7-DAY MICROBIAL CHALLENGE EVALUATION

ONCOERA NEEDLE-FREE VALVE SYSTEMS

SPLIT SEPTUM VALVES

Intravenous therapy is one of the most common invasive procedures and has a high risk of complications. Catheter-related infections, especially central venous catheter infections, increased the intensive care mortality rates to 30%. Comparative studies have also been carried out in terms of vein valves and as a result, split septum valves have come one step ahead among many different designs and have become an indispensable part of intravenous therapy.

ONCOERA NEEDLE-FREE VALVE SYSTEMS

The CDC recommends the split septum design valves in intravenous therapy to reduce the risk of infection.

Oncoera Needle-Free Valves belong to the CDC-recommended Split Septum Valve group.

INFO

Date of Study
2021' May

Manufacturer
Eraser Medikal Ltd. Şti.

Test Lab
Akdeniz University Faculty of Medicine, Histology and Embryology Department & ND Biological and Medical Products Medical Devices Research Laboratory

ONCOERA Safe for your health ERASER® MEDICAL

SUMMARY

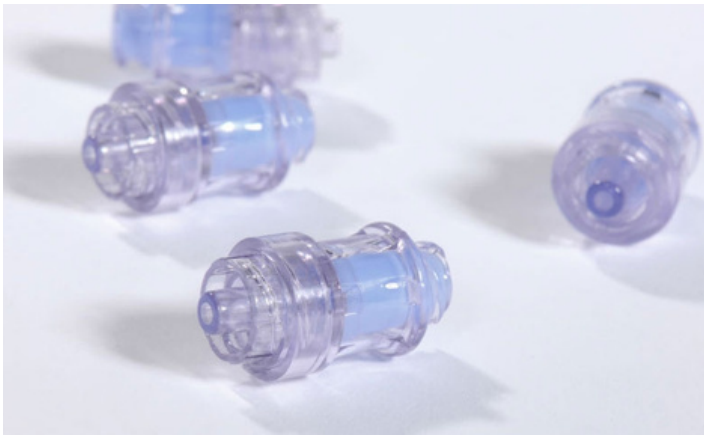
Purpose

To evaluate the microbiological barrier-forming performance of sterile syringe-activated ONCOERA Needle-Free Valve Systems at worst clinical cases (35 activations) over 7 days (168 hours) by using a common nosocomial infection organism, Staphylococcus epidermitis ATCC 12228.

Method

In the study, a total of 10 valves (2 positive control, 2 negative control and 6 sterility control) were used.

Positive Control: The silicone part of each valve was inoculated with the bacteria suspension 5 times a day for 7 days. Then, the valve was accessed by using a sterile syringe and sterile saline without applying the disinfection swab. The liquid passed through the valve was collected and incubated with 5% blood agar at 37oC for 28 hours and colony forming units were numbered.



Negative Control: The silicone part of each valve was disinfected with 70% isopropyl alcohol 5 times a day for 7 days. without inoculation with bacteria suspension. Then, the valve was accessed by using a sterile syringe and sterile saline. The liquid passed through the valve was collected and incubated with 5% blood agar at 37oC for 28 hours and colony forming units were numbered.

Sterility Control: The silicone part of each valve was inoculated with the bacteria suspension 5 times a day for 7 days. Next, disinfected with 70% isopropyl alcohol 5 times a day for 7 days. Then, the valve was accessed by using a sterile syringe and sterile saline. The liquid passed through the valve was collected and incubated with 5% blood agar at 37oC for 28 hours and colony forming units were numbered.

Conclusion

As a result of testing sterile syringe-activated injection valves for 7 days and multiple uses, no growth was detected in the sterility group and the negative control group samples. Growth was observed only in the positive control group as expected.

ONCOERA Needle-Free Valve Systems have been validated to provide a microbiological barrier.

The study was conducted using a higher concentration of challenge organism then typically found in a hospital environment and a non-typical extended time period.

ONCOERA Safe for your health ERASER® MEDICAL

Manufacturer. ERASER MEDİKAL LTD. ŞTİ. Pınar Cd. No:78 Pınarbaşı / Bornova / İzmir, TURKEY
E-mail: info@oncoera.com.tr Phone: +90 232 479 80 60 Fax: +90 232 479 80 25
www.eraser.com.tr www.oncoera.com.tr