

FSN Ref: HHE-2024-003
FSCA Ref: HHE-2024-003

Date: 17th July 2024

Robinson Healthcare Limited
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Worksop S81 9LB, UK

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Urgent Field Safety Notice

Product: Fast Aid Zinc Oxide Tape

Information on Affected Devices

Device Type(s)		
This is a flexible non-stretch support tape with a high tack adhesive		
Commercial name(s)		
Fast Aid Zinc Oxide Tape		
Primary clinical purpose of device(s)		
Indicated for both first aid and sports use, they can be applied directly to the skin to help support joints by immobilising or restricting movement – thus helping protect against new injuries or aggravating old ones.		
Device Model/Catalogue/ part number(s)	Device Name	Unique Device Identifier(s) (UDI-DI)
4482	Fast Aid® Zinc Oxide Non Stretch Tape 1.25cm x 5m	05010058044821
4483	Fast Aid® Zinc Oxide Non Stretch Tape 2.5cm x 5m	05010058044838
4484	Fast Aid® Zinc Oxide Non Stretch Tape 5cm x 5m	05010058044845
Software version		
Not Applicable		
Affected lot number range		
22HL430		
Associated devices		
Not Applicable		

Reason for Field Safety Corrective Action (FSCA)

Description of the product problem
Tape is unable to form or maintain adhesion
Hazard giving rise to the FSCA
Dressing may not adhere adequately to the patient's skin

Type of Action to mitigate the risk

Action To Be Taken by the User	
<input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None	
By when should the action be completed?	As soon as possible
Is customer Reply Required?	Yes

Action Being Taken by the Manufacturer	
<input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other Complaint raised in system being investigated, as per internal procedures, in which relevant actions being undertaken. <input type="checkbox"/> 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	Robinsons Healthcare limited
Address	Lawn Road, Carlton in Lindrick, Worksop, S81 9LB
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	<i>Aga Sikorska-Brzozowska</i>
Date	17/07/24

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: Response form

To be completed and returned with a certificate of destruction before **9th August 2024**

Field Safety Notice
Zinc Oxide Tape

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.

Please complete the table below if you have stock.

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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.

4482	
LOT	Quantity Destroyed
22HL430	

4483	
LOT	Quantity Destroyed
22HL430	

4484	
LOT	Quantity Destroyed
22HL430	

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

Appendix 2: Identifying the product

The affected products are packaged in individual boxes with the Product Name LOT and Date of Manufacture printed in directly onto the box.

Below is an example utilising the Product 4482.

