Date: 17th July 2024

Not Applicable



Robinson Healthcare Limited Lawn Road, Carlton-in-Lindrick

Worksop S81 9LB, UK

Tel: +44 (0)1909 735000 Fax: +44 (0)1909 735040 enquiries@robinsonhealthcare.com www.robinsonhealthcare.com

Urgent Field Safety Notice

Product: Fast Aid Zinc Oxide Tape

Information on Affected Devices

Davis Tame(s)		
Device Type(s)		
This is a flexible non-stretch support tape with a high tack adhesive		
Commercial name(s	s)	
Fast Aid Zinc Oxide	Tape	
Primary clinical pur	pose 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	lg old offes.	
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		

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		
□ Quarantine Device □ Quarantine Device		
□ Return Device		
⊠ Destroy Device		
☐ On-site device 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 customer Reply Required?	Yes	



Action Being Taken by the Manufacturer		
⊠ Product Removal		
☐ On-site device modification/inspection		
□ Software upgrade		
□ IFU or labelling change		
⊠ Other		
Complaint raised in system being investigated, as per internal procedures, in which relevant actions being undertaken.		
□ None		
By when should the action be completed? As soon as possible		
Is the FSN required to be communicated to the patient /lay No		
user?		
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	onal user information letter/sileet?	
Not Applicable		

General Information

FSN Type	New	
For updated FSN, reference	Not Applicable	
number and date of previous FSN	Not Applicable	
For Updated FSN, key new information as follows:		
Not Applicable		
Further advice or information	No	
already expected in follow-up		
FSN?		
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

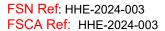
Name	Agnieszka Sikorska-Brzozowska
Job Title	Head of QARAC
Signature	Aga Sikorska-Brzozowska
Date	17/07/24

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 be	elow 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).	
	nsferred our stock of the affected product and lots. We have cipients and undertake to forward a copy of this Field Safety Notice and response form to them.	
We have destro	oyed 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.

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.

