OnGuard® 2 CSTD

Syringe Barrel Challenge – a Litmus-Based Approach

B BRAUN
SHARING EXPERTISE

Introduction

For the last decade, Closed system transfer devices (CSTDs) are widely used to prepare and administer hazardous drugs. The definition of a CSTD according to the National Institute for Occupational Safety and Health (NIOSH) is "a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system" (NIOSH, 2004).[1] CSTDs are designed to protect healthcare workers, involved in the preparation, delivery and disposal of hazardous drugs.

Syringe Adaptors vs Syringe Units

CSTDs from different manufacturers vary in their designs and materials. However, they share common components (e.g., vial adaptor, syringe adaptor and an infusion bag spike [bag adaptor], which connects to an IV bag) (Kagdi, 2020).[2] All these components enable the pharmacist to safely transfer drugs from one container to another. To turn a standard medical-grade syringe into a closed system, most CSTD product lines offer one or more syringe adaptors, which are compatible with all standard Luer lock syringes. EQUASHIELD®, on the other hand, offers pre-bonded syringe units of different volumes—8 different SKUs (Figure 1). EQUASHIELD users must hold supply stocks of several different SKUs, without the flexibility to choose syringe suppliers independently. In addition, EQUASHIELD claims that their syringe units, which comprise a liquid compartment and an air compartment for pressure equalization, are the only products that can prevent contamination from the inside of a used syringe barrel.[3]

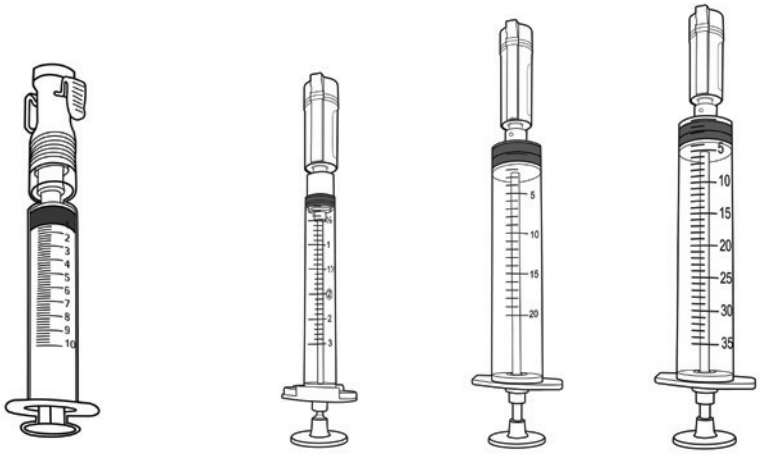

Figure 1. Left: OnGuard® 2 Syringe Adaptor with standard Luer lock syringe; Right: three (out of eight) of EQUASHIELD's Pre-bound Syringe Units

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Objective

The aim of this study was to show that standard medical-grade syringes, such as those manufactured by Becton Dickinson (BD), when used with OnGuard® 2 Syringe Adaptors, do not allow contamination of the exposed inner wall of the used syringe barrel behind the plunger stopper. An aqueous acidic solution was chosen as a non-hazardous and easily detectable drug surrogate.

Materials and Methods

An aqueous solution was adjusted to pH 1.5 using a 1.0 N hydrochloric acid solution. This solution was transferred to a glass vial equipped with an OnGuard 2 Vial Adaptor. Five separate 30-mL BD Luer-Lok syringes were connected to the prepared OnGuard 2 Syringe Adaptor assembly and were tested in the following manner:

- The Syringe Adaptor was connected to the Vial Adaptor (Figure 2).
- The acidic solution was withdrawn into the syringe, so that the entire inner wall of the syringe barrel made contact with the solution (Figure 3).
- The solution was returned to the vial.
- The Syringe Adaptor was disconnected from the Vial Adaptor.
- Litmus blue indicator paper, which turns pink upon contact with an acidic solution, was inserted in the space between the syringe plunger and barrel, thoroughly sampling all the inner walls of the barrel (Figure 4).

As positive controls:

- A drop of the same acidic solution was placed on a strip of litmus blue indicator paper.
- A drop of the same acidic solution was placed, using a needle, on the inner syringe barrel wall of one syringe, followed by litmus paper sampling.

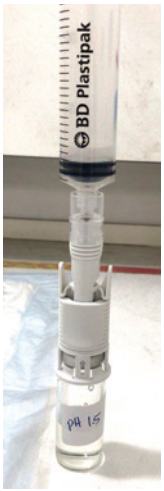

Figure 2. OnGuard® 2 Syringe Adaptor and BD syringe connected to OnGuard® 2 Vial Adaptor and vial containing acidic solution

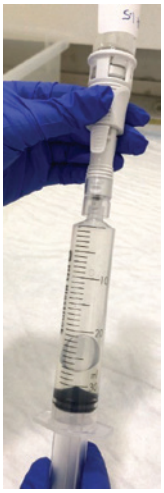

Figure 3. Withdrawal of acidic solution into BD syringe, ensuring contact with all inner walls of the syringe barrel

