FSN Ref HHE-2024-006
FSCA Ref: HHE-2024-006

Date: 18th December 2024

Urgent Field Safety Notice

Product: Procedure Packs

Information on Affected Devices

Device Type(s)
Vernacare Limited provide to the market a number of procedure packs.
Commercial name(s)
Vernacare Limited Procedure Packs
Primary clinical purpose of device(s)
Single-use components in one sterile pack to be used as an ancillary pack during a range of surgical procedures.
Device Model/Catalogue/part number(s)*
28159- Medium Dressing Pack 28174-Woundcare Pack 40 Per Case 28862-Basic Woundcare Pack 28765-Renal Pack
Software version
N/A
Affected serial or lot number range
0324S907 (PN: 21859 – cases: 20) 0223S907 (PN: 28174 – cases: 24) 2823S907 (PN: 28862 – cases: 9) 0424S907 (PN: 28765 – cases: 100 0924S907 (PN: 28765 – cases: 56)
Associated devices
N/A

Reason for Field Safety Corrective Action (FSCA)

Description of the product problem
Regulatory Affairs and Labelling Issue Only. Lack of appropriate symbology following the May 2024 EU Medical Device Regulation 2017/745 implementation.
Hazard giving rise to the FSCA
No associated harm identified to patient or user. This is a regulatory and compliance risk only.

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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

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General Information*

FSN Type*	New

Manufacturer information

Company Name	Vernacare Limited
Company 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	Aga Sikorska-Brzozowska
Date	18/12/2024

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 transfer this notice to other organisations on which this action has an impact.

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

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Appendix 1: Response form

To be completed and returned with a Certificate of Destruction before 28th February 2025

Urgent Field Safety Notice

Product: Procedure Packs

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.

21859	
LOT	**Quantity Destroyed**
0324S907	

28174	
LOT	**Quantity Destroyed**
0223S907	

28862	
LOT	**Quantity Destroyed**
2823S907	

28765	
LOT	**Quantity Destroyed**
0424S907	
0924S907	

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: