We want to describe a couple of cases that serve to demonstrate that the hormone capsule of the Mirena® intrauterine system (IUS) can dislodge during removal thus changing its appearance. As a result, careful examination of the device is required to prevent further unnecessary investigations.

A 58-year-old woman presented to her general practitioner for removal of a Mirena IUS as it was no longer required. It had been inserted at the practice 7 years previously to provide the progesterone component of her hormone replacement therapy.

At the time of removal the cervix and the IUS were viewed on transvaginal ultrasound. More traction than usual was required on the threads to remove the device. On inspection it appeared that the horizontal arms had become detached as they were no longer evident and the vertical main stem of the IUS had been removed with the hormone release capsule attached.

The patient was asymptomatic and was allowed to go home. Transvaginal ultrasound scan performed on an outpatient basis. The scan demonstrated echogenic specks at either end of the endometrium in longitudinal section, and in coronal view.3 In view of this difficulty the patient would have a further LLETZ treatment in the endometrium and in the cervix.

The common theme in the two patients described above and Forrest et al’s patient1 is difficult retrieval of the device requiring more traction on the threads than normal. This presumably led to the hormone capsule being dislodged, either migrating up the device and getting stuck covering the arms or becoming detached altogether. Clinicians should always check IUS devices after removal. They should also be aware that after a difficult removal the capsule can migrate and obscure the arms but the device remains complete.

Knowledge of this possibility will prevent patients being subjected to unnecessary investigations and interventions to find ‘missing’ IUS arms and for appropriate investigations and interventions when the capsule has detached completely.

The whole of the IUS device is radio-opaque and can be located with either X-ray or ultrasound.2 Transvaginal ultrasound is the first-line investigation. It guides the best images to help determine whether or not the IUS is correctly sited within the uterus. The vertical stem of the IUS is visualised in the sagittal plane with multiple reflective parallel planes and in the axial plane as a single echogenic focus.3 However, in the cases reported here the vertical stem was missing. Horizontal arms are rarely seen in the uterus unless it is possible to obtain a coronal view.3 In view of this difficulty abdominal X-ray would confirm whether or not the horizontal arms of the IUS were within the pelvis. This would be useful, especially prior to embarking on hysteroscopic investigation.

References
2 Schering. Contra-indications, warnings, etc. Mirena® Insertion Instructions, June 2007.

Reply
We would like to take the opportunity to respond to Dr Torbe et al.’s letter.1 We consider this an extremely rare, isolated case report of hormone cylinder dislocations in the Mirena® intrauterine system (IUS) similar to the ones described by the authors who have been received by the company’s Pharmacovigilance and Quality Assurance Unit. The company’s investigations have shown that these cases could not be attributed to a quality defect of the product. Difficult removal has been found as the underlying cause and no further adverse effect in the Mirena user are mentioned in the majority of cases.

To make physicians aware of this extremely rare situation, and to avoid unnecessary interventions in search of ‘missing’ Mirena arms, the company has recently introduced the following statement into the safety Information for Mirena: “After removal of Mirena®, the system should be checked to be intact. During difficult removals, single cases have been reported of the hormone capsule sliding over the horizontal arms and hiding them together inside the cylinder. This situation does not require further intervention once completeness of the IUS has been ascertained. The knots of the horizontal arms usually prevent complete detachment of the cylinder from the T-body.”

Implementation of this statement into the local product information is currently ongoing in all countries where Mirena is marketed, and it was submitted at the beginning of December 2008 to the Medicines and Healthcare products Regulatory Agency (MHRA) to be implemented in the UK.

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