Pressure test of Corvida Halo® Closed System Transfer Device

OBJECTIVE:

Evaluate the ability of the Halo® CSTD components to contain air pressure as an indicator of the ability to contain fluid and vapors.

TEST METHOD:

Each set of components was tested to evaluate its ability to withstand 30 psi with no leaks. The Closed Syringe Adaptor was connected and disconnected from the Closed Vial Adaptor fourteen (14) times prior to performing the pressure test. This was done to demonstrate that even after an extreme condition of use, the seals on the Closed Syringe Adaptor and Closed Vial Adaptor continued to seal after repeated needle punctures. After the connection/disconnections, the Closed Syringe Adaptor in the unconnected state was subjected to a calibrated, 30 psi pressure source via the luer fitting on the end of the adaptor. Following this, the Closed Syringe Adaptor was connected to the Closed Vial Adaptor and subjected to 30 psi using the same pressure source connected to the Closed Syringe Adaptor.

- 30 sets of Corvida Halo 13mm Closed Vial Adaptor and Closed Syringe Adaptors were subjected to two sterilization cycles prior to testing
- 30 sets of Corvida Halo 13mm Closed Vial Adaptor and Closed Syringe Adaptors were subjected to two sterilization cycles cycles and one year accelerated aging per ASTM F1980-07 prior to testing
- 30 sets of Corvida Halo 20mm Closed Vial Adaptor and Closed Syringe Adaptors were subjected to two sterilization cycles prior to testing
- 30 sets of Corvida Halo 20mm Closed Vial Adaptor and Closed Syringe Adaptors were subjected to two sterilization cycles cycles and one year accelerated aging per ASTM F1980-07 prior to testing
- 30 sets of Corvida Halo 28mm Closed Vial Adaptor and Closed Syringe Adaptors were subjected to two sterilization cycles prior to testing
- 30 sets of Corvida Halo 28mm Closed Vial Adaptor and Closed Syringe Adaptors were subjected to two sterilization cycles cycles and one year accelerated aging per ASTM F1980-07 prior to testing

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RESULTS:

All product tested (180 of 180) passed the test with no leaks.

CONCLUSION:

The Halo seal system has been designed to assure a high level of safety to the clinician from hazardous drug exposure. This test demonstrated that even after subjected to an extreme number of connections (fourteen), the Halo® components continue to provide containment of pressure. Although it is very unlikely that any of the components would be subjected to 30 psi, this test provides the clinician with the confidence that there is a significant margin of safety when using the Halo® to protect from hazardous drug exposure.

Reference:

1. TPR2017 - CTP1002 System Pressure Test (T=0), February 2015
2. TPR2016 - CTP1002 System Pressure Test (T=1), February 2015