FSN Ref: HHE-2026-003
FSCA Ref: HHE-2026-003

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

Date: 22nd April 2026

Urgent Field Safety Notice

Product: Aural Vent Tubes (PTFE)

For Attention of*: Customers of Exmoor Plastics Limited

Contact details of local representative*
European Representative **Advena Limited,** Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013, Malta. Telephone: +356 2546 6689 Name of Manufacturer **Exmoor Plastics Limited** 1, Western Avenue Matrix Park Buckshaw Village Chorley PR7 7NB United Kingdom

Information on Affected Devices*

Device Type(s)*
Exmoor Plastics Limited Aural Ventilation Tubes
Commercial name(s)
Exmoor Plastics Limited Aural Ventilation Tubes
Primary clinical purpose of device(s)*
The device is intended to be surgically implanted into the eardrum, across the tympanum to drain fluid and act to ventilate the middle ear and equalise pressure.

Device Model	Device Name	Unique Device Identifier(s) (UDI-DI)
E101	Shepards Drain Grommet - Wire/PTFE/White/1.14/2.36/2.36/1.42/2.41	5060180255954
E103	Shepards Drain Grommet - Wire/PTFE/White/0.97/2.08/2.08/1.42/2.41	5060180255978
E104	Shepards Drain Grommet - None/PTFE/White/0.97/2.08/2.08/1.42/2.41	5060180255985
E106	Collar Button Grommet - None/PTFE/White/1.14/2.24/2.24/1.27/1.78	5060180255992
E107	Collar Button Grommet - None/PTFE/White/1.14/3/3/1.27/1.78	5060180256005
E108	Collar Button Grommet - None/PTFE/White/1.4/2.55/2.55/0.85/1.35	5060180256012
E109	Collar Button Grommet - None/PTFE/White/1.75/2.58/2.85/0.95/1.46	5060180256029
E111	Reuter Bobbins Grommet - No Holes/PTFE/White/1.14/2.54/2.54/0.76/1.52	5060180256043
E115X5	Shah Ventilation Tubes - Wire/PTFE/White/1.14/3.61/2.59/1.42/2.41 - pk of 5	5060180256722
E116	Shah Ventilation Tubes - None/PTFE/White/1.14/3.61/2.59/1.42/2.41	5060180256098

Software version
Not Applicable
Affected serial or lot number range

Device Model	Device Name	Lot Number
E101	Shepards Drain Grommet - Wire/PTFE/White/1.14/2.36/2.36/1.42/2.41	11992
E103	Shepards Drain Grommet - Wire/PTFE/White/0.97/2.08/2.08/1.42/2.41	11994
E104	Shepards Drain Grommet - None/PTFE/White/0.97/2.08/2.08/1.42/2.41	12227
E106	Collar Button Grommet - None/PTFE/White/1.14/2.24/2.24/1.27/1.78	12210
E107	Collar Button Grommet - None/PTFE/White/1.14/3/3/1.27/1.78	11995
E108	Collar Button Grommet - None/PTFE/White/1.4/2.55/2.55/0.85/1.35	12211
E109	Collar Button Grommet - None/PTFE/White/1.75/2.58/2.85/0.95/1.46	11996
E111	Reuter Bobbins Grommet - No Holes/PTFE/White/1.14/2.54/2.54/0.76/1.52	10918
E115X5	Shah Ventilation Tubes - Wire/PTFE/White/1.14/3.61/2.59/1.42/2.41 - pk of 5	11997
E116	Shah Ventilation Tubes - None/PTFE/White/1.14/3.61/2.59/1.42/2.41	10921
		11998

Associated devices
Not Applicable

Reason for Field Safety Corrective Action (FSCA)*

Description of the product problem*

During post-sterilisation quality inspections, a small number (approximately 0.1%–0.5%).of Aural Ventilation Tubes, within specific lot numbers, were identified to have compromised sterile barrier integrity.

