B BRAUN

B. Braun Safeflow – 7 day Microbial Challenge Evaluation

Purpose:
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.

Protocol Summary:
AppTec Laboratory Services, Marietta, GA, performed all laboratory testing.
Each of 20 devices was accessed 20 times per day for seven days (140 total activations). Each sample was challenged daily after repeated activations using approximately 1.0 x 10^3 colony forming units (CFU)/ 0.01ml of the challenge organism (Staphylococcus aureus). After routine disinfection of the device, 10 ml of sterile saline was injected through it and passed through a .45µ membrane filter. The filters were incubated on Tryptic Soy Agar (TSA) at 30 - 35º C. for 48 ± 4 hours and the colony forming units (CFUs) enumerated.

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 x 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 x 10^2 to 5.4 x 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 – 35º C for 48 hours. Following the incubation period, the CFU's for each valve filtrate were enumerated.

B BRAUN

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 ºC 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 ºC for seven days.

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.

Conclusion:
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.

Clinical Use Recommendations:

Follow the manufacturer's recommendations in the Instructions For Use: For IV administration use, replace the injection site every 24 hours or per hospital protocol.

Safeflow is distributed by B. Braun Melsungen AG