

The following information is intended for medical or healthcare professionals only

20 micrograms/24 hours Intrauterine Delivery System

Levonorgestrel

Instructions for use and handling

Prescriber Check List

Ask yourself the following questions before prescribing/inserting Levosert®:

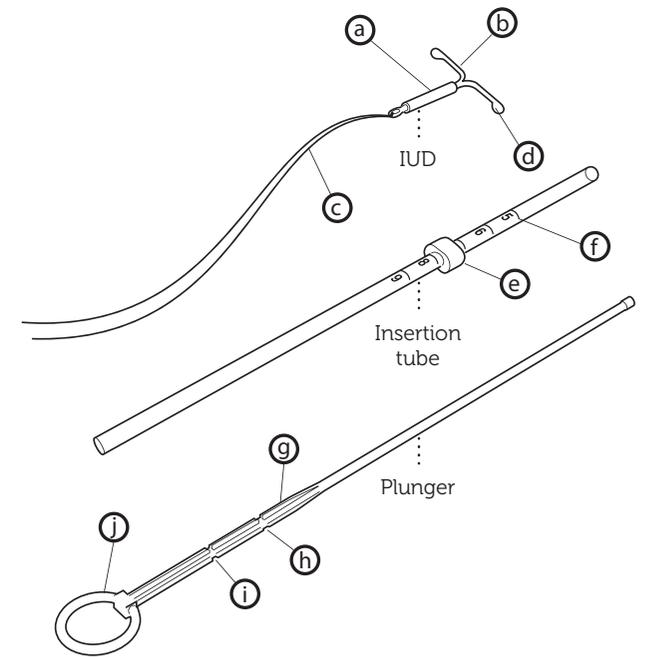
- Have I checked that the patient's needs meet the indications of contraception or heavy menstrual bleeding and for duration of use of up to three years?
- Have I completed the patient card included in the pack and given this to the patient as a reminder (any insertions of more than three years duration should be reported as off label use)?

Conditions for use

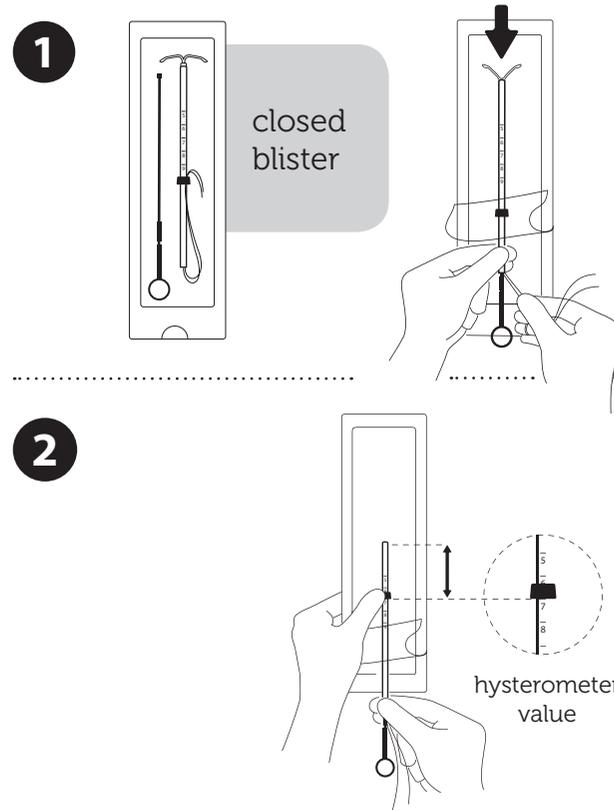
1. In women of fertile age, Levosert® is inserted within seven days of the onset of menstruation. It can be replaced by a new system at any time of the cycle.
2. It is recommended that Levosert® should only be inserted by physicians/health care professionals who have undergone sufficient training and have read carefully these instructions before Levosert® insertion.
3. Levosert® is supplied in a sterile pack which should not be opened until required for insertion. The exposed product should be handled with aseptic precautions. Do not use if the inner package is damaged or open.
4. Determine the position (anteversion, retroversion) and size of the uterus by a gynaecological examination. Exclude pregnancy and contra-indications.
5. Place a speculum, use appropriate antiseptic solution to clean the vagina and cervix.
6. Use cervical dilators if cervical stenosis is diagnosed. Do not force to overcome resistance.
7. Grasp the cervix with a Tenaculum forceps and apply a gentle traction in order to straighten alignment of the cervical canal and uterine cavity.
8. Determine the uterine depth by hysteroscopy. If uterine depth is < 5.5 cm discontinue the procedure.

Description

- (a) Levonorgestrel containing cylinder
- (b) Lateral arms
- (c) Threads
- (d) Knobs
- (e) Flange
- (f) Scale
- (g) Thickened mark
- (h) First indent
- (i) Second indent
- (j) Ring



Preparation for insertion



Introduce the plunger and the IUD in the insertion tube

Partly open the blister (about 1/3 from the bottom) and introduce the plunger in the insertion tube. Extricate the threads from the flange. Pull the thread to introduce the IUD into the tube. The arms of the IUD must stay in an horizontal plan, parallel to the flat side of the flange.

Position the lower edge of the flange at the sounded value

Position the blue flange so as the lower edge of the flange indicates the value found by hysteroscopy. The flat sides of the flange must always remain parallel to the arms. This will allow the arms to open correctly in the uterine cavity.

Levonorgestrel 20mcg 24hrs PIL (Professionals) Malta



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colours/plates:

1. black

2.

3.

4.

5.

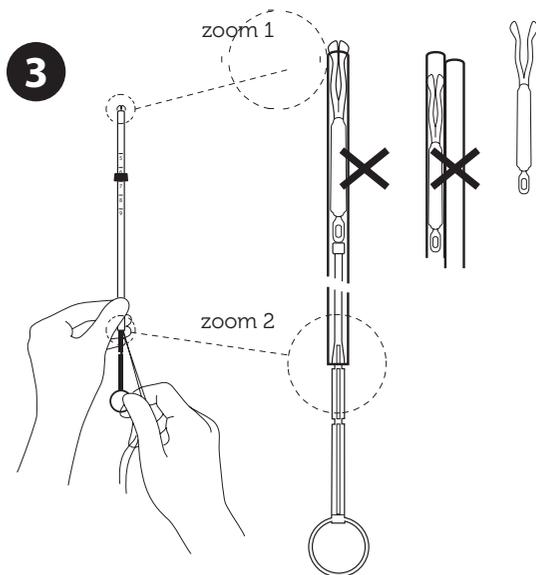
6.

Non Printing Colours

1.

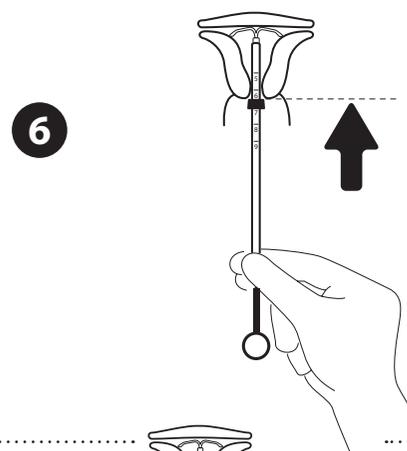
2.

3.



Adjust the position of the IUD in the insertion tube

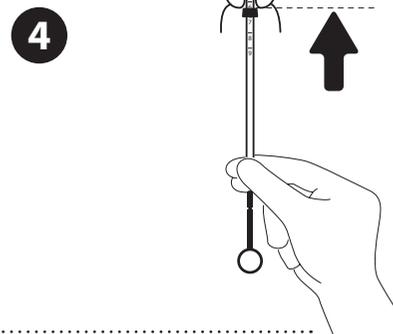
Hold the plunger firmly while pulling the thread and moving the tube to adjust the IUD's position. The knobs of the lateral arms must be closely opposed to each other, slightly above the upper extremity of the insertion tube (see zoom 1) and the distal edge of the tube must be aligned with the first indent of the plunger (see zoom 2). If the tube is not aligned with the first indent of the plunger you must pull the thread more firmly.



