GBUKEnteral
Part of the GBUK Group

Enteral Feeding Devices

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Margaret Jones
HM Assistant Coroner
Stoke-on-Trent & North Staffs Coroners Court

17 June 2021

Dear Madam,

I write regarding concerns raised in your Regulation 28 report to prevent future deaths, relating to the conjoined inquest of Mr Peter Hussey and Mr Stephen Oakes and the steps taken by GBUK Enteral Ltd to address them.

Firstly, addressing concerns raised relating to the device description and the restriction posed by the ENFit connector when used for drainage on some larger Fr size tubes. We have now revised our device labelling and the Instructions For Use (IFU), with all references to drainage now completely removed from our device labelling descriptions.

Within the revised IFU the following additional warnings & precautions are now present:
• Routinely check flow and tube impairment. If the tube is used for drainage, failure to clear the obstruction may cause gas & fluid build-up in stomach, aspiration of gastric contents, aspiration pneumonia and other complications.
• The device should not be used for high volume decompression in emergency situations, and/or decompression of highly viscous fluids other than gastric secretions.
• From sizes 14Fr and above, the internal diameter of the industry standard ENFit ISO 80369-3 connector is smaller than the internal diameter of the tube. Flow rate will be limited by the ENFit connector for these sizes.

The term drainage has been removed from the "Intended Use" section of the IFU and packaging labels. In the revised IFU we clearly identify to the user that the intended use of the product is a feeding tube. The additional warnings & precautions in the revised IFU further explain very clearly the limitations of the tube if the user opts to use the tube for the dual purposes of feeding and drainage. This will be implemented as new stock of these devices are manufactured.

We have also contacted NHS supply chain to request the device description be changed on their website from "Gastrostomy tubes for general use" to "Nasogastric Feeding Tube", which we hope will be implemented soon.

Regarding concerns that our Enteral sales staff were not trained to recognise the restriction posed by the ENFit connector, in order to advise end users. I reiterate the point made in my previous correspondence to you (19th April 2021), that all members of the Enteral sales team fully understand that our Nasogastric Feeding tubes are not a replacement for a Ryles tube, with its primary purpose being that of feeding and its secondary purpose being limited forms of drainage.

We have also ensured that up to date refresher training has been provided to our sales force. This training was given on the 21st April 2021, covering in detail the intended use of

Nasogastric feeding tubes and also specifically ENFit connectors and the impact on the tubes flow rate. A copy of the training presentation has been provided, which you will see contains the key topics of concerns. Staff attending were also tested at the end of the training provided, to ensure all key points had been understood. Any new sales staff will also receive this training and refresher training is provided to our sales force at regular intervals.

I hope this addresses the concerns raised within your report and should you have any queries regarding this letter or require any further clarification please do not hesitate to contact us and we will be more than happy to assist.

Yours faithfully

[redacted]
Technical Director
For and on behalf of GBUK Group Ltd