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Technology for Women's Healthcare
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Field Safety Notice

☒ **Urgent (FSN) - from a FSCA**
☐ **Informative**

Commercial name of the affected product
ANCORA
FSCA-identifier (if applicable)
14022018
Type of action
☐ Device modification
☒ Device exchange
☐ Device destruction
☒ Device recall
☐ Otros / Others:

Date: 07/03/2018
Attention: Healthcare Professional

THIS FIELD SAFETY NOTICE IS AN UPDATE OF THE PREVIOUS ONE DATED 21/02/2018. LOT 0216 HAS BEEN INCLUDED TO RECALL AS PREVENTIVE ACTION. SUCH LOT WAS NOT INCLUDED BEFORE BY MISTAKE.

Details on affected devices:
Intrauterine device – IUD model ANCORA
Ref. 01030000 ANCORA 375 Cu Normal
Ref. 01030400 ANCORA 375 Ag Normal
Ref. 01030200 ANCORA 250 Cu Mini
Lots: 0114 / 0614 / 1114 / 0415

Lots to be replaced as preventive action: 1115 / 0216 / 0616 / 1116 / 0217 / 0417 / 0917
of the following Intrauterine devices:
Ref. 01010500 NOVAPLUS® T 380 Ag Normal
Ref. 01010600 NOVAPLUS® T 380 Ag Mini
Ref. 01010700 NOVAPLUS® T 380 Ag Maxi
Ref. 01020100 NOVAPLUS® T 380 Cu Normal
Ref. 01020200 NOVAPLUS® T 380 Cu Mini
Ref. 01030000 ANCORA 375 Cu Normal
Ref. 01030400 ANCORA 375 Ag Normal
Ref. 01030200 ANCORA 250 Cu Mini
Ref. 01040000 GOLD T® Maxi
Ref. 01040100 GOLD T® Normal
Ref. 01040200 GOLD T® Mini

Description:
An increase in breaks in the horizontal arms (one or both) was observed at the time of the extraction of the IUD model ÁNCORA. After the investigation carried out it can be concluded that the main cause that has generated this situation is a deficient manufacturing of the raw material by the manufacturer / supplier. The mixture between the polymer (Low Density Polyethylene) and Barium Sulphate (material that gives the characteristic of radiopacity to the product - X-ray detection) was correct in proportion (15-25% of Barium Sulphate) but agglomerates have appeared in a random way that can embitter the product in spite that this parameter is controlled and certified by the manufacturer of the raw material.

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The reported ruptures have mostly occurred at the moment of the extraction of the IUD and in the same area of the structure that is the angle of union of the horizontal arms with the vertical axis. This is the part that suffers the greatest mechanical stress in all the IUDs in Ω shape, at the time of insertion but especially in the extraction.
The combination between the extraction system (torsion of the arms) and possible agglomerations of Barium Sulphate in the torsion zone can cause the breakage of the device.

Recommendations:

- Based on the current data and the nature of the breakage (moment of extraction) the efficacy of the IUD is not affected and therefore premature removal of the device is not recommended.
- For programmed extractions it is recommended to perform a slow and constant traction when pulling the threads.

In the event that a rupture should occur and a fragment remains inside the uterus, monitor by ultrasound and assess at the physician's discretion the possibility of:

- Wait for a sufficient period of time to allow the spontaneous expulsion of the fragment during menstruation.
- If it does not occur, remove the fragment with a Mathieu Extractor Gripper or similar through the cervical canal
- In the last case, assess the need to perform a hysteroscopy to remove the fragment

If you have stock of ÁNCORA model of the lots indicated in this communication (0114 / 0614 / 1114 / 0415), please contact your distributor for such stock to be collected and replaced.

Additionally and as preventive action, if you have stock of any subsequent lot to those indicated before (1115 / 0216 / 0616 / 1116 / 0217 / 0417 / 0917 – the corrective actions have been implemented from lot 1217-) and whatever the models (NOVAPLUS® / ANCORA / GOLD T®), they will also be replaced.

We apologize for the inconveniences that this issue might have caused and do not hesitate to contact us for any clarifications you may need.

We ask for confirmation of receipt of this communication.

Transmission of this Field Safety Notice:
This notice needs to be transmitted to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (If appropriate)
Please transfer this notice to other organizations on which this action has an impact. (If appropriate)
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Contact reference person:
EUROGINE, S.L. / CARLOS FALCÓN
cfalcon@eurogine.com / eurogine@eurogine.com

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

Signature

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