FSRH CEU statement regarding Eurogine Field Safety Notice 2018/19
11th May 2021

The FSRH CEU has been made aware of a field safety notice [1] released by the IUD manufacturer Eurogine in 2018 and updated in 2019 relating to the following products:-

- 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

In response to a direct enquiry from the CEU, Eurogine stated that the manufacturing problem has been resolved since 2017.

What is the reason for the field safety notice?

The field safety notice relates to an issue with the uniformity of the mixture of polymer and barium sulphate that constitutes the frame of Eurogine's IUDs. If the problem affects certain critical areas of the IUD frame, this can result in breakage (the arms can detach). The notice advises that breakage is most likely to occur when the device is being removed, but cases are also reported in which breakage may have been associated with spontaneous expulsion. The manufacturer reports a 0.25% extraction breakage rate and a 0.08% spontaneous expulsion/in situ breakage rate although no information is given as to how these figures were calculated or what, if any, active follow up of women who have been fitted with affected devices has been undertaken.

What action does the field safety notice recommend?

Given the low number of reported breakage-related expulsions and breakage-related pregnancies, the field safety notice suggests that in situ devices do not need to be removed early, but suggests that if users attend for follow up, they may be informed of the issue and reminded about signs of spontaneous expulsion so that if they have any concerns they may seek medical attention in a timely manner. Advice is given on safest way to remove affected devices, and on follow up required if a piece of the frame is found to be missing.

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What other information do we have about this?

The FSRH CEU has not identified any additional published evidence regarding outcomes with the affected devices that would inform any recommendation different to that made by the field notice. However, a UK service has reported informally to us that they have experienced higher breakage rates than those quoted in the field safety notice (but they report small numbers of expulsions and no pregnancies).

What does the FSRH CEU recommend?

Services that use Eurogine IUDs should be aware of this problem, ensure that they are no longer using affected devices and report broken devices to the manufacturer.

FSRH CEU recommends that at the time of insertion of any intrauterine contraceptive, all users continue to be advised about risk of expulsion and checking for threads. With regard to existing users of devices affected by this problem, in the absence of evidence of significant numbers of breakage-related adverse events (pregnancies, expulsions or perforations), FSRH CEU recommends that the advice given in the field safety notice is followed:

- users do not need to be recalled for early device replacement, but if they attend they should be made aware of the issue
- care should be taken when removing the devices to use slow, steady traction
- where a broken device is removed or expelled, the missing fragment should be located using ultrasound/x-ray and removed if it is not spontaneously expelled.

References

1. Medicines and Healthcare products Regulatory Agency (MHRA). Gov.uk. Field Safety Notice: 06 to 10 January 2020. Lust from field safety notices (FSNs) from medical device manufacturers from 06 to 10 January 2020. Published 14 January 2020. Eurogine: FSN 21022018 (25 September 2019). Available online here (accessed 11/05/2021)

The Clinical Effectiveness Unit (CEU) was formed to support the Clinical Effectiveness Committee of the Faculty of Sexual & Reproductive Healthcare (FSRH), the largest UK professional membership organisation working at the heart of sexual and reproductive healthcare. The FSRH CEU promotes evidence based clinical practice and it is fully funded by the FSRH through membership fees. It is based in Edinburgh and it provides a members' enquiry service, evidence-based guidance, new SRH product reviews and clinical audit/research. Find out more here.

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