FSN Ref: HHE-2024-007
FSCA Ref: HHE-2024-007

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

**Date:** 20th January 2025

# Urgent Field Safety Notice

## Product: Exmoor Plastics Limited Nasal Splints

## Information on Affected Devices*

| **Device Type(s)*** | | | |
|---|---|---|---|
| A range of flexible, pigmented, shaped-silicone rubber devices used to support the midline nasal septum, to support nasal respiration and prevent adhesions following naso-septal surgery | | | |
| **Commercial name(s)** | | | |
| Exmoor Plastics Limited Grimaldi Nasal Splint | | | |
| **Unique Device Identifier(s) (UDI-DI)** | | | |
| 5060180257637 | | | |
| **Primary clinical purpose of device(s)*** | | | |
| The devices are intended to provide post operative midline nasal septum support and to prevent unwanted adhesions. | | | |
| **Device Model/Catalogue/part number(s)*** | | | |
| N6 Grimaldi Nasal Splint L 80mm x W 35mm x Thickness 0.85mm | | | |
| **Affected serial or lot number range** | | | |
| 76948 | 77344 | 77707 | 77944 |
| 79097 | 79642 | 81056 | |
| **Associated devices** | | | |
| Not Applicable | | | |

## Reason for Field Safety Corrective Action (FSCA)

| **Description of the product problem** |
|---|
| A critical packaging issue has been identified concerning the seal integrity of the primary packaging for Exmoor Plastics Limited N6 Nasal Splints.<br>N6 Nasal Splints are packed within an inner bag and then placed within a heat seal primary pouch.<br>It has come to our attention that for some lots of N6, the inner packaging and Nasal Splint itself have been seen to be trapped in the seal of the primary packaging. |
| **Hazard giving rise to the FSCA** |
| Internal Investigation concluded that for some lots of N6, the inner packaging and Nasal Splint itself have been seen to be trapped in the seal of the primary packaging. This is resulting in a potential breach to the sterile barrier. N6 is sterilised prior to being placed on the market.<br>This issue is visible in certain cases, however, can be subtle. |
| **Probability of problem arising** |
| As per our internal procedures we have identified this as a probability of “Possible” (1 in 100,000 to 1 in 10,000). |
| **Predicted risk to patient/users** |
| Due to a potential breach in the sterile barrier of the nasal splint there is a risk that the sterility of the surgical field or medical procedure has been compromised. This results in an increased risk of infection and post procedure complications for the patient. |
| **Further information to help characterise the problem** |
| The problem can be visualised by the nasal splint or the inner bag in which the nasal splint is contained trapped within the heat seal of the primary pouch. |

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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 |

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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 Plasitcs 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** | Agnieszka Sikorska-Brzozowska |
| **Date** | 1/20/2025 |

| **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.<br><br>Please transfer this notice to other organisations on which this action has an impact.<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>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 6th March 2024

## Urgent Field Safety Notice

## Product: Exmoor Plastics Limited Nasal Splints

| | |
|---|---|
| **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.

| N6 | |
|---|---|
| **LOT** | **Quantity Destroyed** |
| 76948 | |
| 77344 | |
| 77707 | |
| 77944 | |
| 79097 | |
| 79642 | |
| 81056 | |

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

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# 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: