

Field Safety Notice

Product: Caretip 5ml Oral Dispenser Sterile

FSCA-Identifier: GBUK 4956

Type of action: Immediate attention required

Date: 27 August 2020

Contact: info@gbukgroup.com

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

Details on affected devices:

Product Code	NHSSC NPC	Product Description
OS-5	FTA345	Caretip 5ml Oral Dispenser Sterile

Description of the problem - This Field Safety Notice is to advise users of Caretip 5ml Oral syringes that there is an error on the tsp graduation scale.

Specifically, the marking on one quarter teaspoon (which should be 1.25ml) is in error by 0.4ml and therefore the actual volume at this graduation marking is 0.85ml.

There is therefore the potential for patients to be under dosed by 0.4ml if this particular graduation marking is used.

Indications for use – These devices are intended to dispense medicine orally.

Contraindication – There are no known contraindications.

Action to be taken by the user – Only one graduation marking is in error as described above. All other graduation markings are entirely accurate. It is recommended however, that the ml scale is used to accurately dispense medicines using this device.

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.

The undersign confirms that this notice has been notified to 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

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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)1757 600545 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 ✓	
	Yes – I confirm receipt and I understand this Field Safety Notice and the required actions.
	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