

المملكة الصربية السحودية Saudi Food & Drug Authority

Medical Devices Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication

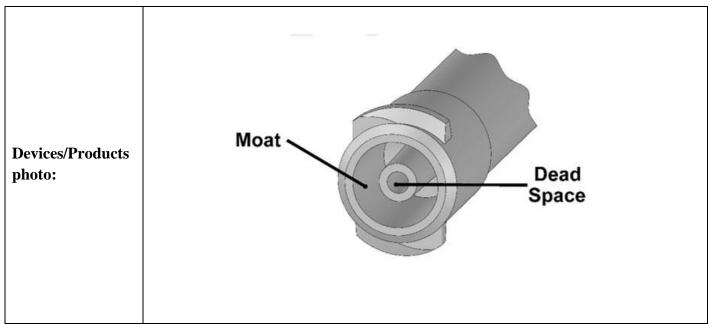
رسالة سلامة

Potential for Medication Overdose with ENFit Low Dose Tip Syringe

Device/ Product Description:	ENFit Low Dose Tip Syringe
Problem:	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.
Recommendation /Actions:	 Recommendations for Health Care Providers and Patients to optimize the accuracy of using the ENFit Low Dose Tip Syringe: Ensure the syringe is free of air bubbles and the moat is free of fluids by flicking the tip of the syringe. Use a filling adapter (e.g ENFit compatible cap) to prevent fluid from entering the moat area. Be aware that using a medicine cup to fill may cause the fluid or medications to enter moat of the syringe and lead to possible overdose. Use a new syringe to flush the medication after administrating to avoid overdose due to the dead space in the syringe. For more information, please click here. If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system (19999) unified call center

SG-2111-362-H 24/11/2021







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