Advanced Medical Solutions Ltd
Premier Park, 33 Road One, Winsford Industrial Estate,
Winsford, Cheshire, CW7 3RT UK
Tel: +44 (0) 1606 836 500 Fax: +44 (0) 1606 863 600
Web:www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

02nd September 2020

Ravinder Uppal
Buyer – Advanced Wound Care Products
NHS Supply Chain
Normanton
Foxbridge Way
West Yorkshire
WF6 1TL,

Dear Device Distributor,

URGENT: FIELD SAFETY NOTICE ref: 24/06/2020-001-FSCA
ACTIVHEAL® Hydrogel 8g (REF 10011131)

Advanced Medical Solutions Ltd ("AMS") recommends to cease use of and to dispose of the Hydrogel tubes identified below (the "Affected Tubes")

Background Information and Scope

AMS has identified that due to a tube quality issue that was determined during the manufacturing process, the sterility of a small number of the Affected Tubes may have been compromised. Investigations have determined a potential root cause and AMS are confident that the quality issue only affects the Affected Tubes and is not present in other batches of the ACTIVHEAL® Hydrogel product.

AMS is taking voluntary action which relates **solely** to:
LOT number(s) 43783, 45556 of ACTIVHEAL® Hydrogel 8g (REF 10011131)

To date, AMS is not aware of any complaints reported in relation to this issue.

Safety Concerns

AMS' Hydrogel product is a sterile product, which works by donating water to a wound surface, and is designed for use underneath a secondary occlusive dressing. The quality issue can affect the sterility of the Hydrogel product, potentially compromising patient safety (potential risk of infection) however based on internal investigation the likelihood is considered low.

The quality issue has led to a small number of the Affected Tubes' sterile seals potentially being compromised. The IFU clearly states *"Do not use is package is damaged"* and this issue is highly likely to be evident on a visual inspection by a Healthcare Professional prior to use, so we consider the probability of potential risk of infection to patients to be very low. It is important to stress that this request to dispose of the Affected Products is a precautionary measure, as no users, customers or authorities have filed complaints or adverse events related to this issue. However, we want to maintain

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the highest standards for product and end user safety and to proceed with the identification and disposal of the Affected Tubes on that basis.

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The purpose of this Field safety notice is to provide information required to identify affected tubes and communicate the necessary actions to be undertaken.

Actions to be Taken by Customers and Distributors

The customers affected by this Field Safety Notice (FSN) are kindly advised to cease use of the Affected Tubes and to dispose of the affected tubes by following the below instructions.

1. Identify users of the affected LOT number(s) 43783, 45556 of ACTIVHEAL® Hydrogel 8g (REF 10011131). This requires you to identify all users of ACTIVHEAL® Hydrogel 8g (REF 10011131), who may be in possession of an affected items and need to be made aware of this issue and the actions to be executed in this Field Safety Corrective Action. Users may be distributors, healthcare professionals, home care workers or patients. Provide copies of this Field Safety Notice to all identified users as soon as is reasonably practicable.
2. Users are instructed to identify if any ACTIVHEAL® Hydrogel 8g (REF 10011131) is within scope of the affected product by identifying if they are from LOT(s) 43783 or 45556.
3. Users are instructed to dispose of any affected tubes.
4. In the event that ACTIVHEAL® Hydrogel 8g (REF 10011131) the responsible HCP should be consulted to determine an alternative ACTIVHEAL® Hydrogel tube from an unaffected LOT or other suitable alternative therapy.
5. Users must contact AMS to coordinate any replacement product as required. Wherever possible AMS will endeavour to provide replacement products.
6. Users must ensure this safety information is passed on to all those who need to be aware of it within the organisation
7. Users must maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective actions.

Transmission of this Field Safety Notice

Please forward this FSN on to the relevant person within your organisation. Please maintain awareness of this FSN and resulting requested actions for an appropriate period to ensure effectiveness of the corrective action.

If you have further distributed any of the Affected Products, please notify the consignees at once of this FSN and pass a copy of it onto them alongside any direct notification you wish to make to such customers. We appreciate your support and assistance with ensuring the effectiveness of this field safety notice.

The undersigned confirms that this notice has been forwarded on to the appropriate authorities.
Yours faithfully,

Rose Guang
QA/RA Director
Advanced Medical Solutions Limited