NEW
FDA cleared under ONB product code and substantiated to prevent microbial ingress up to 7 days

2nd Generation Closed System Transfer Device for Hazardous Drugs
Superior Safety and Ease of Use
Introducing EQUASHIELD® and the all new 2\textsuperscript{nd} generation EQUASHIELD® II closed system

**Safe**

- The only system that prevents syringe plunger contamination (recently identified as a major route of exposure to hazardous drugs).
- Closed pressure equalization prevents the escape of drug and vapors.
- “Dry” connector that remains free of drug residuals.
- Cleared by the FDA under the ONB code and substantiated to prevent microbial ingress for up to 7 days.
- Clinically proven.

**Simple**

- Fully preassembled syringe with connector, requiring no further setups or off the shelf syringes.
- Easy-to-use single motion connectors.

**Closed**

- The only system with encapsulated syringe barrel and plunger.
- Closed internal pressure equalization built in to the syringe.
- Connector permanently welded to syringe.
- Encapsulated plunger that cannot be pulled out of the barrel.
Air bubbles or drug can be ejected back into the vial during drug withdrawal. The new generation prevents migration of drug to the back chamber of the syringe at any time.

The unique Vial Adaptor guides the spike to the center of the vial stopper and prevents angled spiking.

Automatic “Red to Red” alignment of all connectors and prevention of unintended twisting.

System Components:

Syringe Units [1ml to 60ml all sizes], Vial Adaptors [13mm, 20mm, 28mm], Spike Adaptors, Female & Male LL Connectors, Secondary Tubing Sets [with & without drip chamber], Y-Site Extention Tubing.
Simple & Intuitive

1. Click the adaptor onto the vial

2. Slide the syringe over the adaptor and withdraw the desired dose

3. Slide the syringe over the IV bag adaptor and inject medication

3 Step Simplicity saves valuable preparation time
Comparative Study of Vapor Containment Efficiency of Hazardous Drug Transfer Devices
Dr. Igal Bar-Il, Migal Analytical Chemistry Laboratory in Kiryat Shmona, Israel

**Aim:** The purpose of this study was to evaluate the vapor containment efficiency of several commercially available devices, in order to evaluate the airtight sealing properties of each category and to determine which devices can prevent the escape of vapor during the preparation of hazardous drugs.

**Method:** Titanium-tetrachloride was used as a drug substitute simulating normal preparation conditions. Each device was observed during its operation for any release of Titanium vapor into the environment.

**Results:** Only closed systems with full pressure equalization, i.e. Equashield® and Phaseal® prevented the release of Titanium-tetrachloride vapor into the environment.
Syringe plunger contamination by hazardous drugs: A comparative study
Journal of Oncology Pharmacy Practice 2014. Stephen T. Smith, MS, FASHP,
Mark Szlaczky, PharmD
Karmanos Cancer Center, Detroit, MI, USA

**Aim:** Perform a comparative cyclophosphamide contamination level test on the syringe plungers of Becton Dickinson (BD) with Phaseal CSTD vs. Equashield syringe plungers under routine oncological compounding conditions.

**Method:** The ChemoGlo sampling kit and analysis services were used to test for cyclophosphamide contamination levels on the syringe plungers that underwent cycles of drug transfer in a Biological Safety Cabinet. A 50 ml aliquot of cyclophosphamide was drawn into each syringe and then injected back into the cyclophosphamide vial. This drug transfer procedure was immediately repeated twice, 4 times and 8 times for the 3 separate groups of syringes. After the completion of the drug transfers, the plungers were retracted back to the nominal syringe marking, and a wipe test of the exposed plunger was done using the ChemoGlo sampling kit.

“Significant contamination levels were detected on most BD syringe plungers, whereas all Equashield syringes remained uncontaminated ...”

**Results:** Significant contamination levels of 2000 ng and greater were detected on most BD syringe plungers, whereas all Equashield syringes remained uncontaminated at undetectable levels. The contamination levels found on the standard BD syringe plungers confirm previous studies, such as: Favier B, et al. “Contamination of syringe plunger during the sampling of cyclophosphamide solutions”, J Oncol Pharm Practice 2005.
Purpose: To evaluate the effectiveness of a closed system drug-transfer device, Equashield, at reducing surface contamination with antineoplastic agents throughout an ambulatory cancer chemotherapy infusion center.

