URGENT FIELD SAFETY NOTICE

Secufill ™ – RECALL

Date: 14 December 2023

FSCA reference: 23024

Dear Healthcare Professional,

The purpose of this letter is to inform you that MEDEX (a Guerbet Group Company) has decided to voluntarily recall some identified lots of Secufill™ due to the potential for burr particulate formation and subsequent intravascular injection.

1. Issue Description

The particulates originate from the protective cap (on the white end) used in the assembly of the device. During internal controls performed after reception of a customer complaint, some of these particulates have been observed on the Luer-lock of some units of the batches listed in Appendix 1.

2. Reasons for the Field Safety Notice

Some particulates have the potential to detach from the device and, in rare circumstances, might enter the fluid path and be injected into the patients' vascular system with the saline/ contrast medium solution. This may cause an embolism that could damage some organs, thus resulting in serious injury to the patients. To date, MEDEX has not received any report of adverse events nor patient injury related to this matter, and is issuing this notification out of an abundance of caution.

3. Risk to the Patient/ User

In case some particulates are injected intravenously, they could cause organ damage potentially resulting in serious patient injury.

4. Affected Product Specifications

a) Legal Manufacturer:
MEDEX
SRN : FR-MF-000000414
240 allée Jacques Monod – 69800 Saint-Priest – France.

b) Affected product description:
Secufill – Anti-reflux patient connector for all MRI or CT scanner examinations.

c) Refer to the Appendix 1 for product details (product name, reference, lot/serial number, distributed quantity, UDI code, barcode allowing automatic data capture).

MEDEX
240 allée Jacques Monod – 69800 Saint-Priest – France
Tél. : + 33 (0) 4 72 79 20 50 – Fax : + 33 (0) 4 72 79 20 69

SRN : FR-MF-000000414
Forme juridique : SAS – Capital social : 180 000 € – Siège social : 240 allée Jacques Monod
69800 – Saint-Priest – France - RCS : Lyon 340 598 978

d) Period during which the affected units of the device were distributed: **April 2022 to November 2023.**

5. Communication with the Competent/ Regulatory Authorities

The decision to implement this Field Safety Corrective Action (FSCA) was communicated to the HPRA on 19th [19] December 2023.
A follow-up FSCA report will be communicated to ANSM and other Competent/ Regulatory authorities no later than 31 March 2024.

6. MEDEX is Requesting Users to Take the Following Actions

MEDEX distribution records indicate that the product(s) described in the section 4 was/were shipped to you. Therefore, please:

a) Discontinue immediately the use of the products listed in Appendix 1.
b) Check your inventory and quarantine all units from the products listed in Appendix 1 at your facility, and contact your Local Sales Representative to organize the return of the affected products.
c) Make sure that all caregivers and users of these products are made aware of this Field Safety Notice.
d) Complete and sign the enclosed acknowledgment form (in Appendix 2) and return it to the Local Sales Representative (their contact point is indicated in Appendix 2).

MEDEX has notified the Competent/ Regulatory Authorities of the countries concerned by this Field Safety Notice and informed them about this quality defect and the above-written actions.

Please, report all device-related incidents to your Local Sales Representative and/or to your Competent/ Regulatory Authority if appropriate, as this provides important feedback.

7. Actions to Prevent a Recurrence of the Problem

MEDEX has implemented additional control during the manufacturing process to ensure that only batches meeting the approved predefined specifications for particulate formation are released on the market.

We sincerely apologize for any inconvenience that this problem may cause. MEDEX is committed to providing the highest level of support, and we thank you for assisting with this process. Please, contact your Local Sales Representative with any questions regarding this notification. Sincerely,

Elaine Keating
Quality and Compliance Manager
Healthcare 21

Maura Marshall
Regulatory Compliance Coordinator
Healthcare21

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APPENDIX 1: PRODUCT DETAILS

Product Name	ERP Code	Reference	Lot Number	Quantity Affected Units	Date of manufacture Format: yyyy/mm/dd	Use-by Date Format: yyyy/mm/dd	UDI primary packaging Code	Barcode
Secufill®	218684	SECU002	LX221001	88 000	2022-03-07	2025-03-07	01137005504004831725030711220307 10LX221001	370055040048

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APPENDIX 2: HEALTHCARE PROFESSIONAL ACKNOWLEDGEMENT FORM

Acknowledgement requirements:

- Please, verify if you have any of the products listed in the Appendix 1 and complete the information below.
- Please, return your completed form not later than two (2) days after the reception of the Field Safety Notice.

Facility Name	
Contact Name/ Title	
Address	
City, State, Zip	
Country	
Phone number	
E-mail	
Do you have in the stock any product listed in the Appendix 1? **YES ☐ NO ☐**	

PLEASE RETURN YOUR COMPLETED FORM TO:

compliance@hc21.group

Customer action undertaken on behalf of a Healthcare Organization				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the Field Safety Notice.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned the affected devices - enter the number of devices returned and the date of completion.	Qty:	Lot:	Date returned (DD/MM/YY):
		Qty:	Lot:	Date returned (DD/MM/YY):

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☐	No affected devices are available for return.	Customer to complete or enter N/A
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query. Please, contact me (e.g. need for replacement of the product).	Customer to enter their contact details if different from above and brief description of query

By signing this acknowledgement, we confirm that the information in the Field Safety Notice is understood and that the actions described herein will be followed.

Names of the facility representative	Signature

For any question, please contact Healthcare21 local representative:

Jackie Knox Jackie.knox@hc21.group tel 0876976800

Ann Hennessy ann.hennessy@hc21.group tel 0876896907

David Enright david.enright@hc21.group tel 0871318872