Hazard giving rise to the FSCA*

Potentially breached primary packaging

Probability of problem arising

Based on the current investigation and available data, the likelihood of occurrence is considered very remote (approximately 0.1%–0.5%).
In addition, any breach of the sterile barrier is readily visible, and the packaging and instructions for use clearly instructs users not to use the product if the packaging is damaged.

Predicted risk to patient/users

Potential for compromised sterile barrier integrity, which may result in the product being non-sterile at the point of use.

Further information to help characterise the problem

Aural Ventilation Tubes are packaged in a small protective case, which is then placed inside a paper–film pouch to maintain sterility.

Figure 1- Protective case used to package the Aural Ventilation Tubes

Figure 2- Protective case opened, showing the Aural Ventilation Tube

Figure 3- Aural Ventilation Tube present Primary Packaging with default highlighted in red

Background on Issue

Exmoor Plastics Limited recently changed its steam sterilisation supplier for PTFE grommets.
During the onboarding phase with the new supplier, an issue was identified in certain lot numbers during post-sterilisation quality inspections, where a small number of units were found to have a breached sterile barrier.

As a result, a comprehensive review was conducted of all products received from the new steam sterilisation supplier. During this review, several lots from a specific sterilisation cycle were identified for which sterility assurance could not be confirmed with 100% certainty. The assessment concluded that the probability of a sterile barrier breach is less than 0.5%.

Where breaches were identified, they were clearly visible, with the container observed to be adhering to the sterile barrier. Consequently, as a precautionary measure, a voluntary recall has been initiated for all affected lots.

Other information relevant to FSCA

This action is taken to ensure that no potentially compromised product remains in distribution and to uphold patient safety and regulatory compliance.

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
Particular considerations for:	Implantable Device Although the device is implantable, removal of Aural Ventilation Tubes already implanted in patients is not recommended. The issue identified relates to sterile barrier integrity prior to use and does not impact device performance once implanted. Any breach of the sterile barrier is readily visible to the naked eye, and the product labelling clearly states that the device must not be used if the packaging is damaged. As a precautionary measure, patients implanted with devices from affected lot numbers should continue to be monitored in accordance with standard clinical practice.
Is follow-up of patients or review of patients' previous results recommended?	Yes
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

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? *	No
If follow-up FSN expected, what is the further advice expected to relate to:	
Not Applicable	
Anticipated timescale for follow-up FSN	Not Applicable

Manufacturer information

Company Name	Exmoor Plastics Limited
Address	1, Western Avenue Matrix Park Buckshaw Village Chorley PR7 7NB United Kingdom
Website address	https://vernacare.com/
SRN	GB-MF-000025513

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

Appendices

Appendix 1: Response Form (customers)
Appendix 2: Response Form (Distributors/Importers)
Appendix 3: Identifying the product

Signature

Name	Aga Sikorska-Brzozowska
Job Title	Director of QA, RA and Clinical
Signature	
Date	22/04/2026

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..*

Appendix 1: Response form (Customer)

To be completed and returned with a Certificate of Destruction before 5th July 2026

Please only reply if you have received the impacted lot(s), and have been contacted by a distributor or member of Vernacare International

Urgent Field Safety Notice

Product: Aural Vent Tubes (PTFE)

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. ☐

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.

[Product code]	
LOT	**Quantity Destroyed**
[Add or delete rows as necessary]	

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: Response form (Distributor/Importer)

1. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

2. Return acknowledgement to Sender	
Email	
Distributor/Importer Helpline	
Postal Address	
Web Portal	
Deadline for returning the Distributor/Importer reply form*	

3. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I have checked my stock and quarantined inventory	
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	
☐	I have destroyed affected devices – enter number destroyed and date complete.	
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		
Signature*		
Date *		