Methods: Surfaces throughout the cancer center were sampled three times. The first samples were obtained in June 2010 without prior cleaning to measure baseline levels of contamination of the current technique (Chemo Dispensing Pin, B. Braun Medical Inc.). The second samples were obtained in August 2010 after the implementation of the closed system drug-transfer device and cleaning to evaluate if the contamination was removed. The third samples were obtained in August 2011. Wipe samples were taken from five positions in the pharmacy and from five positions in the infusion suite. Wipe samples were also collected from two positions in office areas. Samples were analyzed for cyclophosphamide and 5-fluorouracil.

Results: The results from the first two sets of samples showed contamination with cyclophosphamide on about half of the positions at all locations during both collection periods. However, levels of contamination were very low and mostly just above the detection limit of the analytical method. The highest level of contamination was found on the door and handle in the pharmacy. Contamination with 5-fluorouracil was only observed on the dispensing counter in the pharmacy during the second collection period. The results from the third and final collection period showed no contamination with cyclophosphamide or 5-fluorouracil in the pharmacy, the infusion suite or in offices of the cancer center.

Conclusion: Implementation of the closed system drug-transfer device for preparing and administering chemotherapy eliminated surface contamination with cytotoxic agents at the ambulatory cancer chemotherapy infusion center.

<table>
<thead>
<tr>
<th>Sample code</th>
<th>Department</th>
<th>Date</th>
<th>Description surface</th>
<th>Area surface (cm²)</th>
<th>Total volume NaOH (mL)</th>
<th>CP (ng/mL NaOH)</th>
<th>SFU (ng/mL NaOH)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Pharmacy</td>
<td>19 Aug 2011</td>
<td>Dispensing counter</td>
<td>2500</td>
<td>160</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>B</td>
<td>Pharmacy</td>
<td>19 Aug 2011</td>
<td>Deskilling cabinet</td>
<td>1710</td>
<td>160</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>C</td>
<td>Pharmacy</td>
<td>19 Aug 2011</td>
<td>Floor dispensing area</td>
<td>2500</td>
<td>160</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>D</td>
<td>Pharmacy</td>
<td>19 Aug 2011</td>
<td>Half door + handle</td>
<td>756</td>
<td>160</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>E</td>
<td>Pharmacy</td>
<td>19 Aug 2011</td>
<td>Compounding counter</td>
<td>625</td>
<td>160</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>F</td>
<td>Office</td>
<td>19 Aug 2011</td>
<td>Desk Support Nurse</td>
<td>625</td>
<td>160</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>G</td>
<td>Office</td>
<td>19 Aug 2011</td>
<td>Prop desk</td>
<td>625</td>
<td>160</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>H</td>
<td>Infusion suite</td>
<td>19 Aug 2011</td>
<td>Pyxis machine</td>
<td>480</td>
<td>160</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>I</td>
<td>Infusion suite</td>
<td>19 Aug 2011</td>
<td>Floor</td>
<td>930</td>
<td>160</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>J</td>
<td>Infusion suite</td>
<td>19 Aug 2011</td>
<td>Nurses desk</td>
<td>625</td>
<td>160</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>K</td>
<td>Infusion suite</td>
<td>19 Aug 2011</td>
<td>Chair side table</td>
<td>1200</td>
<td>160</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>L</td>
<td>Infusion suite</td>
<td>19 Aug 2011</td>
<td>Counter fast track</td>
<td>625</td>
<td>160</td>
<td>ND</td>
<td>ND</td>
</tr>
</tbody>
</table>

ND: not detected (CP < 0.10 ng/mL NaOH; SFU < 5 ng/mL NaOH).
Connecting tubing sets, such as secondary to primary tubing, and connecting an IV Push, is safe and easy with EQUASHIELD’s Dry Connectors. Ports remain dry, drug free and the entire System remains Closed.

To disconnect, pull the Connectors apart and dispose of as a completely Closed System.
Fluorescent Evaluation of Dry Connections in the EQUASHIELD®, Phaseal® and Tevadaptor®/Onguard® Closed System Drug Transfer Devices
Dr. Igal Bar-IlIan, Migal Analytical Chemistry Laboratory in Kiryat Shmona, Israel

Objective: Evaluation of EQUASHIELD® closed system drug transfer device during perpetration and administration phases, for determining residual free and dry connections between Syringe Unit, Vial Adaptor and IV bag Spike Adaptor. The Phaseal® system and Tevadaptor®/Onguard® were tested and used as benchmarks.

Method: Vials were filled with 0.05% Fluorescein solution to simulate the preparation phase. A 7ml Fluorescein solution was drawn into the 20ml syringe of each of the 3 tested transfer systems and then 5ml were re-injected back into the vial. After each manipulation the syringe unit was disconnected from its respective vial adapter and checked for leaks using UV light. The process of withdrawing/re-injecting 5ml of Fluorescein solution was repeated 15 times with 10 sets of each of the three tested transfer systems.
A similar process was repeated with 10 sets of each of the three tested transfer systems, thereby syringe units filled with 20ml Fluorescein solution dispensed through IV bag spike adapters. A 2ml solution was injected with each syringe unit into an IV bag, disconnected and checked for leaks. The process was repeated 10 times.

Results: No visual signs of Fluorescein leaks were perceived on any of the 20 EQUASHIELD® devices. All Tevadaptor®/Onguard® systems revealed visual signs of Fluorescein leaks as early as after the first or second manipulation. Visual signs of Fluorescein leaks were detected on 8 of the 20 Phaseal® systems after 14, 11, 15, 13, 8, 7, 10, 10 manipulations respectively.
How EQUASHIELD® Works

EQUASHIELD® Closed Pressure Equalization Prevents the Escape of Vapors and Aerosols

EQUASHIELD® equalizes pressure differentials through a:

- Dual-needle, air-to-liquid closed exchange system
- Factory sealed sterile air chamber

To offset the pressure during withdrawal, the short liquid needle draws medication out of the vial, while the long air needle replaces it with an equal amount of air. The sterile air is drawn from the air chamber sealed within the back of the syringe. During reconstitution of drug powder the process is reversed; the short liquid needle injects liquid into the powder vial, while the long air needle offsets overpressure by drawing toxic vapors into the air chamber at the back of the syringe.

Dry Connectors Prevent Drug Residuals, Spills and Needle Sticks

EQUASHIELD® ensures easy and dry medication transfers with:

- A unique locking mechanism with dual membranes for multiple access
- All connections are made with a simple sliding motion

All EQUASHIELD’s connections are made with a single sliding motion. When two connectors are engaged, the locking mechanism presses the elastic membranes of both connectors tightly together and keeps them locked. The needles pierce through both membranes only after the membranes are locked. During retraction, the needles wipe against the resealing membranes. This prevents any contact between the drug and outer surface of the membranes, leaving the contact area dry and clean of any residual drug.

Needle safe - Needles never move and remain shielded inside a housing beyond reach.
A Fully Self-Contained Syringe Unit with Welded Connector Prevents Spills

Fully preassembled syringe with connector, requiring no further setups or off the shelf syringes.

- Preventing accidental luer disconnections that may result in a spill
- The plunger rod can never be detached from the syringe and cause spill
- Saves valuable time that alternative systems spend on opening two packages and assembly of syringe with connector
- Utilizing a durable factory-sealed, sterile air chamber for pressure equalization

How EQUASHIELD® Works

Double Jacket Enclosure Prevents Syringe-Plunger Contamination

Syringe plunger contamination by hazardous drugs during routine drug preparations and IV pushes is a major route of exposure. This became evident in recently conducted studies, indicating high levels of drug residuals (Cyclophosphamide) on the open syringe plungers, which in turn contaminate the work environment. Unlike other devices that use standard syringes with exposed cylinders and plungers, EQUASHIELD® prevents plunger contamination by:

A double jacket enclosure that encapsulates the syringe barrel and isolates the syringe plunger
Equashield is a privately held medical device company with great experience in the design, production and supply of fluid drug admixing and transfer systems. The company’s proprietary newest product, EQUASHIELD®, is a Closed System Transfer Device for hazardous drugs that exemplifies our credo and commitment to safety and simplicity through innovation. EQUASHIELD® provides unprecedented protection to healthcare workers and their patients, while remaining affordable and simple to use.

All our products are FDA and CE cleared, complying with the strictest regulatory requirements. Our recently expanded and renovated ISO 9001 / ISO13485 production facility, is equipped with class 100,000 (ISO-8) clean rooms, and works in full compliance with U.S. Good Manufacturing Practices. Equashield provides extensive in-house service and easily accessible local support.

By designing and producing innovative protection products, Equashield is creating an environment where medical professionals have the confidence to serve others without compromising their own health and safety.

We strive to provide superior innovative solutions for the protection of healthcare workers around the globe.