Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Intrauterine Device (Novaplus T, GOLD, Ancora IUD)
Device Model	01030000 ANCORA 375 Cu Normal / 01030400 ANCORA 375 Ag Normal / 01030200 ANCORA 250 Cu Mini / 01010500 NOVAPLUS® T 380 Ag Normal / 01010600 NOVAPLUS® T 380 Ag Mini / 01010700 NOVAPLUS® T 380 Ag Maxi / 01020100 NOVAPLUS® T 380 Cu Normal / 01020200 NOVAPLUS® T 380 Cu Mini / 01040000 GOLD T® Maxi / 01040100 GOLD T® Normal / 01040200 GOLD T® Mini
Lot No.	0114/0614/1114/0415/1115/0216/0616/1116/0217/0417/0917
Manufacturer	EUROGINE, S.L
Country of Origin	Spain
Reference	https://ncmdr.sfda.gov.sa/FileDownLoad.ashx?f=ca&fid=8629
Device picture	
Reason of Recall	NHRA initiates this FSN due to an increase in horizontal arm breaks (one or both) at the time of extraction of the Ancora IUD model. The breakage is a result of a deficient manufacturing by the supplier of the raw material that constitutes the IUDs frame.
Action should be taken	• 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.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

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