Push the IUD against the fundus

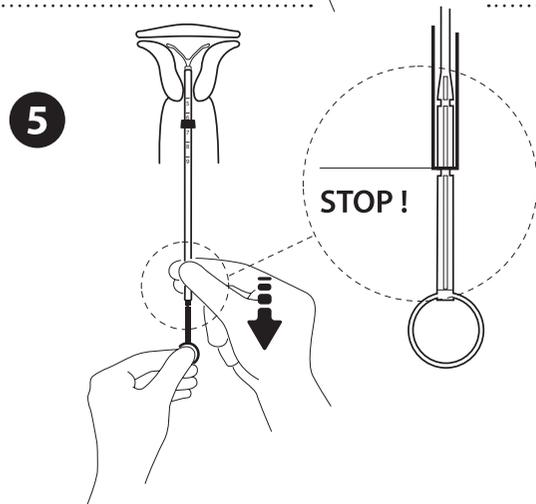
To position the IUD in the uterine cavity, push the insertion tube simultaneously with the plunger, until the blue flange is again in contact with the cervix. Levosert® is then correctly placed in the uterine cavity.

Insertion



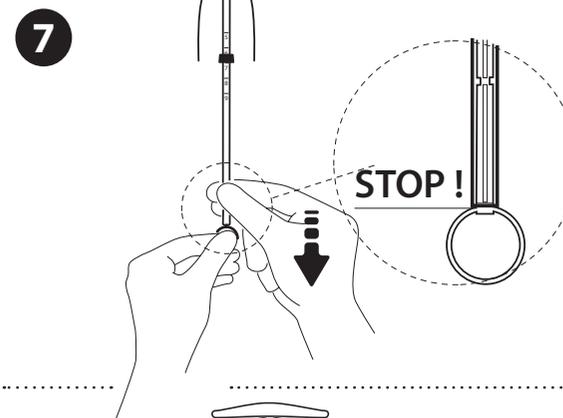
Introduce the device in the cervical canal until the blue flange is in contact with the cervix

Take the whole device out of the blister, by holding firmly the plunger and tube together in the correctly adjusted position. Introduce the assembly into the cervical canal until the blue flange is in contact with the cervix.



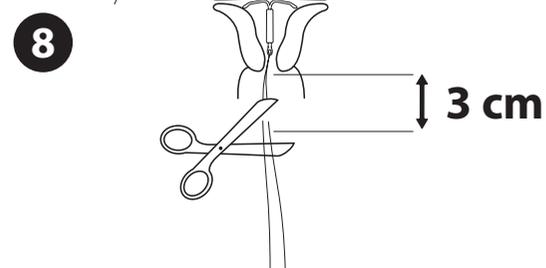
Release the arms of the intrauterine device

Hold the plunger, release the thread and pull the insertion tube down until its lower extremity reaches the second indent of the plunger.



Release the IUD from the tube into the uterine cavity

Without moving the plunger, pull the insertion tube down to the ring of the plunger. A slight resistance marks the passage of the bulge of the plunger. Nevertheless pull down the tube to the ring of the plunger. Levosert® is then released completely from the insertion tube.



Remove sequentially the inserter components and cut the threads

Remove sequentially, first the plunger, then the insertion tube. Cut the threads at around 3 cm from the cervix.

IMPORTANT!

In case of difficult insertion and/or exceptional pain or bleeding during or after insertion, physical examination and ultrasound should be performed immediately to exclude perforation of the uterine body or cervix. If necessary remove the system and insert a new, sterile system. Please report to our pharmacovigilance department any case of uterine perforation or insertion difficulties: Actavis M&S Office, Tarxien Road, Tarxien TXN1095, Malta - phV@actavis.com.mt - Phone: 00356 2248 3330, 00356 2248 3334.

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