Potential for Medication Overdose with ENFit Low Dose Tip Syringe: FDA Safety Communication

November 18, 2021 Update

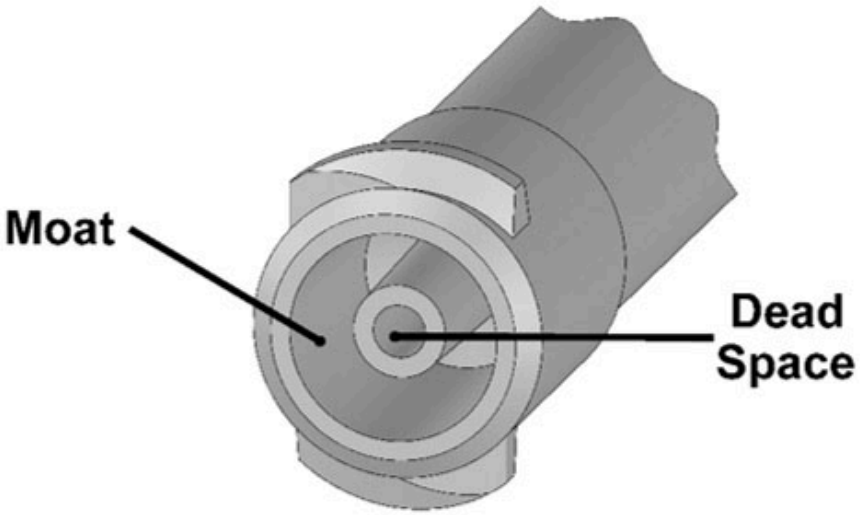
The following article was published in the Journal of Clinical Pharmacy and Therapeutics: Assessing Dosing Errors in Legacy and Low Dose Tip ENFit Syringes (https://onlinelibrary.wiley.com/doi/10.1111/jcpt.13559) (https://public4.pagefreezer.com:443/content/FDA/08-02-2022T03:01/http://public4.pagefreezer.comhttps://public4.pagefreezer.com:443/content/FDA/08-02-2022T03:01/https://www.fda.gov/about-fda/website-policies/website-disclaimer). In the study, a research team at the FDA assessed the risk of medication overdose from the moat area of ENFit LDT syringes by using computer-aided modeling to analyze the maximum possible dosing errors in 0.5 mL and 1.0 mL ENFit LDT syringes and traditional syringes under various clinical use conditions, including varied filling and administration methods.

Study results showed dosing errors are possible for both traditional syringes and the ENFit LDT syringes, depending on the filling and administration methods used. The FDA believes that dose accuracy using ENFit LDT syringes can be optimized when users follow the recommendations provided below.

Date Issued: October 12, 2021

The U.S. Food and Drug Administration (FDA) is informing patients and health care providers about the potential for overdose, under certain clinical use conditions, when using ENFit low dose tip (LDT) syringes.

The FDA is aware of the potential for overdose if the user does not clear the moat area around the tip of the ENFit LDT syringe before administering a medication. The moat area is unique to the design of the ENFit LDT syringes. The FDA is providing recommendations for patients and health care providers to promote the safe use of ENFit LDT syringes, including steps users can take to optimize dose accuracy.



Recommendations for Health Care Providers, Patients, and Caregivers

To optimize dose accuracy using ENFit LDT syringes, users should:

- Ensure the syringe is free of air bubbles and the moat of the syringe is free from fluids by tapping or flicking the tip of the syringe before administering the medication.
- Use a filling adapter, such as an ENFit compatible cap or medication straw, to prevent fluid and medications from entering the moat area of the syringe tip.
- Be aware that using a medicine cup to fill may cause fluid or medications to enter the moat of the syringe and lead to possible overdose.
- Use a new syringe to flush the medication or fluid after administering any medication to prevent overdose due to the dead space (remaining fluid in the tip of the syringe after administration) in the syringe.

The FDA continues to recommend the use of enteral devices and syringes that reduce the risk of misconnections, such as ENFit LDT syringes.

