.

4. High Pressure Application

High Pressure Application (2010) - Engineering data on file.

4.1 Design

The aim of the study was to demonstrate Safeflow's integrity after exposure to elevated internal pressure.

4.2 Background

Safeflow valves accessed with ML connector were exposed to 400 psi for 60 seconds and 1200 psi for 30 seconds of internal fluid pressure.

4.3 Results

Assembled Safeflow valves passed elevated internal pressure test without a leak and without a visible damage. Valves sealing performance and function after the elevated pressure exposure was verified by a back-pressure performance testing.

- The mean back pressure value was 44 psig.
- The +/-3σ values ranged from 40 to 48 psig.
- All samples fell within a +/-3σ distribution.

4.4 Key Findings

The Safeflow valves were assembled per HRC production procedures and accessed by a standard luer (ISO594-2) connector. During pressure testing there was no leakage or damage to the valve. After exposure to 400 psi and 1200 psi internal pressure, Safeflow valves passed the HRC specification for back pressure seal performance (30 psig minimum).

5. Multiple Activations

300 Multiple Activations Evaluation (2010) - Engineering data on file.

5.1 Design

The aim of the study was to demonstrate Safeflow's Luer Activated Injection Site integrity after 300 activations.

5.2 Background

Safeflow valves were tested for sealing performance after 300 activations.

5.3 Results

The assembled Safeflow valves passed backpressure-sealing performance testing after 100, 200, and 300 activations. The mean backpressure value was 41.84 psig (2.88 bar) with a process capability (Cpk) value of 1.88.

5.4 Key Findings

The Safeflow valves were assembled per HRC production procedures and accessed by a standard luer (ISO594-1/-2) connector. After 300 activations, all Safeflow devices passed the HRC specification for backpressure seal performance (30 psig minimum).

6. Safeflow Needleless Connector – Features & Benefits

Negative Displacement Needleless Connector

Safeflow Needleless Connector

Safeflow promotes clinical safety

The Safeflow needleless connector offers convenient and safe needle-free access for injection, aspiration or parallel infusion as a closed system. With its straight fluid path it provides an uninterrupted fluid flow and helps to prevent medication error.[1] The needleless connector has a swabable membrane and a closed system, which is an effective barrier to microbial contamination.[2,3,4,5]

Technical Data

Flow rate:	360 mL/min
Pressure resistance:	400 psi for 60 sec/1,200 psi for 30 sec
Priming volume:	0.09 mL
Multiple accesses:	300 accesses
Flow path:	Straight

Microbial Barrier

Swabable valve forms a closed system as it is designed to prevent microbial ingress and the escape of contaminants.

Multiple Activations

Allows multiple access for direct aspiration or fluid injection.

Straight Fluid Path

Allows rapid delivery and beneficial flow rates for your application.

Literature: 1. Eloot, Sunny et al., How much is catheter flow influenced by the use of closed luer lock access devices?, Nephrol Dial Transplant (2007) 22: 3061–3064, doi:10.1093/ndt/gfm314, Advance Access publication 27 June 2007 (Remark: Swan-Lock® = Safeflow) | 2. Evaluation of the microbial barrier properties of the female valve Safeflow signed by Prof. Dr. med. M. Exner and Dr. rer. nat. J. Gebel, Report DMT 2014-131, 23.02.2015 | 3. Yébenes J et al., „Resistance to the migration of microorganisms of a needle-free disinfectable connector"; AJIC 26, vol. 31, no. 8 (2003): 462 | 4. Kaler W, Chinn R, Successful Disinfection of Needleless Access Ports: A Matter of Time and Friction; DOI: 10.2309/java.12-3-9 (2007) | 5. Jarvis W, MD. Choosing the Best Design for Intravenous Needleless Connectors to Prevent Bloodstream Infections. Infection Control Today, August 2010

For more information, please scan the QR-code or visit:
www.bbraun.com/en/products/b/safeflow

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