Rev 1: September 2018
FSN Ref: FSN-2020-0007 FSCA Ref: FSN-2020-0007

Date: 3 September 2020

Urgent Field Safety Notice
ThermoScientific™ Oxoid™ F100 Nitrofurantoin

For Attention of*: Lab Managers

Contact details of local representative (name, e-mail, telephone, address etc.)*
E.mail : mbd.vigilance@thermofisher.com Telephone: +44(0) 1256 841144 Fax: +44(0) 1256 479525

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Urgent Field Safety Notice (FSN)
ThermoScientific™ Oxoid™ F100 Nitrofurantoin

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Antimicrobial Susceptibility Discs
1.	2. Commercial name(s)
	Oxoid™ Nitrofurantoin Antimicrobial Susceptibility Disks
1.	3. Unique Device Identifier(s) (UDI-DI)
	n/a
1.	4. Primary clinical purpose of device(s)*
	This antimicrobial susceptibility disc has been made available to indicate microorganism sensitivity to Nitrofurantoin using the disc diffusion method
1.	5. Device Model/Catalogue/part number(s)*
	CT0034B
1.	6. Software version
	n/a
1.	7. Affected serial or lot number range
	Lot 2961028
1.	8. Associated devices
	None

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	A technical investigation has confirmed that some packs of Thermo Scientific™ Oxoid™ F100 Nitrofurantoin, CT0034B, Lot 2961028 may contain cartridges of a different product, i.e. CT0023B, Fusidic Acid FD 10 µg.
2.	2. Hazard giving rise to the FSCA*
	If the incorrect disc was used then it could cause delay in reporting the correct antimicrobial result.
2.	3. Probability of problem arising
	Low
2.	4. Predicted risk to patient/users
	The immediate and long term health consequences are minimal. Fusidic acid and nitrofurantoin are used for two diffident purposes. Fusidic acid is for skin and soft tissue infections with Staphylococci and Nitrofurantoin for Gram-negative urinary infections. Users will notice the difference prior to testing, since quality assurance requires that lab staff check the antimicrobial name on the cartridge before applying the disc to the appropriate plated organism. Results would immediately show the difference in susceptibility or resistance. Patient care should not be affected, so the clinical risk is very low even if the Fusidic acid disc was inadvertently added to the urinary tract susceptibility plate.
2.	5. Further information to help characterise the problem
	• Each individual cartridge is correctly labelled and readily identifiable before use. • Each individual disc of each cartridge is printed with the correct ID and readily identifiable at point of use. • Customer in-house laboratory quality control before testing on clinical samples would identify the error.

2.	6. Background on Issue
	There is a high probability that this is a line clearance issue.
2.	7. Other information relevant to FSCA
	Lot 2961028 expiry date 30-Apr-2023

3 Type of Action to mitigate the Risk*		
3.	1. Action To Be Taken by the User* ☒ Identify Device ☒ Quarantine Device ☐ Return Device ☐ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other Inspect product, discard incorrect product and request replacement ☐ None	
3.	2. By when should the action be completed?	Immediately
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes We request that the requirement for review of reported test results should be determined by the appropriate technical expert.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Will replace the incorrect product.	
3	6. By when should the action be completed?	Immediately
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

4 General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Thermo Fisher Scientific
	b. Address	Wade Road, Basingstoke, Hampshire RG24 8PW
	c. Website address	www.thermofisher.com/microbiology
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Acknowledgement form
4.	10. Name	……..
	Signature	……..

Transmission of this Field Safety Notice	
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*

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Customer Reply Form

1. Field Safety Notice (FSN) information				
FSN Reference number*		FSN-2020/0007		
FSN Date*		3 September 2020		
Product/ Device name*		Oxoid™ Nitrofurantoin Antimicrobial Susceptibility Disks		
Product Code(s)		CT0034B		
Batch/Serial Number (s)		2961028		
2. Customer Details				
Account Number				
Organisation Name*				
Organisation Address*				
Department/Unit				
Shipping address if different to above				
Contact Name*				
Title or Function				
Telephone number*				
Email*				
3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.			
☐	I performed all actions requested by the FSN.			
☐	The information and required actions have been brought to the attention of all relevant users and executed.			
☐	I have returned affected devices - enter number of devices returned and date complete or N/A.	Qty :	Lot/Serial Number:	Date Returned : (DD/MM/YY)
		Comments :		
☐	I have destroyed affected devices – enter number destroyed and date complete. – **N/A**	Qty:	Lot/Serial Number:	Date Returned : (DD/MM/YY)
		Qty	Credit ☐ Replacement ☐	
		Comments: **No destruction required**		
☐	No affected devices are available for destruction			
☐	I have a query please contact me (e.g. need for replacement of the product).			
Print Name*				
Signature*				
Date*				
4. Return acknowledgement to sender				
Email		mbd.vigilance@thermofisher.com		
Customer Services Tel. & Fax		Fax : +44(0)1256 334 994		
Deadline for returning the reply form*		**1st October 2020**		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.