FSN Ref: HHE-2024-002
FSCA Ref: HHE-2024-002

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

Date: 15th July 2024

Urgent Field Safety Notice

Product: Silicone Sheets, Discs and Strips

Information on Affected Devices

Device Type(s)		
Silicone Sheets, Discs and Strips intended to separate tissues and/or to provide resilient sheeting during ear, nose and throat procedures.		
Commercial name(s)		
Silicone Sheets, Discs and Strips		
Primary clinical purpose of device(s)		
For recognised procedures in the ear, nose and throat.		
Device Model/Catalogue/ part number(s)	**Device Name**	**Unique Device Identifier(s) (UDI-DI)**
E201	Shah Silicone Rubber Disc (Blue)-Small SD/8.0/0.125B	5060180256128
E202	Shah Silicone Rubber Disc (Blue) - Large SD/8.5/0.125B 64416	5060180256135
E204	Shah Packing Strips (Blue) PS/S/45/5/0,125B	5060180256142
SRS1	Silicone Rubber Sheeting (0.125mm x 40mm x 35mm-clear)	5060180258283
SRS1A	Silicone Rubber Sheet 0.125mm x 40mm x 35mm (Blue)	5060180256128
Software version		
Not Applicable		
Affected lot number range		
E201	71870, 72835, 73262, 71701, 72152, 77748	
E202	72584, 73494	
E204	71702, 72316, 74089, 74276, 74546, 75054, 75600, 75660, 74576, 77264	
SRS1	73142, 75093, 76929, 77167, 72159, 75423, 75495, 77477, 78110	
SRS1A	72000, 72487, 73143, 76169, 78642, 79351	
Associated devices		
Not Applicable		

Reason for Field Safety Corrective Action (FSCA)

Description of the product problem
Potential difference in thickness than that stated on Product Labelling for the disclosed products. For example 0.125mm is stated thickness, 0.31mm is maximum observed through investigation of 0.176mm greater.
Hazard giving rise to the FSCA
Mislabelling of product (product thicker than described on label)
Predicted risk to patient/users
From clinical review no physical harm to patient could be observed due to the use of thicker sheets as sheets up to 1.5mm thickness may be used in typical procedures associated with the intended purpose of the device and are manipulated at the discretion of the clinician to fit to the patient regardless of initial sheet thickness.

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 inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☒ Other Awareness of differing thickness of product than that stated on the label. At discretion of the responsible Health Care Professional to determine the continued use of affected batches. ☐ None	
By when should the action be completed?	As soon as possible
Is customer Reply Required?	No

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: Identifying the product

Signature

Name	Agnieszka Sikorska-Brzozowska
Job Title	Head of QARAC
Signature	Aga 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: 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)