Fluorescent Evaluation of Dry Connections in the EQUASHIELD™ , Phaseal® and Tevadaptor®/Onguard™ Closed System Drug Transfer Devices

Performed on February 5th, 2009 at Migal Analytical Chemistry Laboratory in Kiryat Shmona, Israel,
by Dr. Igal Bar-Ilan - Head of Analytical Chemistry Department.

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.

Phaseal® system by Carmel Pharma and Tevadaptor®/Onguard™ system by Teva Medical Ltd. were used as benchmarks.

METHOD

Preparation phase simulation:
Vial Adaptors and 20ml Syringe Units were used to simulate the preparation phase. EQUASHIELD™ Vial Adaptors were connected to sealed 20ml vials filled with 15ml of 0.05% Fluorescein solution. A 7ml Fluorescein solution was drawn into the 20ml syringe and then 5ml were re-injected back into the vial. The process was repeated 14 additional times withdrawing/re-injecting 5ml of Fluorescein solution.

After each manipulation the Syringe Unit was disconnected from its respective Vial Adaptor and checked for leaks using UV light. Any detected leaks were recorded immediately. This process was repeated with 10 sets of EQUASHIELD™ Syringe Units and Vial Adaptors. Close up photographs of each Vial Adaptor and Syringe Unit were taken after 10 and after 15 manipulations.

Administration phase simulation:
A similar process was repeated with 10 EQUASHIELD™ Syringe Units filled with 20ml Fluorescein solution dispensed through IV bag Spike Adaptors. A 2ml solution was injected with each Syringe Unit into an IV bag, disconnected and checked for leaks. The process was repeated 10 times.

Similarly, Phaseal® Protectors, Injectors and Infusion Adaptors, as well as Tevadaptor®/Onguard™ Vial Adaptors, Syringe Adaptors and Spike Port Adaptors, were used to simulate the drug preparation and administration phases. Every single procedure was followed by checking for leaks using UV light, and by taking close up photographs of the various component membranes after 10 manipulations.

RESULTS

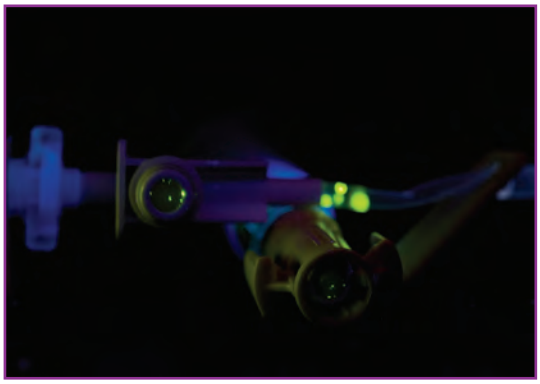
All Tevadaptor®/Onguard™ systems revealed visual signs of Flourescein leaks on the Vial Adaptors, Spike Port Adaptors and Syringe Adaptors as early as after the first or second manipulation (see Figures 1-4). Due to the comprehensive leaks, the number of manipulations was limited to 10 instead of 15.

12 of the 20 tested Phaseal® systems showed no visible signs of Flourescein leaks, whereas visual signs of Flourescein leaks were detected on 8 Phaseal® systems after 14, 11, 15, 13, 8, 7,10, 10 manipulations respectively (see Figures 5 - 8).

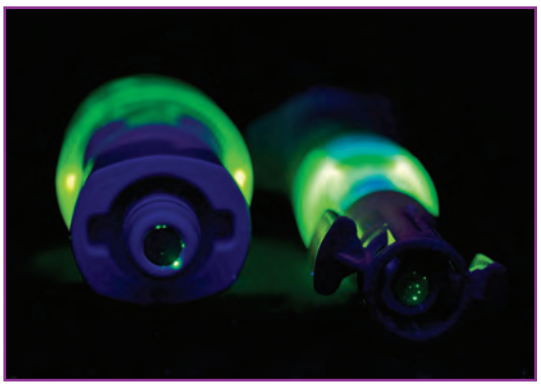
No visual signs of Flourescein leaks were perceived on any of the 20 EQUASHIELD™ devices (see Figures 9-12).

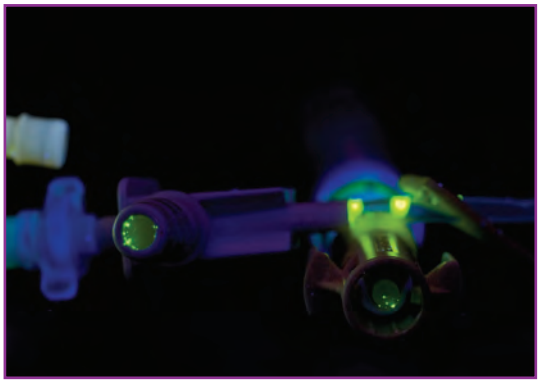
Figures 1 to 4 - Tevadaptor®/Onguard™ by Teva Medical, Ltd.

leaks



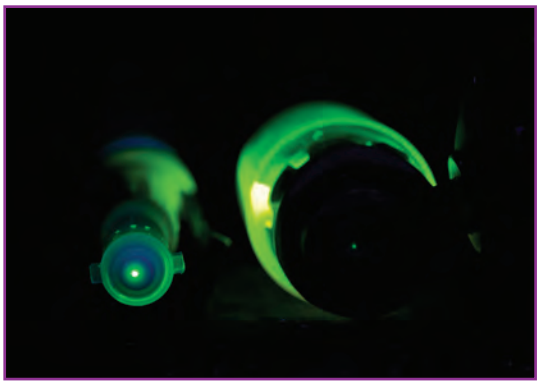
leaks

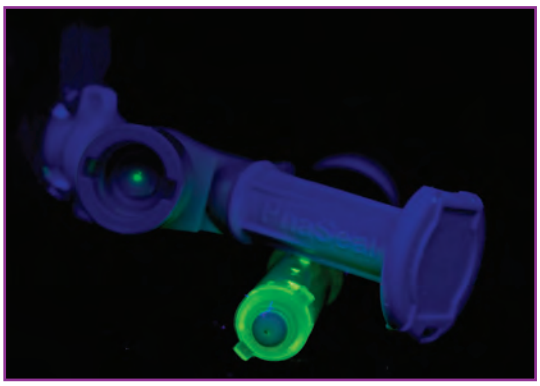




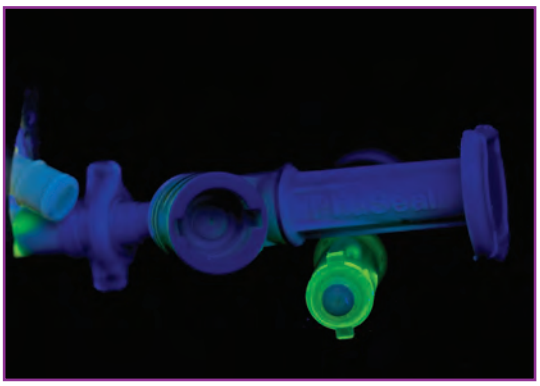
Figures 5 to 8 - Phaseal® by Carmel Pharma

leaks



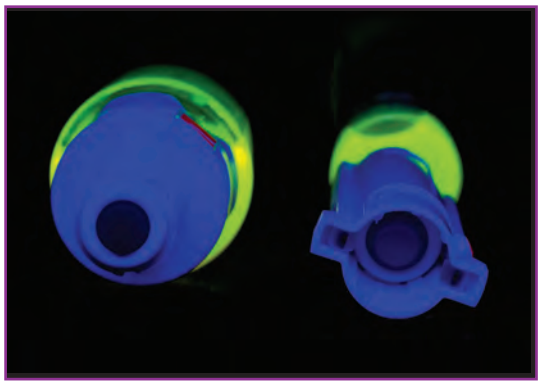


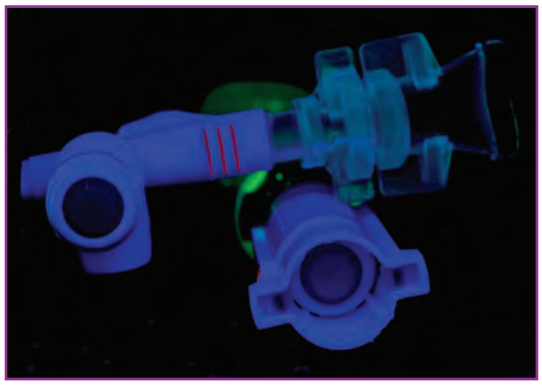
No leaks



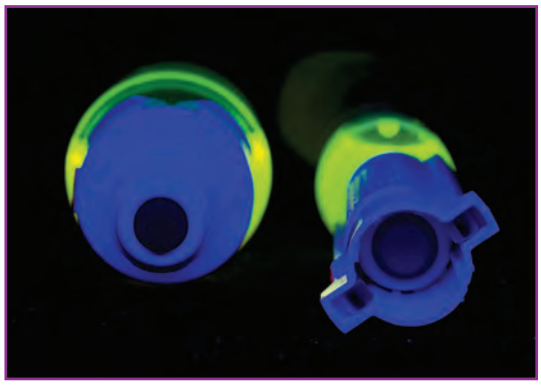
Figures 9 to 12 - EQUASHIELD™ by Equashield Medical

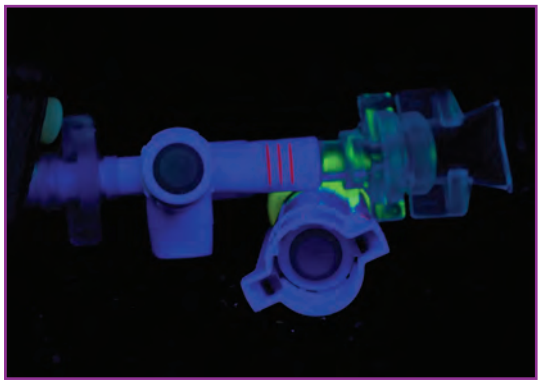
No leaks





No leaks





CONCLUSION

As visual signs of Flourescein leaks were detected in Tevadaptor®/ Onguard™, it is apparent that this system is not airtight and leak-proof, as recommended for closed system drug transfer devices by the National Institute of Occupational Safety and Health and the International Society of Oncology Pharmacy Practitioners.

40% of Phaseal® systems showed leakage after a considerable number of manipulations (between 8 and 15 manipulations).

Only EQUASHIELD™ showed residual free and dry connections during all preparations and administrations. No leakage was perceived with this system.

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