Device Description and Background

To reduce the risk of misconnections and serious patient injuries and death, the FDA recommends use of enteral devices with connectors (https://public4.pagefreezer.com:443/content/FDA/08-02-2022T03:01/https://www.fda.gov/medical-devices/medical-device-connectors/reducing-risks-through-standards-development-medical-device-connectors) that meet the International Organization for Standardization (ISO) (https://www.iso.org/standard/64419.html) (https://public4.pagefreezer.com:443/content/FDA/08-02-2022T03:01/http://public4.pagefreezer.comhttps://public4.pagefreezer.com:443/content/FDA/08-02-2022T03:01/https://www.fda.gov/about-fda/website-policies/website-disclaimer) 80369-1 or ISO 80369-3 standard or that are otherwise designed to reduce the risk of misconnections. There are currently marketed enteral connectors that follow the ISO 80369-3 standards, many of which are identified by the tradename ENFit.

ENFit LDT syringes are generally used to:

- Deliver fluids, like medicine, either orally or through the gastrointestinal tract (enterally) into the body.
- Dispense, measure, or transfer fluids.

ENFit LDT syringes are manufactured and distributed by several manufacturers in syringe sizes between 0.5 mL and 6 mL. The syringe has a gasket, a plunger, and a barrel, with a low dose tip designed to be compatible only with enteral connectors that follow the ISO 80369-3 standard. They are used in all age groups (adults and pediatrics, including neonates) in a variety of settings, including clinical settings by a health care provider or in home settings by patients and caregivers.

Risk of Medication Overdose from Fluid in the Moat Area of the Syringe

The FDA received a complaint about ENFit LDT syringes and the potential for overdose if the moat area around the tip of the syringe was not cleared prior to administering a medication. The FDA has not received reports of injuries associated with medication overdose from the moat area of ENFit LDT syringes.

We believe when using the steps provided above to optimize dose accuracy, the dose accuracy of ENFit LDT syringes is equivalent to the dose accuracy of traditional syringes.

In addition, the FDA reviewed the device labeling for ENFit LDT syringes provided by several manufacturers. Based on this review, the FDA determined that while some manufacturers included adequate information about the potential for overdose and steps users can take to optimize dose accuracy to prevent overdose, not all manufacturers included this information or the information they provided may be incomplete. Accordingly, the FDA sent letters to these manufacturers (see FDA Actions below).

While the FDA's analysis has identified a potential for overdose using ENFit LDT syringes, no patient injuries have been reported. In contrast, serious patient injuries and deaths (https://public4.pagefreezer.com:443/content/FDA/08-02-2022T03:01/https://www.fda.gov/medical-devices/medical-device-connectors/examples-medical-device-misconnections) have been reported due to misconnections. Therefore, the FDA continues to recommend the use of enteral devices and syringes that reduce the risk of misconnections, such as ENFit LDT syringes.

FDA Actions

The FDA sent letters (https://public4.pagefreezer.com:443/content/FDA/08-02-2022T03:01/https://www.fda.gov/media/152862/download) to manufacturers requesting that they update their labeling and training materials to include information about the potential for overdose and steps users can take to optimize dose accuracy as noted in the FDA recommendations above.

The FDA intends to keep the public informed if significant new information becomes available.

Reporting Problems with Your Device

If you think you had a problem with ENFit LDT syringes, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Other Resources

- Guha, S, et al. Assessing dosing errors in legacy and low dose tip ENFit syringes. J Clin Pharm Ther. 2021 (https://doi.org/10.1111/jcpt.13559) (https://public4.pagefreezer.com:443/content/FDA/08-02-2022T03:01/http://public4.pagefreezer.comhttps://public4.pagefreezer.com:443/content/FDA/08-02-2022T03:01/https://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Letter to Manufactures: Potential Postmarket Safety Issue Regarding the Use of ENFit Low Dose Tip (LDT) Syringes and Concerns with Dose Accuracy - October 8, 2021 (https://public4.pagefreezer.com:443/content/FDA/08-02-2022T03:01/https://www.fda.gov/media/152862/download)
- Letter to Manufacturers of Enteral Feeding Tubes, Health Care Professionals, and Hospital Purchasing Departments: The FDA Encourages Use of Enteral Device Connectors that Reduce Risk of Misconnection and Patient Injury – September 7, 2018 (https://public4.pagefreezer.com:443/content/FDA/08-02-2022T03:01/https://www.fda.gov/media/127990/download)

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (MAILTO:DICE@FDA.HHS.GOV) or call 800-638-2041 or 301-796-7100.