

Date: 26th May 2021

URGENT: FIELD SAFETY NOTICE – BW001-25

Brightwake Algivon Honey Dressing and Activon Tube

REFs: Refer to Appendix 1

LOTS: Refer to Appendix 1

Type of Action:

Informing Customers of Product Stolen on the way to sterilization and not to be used.

Attention: Hospitals, Pharmacies, Distributors, Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your attention.

Dear Customer,

Brightwake is issuing this Field Safety Notice to inform customers about an issue with their Algivon Honey Dressings and Activon Tube products, (Refer to Appendix 1 for Catalogue Numbers/REF's and Lot/Batch Numbers). The issue is restricted to the batch numbers listed in Appendix 1 and below.

Catalogue Number (REF)	Product Name	Size	Lot/Batch Numbers
CR3831	Algivon Honey Dressing	5 x 5cm	WO027891
CR3659	Algivon Honey Dressing	10 x 10cm	WO027894
CR3830	Activon Tube	25g	WO028513 and WO028510

Description of the Problem

Brightwake's Algivon Honey Dressing and Activon Tube products were stolen when in transit to be sterilised.

Activon Tubes are not in their final retail packaging prior to sterilisation, the product impacted will not have a retail box.

Algivon Honey Dressings are in final retail cartons and cannot be distinguished from normal sterile product.

Both products are normally sold sterile, as these products were stolen on the way to sterilisation they are non-sterile.

Clinical Impact

The products that have been stolen have not been sterilised, and if used may result in infection or serious injury to the patient. The products are intended to be used sterile.

Corrective Actions by Brightwake

None at present, this is to inform customers not to use the products detailed in **detailed in appendix 1.**

Advice on actions to be taken by Customer.

1. Please do not use any of the products detailed in **appendix 1**.
2. Should you be offered the products detailed in **appendix 1**, please inform **Brightwake Regulatory Affairs Department**: ra@brightwake.co.uk as soon as possible.

If located in the UK please inform the police, using Crime Number: 21000287455 and/or the MHRA at Devices.Compliance@mhra.gov.uk

If located outside the UK please inform **Brightwake Regulatory Affairs Department**: ra@brightwake.co.uk

3. If you identify any of the **Brightwake products detailed in appendix 1** in your stock please inform **Brightwake Regulatory Affairs Department**: ra@brightwake.co.uk as soon as possible.
4. Circulate this Field Safety Notice to all those within your organisation that may use or have recommend the use of the **Brightwake products detailed in appendix 1**.
5. Return the completed Customer Acknowledgment (Reply) Form on page 3 to **Brightwake Regulatory Affairs Department**: ra@brightwake.co.uk as soon as possible or no later than June 15th, 2021.
 - a. NOTE: If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.

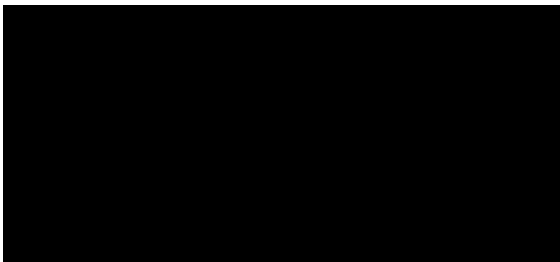
Should you have any questions or experience any issues associated with the product or issue described in this Field Safety Notice, please contact your Brightwake representative or the Brightwake Regulatory Affairs Department: ra@brightwake.co.uk.

We confirm that the appropriate regulatory agencies have been informed of these actions.

Brightwake are committed to ensuring that safe and effective product is available to customers and this Field Safety Notice is taken with due consideration of this commitment.

Thank you for your attention and cooperation.

Yours sincerely,



Customer Acknowledgement Form – **BW001-25**

Brightwake Product

Please read and return the completed and signed form as soon as possible or **no later than June 15th, 2021** to Brightwake Regulatory Affairs Department: ra@brightwake.co.uk

By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.

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CR3830	Activon Tube	20g	WO028513 and WO028510

Name of Trust / Organisation			
Your Facility Address			
Postcode			
Telephone number		E-mail address	

Please list <u>all</u> Facilities / Hospitals covered by your response <i>(e.g. other hospitals within your Trust)</i>	Facility / Hospital Name	Postcode

Your Name		Job Title	
Signature		Date	

Appendix 1: Effect Product Details: Catalogue Number (REF) & Lot/Batch Numbers

Catalogue Number (REF)	Product Name	Size	Lot/Batch Numbers
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