

Rev 1: September 2018  
FSN Ref: FSN-2021-0006

FSCA Ref: FSN-2021-0006

Date: 10-JUNE-2021

## **Urgent Field Safety Notice**

### **ThermoScientific™ Oxoid™ AMC30 Amoxicillin / Clavulanic Acid Antimicrobial Susceptibility Discs CT0223B**

For Attention of\*: Lab Managers

Contact details of local representative (name, e-mail, telephone, address etc.)\*

E.mail : [mbd.vigilance@thermofisher.com](mailto:mbd.vigilance@thermofisher.com)

Telephone: +44(0) 1256 841144

Fax: +44(0) 1256 479525

**Urgent Field Safety Notice (FSN)**  
**ThermoScientific™ Oxoid™ AMC30 Amoxicillin / Clavulanic Acid**  
**Antimicrobial Susceptibility Discs CT0223B**

1. Information on Affected Devices*																																									
1.	1. Device Type(s)* Antimicrobial Susceptibility Discs																																								
1.	2. Commercial name(s) ThermoScientific™ Oxoid™ AMC30 Amoxicillin / Clavulanic Acid Antimicrobial Susceptibility Discs CT0223B																																								
1.	3. Unique Device Identifier(s) (UDI-DI) 05032384006533																																								
1.	4. Primary clinical purpose of device(s)* ThermoScientific™ Oxoid™ Antimicrobial Susceptibility Test Discs are used in the semi-quantitative agar diffusion test method for in vitro susceptibility testing. Used in a diagnostic workflow to aid clinicians in determining potential treatment options for patients suspected of having a microbial infection, these discs are intended to determine susceptibility against microorganisms for which amoxicillin and clavulanic acid have been shown to be active both clinically and in vitro. To be used with a pure, agar grown culture, Oxoid Antimicrobial Susceptibility Test Discs are for professional use only and are neither automated, nor a companion diagnostic.																																								
1.	5. Device Model/Catalogue/part number(s)* CT0223B																																								
1.	6. Software version N/A																																								
1.	7. Affected serial or lot number range																																								
	<table border="1"> <thead> <tr> <th>Lot</th> <th>Expiry date</th> </tr> </thead> <tbody> <tr><td>2341375</td><td>29.05.2021</td></tr> <tr><td>2343397</td><td>03.06.2021</td></tr> <tr><td>2394162</td><td>29.08.2021</td></tr> <tr><td>2403210</td><td>16.09.2021</td></tr> <tr><td>2408058</td><td>02.10.2021</td></tr> <tr><td>2438023</td><td>27.11.2021</td></tr> <tr><td>2438086</td><td>27.11.2021</td></tr> <tr><td>2457651</td><td>06.01.2022</td></tr> <tr><td>2463120</td><td>14.01.2022</td></tr> <tr><td>2464593</td><td>13.01.2022</td></tr> <tr><td>2491412</td><td>14.03.2022</td></tr> <tr><td>2511707</td><td>24.04.2022</td></tr> <tr><td>2609976</td><td>16.07.2022</td></tr> <tr><td>2832507</td><td>05.08.2022</td></tr> <tr><td>2840771</td><td>26.08.2022</td></tr> <tr><td>2935065</td><td>18.02.2023</td></tr> <tr><td>2958576</td><td>15.04.2023</td></tr> <tr><td>2968037</td><td>20.04.2023</td></tr> <tr><td>2978564</td><td>20.05.2023</td></tr> </tbody> </table>	Lot	Expiry date	2341375	29.05.2021	2343397	03.06.2021	2394162	29.08.2021	2403210	16.09.2021	2408058	02.10.2021	2438023	27.11.2021	2438086	27.11.2021	2457651	06.01.2022	2463120	14.01.2022	2464593	13.01.2022	2491412	14.03.2022	2511707	24.04.2022	2609976	16.07.2022	2832507	05.08.2022	2840771	26.08.2022	2935065	18.02.2023	2958576	15.04.2023	2968037	20.04.2023	2978564	20.05.2023
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1.	8. Associated devices N/A																																								

<b>2. Reason for Field Safety Corrective Action (FSCA)*</b>	
2.	<p>1. Description of the product problem*</p> <p>An internal investigation by Oxoid Limited, part of Thermo Fisher Scientific, has confirmed that the above lots of CT0223B, <u>ThermoScientific™ Oxoid™</u> Amoxicillin/Clavulanic Acid Antimicrobial Susceptibility Discs, are giving small zones of inhibition for Quality Control organism <i>Escherichia coli</i> ATCC®35218™. The zones of inhibition are outside the specified CLSI/EUCAST 17-22 mm limits.</p>
2.	<p>2. Hazard giving rise to the FSCA*</p> <p>Continued use of these lots could produce false resistance results leading to minor delays in overall effective therapy.</p>
2.	<p>3. Probability of problem arising</p> <p>The data collected demonstrates that the identified batches would have performed satisfactorily if used within the first year of their allotted shelf-life. Quality control testing in the clinical laboratory should identify out of specification zones readily and clinical tests would not be reported.</p>
2.	<p>4. Predicted risk to patient/users</p> <p>No identified risk to user.  Potential to exhibit false resistance to clinical strains which may in turn result in a different antimicrobial agent being used for patient treatment. The clinical risk of this setting is considered low as resistance to amoxicillin-clavulanic acid in clinical settings where it is used for oral treatment (e.g. uncomplicated urinary infections) are relatively low (≤15 %). It is currently unknown if smaller concentrations of the two agents in these batches would show false resistance to isolates (particularly ESBLs) with lower MICs to amoxicillin.</p>
2.	<p>5. Further information to help characterise the problem</p> <p>If Quality Control testing is performed, this issue will be detected by producing small, out of specification zones of inhibition with <i>Escherichia Coli</i> ATCC®35218™.</p>
2.	<p>6. Background on Issue</p> <p>This issue is currently suspected to be caused by differing levels of residual moisture in the product, leading to faster rates of degradation of the primary antibiotic and the beta-lactamase inhibitor.</p>
2.	<p>7. Other information relevant to FSCA</p> <p>N/A</p>

<b>3. Type of Action to mitigate the Risk*</b>	
3.	<p>1. Action To Be Taken by the User*</p> <p><input checked="" type="checkbox"/> Identify Device    <input checked="" type="checkbox"/> Quarantine Device    <input type="checkbox"/> Return Device    <input checked="" type="checkbox"/> Destroy Device</p> <p><input type="checkbox"/> On-site device modification/inspection</p> <p><input checked="" type="checkbox"/> Follow patient management recommendations</p> <p><input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)</p> <p><input type="checkbox"/> Other            <input type="checkbox"/> None</p>
3.	<p>2. By when should the action be completed?</p> <p>Without undue delay</p>


3.	3. Particular considerations for: IVD	
	Is follow-up of patients or review of patients' previous results recommended? Yes	
	Clinical tests whereby this product has produced a result above the resistance breakpoint should be reviewed and retested as required.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer	
	<input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None	
3	6. By when should the action be completed?	Without undue delay
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. N/A

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/mic robiology
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	

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4.	9. List of attachments/appendices:	Customer Response Form
4.	10. Name	James Filer Vice President, Quality and Regulatory, MBD
	Signature	

<b>Transmission of this Field Safety Notice</b>	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>

### Customer Reply Form

1. Field Safety Notice (FSN) information			
FSN Reference number*	FSN-2021-0006		
FSN Date*	10 June 2021		
Product/ Device name*	ThermoScientific™ Oxoid™ AMC30 Amoxicillin / Clavulanic Acid Antimicrobial Susceptibility Discs		
Product Code(s)	CT0223B		
Batch/Serial Number (s)	Various – refer to Field Safety Notice		
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			
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.		
<input type="checkbox"/>	I performed all actions requested by the FSN.		
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.		
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete or <b>N/A</b>	Qty:	Lot/Serial Number:      Date Returned (DD/MM/YY)
		Comments:	
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:      Date Returned (DD/MM/YY)
		Qty	Credit <input type="checkbox"/> Replacement <input type="checkbox"/>
		Comments:	
<input type="checkbox"/>	No affected devices are available for return/ destruction		
<input type="checkbox"/>	Other Action (Define):		
<input type="checkbox"/>	I do not have any affected devices.		
<input type="checkbox"/>	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	<a href="mailto:MBD.vigilance@thermofisher.com">MBD.vigilance@thermofisher.com</a>		
Telephone Number & Fax	Tel : +44(0) 1256 841144 Fax :+44(0) 1256 479525		
Deadline for returning the reply form*	<b>9 July 2021</b>		

Mandatory fields are marked with \*

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**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.**