Date: 17th July 2024

Device Type(s)

Not Applicable



Robinson Healthcare Limited Lawn Road, Carlton-in-Lindrick

Worksop S81 9LB, UK

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Urgent Field Safety Notice

Product: Fast Aid Zinc Oxide Tape

Information on Affected Devices

| 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 | st aid and sports use, they can be a | applied directly to the skin to help |
| support joints by imr | nobilising or restricting movement - | thus helping protect against new |
| injuries or aggravatin | g old ones. | |
| Device | | Unique Device Identifier(s) |
| Model/Catalogue/ | Device Name | (UDI-DI) |
| part number(s) | | (001-01) |
| 4482 | Fast Aid® Zinc Oxide Non Stretch | 05010058044821 |
| 1102 | Tape 1.25cm x 5m | 00010000011021 |
| 4483 | Fast Aid® Zinc Oxide Non Stretch | 05010058044838 |
| 1100 | Tape 2.5cm x 5m | 00010000011000 |
| 4484 | Fast Aid® Zinc Oxide Non Stretch | 05010058044845 |
| | Tape 5cm x 5m | 00010000011010 |
| 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 | | |
|--|---------------------|--|
| ☑ Identify 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 | | |
|--|---------------------|--|
| | | |
| ☐ On-site device modification/insp | pection | |
| ☐ 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 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 | Not Applicable | |
| number and date of previous FSN | | |
| 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

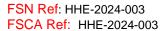
| Name | Agnieszka Sikorska-Brzozowska |
|-----------|-------------------------------|
| Job Title | Head of QARAC |
| Signature | Aga Sikorska-Brzozowska |
| Date | 17/07/24 |

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 | byed 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.

