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JT Job No.: 258006
Item No.: 81911002
Drawn up/OS: Marianne Murto
Date: 26.9.2013
Client: Bayer Oy

Dimensions (mm):
50 x 120
Reeling: 2

Font / Font size / Spacing:
BayerSans / 6,5 pt / 7,15 pt

Colors: Pms 321, warm red, black

Uncoated area: –

Pharmacode: 2377

☐ New proof required ☐ Proof approved

Approved for printing / Date

Mirena®
Levonorgestrel
20 micrograms/24 hours
intrauterine delivery system

1 sterile intrauterine delivery system contains:
Levonorgestrel. 52 mg
Constit. q.s.

81911002

Store below 30°C
Keep out of the reach and sight of children

To be inserted by a health care professional
Sterile unless the blister is damaged or open

- **For loading, push the slider upwards**
- **This system cannot be re-loaded**
- **Please read the complete insertion instructions before insertion**

Manufacturer:
Bayer Oy
Pansiontie 47,
20210 Turku, Finland

Harus dengan resep dokter

Reg. No.: DKI0775601476A1

MAL19986422AZ
Controlled Medicine/Ubat Terkawal
SIN 07915P
BRU 11070730P

Lot No:

Mfg Dt:

To be inserted before:
(ยาสิ้นอายุ)

83261634

Mirena®

20 micrograms/24 hours intrauterine delivery system

BAYER

Insertion Instructions

To be inserted by a health care professional using aseptic technique.

Mirena is supplied within an inserter in a sterile package which should not be opened until needed for insertion. Do not resterilize. As supplied, Mirena is for single use only. Do not use if the inner package is damaged or open. Do not insert after the expiry month and year shown on the label.

For timing of insertion, please consult the Mirena prescribing information.

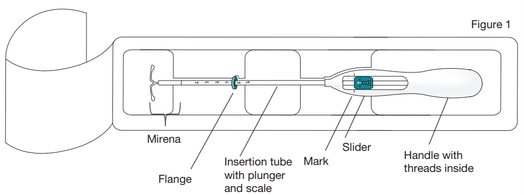
Preparation for insertion

- Examine the patient to establish the size and position of the uterus, in order to detect any signs of acute genital infections or other contraindications for the insertion of Mirena and to exclude pregnancy.
- Insert a speculum, visualize the cervix, and then thoroughly cleanse the cervix and vagina with a suitable antiseptic solution.
- Employ an assistant as necessary.
- Grasp the anterior lip of the cervix with a tenaculum or other forceps to stabilize the uterus. If the uterus is retroverted, it may be more appropriate to grasp the posterior lip of the cervix. Gentle traction on the forceps can be applied to straighten the cervical canal. The forceps should remain in position and gentle counter traction on the cervix should be maintained throughout the insertion procedure.
- Advance a uterine sound through the cervical canal to the fundus to measure the depth and confirm the direction of the uterine cavity and to exclude any evidence of intrauterine abnormalities (e.g., septum, submucous fibroids) or a previously inserted intrauterine contraceptive which has not been removed. If difficulty is encountered, consider dilatation of the canal. If cervical dilatation is required, consider using analgesics and/or a paracervical block.

Insertion

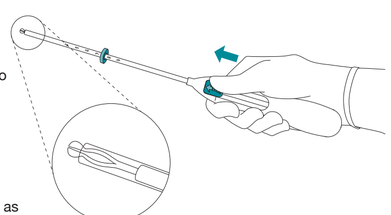
1. First, open the sterile package completely (Figure 1). Then use sterile technique and sterile gloves.

Figure 1



2. Push the slider **forward** in the direction of the arrow to the furthest position to load Mirena into the insertion tube (Figure 2).

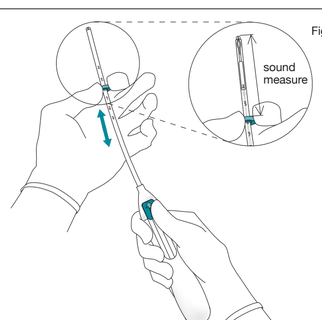
Figure 2



IMPORTANT!
Do not pull the slider downwards as this may prematurely release Mirena. Once released, Mirena cannot be re-loaded.

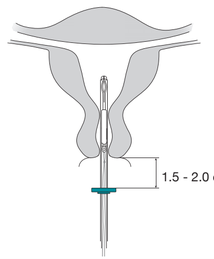
3. Holding the slider in the furthest position, set the **upper** edge of the flange to correspond to the sound measurement of the uterine depth (Figure 3).

Figure 3



4. While holding the slider in the **furthest** position, advance the inserter through the cervix until the flange is approx. 1.5-2.0 cm from the uterine cervix (Figure 4).

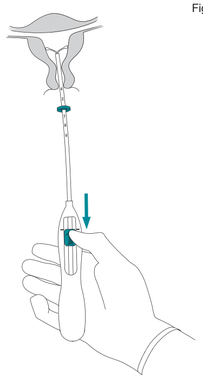
Figure 4



IMPORTANT! Do not force the inserter. Dilate the cervical canal, if necessary.

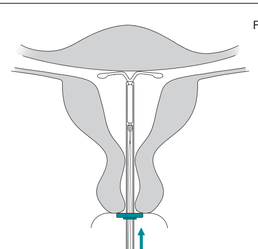
5. While holding the inserter steady, **pull the slider to the mark** to open the horizontal arms of Mirena (Figure 5). Wait 5 -10 seconds for the horizontal arms to open completely.

Figure 5



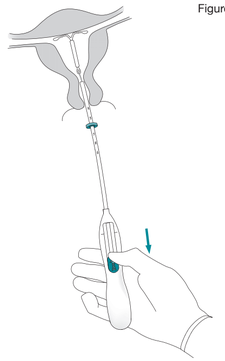
6. Advance the inserter gently towards the fundus of the uterus **until the flange touches the cervix**. Mirena is now in the fundal position (Figure 6).

Figure 6



7. Holding the inserter in place, release Mirena by pulling **the slider all the way down** (Figure 7). While holding the slider all the way down, gently remove the inserter by pulling it out. **Cut the threads** to leave about 2-3 cm visible outside of the cervix.

Figure 7



IMPORTANT! Should you suspect that the system is not in the correct position, check placement (e.g. with ultrasound). Remove the system if it is not positioned properly within the uterine cavity. A removed system must not be re-inserted.

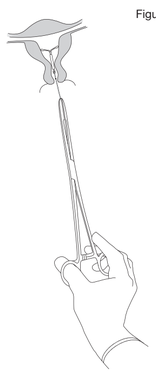
Removal / replacement

For removal/replacement, please consult the Mirena prescribing information.

Mirena is removed by pulling on the threads with a forceps (Figure 8).

You may insert a new Mirena immediately following removal.

Figure 8



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V-2011

PRINT & PACKAGE
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JT Job No.: 216967
Item No.: 83261634
Drawn up/OS: Miia Vainio
Date: 24/10/2011
Client: Bayer Oy
Folding:
Dimensions (mm): 490 x 280 mm
Folded (W x L mm): 70 x 280 mm

Font / Font size / Spacing:
Helvetica Neue / 10 pt
Colors: 2/0 321, musta
Pharmacode: 2469

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