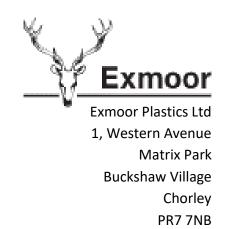
Date: 15th July 2024



United Kingdom

Urgent Field Safety Notice

Product: Aural Vent Tubes

Information on Affected Devices

Device	Type(s)		
The device is to be used as a ventilation tube with the purpose of ventilating the middle ear			
cleft			-
Commo	ercial name(s)	
Aural V	ent Tubes		
Primar	y clinical pui	rpose of device(s)	
The dev	ices are inte	nded to be used as a ventilation tube with	the purpose of ventilating the
middle	ear cleft		-
D	evice		Unique Device
Model/Catalogue/		Device Name	Identifier(s) (UDI-DI)
part number(s)			identifier(s) (ODI-DI)
	E104	Shepards Drain without wire 0.97 mm	5060180255985
E106		Collar Button 1.14 mm	5060180255992
Softwa	re version		
N/A			
Affecte	d serial or lo	ot number range	
E104	79182,7873	8, 80246, 79969, 79182.	
F106	80247, 8104	48, 80068, 81838	

Reason for Field Safety Corrective Action (FSCA)

Description of the product problem

Incorrect material was packed into the final product packaging.

Difference in dimensions (diameter of outer surface and aperture as well as shape).

Hazard giving rise to the FSCA

Associated devices

N/A

There is a risk that the incorrect raw materials are used on these products, incorrect material may have been packed into the final product packaging



Type of Action to mitigate the risk

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		
All impacted product is to be identified and destroyed. Upon returning the completed response form below (Appendix 1) and a certificate of destruction, a credit note will be issued		
By when should the action be		
completed?	As soon as possible	
	As soon as possible Yes	
completed? Is customer Reply Required?	Yes	
completed?	Yes	
completed? Is customer Reply Required? Action Being Taken by the Manufac	Yes	
completed? Is customer Reply Required? Action Being Taken by the Manufac Product Removal	Yes	
completed? Is customer Reply Required? Action Being Taken by the Manufac Product Removal On-site device modification/insp	Yes	
completed? Is customer Reply Required? Action Being Taken by the Manufactor ☑ Product Removal ☑ On-site device modification/insp	Yes	
completed? Is customer Reply Required? Action Being Taken by the Manufactor □ Product Removal □ On-site device modification/inspector □ Software upgrade □ IFU or labelling change □ Other	Yes	
completed? Is customer Reply Required? Action Being Taken by the Manufactory □ Product Removal □ On-site device modification/insp □ Software upgrade □ IFU or labelling change □ Other Complaint raised in system being in	Yes turer ection	
completed? Is customer Reply Required? Action Being Taken by the Manufac ☑ Product Removal ☑ On-site device modification/insp ☐ Software upgrade ☐ IFU or labelling change ☑ Other Complaint raised in system being in relevant actions being undertaken.	Yes turer ection	



If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?

Not Applicable

General Information

F	SN 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		No
already expected in follow-up FSN?		
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	
Website address https://vernacare.com/		rnacare.com/
The Competent (Regulatory) Authority of your country has been informed about this communication to customers.		

Appendices

Appendix 1: Response Form.

Appendix 2: Identifying the product

Signature

Name	Agnieszka Sikorska-Brzozowska	
Job Title	Head of QARAC	
Signature	Agnieszka Sikorska-Brzozowska	
Date		

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 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

To be completed and returned with a Certificate of Destruction before 30th August 2024

Urgent Field Safety Notice

Product: Aural Vent Tubes

Customer name		
Department		
Organisation		
Address		
Tel. Number		
E-mail Address		
Please tick the boxes be	elow 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).	
	nsferred our stock of the affected product and lots. We have cipients and undertake to forward a copy of this Field Safety Notice and response form to them.	
We have destro	byed affected stock as indicated in the table below and have attached a certificate	



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.

E1	04
LOT	Quantity Destroyed
79182	
78738	
80246	
79969	
79182	

E106		
LOT	Quantity Destroyed	
80247		
81048		
80068		
81838		

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 utilising the Product SRS1A(29)

