

Urgent Field Safety Notice

HYDROFRAME™ WITH MANUKA HONEY ((X)MHWAFH33)

FSCA-2020-09-09

Device Modification to Correct Missing Label Information.

Batches:	Part N.umber	Description
KL522	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KL523	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KL524	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KL535	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KL536	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KL537	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KL576	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KL582	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KM662	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KM663	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KM669	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KM670	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KM715	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KN632	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KN633	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KN637	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KN638	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KN639	(X)MHWAFH33	HydroFrame™ With Manuka Honey
KN691	(X)MHWAFH33	HydroFrame™ With Manuka Honey

Date: 09 September 2020

Attention: To whom it may concern/ Dear Patient (delete as appropriate)

We, the Welland Medical company, are proactively informing our customers of an issue related to the above listed batches of **Hydroframe™ With Manuka Honey**, a flange extender used to provide extra security /comfort for an ostomy appliance.

Description of the problem:

The **HydroFrame™ With Manuka Honey** has the statement "with Manuka Honey" printed on the clam pack insert (IFU). As part of update to product labelling, this information was to be added to the product label not the insert. For the batches listed above, the product was released without a statement identifying that the product contains Manuka Honey.

This is only a potential issue for users who are allergic/sensitive to Manuka Honey.

The product code includes the letters MH indicating Manuka Honey is present and this code is correctly printed on the clam pack insert. The product has Welland's Manuka Honey logo printed on each Hydroframe™.

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The IFU contains the Caution Statements; For use on intact skin only. Discontinue use if irritation occurs. In the event of a serious incident, seek medical advice; in each language of the EU.

For these reasons, the risk is limited for the patients or users.

Actions to be taken by the customer:

Our records have shown that you have received an effected batch of **Hydroframe™ With Manuka Honey** as listed in the table above.

We kindly ask you to initiate the following actions immediately: .

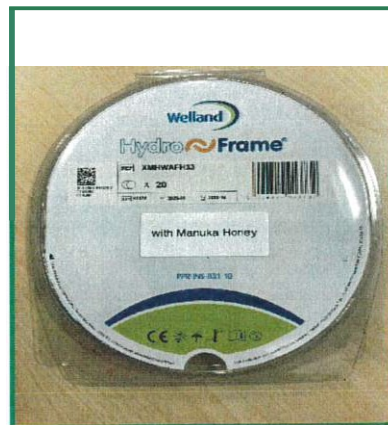
1. Review this Field Safety Notice in its entirety and forward this correction notification to your customers to ensure they are aware of the missing labelling and the fact that the product contains Manuka Honey. The letter in Appendix 1 can be used for end users/patients.
2. Request that stock at your customer but, not with End User/Patient be quarantined and returned to the distributor.
3. Quarantine the device in your inventory
4. Add the additional label provided by Weiland Medical Ud (Instructions to follow) or
5. Return the product to Weiland Medical Ud
6. Fill the enclosed confirmation form (Appendix 2)



X - Product Without M.anuka Honey label



✓ - Product with Manuka Honey label



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Competent Authorities are being notified that Weiland Medical Ltd is voluntarily taking this action.

If more information is needed, please contact:

Complaints@wellandmedical.com

Tel: +44 (0) 1293 615455

We apologise for any inconvenience this may cause and we appreciate your assistance in closing this matter.

Please could you complete the attached acknowledgment of receipt and we request that you sign and return via email or Fax to confirm that you have received this notice.

Yours sincerely

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A CliniMed Group Company

Registered Office: Cavell House, Knives Beech Way, Loudwater, High Wycombe,
Bucks HP10 90Y United Kingdom Registered in England 2170535 VAT No. 475 6939 87

1, INVESTORS
3 IN PEOPLE Gold

APPENDIX 1 End User/Patient Notification

Dear Sir/Madam,

Weiland Medical, are proactively informing our customers of an issue related to a limited number of batches of **Hydroframe™ With Manuka Honey**. Our records have shown that you have received an affected batch of **Hydroframe™ With Manuka Honey**.

Description of the problem:

The **HydroFrame™ With Manuka Honey** has the statement "with Manuka Honey" printed on the clam pack insert (IFU). As part of an update to product labelling, this information was to be added to the product label and removed from the insert (IFU). For some batches, the product was released without a statement on the label identifying that the product contains Manuka Honey.



There is no need for you to return this product as Weiland Medical only wish to inform you of the above issue.

However, if you have received this product and you are allergic/sensitive to Manuka Honey please arrange for your product to be returned to your supplier.

Competent Authorities are being notified that Weiland Medical Ud is voluntarily taking this action.

If more information is needed, please contact your supplier.

We apologise for any inconvenience this may cause .

Yours sincerely

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APPENDIX 2

ACKNOWLEDGEMENT OF RECEIPT

Please complete this form and return to complaints@wellandmedical.com or Fax: +44(0) 1293 615411, please mark for attention of Arnya Traher

Ref: FSN 2020-09-09- HydroFrame™ with Manuka Honey

Batches:	Part Number	Description
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KN691	(X)MHWAFH33	HydroFrame _{r M} With Manuka Honey

D 1. We have received the Field Safety Notice and confirm we have no remaining products in stock.

D 2. We have received the Field Safety Notice and confirm that we have quarantined the following stock:

Product Code	Lot/Batch Number	Quantity Quarantined

D 3. We wish to add labels to the following stock.

Product Code	Lot/Batch Number	Quantitv to be Labelled

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D 4. We wish to return following stock.

Product Code	Lot/Batch Number	Quantitv Quarantined

D 5. We have not shipped any products affected by this Field Safety Notice to third parties.

D 6. We have notified our customers who are affected by this recall notice and we will request that product is returned to us for either relabelling or return to Weiland Medical Ltd. End Users do not have to return the product for relabelling but must return if they should not be using products containing Manuka Honey.

Signature: Date:
 Name:
 Position:
 Telephone Number:
 Company Name: