

## **Package leaflet: Information for the user**

### **Levosert 52 mg Intrauterine Delivery System** levonorgestrel

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Levosert is and what it is used for
2. What you need to know before you use Levosert
3. How to use Levosert
4. Possible side effects
5. How to store Levosert
6. Contents of the pack and other information

#### **1. What Levosert is and what it is used for**

Levosert is an intrauterine delivery system (IUS) for insertion in the womb (uterus), where it slowly releases the hormone levonorgestrel.

It is used for:

##### Contraception

Levosert is an effective, long-term and non-permanent (reversible) method of contraception. Levosert prevents pregnancy by thinning the lining of your womb (uterus), by making the normal mucus in the opening of the womb (cervical canal) thicker, so that the sperm cannot get through to fertilise the egg and by preventing the release of eggs (ovulation) in some women. Furthermore, the presence of the T-shaped frame causes local effects on the lining of the womb.

Levosert should be removed after 8 years of use when used for contraception.

##### Treating heavy menstrual bleeding

Levosert is also useful for reducing menstrual blood flow, so it can be used if you suffer from heavy menstrual bleeding (periods). This is called menorrhagia. The hormone in Levosert acts by thinning the lining of your uterus, so that there is less bleeding every month.

Levosert should be removed or exchanged after 8 years of use, or earlier if heavy or bothersome menstrual bleeding returns.

##### Children and adolescents.

Levosert is not indicated for use before the first menstrual bleeding (menarche).

#### **2. What you need to know before you use Levosert**

##### **Do not use Levosert**

- if you are pregnant or suspect that you may be pregnant;
- if you have or have had pelvic inflammatory disease;
- if you have an unusual or unpleasant vaginal discharge, or vaginal itching, as this may indicate an infection;
- if you have or have had inflammation of the lining of your womb following delivery of your baby;

- if you have or have had an infection of the womb after delivery or after abortion during the past 3 months;
- if you have or have had inflammation of the cervix (neck of your womb);
- if you have or have had an abnormal smear test (changes in the cervix);
- if you have or have had liver problems;
- if you have liver tumour;
- if you have an abnormal womb, including uterine fibroids, especially those that distort the uterine cavity;
- if you have an abnormal vaginal bleeding pattern;
- if you have any condition which makes you susceptible to infections. A doctor will have told you if you have this.
- if you have or have had hormone dependent cancer, such as breast cancer;
- if you have or have had any type of cancer or suspected cancer including blood (leukaemia), uterine and cervical cancer, unless in remission;
- if you have or have had trophoblastic disease. A doctor will have told you if you have this.
- if you are allergic (hypersensitive) to levonorgestrel or any of the other ingredients of this medicine (listed in section 6).

### **Warnings and precautions**

Before you have Levosert fitted, your doctor or nurse will carry out some tests to make sure that Levosert is suitable for you to use. This will include a pelvic examination and may also include other examinations such as a breast examination, if your doctor or nurse feels this is appropriate.

Genital infections will need to be successfully treated before you can have Levosert fitted.

If you have epilepsy, tell the doctor or nurse fitting Levosert because, although rare, a fit can occur during insertion. Some women might feel faint after the procedure. This is normal and your doctor or nurse will tell you to rest for a while.

Levosert may not be suitable for all women.

Levosert, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease (e.g. chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B and syphilis). You will need condoms to protect yourself from these diseases.

### **Talk to your doctor before using Levosert:**

- if you have or develop migraine, dizziness, blurred vision, unusually bad headaches or if you have headaches more often than before;
- if you have yellowing of the skin or whites of the eyes (jaundice);
- if you are diabetic (too high blood glucose level), have high blood pressure or abnormal blood lipid levels;
- if you have had cancer affecting your blood (including leukaemia) which is now in remission;
- if you are on long-term steroid therapy;
- if you have ever had an ectopic pregnancy (development of the foetus outside the womb) or a history of ovarian cysts;
- if you have had or have severe arterial disease, such as heart attack, or stroke, or if you have any heart problems;
- if you have a history of blood clots (thrombosis);
- if you are taking any other medicines as some medicines may stop Levosert from working properly;
- if you have irregular bleedings;
- if you have fits (epilepsy).

Your doctor will decide if you can use Levosert if you have or have had some of the above conditions.

