

May 19, 2015

Your response is required IMMEDIATELY (please complete pages 4-6).

MEDICAL DEVICE RECALL
Mucollex / Mucolytic Agent

URGENT MEDICAL DEVICE RECALL

[Insert Distributor name

Attn:

Distributor address]

Dear Thermo Fisher Scientific Dealer Partner:

The purpose of this letter is to advise you that Richard Allan Scientific, part of Thermo Fisher Scientific, is voluntarily recalling multiple lots of Mucollex& Mucolytic Agent (see page 2)..

Mucollex is indicated for use as a mucoliquefying preservative, intended for use in the preparation of mucoid cytology specimens. Mucollex liquefies mucus and allows for cytologic diagnostic results.

REASON FOR VOLUNTARY RECALL:

The affected lots contain non-viable fungal contamination.

RISK TO HEALTH:

No adverse health consequences. It is not likely that use will cause any adverse events.

Use of this product during patient cytology specimen preparation would not be expected to result in any immediate or long range adverse health consequences for patients. The presence of this nonviable fungal contaminant would not be expected to alter cellular preservation and appearance, and would not affect any underlying cellular pathologic changes intended to be observed during specimen interpretation by the clinical pathologist.

The presence of fungal material in a patient's mucoid specimen as a result of being processed with the affected lots of Mucollex would not be expected to be misinterpreted as invasive fungal disease by the clinical pathologist or by the patient's treating provider, and therefore would not be expected to lead to misdiagnosis and/or unnecessary treatment. Invasive fungal disease demonstrates characteristic histopathologic and cytopathologic changes, and such findings would not be expected to occur in patient specimens contaminated with the nonviable fungal material present in the Mucollex lots. A separate microbiologic culture of a patient's mucoid specimen would verify the absence of clinical infection.

PRODUCT AND DISTRIBUTION INFORMATION:

Product Code	Product Name	Lot Number	EXP Date	Quantity
76166	Richard Allan Scientific Mucolytic Agent 1 pint / 473 ml	313839	Dec-16	20
		311157	Oct-16	11
		306726	Aug-16	12
		297142	Jun-16	10
		296289	May-16	11
		290486	Mar-16	11
		289488	Mar-16	8
		276824	Nov-15	10
		271110	Oct-15	12
		265368	Aug-15	11
9990370	Shandon Mucolexx 500ml/0.13gal	328311	Mar-17	2
		324252	Feb-17	10
		314543	Dec-16	22
		304548	Jul-16	19
		289566	Mar-16	38
		282598	Dec-15	24
		276182	Nov-15	10
		267432	Aug-15	35
255776	Apr-15	25		
9990371	Shandon Mucolexx 4L / 1.06 gal	311289	Oct-16	19
		299148	Jun-16	19
		285035	Feb-16	24
		273852	Oct-15	15
		263847	Jul-15	15
9990375	Shandon Mucolexx 120 ml	312363	Oct-16	10
		255325	Apr-15	17

ACTIONS TO BE TAKEN BY THE DISTRIBUTOR:

Our records indicate that you may have purchased one or more of the above products for re-sale to your customers.

- Please review the inventory in your warehouse/distribution centers to see if the above listed product is still under your control. If you have product still in inventory please place it in quarantine/hold and contact Richard Allan Scientific to arrange for product return and credit. You should complete the attached Recall Response Form (pages 4-6) in regard to inventory you have received and/or which is still in stock.
- In addition, please contact your affected customer base, advise them of the situation, and provide them with a copy of this letter. You should insert your contact information, email and fax numbers in the Recall Response Form(pages 4-6) and request that they return the Recall Response Form to you.
 - If you would prefer that Richard Allan Scientific contact your customers about this recall, please include a list of customer contact information with the enclosed Recall Response Form.

ACTIONS BY THE MANUFACTURER:

Root Cause: Richard Allan Scientific has identified the primary root cause of this issue. A raw material that was used in the production of all of the affected lots was contaminated with fungus.

Corrective Action: Richard Allan Scientific has removed the affected lot of raw material and replaced it with a new lot. Richard Allan Scientific is also undertaking additional actions to prevent recurrence.

We appreciate your immediate attention to this field correction. By returning the attached Recall Response Form(pages 4-6) IMMEDIATELY, you will facilitate our reporting of this matter to the regulatory authorities. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

If you have any questions, please contact Sarah Rickert at +1-269-544-5628 (USA) or sarah.rickert@thermofisher.com.

Sincerely,



Sarah Rickert
Quality Assurance & Regulatory Affairs Manager

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgment & Receipt Form
Response Required

CUSTOMER INFORMATION:

Customer name: _____

Site Name: _____

Address: _____

E-Mail: _____

Phone: _____

FAX: _____

Mucolexx / Mucolytic Agent

Product Code	Product Name	Lot Number	EXP Date
76166	Richard Allan Scientific Mucolytic Agent 1 pint / 473 ml	313839	Dec-16
		311157	Oct-16
		306726	Aug-16
		297142	Jun-16
		296289	May-16
		290486	Mar-16
		289488	Mar-16
		276824	Nov-15
		271110	Oct-15
9990370	Shandon Mucolexx 500ml/0.13gal	265368	Aug-15
		328311	Mar-17
		324252	Feb-17
		314543	Dec-16
		304548	Jul-16
		289566	Mar-16
		282598	Dec-15
		276182	Nov-15
		267432	Aug-15
9990371	Shandon Mucolexx 4L / 1.06 gal	255776	Apr-15
		311289	Oct-16
		299148	Jun-16
		285035	Feb-16
		273852	Oct-15
9990375	Shandon Mucolexx 120 ml	263847	Jul-15
		312363	Oct-16
		255325	Apr-15

I have read and understand the attached Customer Letter and recall instructions: _____ (initials)

Any adverse events associated with the recalled product? _____ Yes _____ No

If yes, please explain:

If you have already used some of the above product please include the amount used on following table.

If product has been or will be destroyed please attach disposal record. Disposal must follow each site's safe disposal requirements.

DISTRIBUTORS:

Choose one (check appropriate box):

I have identified and notified my customers that were shipped or may have been shipped product affected by this letter by [specify date and method of notification]:

or

Attached is a list of customers who received / may have received affected product. Please notify my customers.

AFFECTED PRODUCT INFORMATION:

Manufacturer's Product No.	Product Name	Affected Lot Number	Quantity in Inventory	Quantity Destroyed / Returned	Quantity already used
76166	Richard Allan Scientific Mucolytic Agent 1 pint / 473 ml				
9990370	Shandon Mucolexx 500ml/0.13gal				
9990371	Shandon Mucolexx 4L / 1.06 gal				
9990375	Shandon Mucolexx 120 ml				

If there is no product in inventory, please document "0" in the "Quantity in Inventory" column.
 If there are multiple lot numbers for a product, please document the lot number and quantity for each lot number.
 Use additional sheet(s) if necessary.

RETURN RESPONSE (please provide additional information, if applicable):

PLEASE RETURN COMPLETED RESPONSE FORMS TO THE FOLLOWING EMAIL sarah.rickert@thermofisher.com OR FAX NUMBER +1-269-372-2674, ATTN: Sarah Rickert

Signature of Receipt by Customer: _____

Name/Title:	
Telephone:	
Site Name	
Address	
City, State	
Country	
Email Address:	