

# Tevadaptor® Elastomer Integrity Testing



## Head-to-Head Comparison of Visual Inspection and Wipe Tests of 3 Leading CSTDs

Preparation of cytotoxic drugs using syringe and needle potentially exposes pharmacists and nurses to long term health hazards <sup>1,2</sup>. The Tevadaptor® CSTD (Closed System Transfer Device) mechanically prohibits the release of drug in vapor, aerosol or liquid form during drug preparation and administration <sup>3</sup>.

Testing of Tevadaptor® using the recent NIOSH draft protocol and 2-phenoxyethanol (2-POE) as the surrogate demonstrated that Tevadaptor® functions as an effective CSTD <sup>4</sup>. Tevadaptor® prevents the release of hazardous drugs as vapor, liquid and aerosols during compounding and administration, with containment efficacies equivalent to competing CSTDs, hence protecting pharmacists from exposure to these drug substances.

Independent head-to-head testing of Tevadaptor® with PhaSeal™ and Equashield® using Doxorubicin, a highly visible red cytotoxic drug, showed no traces of the drug on septa or wipe pads for ten activations with the Tevadaptor® <sup>5</sup>.

Tevadaptor® is proven to provide excellent performance and elastomer integrity for up to ten activations when compared to other CSTDs tested <sup>5</sup>.

### Septum Surface

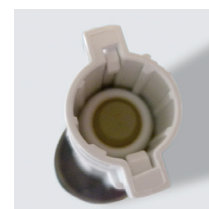
Test Results for Tevadaptor®, PhaSeal™ and Equashield®.



Tevadaptor® Syringe Adaptor



PhaSeal™ Injector



Equashield® Syringe Unit



Tevadaptor® Vial Adaptor



PhaSeal™ Protector



Equashield® Vial Adaptor

Tevadaptor® and Equashield® shows no drug traces on the septum or on wipes for ten activations.

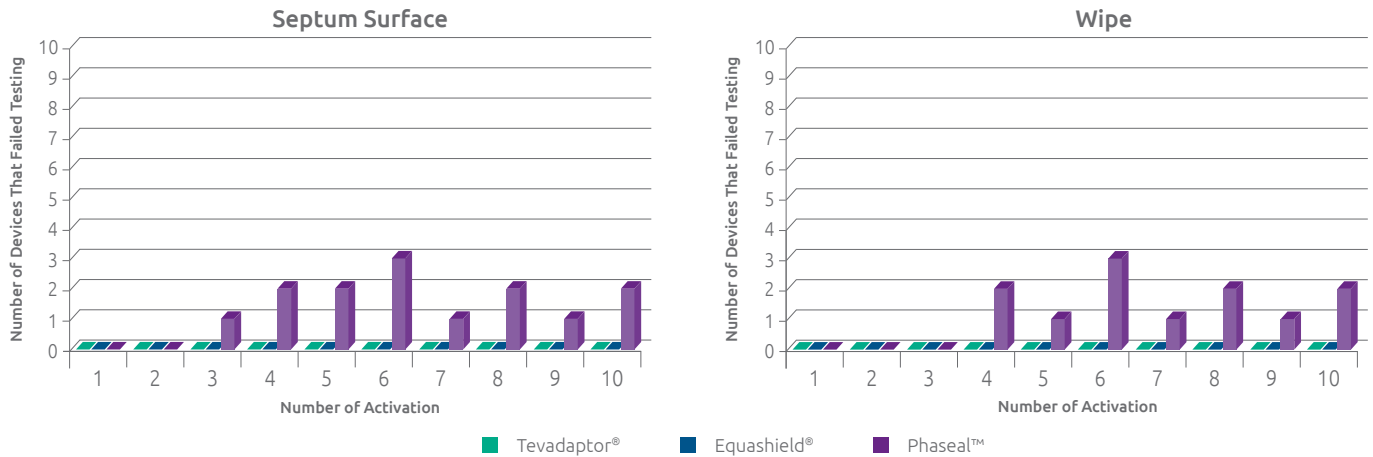
PhaSeal™ demonstrates Doxorubicin droplets from the third activation.

## Test Methodology for Elastomer Integrity

**Tevadaptor® delivers proven performance with no detectable drug remains when using visual inspection and wipe tests.**

BioPharma Stability Testing Laboratory (BSTL, UK), an independent research lab, tested ten Tevadaptor® device sets (syringe adaptor + vial adaptor) using Doxorubicin, a highly visible cytotoxic drug, each for ten consecutive activations. The same test was repeated for PhaSeal™ and Equashield®.

Testing included connecting the two components together to make a drug withdrawal from the vial, and then the components were disconnected. The septa of the two components were examined for Doxorubicin traces, and then wiped with a sterile alcohol pad which was examined for drug remains as well. The procedure was repeated ten times.



## Test Results as Analyzed by BSTL

Results demonstrate that Tevadaptor® shows no traces on the septa surfaces or on sterilization wipes for ten consecutive activations. Equashield® showed similar performance as Tevadaptor®, while PhaSeal™ showed Doxorubicin droplets on the septum from the third activation and/or traces on wipes from the fourth activation.

## Tevadaptor® Now Features Upgraded Elastomer Design for Even Better Performance



The flat elastomer surface is easily accessible for aseptic cleaning

**Tevadaptor® is proven to provide excellent performance and elastomer integrity for ten consecutive activations with Doxorubicin. This is confirmed by comparison to other CSTDs in the market through testing in an independent laboratory with a highly visible, real hazardous drug.**

## References

1. Sessink PJ, Urinary cyclophosphamide excretion and chromosomal aberrations in peripheral blood lymphocytes after occupational exposure to antineoplastic agents. *Mutat Res.* 1994 Sep 1;309(2):193-9.
2. NIOSH. (2004) Preventing occupational exposure to antineoplastic and other hazardous drugs in health care settings. Publication Number 2004-165. National Institute for Occupational Safety and Health. Centers for Disease Control and Prevention. US Department of Health and Human Services. Available from: <https://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf>.
3. Tevadaptor Indications for Use.
4. Assessment of vapour containment performance for closed system drug transfer devices (CSTDs) that either employ a mechanically closed physical barrier or air filtration technology – a universal protocol to assess CSTDs. Wilkinson AS. Presented at ASHP 2016.
5. Tevadaptor Data on File. Doxorubicin data. study 174.