

Urgent Field Safety Notice**MHRA REF: 2023/003/028/601/038****Internal REF: CC-89****FSN/FSCA 6th April 2023****Field Safety Notice/Field Safety Corrective Action - Product Recall****Dear Customer**

This letter is to inform you of a potential patient safety issue concerning Exmoor Plastics Nasal Splints. You have been sent this Field Safety Corrective Action notice because our records indicate that you may have received potentially faulty product.

We request your co-operation in identifying and quarantining potentially affected batches of products in the interests of patient safety.

Description of the problem:

Exmoor Plastics, the legal manufacturer of the Exmoor Plastics® range of single-use instruments, has been made aware of a potential manufacturing defect concerning the nasal splints produced by the company. Product coatings used in the production process have not been removed prior to packaging. The coating is an inert talc and we have had no reports of serious incidents from the field.



Figure 1. Image of nasal splint

As Exmoor Plastics Ltd is dedicated to delivering high standards of product quality and safety, we have taken the decision to voluntarily recall all batches of potentially affected products which may be affected.

A complete list of potentially affected products and manufacturing lot (batch) numbers is provided on the attached response form for your convenience.

Requested action to be taken by the end user (Healthcare Facilities):

Please check your stock of product:

1. Identify if you have any of the affected products and batches in stock.

The affected products and a list of product codes (**REF**) and batches (**LOT**) are listed on the response form (attached). Please refer to Appendix 1 for a guide to checking our labels.

2. Segregate and quarantine affected batches of products to prevent them from being used clinically.**3. Complete the Response Form (attached)**

Please indicate the quantity of individual packs per product and batch (LOT) number.

4. Scan and email the completed form to product.safety@vernagroup.com**5. For the UK, return the affected batches of products to Exmoor Plastics Ltd (the manufacture facility)**

Please secure the box with standard packaging tape and return to Exmoor Plastics via your chosen courier (Postal address and return reference below). Alternatively, you can contact Exmoor Plastics Ltd who will arrange for your goods to be collected. Exmoor will issue a credit for all returned goods.

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| F.A.O. Quality EPL 001 Exmoor Plastics Ltd Manufacture Facility (Vernacare) Lawn Road Carlton-In-Lindrick Worksop Nottinghamshire S81 9LB United Kingdom |
|--|

6. For International Markets (outside of the UK), dispose of all affected product and provide disposal confirmation to product.safety@vernagroup.com in order to obtain reimbursement.**Transmission of this field safety notice:**

Forward this notice to all departments/teams within your organisation who may have received the affected batches of products and ask that they complete the attached form.

Requested action to be taken by Distributors:Goods in stock**1. Identify if you have any of the affected products and batches in stock.**

The affected products and a list of product codes (**REF**) and batches (**LOT**) are listed on the response form (attached) for convenience. Please refer to Appendix 1 for a guide to checking our labels.

2. Segregate and quarantine affected batches of products to prevent them from being delivered to customers and end-users.

3. **Complete the Response Form (attached)**

Please indicate the quantity of individual packs per product and batch (LOT) number.

4. **Scan and email the completed form to product.safety@vernagroup.com**

5. **For the UK, return the affected batches of products to Emoor Plastics Ltd (the manufacture facility)**

Please contact Exmoor Plastics Ltd who will arrange for your goods to be collected. Exmoor Plastics will issue a credit for all returned goods.

6. **For International Markets (outside of the UK), dispose of all affected product and provide disposal confirmation to product.safety@vernagroup.com in order to obtain reimbursement.**

Goods already distributed:

Distributors are requested to contact their customers and forward this notice on to them.

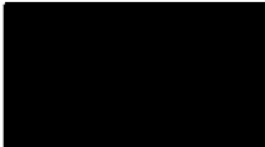
If you have already distributed the affected batches of products, please consult your delivery records and identify all recipients to whom you have supplied the affected batches of products.

If you are unable to identify what has been supplied by lot number, please identify all recipients to whom you have supplied the products during the period 2022-06-01 and 2023-03-20.

We apologise for any inconvenience caused by this matter and thank you for your cooperation.

If you are unsure what to do or need further information, please call us quoting "Nasal Splint Recall" on 01909 735000 or email us at product.safety@vernagroup.com

Kind regards



Interim Site Quality Manager

Response form

Field Safety Corrective Action 6th April 2023

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 identified and quarantined stock of the product in the lots listed below. We have completed the table above.

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.

| Brown Nasal Splint – REF N3 | | | | | |
|--|-----------------------|-------|-----------------------|-------|-----------------------|
| LOT | QTY Return/Destroy | LOT | QTY Return/Destroy | LOT | QTY Return/Destroy |
| 70305 | | 70653 | | 71973 | |
| Mackay Nasal Splint – REF N4 | | | | | |
| LOT | QTY Return/Destroy | LOT | QTY Return/Destroy | LOT | QTY Return/Destroy |
| 71237 | | 71977 | | n/a | n/a |
| Grimaldi Nasal Splint (small) – REF N5 | | | | | |
| LOT | QTY Return/Destroy | LOT | QTY Return/Destroy | LOT | QTY Return/Destroy |
| 70058 | | 70662 | | 71978 | |
| Grimaldi Nasal Splint (large) – Ref N6 | | | | | |
| LOT | QTY Return/Destroy | LOT | QTY Return/Destroy | LOT | QTY Return/Destroy |
| 70671 | | 71871 | | n/a | n/a |
| Shah Nasal Splint (60mm x 27mm x 0.85mm)– Ref N7 | | | | | |
| LOT | QTY Return/Destroy | LOT | QTY Return/Destroy | LOT | QTY Return/Destroy |
| 70650 | | 71996 | | n/a | n/a |
| Shah Nasal Splint (65mm x 31mm x 0.85mm)– Ref N8 | | | | | |
| LOT | QTY Return/Destroy | LOT | QTY Return/Destroy | LOT | QTY Return/Destroy |
| 71627 | | 71238 | | 71974 | |
| 72320 | | n/a | n/a | n/a | n/a |
| Shah Nasal Splint (70mm x 37mm x 0.85mm) – Ref N9 | | | | | |
| LOT | QTY Return/Destroy | LOT | QTY Return/Destroy | LOT | QTY Return/Destroy |
| 71239 | | 71873 | | 70905 | |
| Shah Nasal Splint (60mm x 27mm x 1.25mm) – Ref N10 | | | | | |
| LOT | QTY Return/Destroy | LOT | QTY Return/Destroy | LOT | QTY Return/Destroy |
| 70300 | | 72322 | | n/a | n/a |
| Shah Nasal Splint (65mm x 31mm x 1.25mm) – Ref N11 | | | | | |
| LOT | QTY Return/Destroy | LOT | QTY Return/Destroy | LOT | QTY Return/Destroy |
| 71626 | | 71997 | | n/a | n/a |
| Shah Nasal Splint (70mm x 37mm x 1.25mm) – Ref N12 | | | | | |
| LOT | QTY Return/Destroy | LOT | QTY Return/Destroy | LOT | QTY Return/Destroy |
| 70151 | | 71979 | | n/a | n/a |
| Shah Nasal Splint (60mm x 27mm x 1.75mm) – Ref N13 | | | | | |
| LOT | QTY Return/Destroy | LOT | QTY Return/Destroy | LOT | QTY Return/Destroy |
| 70367 | | n/a | n/a | n/a | n/a |
| Nasal Splint Pairs – REF N23 | | | | | |
| LOT | QTY Return/Destroy | LOT | QTY Return/Destroy | LOT | QTY Return/Destroy |
| 70306 | | n/a | n/a | n/a | n/a |

Can you 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.

Please scan and e mail this form to; product.safety@vernagroup.com

For help in completing this form, please call 01909 735000 or e-mail us at the above address quoting “Nasal Splint Recall”.

Change Table

| | |
|---------|---|
| Issue 1 | New |
| Issue 2 | Addition of destruction instruction for international markets |

Appendix 1.

Guide to identifying the product REF, the LOT (batch) code and Date of Manufacture (DOM)

The individual packs of affected stock have the part REF, LOT and Date of Manufacture printed in black ink directly onto the front of the branded packaging, and on the case label.

Case Label