You must also tell your doctor if any of these conditions occur for the first time whilst you have Levosert in place.

You must see a doctor or nurse as soon as possible if you develop painful swelling in your leg, sudden chest pain or difficulty in breathing as these may be a sign of a blood clot. It is important that any blood clots are treated promptly.

### Expulsion

The muscular contractions of the womb during menstruation may sometimes push the IUS out of place or expel it. This is more likely to occur if you are overweight at the time of IUS insertion or have a history of heavy periods. If the IUS is out of place, it may not work as intended and therefore, the risk of pregnancy is increased. If the IUS is expelled, you are not protected against pregnancy anymore. Possible symptoms of an expulsion are pain and abnormal bleeding but Levosert may also come out without you noticing. As Levosert decreases menstrual flow, increase of menstrual flow may be indicative of an expulsion.

It is recommended that you check for the threads with your finger, for example while having a shower. See also section 3 “How to use Levosert – How can I tell whether the system is in place?”. If you have signs indicative of an expulsion or you cannot feel the threads, you should use another contraceptive (such as condoms), and consult your healthcare professional.

### Psychiatric disorders

Some women using hormonal contraceptives including Levosert have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

### Levosert and smoking

Women are advised to give up smoking. Smoking increases the risk of developing a heart attack, stroke, or blood clot.

### Use of tampons and menstrual cups

Use of sanitary pads is recommended. If tampons or menstrual cups are used, you should change them with care so as not to pull the threads of Levosert.

### **Other medicines and Levosert**

The effect of hormonal contraceptives such as Levosert may be reduced by medicines that increase the amounts of enzymes made by the liver. Please tell your doctor if you are taking:

- phenobarbital, phenytoin or carbamazepine (to treat epilepsy);
- griseofulvin (an antifungal);
- rifampicin or rifabutin (antibiotics);
- nevirapine or efavirenz (for HIV).

Tell your doctor if you are taking, have recently taken or might take any other medicines. Levosert should not be taken simultaneously with another hormonal contraceptive method.

### **Pregnancy, breast-feeding and fertility**

**Levosert must not be used during pregnancy or if you may suspect that you are pregnant.**

### Can I become pregnant whilst using Levosert?

It is very rare for women to become pregnant with Levosert in place.

Missing a period may not mean that you are pregnant. Some women may not have periods whilst using the system.

If you have not had a period for 6 weeks then consider having a pregnancy test. If this is negative there is no need to carry out another test, unless you have other signs of pregnancy, e.g. sickness, tiredness or breast tenderness.

If you become pregnant with Levosert in place, you should see your healthcare professional immediately to have Levosert removed. The removal may cause a miscarriage. However, if Levosert is

left in place during pregnancy, not only is the risk of having a miscarriage higher, but also the risk of preterm labor. If Levosert cannot be removed, talk with your healthcare professional about the benefits and risks of continuing the pregnancy. If the pregnancy is continued, you will be closely monitored during your pregnancy and you should contact your doctor right away if you experience stomach cramps, pain in your stomach or fever.

Levosert contains a hormone, called levonorgestrel, and there have been isolated reports of effects on the genitalia of female babies if exposed to levonorgestrel intra-uterine devices while in the womb.

#### What if I want a baby?

If you want a baby, ask your doctor to remove Levosert. Your usual level of fertility will return very quickly after the system is removed.

#### Can I breast feed while using Levosert?

Very small amounts of the hormone in Levosert are found in breast milk. A risk to the newborns/infants is not expected. Breast-feeding can be continued during use of Levosert.

#### **Driving and using machines**

There are no known effects on the ability to drive or use machines.

#### **Levosert contains barium sulphate.**

The T-frame of Levosert contains barium sulphate so that it can be seen on X-rays.

### **3. How to use Levosert**

Only a doctor or specially trained nurse can fit the system (see special instructions for insertion in the package).

They will explain the fitting procedure and any risks associated with its usage. You will then be examined by your doctor or nurse before Levosert is fitted. If you have any concerns over its usage you should discuss it with them.

