

Rev 1: September 2018
FSN Ref: FSN-2024-004


FSCA Ref: 2024-004

Date: 19 November 2024

Urgent Field Safety Notice

VERSATREK MYCO AS, 5/BX (Y71144-2)

For Attention of*: Lab Managers

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


Urgent Field Safety Notice
VERSATREK MYCO AS, 5/BX (Y71144-2)

1. Information on Affected Devices*	
1.	1. Device Type(s)* IVD
1.	2. Commercial name(s) VERSATREK MYCO AS, 5/BX
1.	3. Unique Device Identifier(s) (UDI-DI) 848838091711
1.	4. Primary clinical purpose of device(s)* VersaTREK Myco, with VersaTREK Myco GS and either VersaTREK Myco AS or VersaTREK Myco PVNA added, is a selective liquid growth medium for use with the VersaTREK Automated Microbial Detection System (VTI) for the recovery of mycobacteria from sterile body specimens and from digested-decontaminated clinical specimens.
1.	5. Device Model/Catalogue/part number(s)* Y71144-2
1.	6. Software version N/A
1.	7. Affected serial or lot number range 440824
1.	8. Associated devices N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* An internal technical investigation confirmed that VERSATREK MYCO AS, 5/BX, Y71144-2 lot 440824 is labelled with an incorrect expiration date of May 2026. The correct expiration date based on the product's date of manufacture should be May 2025.
2.	2. Hazard giving rise to the FSCA* There is no risk to health associated with this issue as it is still within established two-year expiration until May 2025.
2.	3. Probability of problem arising High
2.	4. Predicted risk to patient/users There is no risk to health associated with this issue as it is still within established two-year expiration until May 2025.
2.	5. Further information to help characterise the problem N/A
2.	6. Background on Issue Internally identified.
2.	7. Other information relevant to FSCA N/A


3. Type of Action to mitigate the Risk*		
3.	1. Action To Be Taken by the User*	
	<input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> 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? No	
3.	4. Is customer Reply Required? * <i>(If yes, form attached specifying deadline for return)</i>	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?	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? No Not appended to this FSN	

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

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4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Remel, Inc.
	b. Address	12076 Santa Fe Trail Drive Lenexa, KS 66215
	c. Website address	www.thermofisher.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes	
4.	9. List of attachments/appendices:	Customer Response Form <i>(Required)</i>
4.	10. Name	

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.*

Customer Reply Form

1. Field Safety Notice (FSN) information			
FSN Reference number*	2024-004		
FSN Date*	15 November 2024		
Product/ Device name*	VERSATREK MYCO AS, 5/BX		
Product Code(s)	Y711442		
Batch/Serial Number (s)	440824		
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 N/A	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 Completed (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	MBD.vigilance@thermofisher.com		
Telephone Number & Fax	Tel : +44(0) 1256 841144 & Fax :+44(0) 1256 479525		
Postal Address			
Deadline for returning the reply form*	13 DECEMBER 2024		

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.

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