FDA Home > Medical Devices > Databases

Class 1 Device Recall 10 NBF

Date Posted: October 09, 2014
Recall Status: Open
Recall Number: Z-0014-2015
Recall Event ID: 6927623
Product Classification: Fixative, Formalin-Containing - Product Code LDY25
Product: Richard-Allan Scientific 10% Neutral Buffered Formalin. Product Usage: 10% NBF is used to store and fixate tissue prior to grossing and histological examination. It is a primary fixative that prevents autolysis (degradation) of tissue.
Code Information: Product Code: LC-0060; Lot Number: 300445
Recalling Firm/Manufacturer: Richard-Allan Scientific Company
4481 Campus Dr
Kalamazoo, Michigan 49008-2590
For Additional Information Contact: Sarah Rickert
616-385-4466
Manufacturer Reason for Recall: The affected lots could have NBF concentrations that are lower or higher than the desired specifications.
FDA Determined Cause: COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Mix-Up of Materials/Components
Action: The firm issued an "URGENT MEDICAL DEVICE RECALL" letter to all affected customers. The notification identified the affected products, reason for voluntary recall, risk to health, actions to be taken, and instructions to complete the attached Acknowledgement Form. For questions, contact Sarah Rickert at 269-544-5628 or sarah.rickert@thermofisher.com.
Quantity in Commerce: 80 cases
Distribution: Worldwide Distribution-USA (nationwide) including the states of PA, IL, CA, TX, GA, WA, MA, KY, OH, NY, VA, NC, IN, NJ, MN, UT, HI, FL, KS, TN, MO, MI, MD, LA, NM, DE, CO, WV, OR, WI, AZ, SC, IA, and NE and the country of Canada.
Total Product Life Cycle: TPLC Device Report26

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.552
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm

### Class 1 Recall 10 NBF

**Date Posted**: October 09, 2014

**Recall Status**: Open

**Recall Number**: Z-0016-2015

**Recall Event ID**: 692783

**Product Classification**: Fixative, Formalin-Containing - Product Code LDY

**Product**: Richard-Allan Scientific 10% Neutral Buffered Formalin. Product Usage: 10% NBF is used to store and fixate tissue prior to grossing and histological examination. It is a primary fixative that prevents autolysis (degradation) of tissue.

**Code Information**: Product Code: 51401 Lot Number: 300649

**Recalling Firm/Manufacturer**: Richard-Allan Scientific Company
4481 Campus Dr
Kalamazoo, Michigan 49008-2590

**For Additional Information Contact**: Sarah Rickert
616-385-4466

**Manufacturer Reason for Recall**: The affected lots could have NBF concentrations that are lower or higher than the desired specifications.

**FDA Determined Cause**: COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Mix-Up of Materials/Components

**Action**: The firm issued an "URGENT MEDICAL DEVICE RECALL" letter to all affected customers. The notification identified the affected products, reason for voluntary recall, risk to health, actions to be taken, and instructions to complete the attached Acknowledgement Form. For questions, contact Sarah Rickert at 269-544-5628 or sarah.rickert@thermofisher.com.

**Quantity in Commerce**: 199 cases

**Distribution**: Worldwide Distribution-USA (nationwide) including the states of PA, IL, CA, TX, GA, WA, MA, KY, OH, NY, VA, NC, IN, NJ, MN, UT, HI, FL, KS, TN, MO, MI, MD, LA, NM, DE, CO, WV, OR, WI, AZ, SC, IA, and NE and the country of Canada.

**Total Product Life Cycle**: TPLC Device Report

---

1. For details about termination of a recall see **Code of Federal Regulations (CFR) Title 21 §7.55**
2. Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

---

**Links on this page**:

3. [http://www.fda.gov/default.htm](http://www.fda.gov/default.htm)
4. [http://www.fda.gov/MedicalDevices/default.htm](http://www.fda.gov/MedicalDevices/default.htm)