#### **Starting to use Levosert**

- Before Levosert is inserted, it needs to be ensured that you are not pregnant.
- You should have Levosert inserted within 7 days from the start of your menstrual period. When Levosert is inserted on these days, Levosert works right away and will prevent you getting pregnant.
- If you cannot have Levosert inserted 7 days from the start of your menstrual period or if your menstrual period comes at unpredictable times, then Levosert can be inserted on any other day. In this case, you must not have had sexual intercourse without contraception since your last menstrual period, and you should have a negative pregnancy test before insertion. Also, Levosert may not reliably prevent pregnancy right away. Therefore, you should use a barrier method of contraception (such as condoms) or abstain from vaginal intercourse during the first 7 days after Levosert is inserted.
- Levosert is not suitable for use as an emergency contraceptive (postcoital contraceptive).

#### **Starting to use Levosert after giving birth**

- Levosert can be inserted after giving birth once the uterus has returned to normal size, but not earlier than 6 weeks after delivery (see section 4 “Possible side effects – Perforation”).
- See also “Starting to use Levosert” above for what else you need to know about the timing of insertion.

#### **Starting to use Levosert after an abortion**

Levosert can be inserted immediately after an abortion, if the pregnancy was less than 3 months along provided that there are no genital infections. Levosert will then work right away.

#### **Replacing Levosert**

Levosert can be replaced by a new Levosert at any time of your menstrual cycle. Levosert will then

work right away.

**Changing from another contraceptive method (such as combined hormonal contraceptives, implant)**

- Levosert can be inserted immediately if it is reasonably certain that you are not pregnant.
- If it has been more than 7 days since your menstrual bleeding began, you should abstain from vaginal intercourse or use additional contraceptive protection for the next 7 days.

**Placement of Levosert**

Examination by your healthcare professional before placement may include:

- a cervical smear test (Pap smear)
- examination of the breasts
- other tests, e.g. for infections, including sexually transmitted diseases, pregnancy test, as necessary. Your healthcare professional will also do a gynaecological examination to determine the position and size of the womb.

After a gynaecological examination

- An instrument called a speculum is placed into the vagina, and the cervix may be cleansed with an antiseptic solution. Levosert is then placed into the womb using a thin, flexible plastic tube (the placement tube). Local anaesthesia may be applied to the cervix prior to placement.
- Some women feel dizzy or faint during placement or after Levosert is placed or removed.
- You may experience some pain and bleeding during or just after placement.

After placement of Levosert you should receive a patient reminder card from your doctor for follow-up examinations. Bring this with you to every scheduled appointment.

**How quickly should Levosert work?**

*Contraception*

If Levosert is inserted into your womb either during your period or within 7 days from the beginning of your period or you have a device and it is time to replace it with a new one or if you just had an abortion, you are protected from pregnancy as soon as the system is fitted.

*Heavy menstrual bleeding*

Levosert usually results in lighter periods after 3 to 6 months of treatment.

**How will Levosert affect my periods?**

Many women have spotting (a small amount of blood loss) for the first 3-6 months after the system is fitted. Others will have prolonged or heavy bleeding. You may have an increase in bleeding however, usually in the first 2 to 3 months, before a reduction in blood loss is achieved. Overall, you are likely to have fewer days of bleeding in each month and you might eventually have no periods at all. This is due to the effect of the hormone (levonorgestrel) on the lining of the womb. If a remarkable reduction in blood loss is not achieved after 3 to 6 months, other treatments should be considered.

If you have had Levosert fitted for quite a long time and then start to have bleeding problems, contact your doctor or healthcare provider for advice.

**How often should I have the system checked?**

You should have your Levosert checked 4 to 6 weeks after placement, and thereafter regularly, at least once a year until it is removed. Your doctor may determine how often and what kinds of check-ups are required in your particular case. Bring the patient reminder card you have received from your doctor to every scheduled appointment. In addition, you should contact your doctor if any of the symptoms described in section 2 “Warnings and precautions” occur.

**How can I tell whether the system is in place?**

After each menstrual period, you can feel for the two thin threads attached to the lower end of the system. Your doctor will show you how to do this.

**Do not pull** the threads because you may accidentally pull it out. If you cannot feel the threads, contact your doctor or nurse as soon as possible and in the meantime avoid intercourse or use a barrier contraceptive (such as condoms). The threads may have simply drawn up into the womb or cervical canal. If the threads still cannot be found by your doctor or nurse, they may have broken off, or Levosert may have come out by itself, or in rare cases it may have perforated the wall of your womb (uterine perforation, see section 4).

You should also go to your doctor if you can feel the lower end of the device itself or you or your partner feel pain or discomfort during sexual intercourse.

