Healthcare Quality and Strategy Directorate
Pharmacy and Medicines Division

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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

5 January 2017

Dear Healthcare Professional,

DRUG ALERT CLASS 4 no 2 2017 – Caution in Use

Please see the attached drug alert for onward transmission as below.
Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors forward this alert to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Pharmacy and Medicines Division

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy, GP and Clinic Level

Date: 5th January 2017 EL 17(A) 02 Our Ref: MDR 051-12/16

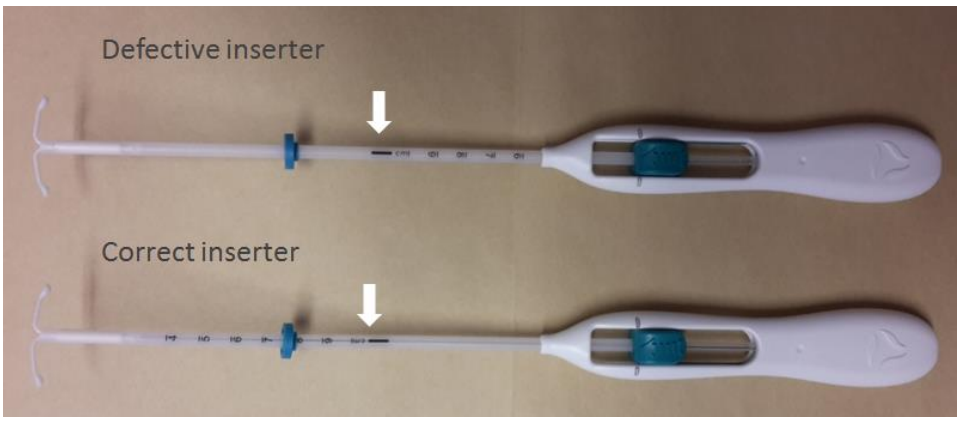
Dear Healthcare Professional,

Bayer plc

Mirena 20 micrograms / 24 hours intrauterine delivery system PL 00010/0547

Batch Number	Expiry Date	Pack Size	First Distributed
TU01BPE	Jun 2019	1 x 1	29 Aug 2016

Any stock on hand from the above batch should be inspected to ensure that the insertion tube is mounted correctly. This can be done without opening the blister. The picture below shows correctly and incorrectly mounted inserters.



Any incorrectly mounted insertion tubes identified should be reported to Bayer plc by telephone, 01635 563116 or by email, medical.information@bayer.co.uk

Background
Bayer plc has informed us that they have received two complaints globally concerning Mirena inserters with an insertion tube which is mounted inversely to the handle. This has resulted in inversion of the insertion depth scale, which may lead to incorrect insertion depth and the possibility of a reduced efficacy or adverse events. A very small number of Mirena inserters may potentially be affected by this issue.

An investigation has shown that both complaints involve one batch of inserters and Mirena batch TU01BPE has been manufactured using inserters from the same batch.

More detailed advice for Healthcare Professionals can be found in the attached letter, which has also been distributed by Bayer.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS Regional Teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

Alison Bunce

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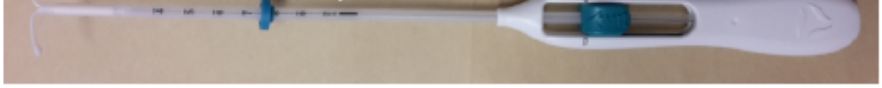


The "cm" scale should start at the tip of the insertion tube and increase towards the handle of the inserter.

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

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

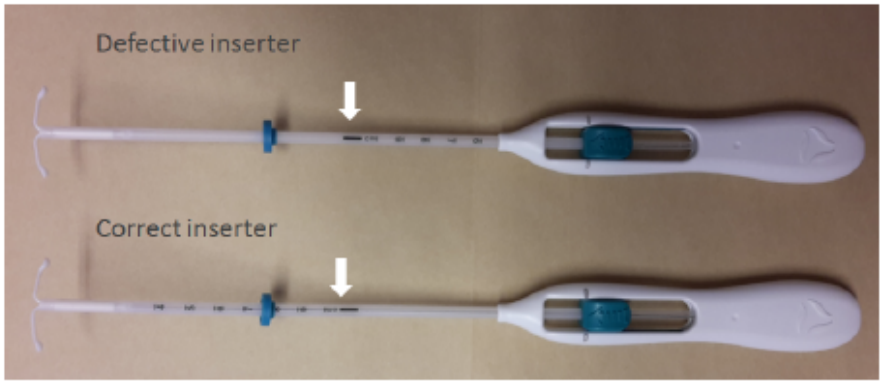
Bayer has received two complaints concerning Mirena® inserters with an inverted mounted insertion tube (please refer to the picture below).

- 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:

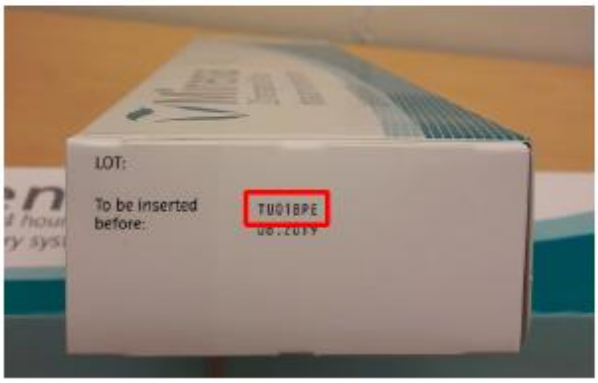


The "cm" scale should start at the tip of the insertion tube and increase towards the handle of the inserter.

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

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.

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)[1] 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® with an inversely mounted insertion tube to medical.information@bayer.co.uk as well as any associated adverse events.

Please report all adverse drug reaction (ADRs) concerning Mirena®
To Bayer: pvuk@bayer.com
To the MHRA: Yellow Card Scheme 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

Yours sincerely,

Dr Luis-Felipe Graterol
Medical Director

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