

URGENT FIELD SAFETY NOTICE - Ref: PHFSN0117

Voluntary Recall

Affected Product: Custom Procedure packs containing Medtronic Covidien Devon™ Light Gloves

Affected Batch: See the attached list

13th February 2017

Dear Customer,

You are receiving this letter as our records indicate that you have received the above mentioned device within a procedure pack manufactured by Pennine Healthcare. Details of the affected packs are contained on the attached list.

Issue: Medtronic Ltd has initiated a product recall of its Covidien Devon™ Light Glove due to customer reports that the Devon™ Light Gloves may split on application. For full details of the recall, and the risks posed by this issue, please refer to the copy of the Medtronic Ltd Field Safety Notice provided.

Action:

1. Please use the attached list to identify all affected, unused procedure packs in your stock.
2. Please affix a copy of this Field Safety Notice to each pack and ensure that all relevant personnel are aware of the contents of this notice.
3. When presented for surgery, remove the impacted Covidien Devon™ Light Glove(s) from the pack, and replace with an alternative at your cost.
4. Please destroy the impacted Covidien Devon™ Light Glove(s) upon removal from the pack.
5. Complete the attached reply form to confirm that you have read and understood the contents of this Field Safety Notice.
6. Upon receipt of the completed reply form, Pennine Healthcare will arrange for credit for the unused impacted light gloves you have received.
7. Maintain awareness of this Field Safety Notice until all Covidien Devon™ Light Glove(s) have been removed and destroyed from the affected procedure packs.

Pennine

This notice should be passed on to all persons who need to be aware within your organisation, or to any organisation where the affected procedure packs have been distributed.

We confirm that this Field Safety Notice has been notified to the MHRA.

Yours sincerely

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13 FEB 2017

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CUSTOMER REPLY FORM

Name	
Position	
Company/Institute ¹	
Address	

¹ We do not have any stock of the affected procedure packs

Quantity of affected procedure packs in stock

Lot	Qty.

1 hereby confirm that all impacted Covidien Devon™ Light Glove have been, or will be, destroyed in line with action point 4 above. (Only applicable if impacted procedure packs are in stock)

Sign	
Date	

1 hereby confirm that I have read and understood the contents of this Field Safety Notice.

Sign	
Date	

Please scan and return the completed reply form to:

regaffairs@penninehealthcare.co.uk