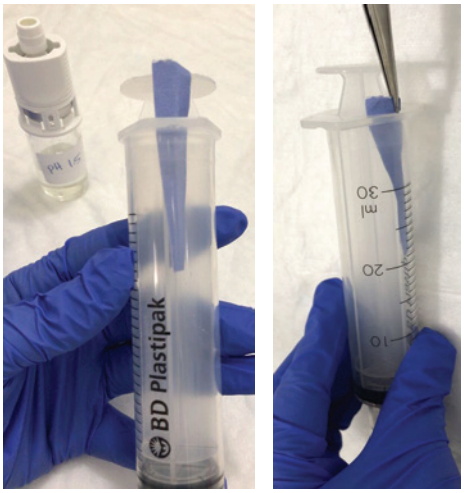

Figure 4. Sampling of inner syringe barrel walls with litmus blue indicator paper

Results

All 5 litmus paper strips did not show any change in color, indicating the absence of the acidic solution on the inner wall of the syringe barrel (Figure 5). In both positive controls, a color change of the litmus paper to pink was readily apparent (Figure 6).

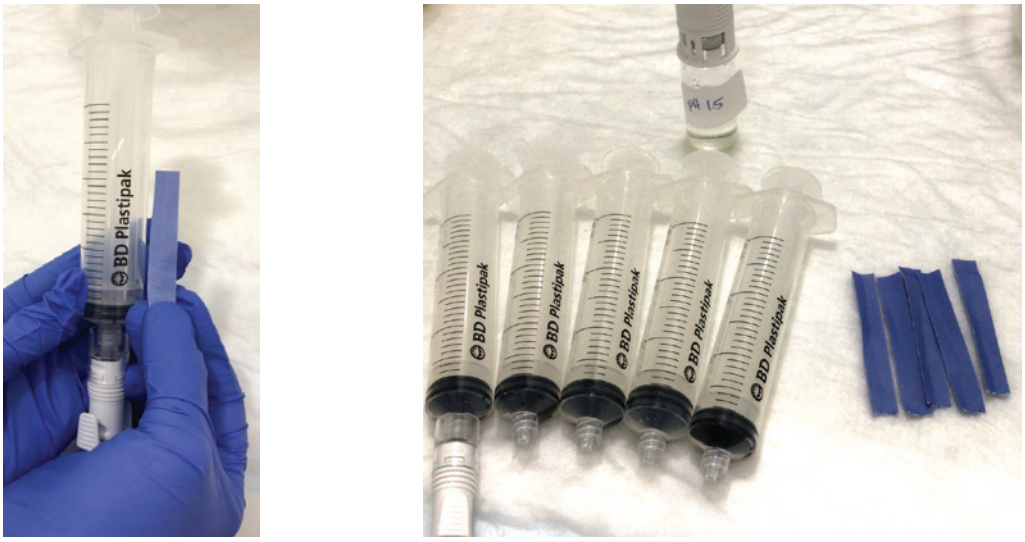

Figure 5. Test results: no color change on litmus blue indicator paper after sampling inner syringe barrels

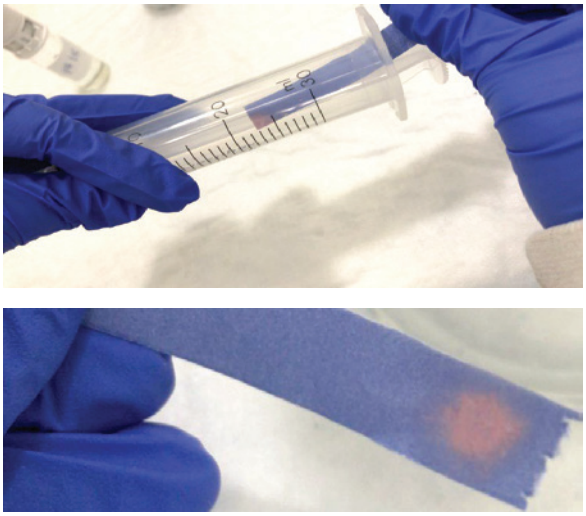

Figure 6. Positive control results: Top – pink color change observed following placement of acidic solution on the inner wall of a syringe barrel; Bottom – pink color change observed following purposeful placement of acidic solution on a strip of litmus blue indicator paper

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Discussion

This study verifies that the exposed part of the inner barrel of the BD Luer-Lok™ syringes, when used with an OnGuard® 2 Syringe Adaptor, was not contaminated with acidic drug surrogate solution following use. Therefore, the syringe plunger sufficiently wipe the inner walls of the syringe barrel clean upon injection of surrogate.

Conclusions

The plunger stopper of standard medical-grade Luer Lock syringes wipes off any solution present on the inner wall of the barrel after the plunger is fully depressed, removing all solution from behind the stopper and preventing exposure to users.

This study shows that the use of standard medical-grade Luer Lock syringes with the Onguard 2 Syringe Adaptor does not lead to exposure from fluid left behind the plunger stopper in the inner surface of the barrel. Therefore, no difference is shown and there is no need to use specifically designed syringes, like EQUASHIELD®.

References

1. NIOSH Alert. Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings. Available at: https://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf
2. Kagdi R, et al. Determination of Holdup Volume and Transient Contact Compatibility of Closed System Transfer Devices for a Reconstituted Lyophilized Drug Product. J Phar Sci. 2020 Aug; 109(11):3509-3511
3. www.equashield.com/product-cstd

OnGuard® 2 is manufactured by Simplivia Healthcare Ltd. and distributed by B. Braun Medical Inc.