FSN Ref: HHE-2024-004
FSCA Ref: HHE-2024-004

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

Date: 15th July 2024

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		
Commercial name(s)		
Aural Vent Tubes		
Primary clinical purpose of device(s)		
The devices are intended to be used as a ventilation tube with the purpose of ventilating the middle ear cleft		
Device Model/Catalogue/ part number(s)	**Device Name**	**Unique Device Identifier(s) (UDI-DI)**
E104	Shepards Drain without wire 0.97 mm	5060180255985
E106	Collar Button 1.14 mm	5060180255992
Software version		
N/A		
Affected serial or lot number range		
E104	79182,78738, 80246, 79969, 79182.	
E106	80247, 81048, 80068, 81838	
Associated devices		
N/A		

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
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
Is customer Reply Required?	Yes

Action Being Taken by the Manufacturer	
☒ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other Complaint raised in system being investigated, as per internal procedures, in which relevant actions being undertaken. ☐ 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?
Not Applicable

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
Website address	https://vernacare.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	7/15/2024

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 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.

E104	
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)