المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

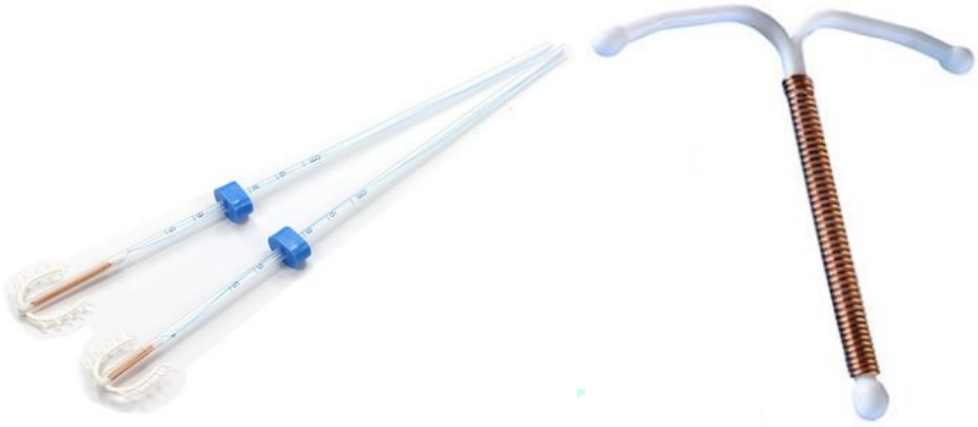
Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication رسالة سلامة

Horizontal Arm Breaks at the Time of Extraction of the Intrauterine Device

Device/ Product Description:	Intrauterine Device (Novaplus T, GOLD, Ancora IUD)	
Affected Lot Number:	Ref. Number	Lot Number
	01030000 ANCORA 375 Cu Normal 01030400 ANCORA 375 Ag Normal 01030200 ANCORA 250 Cu Mini 01010500 NOVAPLUS(r) T 380 Ag Normal 01010600 NOVAPLUS(r) T 380 Ag Mini 01010700 NOVAPLUS(r) T 380 Ag Maxi 01020100 NOVAPLUS(r) T 380 Cu Normal 01020200 NOVAPLUS(r) T 380 Cu Mini 01040000 GOLD T(r) Maxi 01040100 GOLD T(r) Normal 01040200 GOLD T(r) Mini	0114/0614/1114/0415/1115/0216/ 0616/1116/0217/0417/0917
Manufacturer:	EUROGINE, S.L.	
Problem:	An increase in horizontal arm breaks (one or both) was observed at the time of extraction of the Ancora IUD model. The technical research that was carried out concluded that the breakage is a result of a deficient manufacturing by the supplier of the raw material that constitutes the IUDs frame.	
Recommendation /Actions:	• Make sure that this document is reached to the end-users. • Identify and discontinue insertion of any affected product in your inventory. • Premature removal of successfully inserted IUDs is not recommended. Planned removals of affected IUDs should be performed with slow and constant traction when pulling the threads. • Contact the authorized representative for required support.	

	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
Devices/Products photo:	
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