Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

نتقدم بثقة
Moving Forward with Confidence

رؤية عُمان 2040

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 76 **dated** 19/4/2023 **Regarding NCMDR Recall of Exmoor Plastics Nasal Splints from (mfr: Exmoor Plastics Ltd).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ISO 9001:2015 CERTIFIED QUALITY MANAGEMENT SYSTEMS

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
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سلطنة عُمان
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Circular No. 76 / 2023

28 -09-1444 H

19 -04-2023

Recall of Exmoor Plastics Nasal Splints from Exmoor Plastics Ltd.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19510
Product	Exmoor Plastics Nasal Splints.
Description	Nasal Splints.
Manufacturer	Exmoor Plastics Ltd.
Local agent	AMICO.
The affected products	Refer to page 5 in the attachment.
Reason	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.
Action	1. Identify if you have any of the affected products and batches in stock. 2. Segregate and quarantine affected batches of products to prevent them from being used clinically. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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

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.

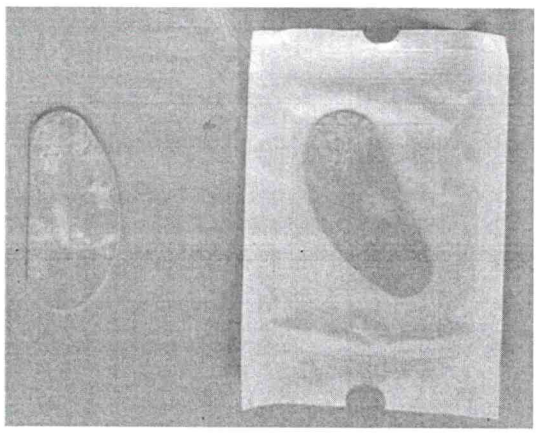

Figure 1. Image of nasal splint

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.

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

Maddy Hill
Interim Site Quality Manager

Exmoor

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.

Exmoor

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