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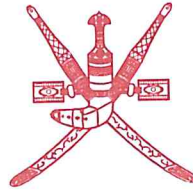
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 209..... dated 4/12/2011. Regarding SFDA, FSCA of ENFit Low Dose Tip Syringe from (mrf: Several manufacturers).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



Circular No. 209/2021

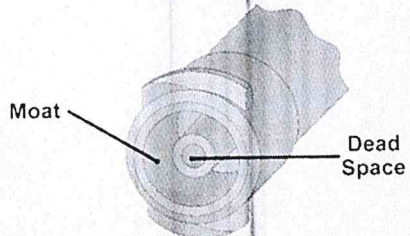
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بالقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman Vision

Field Safety Corrective Action of ENFit Low Dose Tip Syringe from Several manufacturers.

Source	SFDA-Saudi Food & Drug Authority.
Product	ENFit Low Dose Tip Syringe.
Description	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.
Manufacturer	Several manufacturers .
The affected products	Syringe sizes between 0.5 mL and 6 ML.
Reason	The potential for overdose if the user does not clear the moat area around the tip of the ENF it LDT syringe before administering a medication.
Action	<ol style="list-style-type: none">1. Ensure the syringe is free of air bubbles and the moat is free of fluids by flicking the tip of the syringe.2. Use a filling adapter (e.g ENFit compatible cap) to prevent fluid from entering the moat area.3. 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.4. Use a new syringe to flush the medication after administrating to avoid overdose due to the dead space in the syringe.5. Contact the local agent for remedial action.
Product Picture	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om



Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



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