



Exmoor Plastics Ltd
1, Western Avenue Matrix
Park Buckshaw Village
Chorley PR7 7NB United
Kingdom

Date: 20/05/2025

Urgent Field Safety Notice

Product: Suction Clearance Kits

Information on Affected Devices

Device Type(s)*	
The suction clearance kits are compiled of instruments commonly used in surgical procedures where suction clearance of the external ear canal is required.	
They are both supplied with:	
• 2.11mm S105 Suction Tube • 1.24mm S4 Fine End • Cleaning rod • Cleaning wire	
SC4JH is supplied with a Jobson Horne Probe, whilst the SC6 is supplied with a Wax Curette.	
Both are used for clearing wax and debris from the ear canal.	
Both are offered based on clinical assessment of the patients' needs and user preference.	
Commercial name(s)	
Exmoor Plastics Limited Suction Clearance Kits	
Unique Device Identifier(s) (UDI-DI)	
SC4JH	5060180258269
SC6	5060180255015
Primary clinical purpose of device(s)*	
This device is intended to enable suction clearance of the external ear canal with the purpose of clearing ear wax/debris from the ear canal	
Device Model/Catalogue/part number(s)*	
SC4JH - Suction Clearance Kit with Jobson Horne Probe	SC6 -
Suction Clearance Kit with Wax Curette	
Affected serial or lot number range	
3 lots: 85695, 85694, 85761	
Associated devices	
Not applicable.	

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Reason for Field Safety Corrective Action (FSCA)

Description of the product problem*
A packaging issue has been identified concerning a primary packaging component used to encapsulate the components within our Suction Clearance Kits. A white crepe has been used in replacement of the standard green crepe in the affected LOTs. This crepe paper is used to wrap the devices of the kit before they are placed into the primary peel pouch for sterilization. This white crepe is currently pending verification and Exmoor Plastics Limited is awaiting final confirmation.
Hazard giving rise to the FSCA*
The affected lots were created for the purpose of a sterilisation verification study to examine the new primary packaging component. The products were inadvertently released to the market prior to the receipt of final test verification results.
Probability of problem arising
The final test verification results are still pending at this time, but initial review indicates that the products do not pose harm to the end user and there is a very low risk of problems arising.
Predicted risk to patient/users
There has been no immediate risk identified to patients and users following the initial results of this verification.
Further information to help characterise the problem
At the signing of this document, there have been no complaints or links to issues or harm arising from this packaging issue with this product; this issue was detected internally and proactively escalated as a preventative measure.
Background on Issue
Exmoor Plastics Limited were made aware by one of their subcontractors that product containing white crepe paper had been inadvertently released to market. This product was manufactured as part of an ongoing change to examine the use of alternative crepe papers in Exmoor Plastics Limited Suction Clearance Kits. A full root cause investigation is currently in process.
Other information relevant to FSCA
Subsequent testing is currently being performed to verify the white crepe and will be made available as required.



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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
☐	None
By when should the action be completed?	
As soon as possible	
Is follow-up of patients or review of patients' previous results recommended?	
No	
Is customer Reply Required? * (If yes, form attached specifying deadline for return)	
Yes	

Action To Be Taken by the Manufacturer

☒	Product Removal
☐	On-site device modification/inspection
☐	Software upgrade
☐	IFU or labelling change
☐	Other
☐	None
By when should the action be completed?	
As soon as possible	
Is the FSN required to be communicated to the patient /lay user?	
No	
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	



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General Information*

FSN Type*	New
For updated FSN, reference number and date of previous FSN	Not Applicable
For Updated FSN, key new information as follows:	
Not Applicable	
Further advice or information already expected in follow-up FSN? *	Not planned yet

Manufacturer information

Company Name	Exmoor Plastics Limited
Address	1 Western Avenue, Matrix Park, Buckshaw Village, Chorley, PR7 7NB
Website address	https://vernacare.com/brands/exmoor

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

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Appendices

Appendix 1: Response Form.

Appendix 2: Identifying the product

Signature

Name	Agnieszka Sikorska-Brzozowska
Job Title	Head of QARAC
Signature	<u>Aga Sikorska-Brzozowska</u> Aga Sikorska-Brzozowska (May 20, 2025 09:29 GMT+1)
Date	20/05/2025

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.