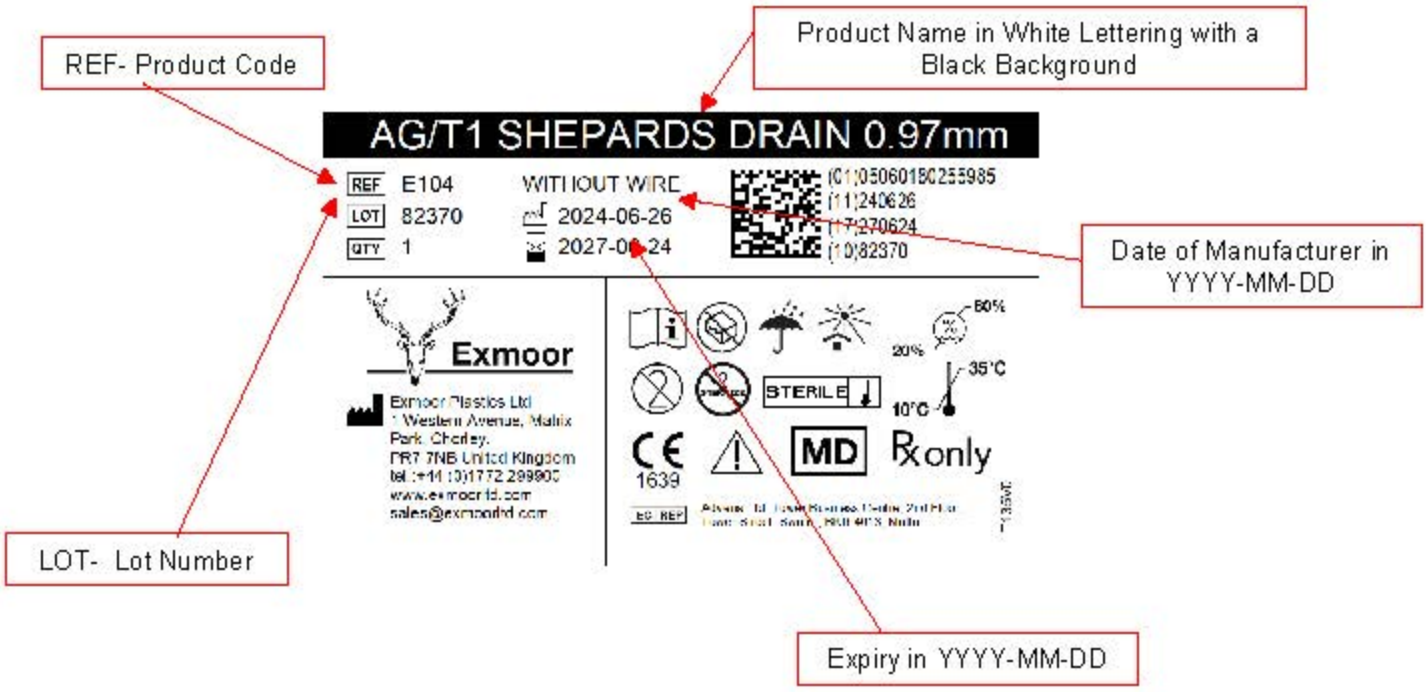
Mandatory fields are marked with *

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.

Appendix 3: 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:



Form Title

Final Audit Report 2026-04-22

Created:	2026-04-22
By:	Anna Gabbott (anna.gabbott@vernagroup.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAdBr3SzSZjvrJyQMq6zlvcmyYbFUgQU5-

"Form Title" History

Document created by Anna Gabbott (anna.gabbott@vernagroup.com)
2026-04-22 - 12:17:32 PM GMT

Document emailed to Aga Sikorska (aga.sikorska@vernagroup.com) for signature
2026-04-22 - 12:17:37 PM GMT

Email viewed by Aga Sikorska (aga.sikorska@vernagroup.com)
2026-04-22 - 12:44:01 PM GMT

Document e-signed by Aga Sikorska (aga.sikorska@vernagroup.com)
Signature Date: 2026-04-22 - 12:44:36 PM GMT - Time Source: server

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2026-04-22 - 12:44:36 PM GMT