

Marseille, February 14th, 2017

URGENT FIELD SAFETY NOTICE ENTRAL ENFit™ NASOGASTRIC FEEDING TUBES - RANGES NST, SFT, AND DFT

Type of action: Modification to instructions for use

To whom it may concern,

Details on affected devices:

ENTRAL ENFit™ nasogastric feeding tubes - Ranges NST, SFT, AND DFT.

Examples: NSTx-yy (x for the Fr size of the tube / yy for the length of the tube).
SFTx-yy (x for the Fr size of the tube / yy for the length of the tube).
DFTx-yy (x for the Fr size of the tube / yy for the length of the tube).

Description of the problem:

It has been brought to our attention that choosing the correct nasogastric feeding tube – ranges NST, SFT, and DFT, for the appropriate patient group can be difficult for users.

This potential confusion has been raised by one customer.

The associated risk is to use a tube with an inappropriate length of centimetre marks on the tube, and as a consequence the centimetre marks are out of the range which could potentially lead to the introduction of excessive or insufficient tubing.

Action to be taken by the user:

Before the introduction of an ENTRAL ENFit™ nasogastric feeding tube, the user needs to verify that the tube chosen is the appropriate one for the patient to be fed.

The way to choose the appropriate tube is to compare the size of the patient to the length of the centimetre marks printed on the tube.

The table below shows the length of the centimetre marks (graduations printed on the tube) and the corresponding patient group depending on the size of the patient:

Graduations printed on the tube	Corresponding patient group: size of the patient
From 5 to 35cm	From approx. 15cm to approx. 90cm
From 5 to 40cm	
From 10 to 40cm	From approx. 60cm to approx. 150cm
From 20 to 60cm	
From 20 to 75cm	From approx. 60cm to approx. 180cm
From 20 to 85cm	
From 20 to 80cm	
From 30 to 85cm	

The choice of nasogastric feeding tube must be confirmed by a clinician.

Corrective and preventive actions:

The instructions for use will be updated so that they are clear in relation to what range of tube should be used for each patient group.



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