Medical Device Advisory

Health Products Regulation Group
Health Sciences Authority
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RISK OF MEDICATION OVERDOSE FROM THE USE OF ENFIT™ LOW DOSE TIP SYRINGE

The Health Sciences Authority (HSA) would like to remind healthcare professionals and users of enteral devices in healthcare institutions, on the risk of medication overdose when using ENFit™ Low Dose Tip (LDT) syringes.

ENFit™ Enteral Devices

2 Enteral access devices, such as feeding tubes, administration sets and syringes, allow for the delivery of nutrition and medications into the gastrointestinal tract of patients who are unable to maintain their needs with oral intake. ENFit™ is the trade name for standard enteral connectors that are compliant with dimensions, shape and functional requirements under ISO 80369-3*, designed to reduce the risk of misconnections.

3 ENFit™ Low Dose Tip (LDT) syringes were introduced to address concerns regarding dose accuracy when delivering low volume (≤ 5ml) medications. As compared to standard volume ENFit™ syringes, ENFit™ LDT syringes have a low dose tip to reduce dead space volume.

Risk of Medication Overdose from Fluid in Moat Area of ENfit™ LDT Syringes

4 The area between the low dose tip and the outer ring of the ENFit™ LDT syringe, is commonly referred to as the “moat”. The moat area, which is unique to ENfit™ LDT Syringes, is not part of the fluid path but may retain excess medication during syringe filling. There is potential for medication overdose if the user does not clear excess medication in the moat area around the tip before administering the medication. The risk of medication overdose is especially significant for medications that have a narrow therapeutic index.

Recommendations for Healthcare Institutions and End Users on Ensuring Dose Accuracy

5 HSA recommends adherence to the manufacturer’s Instructions for Use (IFU) and the following best practices to ensure dosing accuracy when using an ENFit™ LDT syringe:

- Ensure that the moat area is free from fluids (e.g. by flicking or tapping the end of syringe) before administering the medication.

**The ISO 80369 series of standards aim to avoid misconnection between two unrelated delivery systems (e.g. enteral syringe connected to an intravenous catheter) which can cause patient injuries or deaths. Part 3 of ISO 80369 covers connector design unique to enteral applications.*

- Use a filling adapter, such as an ENFit™ compatible cap or medication straw, to prevent medications from entering the moat area.
- Be aware that using a medicine cup to fill may cause the medication to enter the moat area and lead to possible overdose.
- Ensure that the syringe is free of air bubbles before administering the medication regardless of the method chosen above to fill the ENFit™ LDT syringe.
- Use a new syringe to flush the medication after administration to prevent medication overdose due to the dead space in the syringe.

6 HSA will be working closely with local dealers of ENFit™ LDT syringes to ensure that the essential instructions and warnings on optimising dose accuracy are captured in the IFU.

Reporting of Overdose Incidents related to ENFit™ LDT syringes

7 To date, HSA has not received any local reports of medication overdose associated with the use of ENFit™ LDT syringes.

8 Please report any adverse events (AE) and/or suspected adverse reactions associated with ENFit™ LDT syringes to the Medical Devices Branch, Health Products Regulation Group, HSA at Tel: 6866 1048, Fax: 6478 9028, or report online at https://www.hsa.gov.sg/adverse-events/healthcare-professionals'-guide-to-adverse-events-reporting. Confirmation of the causality of the AE is not a prerequisite for reporting to HSA; as long as there is a suspicion that a medical device may be related to a serious adverse event, an AE report may be submitted.

Thank you.

Yours faithfully,

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How to report medical device adverse events?

Option 1. Complete our e-Form online:

Option 2. Complete our Medical Device Adverse Event Reporting Form: