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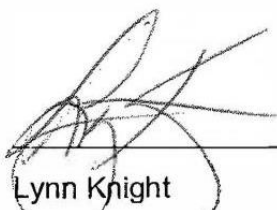
04-01-2019

Summary Report for NVX-T-039:

On behalf of C Change Surgical, Novex Innovations performed a study/protocol to assess the ability of the RSC-1L (Reusable Slush Container™), PCS-1.0 (Protective Container System™), and the SurgiSLUSH™ freezer to maintain sterility of liquids used to create surgical slush.

Tests within this protocol are designed to collect and assess scientific data to verify that the protective container is operating as expected to provide a high sterility assurance level for the SurgiSLUSH™.

An operating room back table was simulated in an aseptic area. The RSC-1L were cleaned according to published cleaning instructions and sterilized using the recommended pouch cycle in gravity steam sterilizer. They were then opened onto the sterile field and filled with saline. The RSC-1L were inserted into the PCS-1.0 in accordance with the IFU and sealed. The PCS-1.0 were removed from the sterile field and placed into the SurgiSLUSH™ freezer to be cooled. The SurgiSLUSH™ freezer was located approximately 100 feet outside of the aseptic area. Once the cooling cycle completed, the RSC-1L were removed, taken back to the sterile field and presented. The PSC-1.0 were discarded and the RSC-1L were swabbed for Aerobic, Anaerobic and Fastidious Bacteria. The culturing represented 100% the sides, top and bottom. The cultures were tested at a third-party laboratory and showed no growth after 14 days.



Lynn Knight
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04-02-2019

Date