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Technology for Women's Healthcare
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# UPDATE OF INFORMATION RELATING TO FIELD SAFETY NOTICE

**Reference:** FSN 21022018 rev2
**Date:** 25/09/2019

To the attention of the Healthcare Professional:

In accordance with the request of the Spanish Agency for Medicines and Medical Devices (AEMPS), this updated information is communicated related to the FSN 21022018 rev dated 07/03/2018.

**Products involved**:
Ref. 01030000 ANCORA 375 Cu Normal
Ref. 01030400 ANCORA 375 Ag Normal
Ref. 01030200 ANCORA 250 Cu Mini
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. 01040000 GOLD T® Maxi
Ref. 01040100 GOLD T® Normal
Ref. 01040200 GOLD T® Mini

**Lots included**: 0114/0614/1114/0415/1115/0216/0616/1116/0217/0417/0917

**Summary**:
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. The mixture between the polymer and barium sulfate (material that confers the radiopacity characteristic to the product for X-ray detection) was correct in its proportion, but not in its dispersion, thus promoting the random appearance of barium sulfate agglomerates that, located in especially critical areas of the frame, could weaken it until it breaks.

**Additional Information**:

1. Initially, most of the cases reported were breakages in extraction of the Ancora model. Subsequently, cases of breakage in extraction and in situ with total or partial spontaneous expulsion of the 3 models of IUDs (Ancora, Novaplus® and Gold T®) have been reported.
   Updated breakage rate and breakage time:
   - Extraction breakage: 0.25%
   - In situ breakage / Spontaneous expulsion: 0.08%

   *The known expulsion rate for intrauterine devices is 1 in 20 women in the 5 years of use*.
   It is confirmed that in most cases the breaks occur at the time of extraction.
   Breaking in situ could result in total or partial expulsion. Symptoms that might suggest an expulsion are:
   - Tensile threads absent or longer than expected
   - Abdominal pain
   - Intermenstrual or postcoital bleeding
   - Pain during intercourse

   Some expulsions are asymptomatic.
2. Cases of pregnancies possibly related to ruptures have been reported.
   Updated pregnancy rate: 0.003%
   *The known pregnancy rate for intrauterine devices is 0.1% to 1%*.
3. No cases of uterine perforation have been reported.

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Updated uterine perforation rate: 0%
*The known uterine perforation rate for intrauterine devices is 0.1% to 0.2%.*

Recommendations:
Given the low incidence rate known, premature removal of the IUD is not recommended and it is confirmed that the affectation of the raw material is random and occurs in a low percentage of cases. However, in the follow-up visits of the patients, it is advisable to inform / remind them about the way to identify a possible spontaneous expulsion of the IUD and the signs that indicate that it is necessary to go to the doctor.
In the case of programmed extractions, it is recommended to carry out a slow and constant pulling of the threads and verify that the IUD is complete.
In the event of a breakage -while extraction or in situ- and when a piece remains in the uterus:

- Inform the user that contraceptive protection could be compromised and the need to use other contraceptive methods.
- Confirm the location of the fragment by ultrasound; if this is inconclusive, consider an abdominal x-ray. It has been reported that the fragment can often be extracted with a Mathieu Extractor Clamp or similar.
- Wait, if there is no medical reason or urgency that indicates otherwise, enough time (2-3 menstruations) to enable spontaneous expulsion with menstruation. It has been reported that the expulsion of the fragment with menstruation often occurs.
- Perform a hysteroscopy; new confirmation of location of the fragment by image diagnostic prior to the intervention is recommended; an expulsion could have occurred and the intervention could be avoided.

As a general criterion, paracervical block and/or oral medication is recommended, always under medical prescription, to reduce the patient's anxiety during the intervention and subsequent discomfort.

Intrauterine devices have a high rate of effectiveness. Before inserting an IUD, the woman should be given complete information about benefits, risks, contraindications, adverse effects, symptoms and signs that could make it necessary to consult with a physician, and on how to perform self-checks for presence verification of the tensile threads. Likewise, the physician should register the model and size of the IUD, date of insertion, expected date of extraction and traceability, and transmit this information to the user to preserve it.

Communication of this FSN Update:
Please, be aware of this Update of FSN and the resulting action during an adequate period to guarantee the effectiveness of the corrective actions and transmit it to anyone who should be aware of the information contained therein, including other companies in which this information would have an impact (if applicable).

Best regards.

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The undersigned confirms that this FSN Update has been notified to the corresponding National Agency.