Please transfer this notice to other organisations on which this action has an impact.

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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Appendix 1: Response form

To be completed and returned with a Certificate of Destruction before 28th June 2025

Urgent Field Safety Notice

Product: Exmoor Plastics Limited Suction Clearance Kits

Customer name	
Department	
Organisation	
Address	
Tel. Number	
E-mail Address	

Please tick the boxes below which apply:

We have none of the affected batches of products listed below in stock and have not sold or transferred them (no further action required). ☐

We have sold or transferred our stock of the affected product and lots. We have identified the recipients and undertake to forward a copy of this Field Safety Notice and response form to them. ☐

We have destroyed affected stock as indicated in the table below and have attached a certificate of destruction. ☐



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Please complete the table below if you have stock.

Please indicate the quantity of individual packs you have in the appropriate box against each LOT

If you do not have stock of these items, you do not need to complete this table.

SC6, SC4JH	
LOT	Quantity Destroyed
85695	
85694	
85761	

Please sign below, even if you do not have any stock and have not completed the table above to acknowledge receipt of this Field Safety Notice.

Signed Print

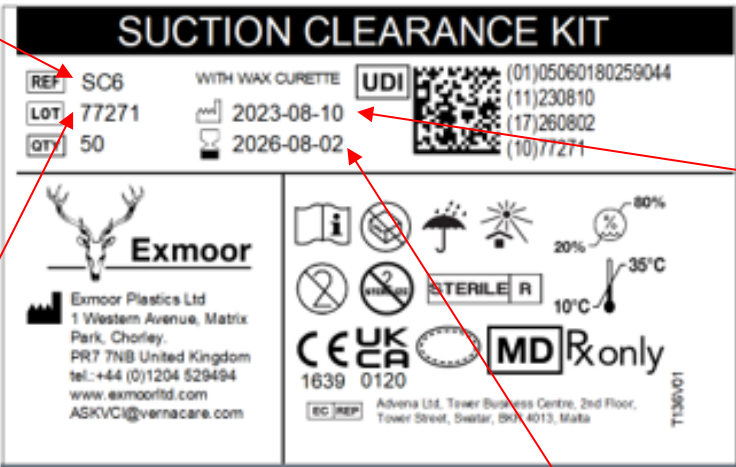
Position Date

Thank you for your cooperation.

Please scan and e mail this form to; product.safety@vernagroup.com

Appendix 2: Identifying the product

The individual packs of affected stock have the part Product Name REF, LOT and Date of Manufacture printed in black ink directly onto the front of the brand packaging and on the case label. Below is an example:



REF- Product Code

Product Name in White Lettering with a Black Background

REF SC6

LOT 77271

LOT- Lot Number

WITH WAX CURETTE

2023-08-10

2026-08-02

UDI

QR Code

(01)05060180259044
(11)230810
(17)260802
(10)77271

Date of Manufacturer in YYYY-MM-DD

Exmoor

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ASKVC1@vernacare.com

STERILE R

CE UKCA MD R only

1639 0120

Advona Ltd, Tower Business Centre, 2nd Floor,
Tower Street, Swale, BN1 013, Malta

Expiry in YYYY-MM-DD

Form Title

Final Audit Report

2025-05-20

Created:	2025-05-20
By:	Tracy Avery (tracy.avery@vernacare.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA1p7wGnxFEJQHZ7xNpZlbLSQIWAsjLvD0

"Form Title" History

-  Document created by Tracy Avery (tracy.avery@vernacare.com)
2025-05-20 - 7:58:46 AM GMT
-  Document emailed to aga.sikorska@vernacare.com for signature
2025-05-20 - 7:58:50 AM GMT
-  Email viewed by aga.sikorska@vernacare.com
2025-05-20 - 8:27:19 AM GMT
-  Signer aga.sikorska@vernacare.com entered name at signing as Aga Sikorska-Brzozwska
2025-05-20 - 8:29:30 AM GMT
-  Document e-signed by Aga Sikorska-Brzozwska (aga.sikorska@vernacare.com)
Signature Date: 2025-05-20 - 8:29:32 AM GMT - Time Source: server
-  Agreement completed.
2025-05-20 - 8:29:32 AM GMT