Enteral Plastic Safety Group (EPSG)* Statement

ISO 80369-3: IMPORTANT UPDATE – ENFit Implementation

Issued May 2016

As part of a carefully planned 2–stage process, ENFit implementation commenced in September 2015 throughout the UK. ENFit is the global enteral feeding device connector design that complies with the new International Standard (ISO 80369-3).

The first stage of the process, introduction of transition giving sets and gravity sets is now well underway, with many patients already using these with their existing enteral feeding tubes.

The second stage of the plan was to introduce ENFit enteral feeding tubes and all related ancillary items from March 2016, in order to complete the implementation process.

Questions were raised towards the end of 2015 around the accuracy of low dose syringes using the new ENFit connection, and a decision was taken by the global group responsible for the introduction of ENFit (GEDSA) to carry out further independent lab testing on these syringes to ensure accuracy prior to launch. This is now complete and a summary of the findings is available from the GEDSA website.

The 2nd phase of the implementation will now begin from the 4th July 2016.

Until this date, the EPSG recommend administration of medication in line with local best practice. Your syringe supplier can provide further details and product information as required.

Furthermore, it has been agreed by members that transition sets will continue to be available until the end of 2016, to ensure full compliance with the ENFit system, and from then, adaptors will be supplied separately for any remaining patients not yet transitioned to the ENFit system.

Full details regarding this statement, the International Standard and the introduction of ENFit are available from all EPSG members as listed below.

*The EPSG (Enteral Plastic Safety Group) represents all leading UK enteral feeding devices suppliers, with clinical representation from the PENG of the BDA, NNNG and supported by PINNT, BAPEN and BPNG. The aim of this forum is to discuss enteral feeding device safety from both a clinical and manufacturing perspective. The term 'enteral feeding device' refers to any type of feeding tube that is placed into the gastro-intestinal tract i.e. naso-gastric (NG), naso-jejunal (NJ), gastrostomy (Button, PEG/RIG) or jejunostomy (JEJ), as well as giving/extension sets, syringes and enteral feeding pumps. The following companies are members of the EPSG: Abbott; Corpak; Covidien; Fresenius Kabi; GBUK Enteral (Enteral UK); Intervene; Medicina; Nutricia; Vygon. **Devices that will have the new connector include: enteral giving sets, enteral syringes, all enteral feeding tubes, all enteral accessories.

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