

Field Safety Notice

Product: Carefeed ISOSAF Nasogastric Tube
FSCA-Identifier: 22/01/2018
Type of action: Immediate attention required
Date: 24/01/2018

Attention - Risk/ Safety Managers, Clinicians, Nursing, Theatre staff and Anaesthesia, ICU, HDU, Paediatrics and other users of these devices.

Details on affected devices: Carefeed ISOSAF Nasogastric Tubes

Product Code	NHSSC NPC
CF01.04.050ISOSAF	FWM2644
CF01.04.075ISOSAF	FWM2645
CF01.05.050ISOSAF	FWM2421
CF01.05.075ISOSAF	FWM2646
CF01.06.050ISOSAF	FWM2420
CF01.06.075ISOSAF	FWM2422
CF01.08.050ISOSAF	FWM2647
CF01.08.075ISOSAF	FWM2423
CF01.08.092ISOSAF	FWM2648
CF01.10.075ISOSAF	FWM2652
CF01.10.092ISOSAF	FWM2649
CF01.12.075ISOSAF	FWM2643
CF01.12.092ISOSAF	FWM2650
CF01.14.092ISOSAF	FWM2651

<https://www.gbukenteral.com/products/carefeed-feeding-and-drainage-tubes/>

Description of the problem - This Field Safety Notice is to clarify the correct usage of Carefeed NG tube.

Carefeed Indications for use - Carefeed should be used to administer fluid, nutrition, medication and / or drainage of gastric secretions.

Carefeed Contraindication - Carefeed should not be used for high volume decompression in emergency situations, and / or decompression of highly viscous fluid other than gastric secretions. This is due to narrow dimensions of the new ISO 80369-3 ENFit connector.

Action to be taken by the user - Use Carefeed NG tubes for the indicated purpose of feeding and drainage of gastric secretions only. For situations where quick decompression of high amounts of stomach content and/or the connection to a suction unit might be required, large bore decompression tubes with a wider connector should be used.

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. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. GBUK Enteral expect product with amended IFU literature to be available by 24th April 2018.

Contact reference person - Cornelia Haindl, email: Conny.Haindl@GBUKGroup.com, phone number: 01757 282945.

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

Yours sincerely,



Mr Mike Geering
GBUK Enteral Ltd, Woodland House, Blackwood Hall, North Duffield, Selby, North Yorkshire, YO8 5DD.

Acknowledgement of Field Safety Notice

Product: Carefeed ISOSAF Nasogastric Tube
FSCA-Identifier: 22/01/2018
Type of action: Immediate attention required
Date: 24/01/2018

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 victoria.martin@gbukgroup.com, fax +44(0)1757 600545 or by post to the following address:

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

Check One Box <input checked="" type="checkbox"/>	
<input type="checkbox"/>	Yes – I confirm receipt and I understand this Field Safety Notice and the required actions.
<input type="checkbox"/>	No – I do not understand this Field Safety Notice. I would like a representative of GBUK Enteral to contact me

Customer Name:	
Address:	
Phone Number:	
Email Address:	

Customer Signature

Date