



March 4, 2018

## **IMPORTANT NOTIFICATION OF FIELD CORRECTION**

### **Belzer UW® Cold Storage Solution - 2-liter Bags**

Dear Valued Customer:

We are writing to alert you that Preservation Solutions Inc. (PSI), the manufacturer of our 2-liter bags of Belzer UW® Cold Storage Solution, has informed us that two (2) units, one distributed and one in production, have been confirmed to have a pinhole leak at the base of the injection port (the point at which the port is sonically welded into the body of the bag). Such a leak, if present, compromises sterility and could lead to contamination of the solution and contamination of any organs flushed or placed in the cold storage solution. Fortunately, neither unit was used in a transplant procedure. PSI has since conducted an inspection of 1,500 2-liter units in inventory, and not one unit with the defect was found.

The defect incidence is very low; but out of an abundance of caution, PSI, with the concurrence and commitment of Bridge to Life Ltd to the corrective activity, has decided to do a Field Correction of all 2-liter bags currently in distribution. This decision has the agreement and concurrence of the FDA. The efficacy of its products is known, but unless Bridge to Life Ltd knows that they each and every unit is 100% safe, they simply cannot be used in a transplant procedure.

The Field Correction will entail trained PSI personnel performing a 100% inspection of all 2-liter bags that have been distributed to rule out the presence of the defect. Any 2-liter bag found to exhibit the defect will be destroyed.

As an accommodation to PSI, Bridge to Life Ltd has agreed to ask its U.S. customers to return all 2-liter bags to its warehouse in Columbia, SC, so that PSI can conduct the inspections in a single location and thereby avoid having to visit each of our customer's facilities to perform the inspections. Therefore, Bridge to Life Ltd requests that you return **ALL** 2-liter bags of Belzer UW® Cold Storage Solution currently in your inventory to Bridge to Life's South Carolina facility. Attached to this letter is a form that requests that you identify the number of 2-liter bags of Belzer UW® Cold Storage Solution by lot number that are being returned. If you have no 2-liter bags of solution in your inventory, please return the form and indicate that no bags are being returned. That will avoid you receiving unnecessary (but FDA required) follow-up calls to confirm that you received this notice.

Please note that this notice **DOES NOT APPLY to Belzer UW® Cold Storage Solution in 1-liter bags**. There have been NO reports of a leak or any other defects of the organ preservation solution in 1-liter bags. Thermo Fisher, the manufacturer of the bags, has confirmed to PSI that different tooling is used to perform the sonic weld of the injection port in the 1-liter bag than the 2-liter bag.

Please contact **Kat Buxton at 803-545-0080** or **email the same at k.buxton@b2ll.com** if you have any questions and to receive a Return Authorization number, with 3rd party shipping number. You will receive replacement 2-liter bags of Belzer UW® Cold Storage Solution as soon as they are available. Alternatively, you can receive two (2) 1-liter bags for each 2-liter bag that is returned. Please indicate on the attached form if this is your preferred option.

In case you are not familiar with Field Corrections, we have attached a Q and A. We thank you for your assistance.

Sincerely,

Bridge to Life Ltd.