

January 2017

## Levonorgestrel Intrauterine Delivery System - Mirena®

### Information about an observed Insertion Tube Defect UK Batch TU01BPE

Dear Healthcare Professional,

Bayer would like to inform you of the following:

#### Summary

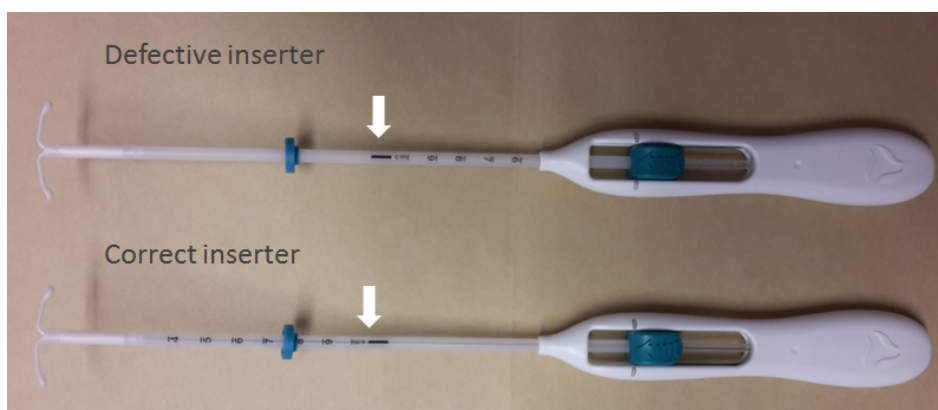
Bayer has received two complaints concerning Mirena® inserters with an inverted mounted insertion tube (please refer to the picture below).

- Check the batch number before use
- If the batch number is TU01BPE, ensure the insertion tube is correctly mounted (please see picture below)
- Only use Mirena® with a correctly mounted insertion tube
- The use of a Mirena® with an inversely mounted insertion tube may potentially lead to incorrect insertion depth (too deep or not deep enough) and an incorrect position of Mirena®. This may decrease the effectiveness of Mirena or result in adverse events. For example, if the inserter is advanced too far, uterine perforation may occur.

#### Further information on the safety concern and the recommendations

##### Description of the defective inserter

The insertion tube is mounted inversely to the inserter handle. This results in an incorrectly positioned and invertedly appearing scale on the tube. Please refer to the picture below:



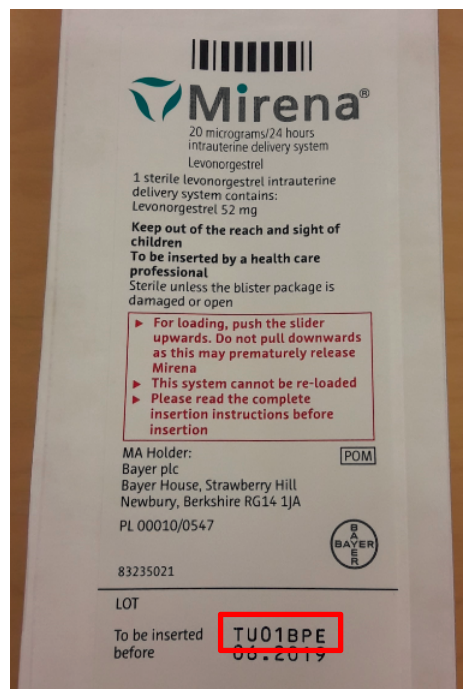
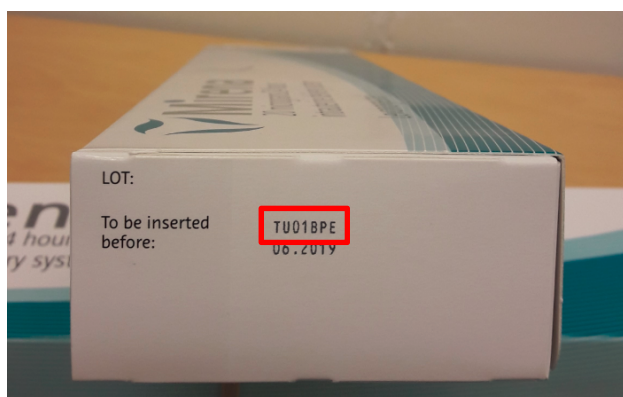
The “cm” scale should start at the tip of the insertion tube and increase towards the handle of the inserter.

Based on the current investigation, a very small number of inserters are affected. So far, only two such units have been identified globally.

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The affected batch is TU01BPE.

The batch number is printed on the side of the folding box and the immediate packaging as shown in the following pictures:



### Advice to Healthcare Professionals

**Only use a Mirena with a correctly mounted insertion tube;** please refer to picture above. Even though the chances that you will encounter an inserter with misplaced inserter tube and inverted scale are considered low, Bayer asks you to thoroughly check the inserter prior to use. If the inserter is found to be defective please contact the Medical Information department using the contact details below.

Use of an inserter with an inversely mounted insertion tube may result in incorrect positioning of Mirena. Fundal positioning of Mirena is important in order to prevent expulsion and ensure efficacy. If the inserter is advanced too far, uterine perforation may occur.

Women who have undergone a successful insertion procedure for Mirena from the potentially affected batch do not need follow-up examination beyond what is recommended in the UK SmPC. In accordance with the Mirena SmPC, the woman should be re-examined six weeks after insertion.

If the threads alone can be felt at the six week check, then it is highly likely that the Mirena is intra-uterine in position. Placement may also be verified at the six week check using ultrasound if there is any concern.



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A displaced Mirena should be removed and a new device inserted or alternative method of contraception offered.

In addition, the Faculty of Sexual & Reproductive Healthcare (FSRH)<sup>1</sup> advises that:

- If there is any uncertainty about a possible uterine perforation, an ultrasound scan should be arranged as soon as possible.
- Women may be followed-up within 3-6 weeks post-insertion or opt to check their own threads if they can do this reliably.
- An ultrasound scan should be performed if the threads are not visible on speculum examination.
- Women should be advised about the signs and symptoms of pelvic infection, uterine perforation, device expulsion or possible pregnancy, and to seek medical attention if the threads are not palpable or if they experience said symptoms.

Women who have had a recent Mirena fitting and are worried, should be advised to check the presence of the threads in the vagina. If a woman is still worried or her HCP has concerns, she should be advised to make a routine appointment to have her Mirena placement confirmed.

### Call for reporting

Please report any Mirena<sup>®</sup> with an inversely mounted insertion tube to [medical.information@bayer.co.uk](mailto:medical.information@bayer.co.uk) as well as any associated adverse events.

Please report all adverse drug reaction (ADRs) concerning Mirena<sup>®</sup>

To Bayer: [pvuk@bayer.com](mailto:pvuk@bayer.com)

To the MHRA: Yellow Card Scheme [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

### Company contact point

In case of questions please contact the Bayer Medical Information department as follows:

Telephone: 01635 563116

Email: [medical.information@bayer.co.uk](mailto:medical.information@bayer.co.uk)

Yours sincerely,

A handwritten signature in black ink, appearing to read "Dr Luis-Felipe Graterol".

Dr Luis-Felipe Graterol  
Medical Director

1 FSRH Clinical Guidance: Intrauterine Contraception (April 2015)  
<https://www.fsrh.org/standards-and-guidance/documents/ceuguidanceintrauterinecontraception/>