#### **What happens if the system comes out by itself?**

If the system comes out either completely or partially, you may not be protected against pregnancy. It is rare but possible for this to happen without you noticing during your menstrual period. An unusual increase in the amount of bleeding during your period might be a sign that this has happened. Tell your doctor or healthcare provider if there are any unexpected changes in your bleeding pattern.

#### **Removal of Levosert**

Levosert should be removed or exchanged after 8 years of use, or earlier if heavy or bothersome menstrual bleeding returns.

Your doctor can easily remove the system at any time, after which pregnancy is possible. Some women feel dizzy or faint during or after Levosert is removed. You may experience some pain and bleeding during removal of Levosert.

#### ***Continuation of contraception after removal***

If pregnancy is not desired, Levosert should not be removed after the seventh day of the menstrual cycle (monthly period) unless you use other methods of contraception (e.g. condoms) for at least 7 days before the IUS removal.

If you have irregular periods (menses) or no periods, you should use a barrier method of contraception for 7 days before removal.

A new Levosert can also be placed immediately after removal, in which case no additional protection is needed. **If you do not wish to continue using the same method, ask your doctor for advice about other reliable contraceptive methods.**

If you have any further questions on the use of this medicine, ask your doctor.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

With Levosert, side effects are most common during the first months after the system is fitted and decrease as time goes on.

**If you experience any of the following serious side effects please contact your doctor or nurse immediately:**

- **Severe pain or fever developing shortly after insertion** may mean that you have a severe infection which must be treated immediately. In rare cases very severe infection (sepsis) can occur.
- **Severe pain and continued bleeding** as this might be a sign of damage or tear in the wall of the womb (perforation). Perforation is uncommon, but occurs most often during the fitting of the Levosert, although the perforation may not be detected until sometime later. A Levosert which has become lodged outside the cavity of the womb is not effective in preventing pregnancy and must be removed as soon as possible; very rarely this may require surgery. The risk of perforation is low, but is increased in breast-feeding women and in women who have had a baby up to 36 weeks before insertion and may be increased in women with the uterus fixed and

leaning backwards (fixed retroverted uterus). If you suspect you may have experienced a perforation, seek prompt advice from a healthcare provider and remind them that you have Levosert inserted, especially if they were not the person who inserted it.

Possible signs and symptoms of perforation may include:

- severe pain (like menstrual cramps) or more pain than expected
  - heavy bleeding (after insertion)
  - pain or bleeding which continues for more than a few weeks
  - sudden changes in your periods
  - pain during sex
  - you can no longer feel the Levosert threads (see “How can I tell whether the system is in place?” in section 3).
- **Lower abdominal pain especially if you also have a fever or have missed a period or have unexpected bleeding**, as this might be a sign of ectopic pregnancy (development of the foetus outside the womb). The absolute risk of ectopic pregnancy in Levosert users is low. However, when a woman becomes pregnant with Levosert in place, the relative likelihood of ectopic pregnancy is increased.
- **Lower abdominal pain or experience painful or difficult sex** as this might be a sign of ovarian cysts or pelvic inflammatory disease. This is important as pelvic infections can reduce your chances of having a baby and can increase the risk of ectopic pregnancy.

#### Other side effects

**Very common** (may affect more than 1 in 10 women) side effects can include:

- absent, light or infrequent menstrual periods (see “How will Levosert affect my periods?” in section 3),
- vaginal bleeding including spotting;
- bacterial or fungal infections of the vagina and the outer genitalia (vulva);
- spots (acne).

**Common** (may affect up to 1 in 10 women) side effects can include:

- depression, nervousness or other mood changes;
- reduced sex drive;
- headache;
- migraine;
- feeling faint (presyncope);
- dizziness;
- back pain;
- abdominal discomfort;
- feeling sick (nausea);
- bloated abdomen;
- vomiting;
- painful periods;
- increased vaginal discharge;
- tender, painful breasts;
- spasm of the womb;
- Levosert coming out by itself;
- weight gain.

**Uncommon** (may affect up to 1 in 100 women) side effects can include:

- fainting;
- eczema;
- inflammation of the neck of the womb (cervicitis);
- bloating or swelling of your legs or ankles;
- increased growth of hair on the face and body;
- hair loss;
- itchy skin (pruritus);

- skin discolouration or increased skin pigment, especially on the face (chloasma).

**Rare** (may affect up to 1 in 1,000 women) side effects can include:

- rashes, itching.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Levosert**

Store in the original package. Keep the pouch in the outer carton in order to protect from light. Keep the pack tightly closed. Only your doctor or healthcare provider should open this.

Keep this medicine out of the sight and reach of children.

Do not use the system after the expiry date which is stated on the label and the outer pack after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Levosert contains**

- Levosert contains 52 mg of levonorgestrel, the active substance. The hormone is contained within a substance called polydimethylsiloxane. This is surrounded by a membrane (skin) also made of polydimethylsiloxane.

### **What Levosert looks like and contents of the pack**

- Levosert consists of a small T-shaped frame made from a plastic called polyethylene. This structure provides a device for releasing the hormone gradually into the uterus (womb).
- There are two fine threads, made of polypropylene and copper phthalocyanine blue, attached to the bottom of the frame. These allow easy removal and allow you or your doctor to check that the device is in place.

Levosert IUS with the inserter device is individually packed into a peel pouch that is made up of 2 sheets: thermoformed pouch (polyester) package with a peelable lid.

Each pack contains one or five Levosert in peel pouch or pouches, that is single packed into one or five separated folding cartons with the patient information leaflet and the patient reminder card.

Pack sizes:

One Intrauterine System with the inserter device.

Five Intrauterine System with the inserter device.

Multipack five packs of one Intrauterine System with one inserter device.

Not all pack sizes may be marketed.



## **Marketing Authorisation Holder and Manufacturer**

### Marketing Authorisation Holder

Gedeon Richter Plc.  
Gyömrői út 19-21.  
1103 Budapest  
Hungary

### Manufacturer

Odyssea Pharma SA  
Rue du Travail 16  
4460 Grâce Hollogne  
Belgium

Gedeon Richter Plc.  
Gyömrői út 19-21.  
1103 Budapest  
Hungary

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

Austria	Levosert
Cyprus	Levosert
Germany	Levosert
Denmark	Levosert Two
Spain	Levosert
Ireland	Levosert
Iceland	Levosert
Italy	Benilexa
Malta	Levosert
Norway	Levosert
Sweden	Levosert
Slovenia	Levosert
United Kingdom	Benilexa Two Handed

**This leaflet was last revised in**

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**The following information is intended for healthcare professionals only**

## Instructions for use and handling

### Levosert 52 mg Intrauterine Delivery System Levonorgestrel

#### 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 eight 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 eight years in duration should be reported as **off label use**)

Please read the following instructions for use carefully as there may be some difference in the type of inserter device compared with other IUDs you have used previously:

#### Insertion instructions

##### **To be inserted by a healthcare professional using aseptic technique.**

It is recommended that Levosert should only be inserted by healthcare professionals who are experienced in IUS insertions and/or have undergone sufficient training on the Levosert insertion procedure and have read carefully these instructions before Levosert insertion.

Levosert is supplied in a sterile pack which should not be opened until required for insertion. Do not resterilise. For single use only. The exposed product should be handled with aseptic precautions. If the seal of the sterile package is broken, the product should be discarded (see Summary of Product Characteristics section 6.6 for disposal instructions). Do not use if the inner package is damaged or open. Do not insert after the expiry date which is stated on the carton and the tray with peelable lid after EXP. The expiry date refers to the last day of that month.

For timing of insertion, please see Summary of Product Characteristics section 4.2.

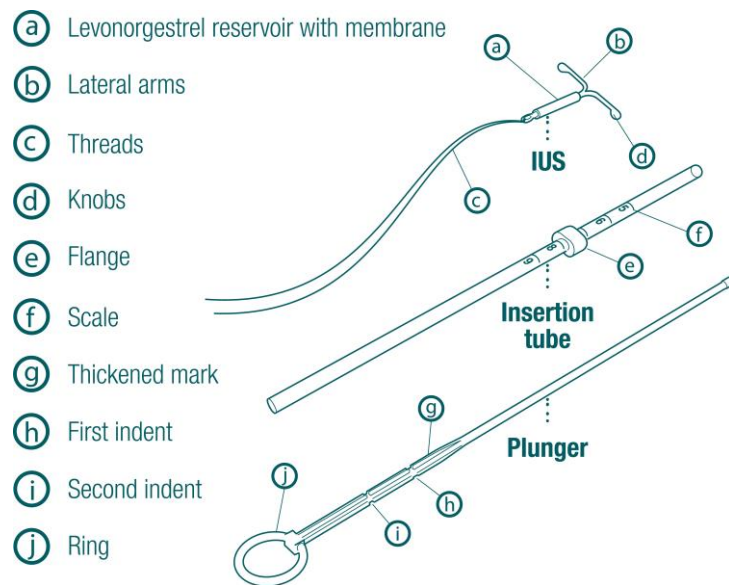
Levosert is supplied with a patient reminder card in the outer carton. Complete the patient reminder card and give it to the patient, after insertion.

#### Preparation for insertion

- Examine the patient to rule out contraindications for the insertion of Levosert (see Summary of Product Characteristics section 4.3 and section 4.4 under Medical examination/consultation).
- 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. If uterine depth is < 5.5 cm discontinue the procedure. 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.

## Description

Figure 1



## Getting ready for insertion

Figure 2

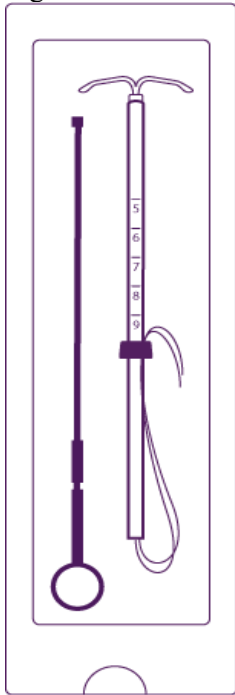
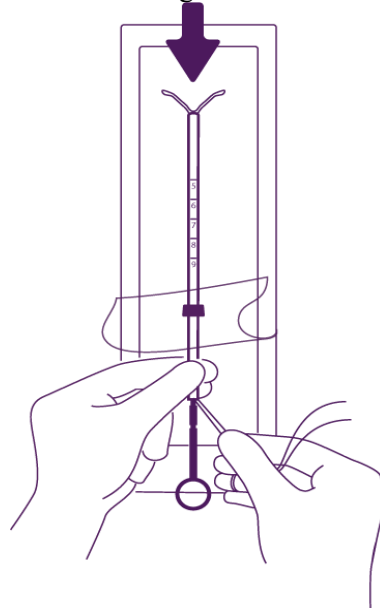


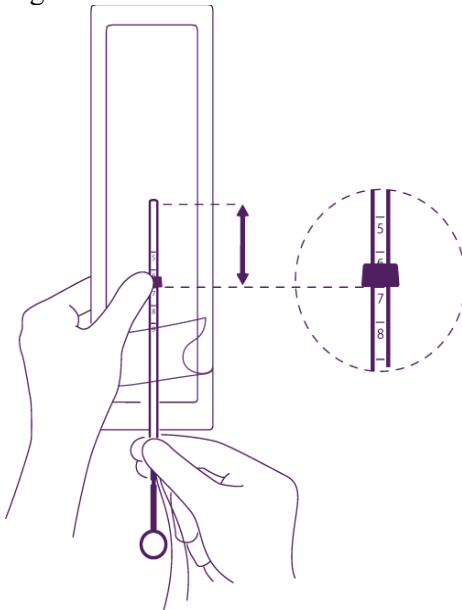
Figure 3



*Introduce the plunger and the IUS in the insertion tube*

Partly open the pouch (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 IUS into the tube. The arms of the IUS must stay in a horizontal plane, parallel to the flat side of the flange.

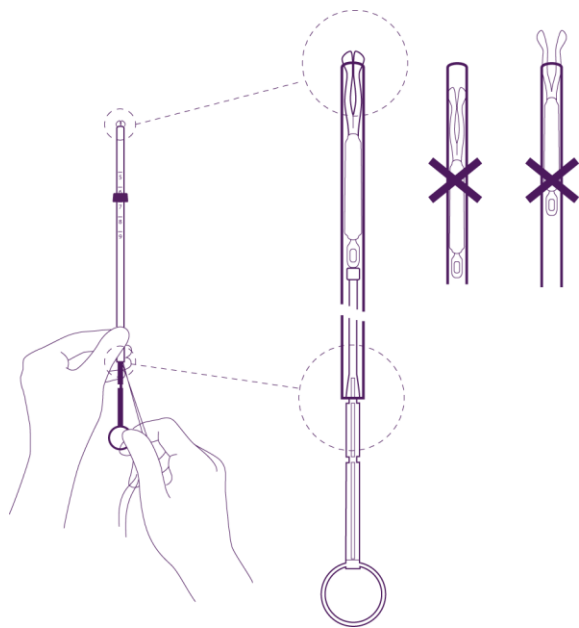
Figure 4



*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.

