Mirena® removal from a nulliparous woman: response from Bayer HealthCare

We thank you for the opportunity to respond to Dr Manning's letter, published in this issue of the Journal.¹

Bayer HealthCare Pharmaceuticals Quality Assurance unit has previously received isolated reports of similar cases, also usually associated with difficult removal of Mirena®. The frequency of the phenomenon described by Dr Manning cannot, unfortunately, be precisely estimated, but it is most likely extremely low. This is because the reporting frequency (based on spontaneous reports to our Quality Assurance) is under 10 reports per million units sold.

In order to educate clinicians about the very rare possibility of hormone cylinder movement, we updated our Summary of Product Characteristics in January 2009 to include the following text: "After removal of Mirena, the system should be checked to ensure it is intact. During difficult removals, single cases have been reported of the hormone cylinder sliding over the horizontal arms and hiding them inside the cylinder. This situation does not require further intervention once completeness of the IUS has been ascertained. The knobs of the horizontal arms usually prevent complete detachment of the cylinder from the T-body".²

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Competing interests The authors are all employees of Bayer HealthCare Pharmaceuticals, the manufacturer of Mirena®.

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