

Neutron[®] Needlefree Catheter Patency Device Disinfection Recommendation

According to the Neutron device directions for use, the split-septum seal should be *scrubbed before each use in accordance with validated facility protocol*. The Neutron device has a dedicated internal fluid pathway consisting of an internal blunt cannula and a silicone split-septum seal. External to this fluid pathway is the housing, which allows connection to the device through ISO-compliant male luers, including syringes and administration sets. During activation, a seal is created between the tip of the male luer and the top of the pre-slit silicone that is then compressed to access the internal fluid path. Proper disinfection of the pre-slit silicone is important to ensure a sterile site at each access.

ICU Medical has evaluated the Neutron device's ability to be effectively disinfected in order to prevent microbial ingress in accordance with the FDA Guidance for Medical Devices with Sharps Injury Prevention Features.¹ The study followed a pre-determined disinfection procedure, which is described as an *"aggressive circular motion for three seconds."* This disinfection or "scrub" was done using a standard IPA swab with *70% isopropyl alcohol*. The results of the study demonstrate that if you use this technique prior to access, the injection site of the Neutron device will be sterilized such that it prohibits ingress and transfer of bacteria.

The Neutron device is chemically compatible with isopropyl alcohol, betadine, and chlorhexidine disinfectants and may also be used with disinfecting cap products. Some of these disinfectants, however, such as betadine and chlorhexidine, leave residuals on the device that can build up over time. These residuals will not interfere with the Neutron device function and can be routinely removed using a standard isopropyl swab.

If there are further questions or concerns, please visit our website at www.icumed.com or contact the corporate offices at 949-366-2183 or 800-824-7890.

Technical Services
ICU Medical Inc.

1. Data on file at ICU Medical. Evaluation of the Neutron™ needlefree catheter patency device technology and resistance to microbial ingress. M1-1313 Rev. 01.