

URGENT FIELD SAFETY NOTICE – Ref: PHFSN0116

Voluntary Recall

Affected Product: Baxter Uromatic TUR Admin. Set

Affected Batch: See table below

5th February 2016

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 detailed below.

Pack Code	Description	Lot Number

Issue: Baxter has initiated a product recall of their Uromatic Tur Admin. Set due to customer complaints related to the disconnection of the spike from the tubing of the set. For full details of the recall please refer to the copy of the Baxter FSN provided.

Action:

1. Identify all stock of the affected batch.
2. Do not use the impacted Baxter Uromatic Tur Admin. Set.
3. Complete the attached reply form to confirm that you have read and understood the contents of this Field Safety Notice.
4. Upon receipt of the completed reply form, Pennine Healthcare will arrange for replacement stock of the affected devices.
5. Until replacement products are available, please remove the affected Baxter Uromatic Tur Admin. Set when the procedure pack is opened and presented for surgery.
6. Retain all affected Baxter Uromatic Tur Admin Sets in quarantine until we can arrange for return to Baxter.

7. Maintain awareness of this Field Safety Notice until all stock of the affected batch has been destroyed or returned to Pennine Healthcare.

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 transferred.

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

Yours sincerely

Print Name: Gareth Hazlewood

Signed:

Position: Deputy Quality Manager

Date:

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Customer Reply Form

Name	
Position	
Company/Institute	
Address	

We do not have any stock of the affected procedure packs

Quantity of affected procedure packs in stock

Lot	Qty.

I 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