



March 4, 2017

Field Correction Question & Answer

Q: What is a Field Correction?

A: It is typically a situation in which the Manufacturer (or another party in the distribution chain) undertakes an activity or activities to correct an error or defect in devices when they are “in the field,” as opposed to bringing all the devices subject to the Field Correction back to the place of manufacture.

Q: Why is the defect in the 2-liter Belzer UW[®] Cold Storage Solution able to be corrected in the field?

The defect is a **potential** for the 2-liter bag to have a pinhole leak at the base of the injection port. The manufacturer tells us that based on its ongoing investigation of the situation, only a very small proportion of units subject to the withdrawal will be found to have a leak. Because a unit exhibiting the defect is readily observable by a trained inspector, the units with the defect can be culled from those that have no leak. After inspection a product confirmed to be free of the defect will be able to be returned to the field for use.

Q: Why is the Field Correction Inspection not being done at my facility?

A: Bridge to Life has hundreds of customers, and only a few of our largest customers are expected to have more than a case or two of the 2-liter product in inventory. Therefore, to avoid the cost of and time for the manufacturer’s Field Correction Inspector to travel to hundreds of facilities around the country to inspect only a few devices at each one, the manufacturer asked if we would have the 2-liter products brought back to our distribution center in South Carolina for a single inspection of all returned units. Realizing the efficiencies of this process, and the time that would be saved, we agreed.

Q: Can we do our own inspections?

The interests of public health requires that the Field Correction inspections be consistent and have the highest likelihood of not missing a 2-liter bag with a defect. An inspector who has seen the defect in units will be more likely to find bags exhibiting the defect.

Q: Is this Field Correction a recall?

FDA deems a correction of this nature to be a Recall, and will so classify it. But the nature of the corrective activity allows it to be termed a “Field Correction” under FDA policy and practice.