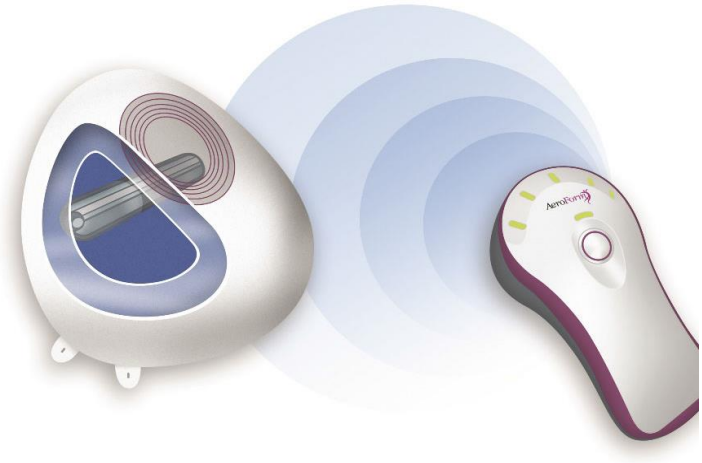
Safety Communication

Master Keys Used with AeroForm Tissue Expanders: May Be Inadvertently Programmed with the Incorrect Patient Fill Limits

Device/ Product Name:	Master Keys provided with Small 400 cc AeroForm Tissue Expanders (Skin Expansion Implants)
Lot numbers/Serials:	**Catalog No.**: BR125-400 **FGS No.**: FGS-0014-01 **Lot No.:** F05085 **Distribution Date:** 2018 May 14 to 2018 Jun 19
Manufacturer:	AirXpanders Inc
Problem:	The master keys provided with AeroForm Tissue Expanders were inadvertently programmed with the incorrect patient fill limits. The incorrectly programmed master key allows the tissue expander to dose/fill beyond the labeled volume, up to 80 cc greater than the labeled total volume of 400 cc (for a total potential volume of approximately 480 cc).
Recommendation/Actions:	• **Saudi FDA assures that these devices have not been cleared by SFDA via Saudi Arabia ports of entry. However, users may get them through any other means.** • If you have affected product not currently implanted **inform Saudi FDA** and complete the Customer Acknowledgment Form, and return it to AirXpanders using the instructions on the form. • For affected products that have been implanted, the recommendations from the manufacturer are as the following: 1- Return of dosage controller (for patients at any stage of expansion) - If the AeroForm tissue expander from this lot has been implanted, the paired dosage controller(s) may be returned to AirXpanders for reprogramming. Record the number of dosage controllers planned for return on the Customer Acknowledgment Form. - An AirXpanders sales representative will provide your facility with return kits for the paired dosage controller(s). - The returned dosage controllers will be reprogrammed with the correct fill limits, taking into account already delivered doses, and returned to physicians within 'approximately five business days.

	- Upon return of the reprogrammed dosage controllers, patients/physicians may continue with regularly scheduled dosing. 2- Retain dosage controller (for patients in late stages of expansion) - When four green lights are illuminated, stop dosing, because the Expander has reached full volume. - Stop dosing when patients experience any discomfort
Devices/Products photo:	

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for corrective action.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

For further information, please **Contact us:**

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

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Sincerely,
NCMDR Team