

URGENT FIELD SAFETY NOTICE

Product: Nutricare Infant Clear Nasogastric Feeding Tube 6Fr 50cm Sterile

Date: 26th June 2019

Type of action: Recall – Immediate Action Required

Contact for recall: info@gbukgroup.com

Details on affected devices:

Product Code	Product Description	Batch Number
NCI06.050ISOSAF-ROW	Nutricare Infant Clear Nasogastric Feeding Tube 6Fr 50cm (Sterile)	18001594

Description of the problem

GBUK has voluntarily initiated the recall of the specific product code and batch number listed above.

There have been complaints relating to the outside wall of the Naso-gastric feeding tube splitting at a point of contact with the ENFIT connector.

Should the event described above occur, feed may leak from the tube or the tube may become separated from the ENfit connector.

Although the patient risk is considered low, this may result in the patient not receiving feed and adequate nutrition until the device is replaced.

Action to be taken by the user

GBUK records show that you have received the above product code and batch combination.

1. Immediately remove any affected product that is in situ with any patient.
2. Immediately quarantine any stock of NCI06.050ISOSAF-ROW batch 18001594 you have.
3. Please complete page 2 of this field safety notice and return to GBUK Enteral, who shall then arrange collection of the stock you have quarantined of this batch number.

Transmission of this Field Safety Notice - This notice needs to be passed on all those who need to be aware within your organisation, or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact.

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency

Yours sincerely,

XXX

Acknowledgement of Field Safety Notice

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Upon receipt of the attached information please confirm your receipt and understanding in the boxes below. Please return this sheet to GBUK Enteral by email to: info@gbukgroup.com, fax +44(0) 845 280 3160 or by post to the following address:

GBUK Enteral, FAO – Andrea Wetton
Woodland House,
Blackwood Hall Business Park,
North Duffield,
Selby,
North Yorkshire,
YO8 5DD.

Check One Box ✓	
	STOCK QUANRANTINED I understand the field safety notice and have quarantined remaining stock of NCI06.050ISOSAF-ROW batch 18001594
	NO STOCK REMAINING I understand the field safety notice but do not have any remaining stock of NCI06.050ISOSAF-ROW batch 18001594

Customer Name:	
Address:	
Phone Number:	
Email Address:	

Customer Signature

Date