STUDY SUMMARY

Engineering Analysis of Comparative Push/Pull Forces Using Closed System Transfer Device (CSTD) Systems

BACKGROUND

Modern CSTDs employ a variety of technologies designed to limit the exposure of hazardous drugs during compounding and administration. When used exactly, according to protocol, most systems provide an acceptable level of protection during the pharmacy compounding process. However, new reports have suggested that some of these technologies may introduce new harms, such as repetitive stress injuries (RSIs), as a result of their design. All but one of the CSTDs evaluated use integral needles in the transfer system components, often doubling the force or pressure required to transfer the drug amongst various containers. One of the systems also incorporates an integral syringe as part of the transfer device, which can increase the strain forces. This system markets two different 60cc syringe units, one of which is designed to decrease the force. These new risks should be considered when evaluating CSTDs, as technician injury can significantly affect both efficiency and economics of the workplace when technicians are unable to perform their duties.

PROTOCOL

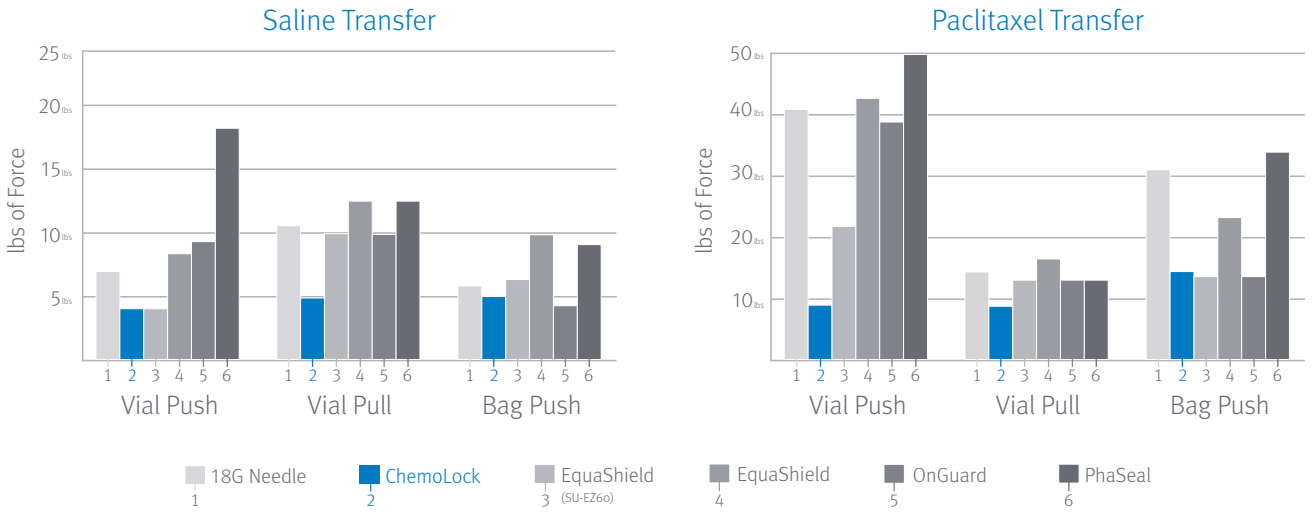
In order to investigate how CSTDs compare in their ability to transfer drugs with minimal technician strain, a protocol was developed to measure the transfer forces. Using an Instron® machine at a speed of 12" per minute, each CSTD was set up to mimic a 60cc push into a vial spike, a 60cc aspiration from a vial, and a 60cc push into a bag spike. An 18G needle was also tested in each scenario for comparison. Paclitaxel was chosen as the drug transfer media to represent a worst-case scenario for viscosity, and saline was chosen to represent less viscous drugs.

- ChemoLock® (ICU Medical, Inc. – Needlefree CSTD)
- EquaShield® (Equashield, LLC – Dual-Needle + Syringe CSTD)
- OnGuard™ (B. Braun Medical Inc. – Single-Needle CSTD)
- PhaSeal™ (Becton, Dickinson and Company – Dual-Needle CSTD)

RESULTS

The CSTD that functions without needles provided the lowest transfer forces for both the push and pull operation. The CSTDs that incorporate needles required significantly higher push/pull forces, suggesting that technicians may experience increased strain during the compounding process.

Comparison of Push/Pull Forces



SUMMARY

The introduction of a CSTD into the workplace should provide the benefit of limiting the exposure of hazardous drugs during compounding, adminstration, and disposal, yet at the same time should not introduce new risks, such as RSIs to pharmacists and technicians. The results of this engineering analysis show significant differences in required push/pull transfer forces between CSTD systems, suggesting that the design of a CSTD influences the ability of a technician to safely and efficiently compound medications. Further engineering principles, such as the ability of a CSTD to prevent deactivation by the user, should also be considered when selecting a CSTD.