Figure 5



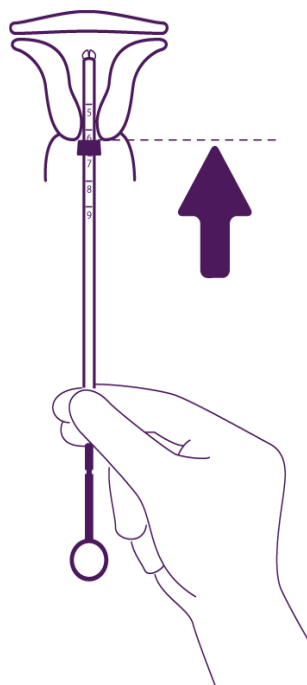
*Adjust the position of the IUS in the insertion tube*

Hold the plunger firmly while pulling the thread and moving the tube to adjust the position of the IUS.

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.

## Insertion

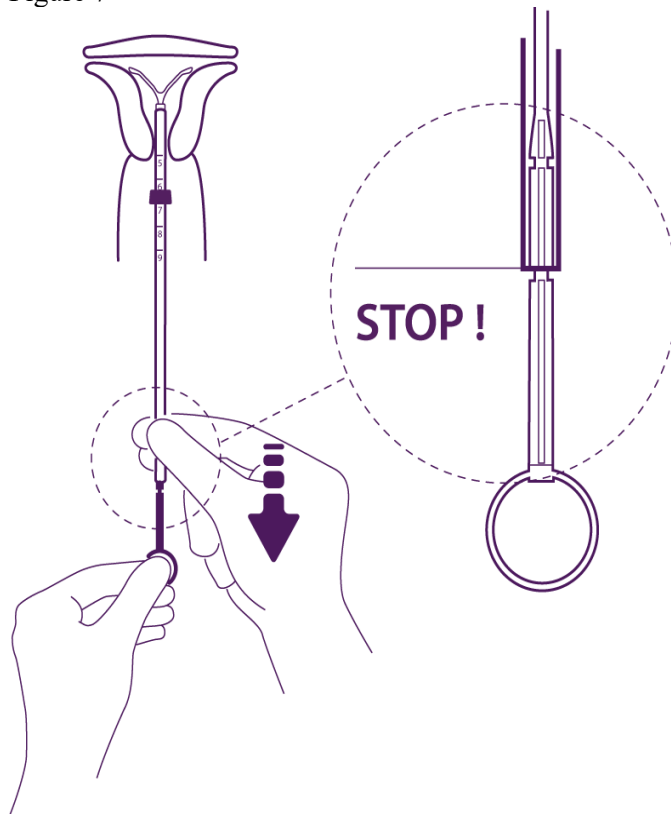
Figure 6



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

Take the whole device out of the pouch, 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.

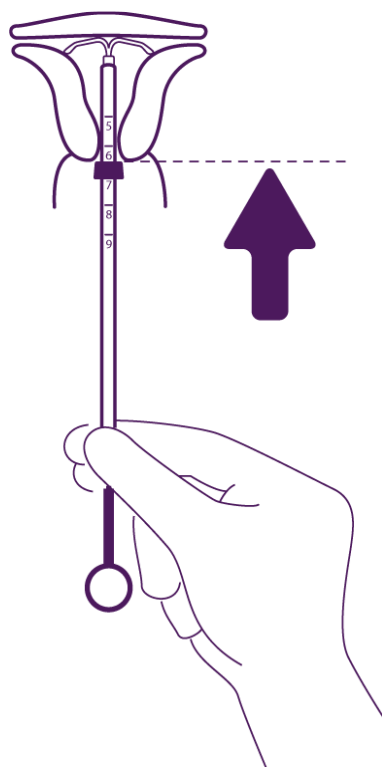
Figure 7



*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.

Figure 8



*Push the IUS against the fundus*

To position the IUS 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.

Figure 9

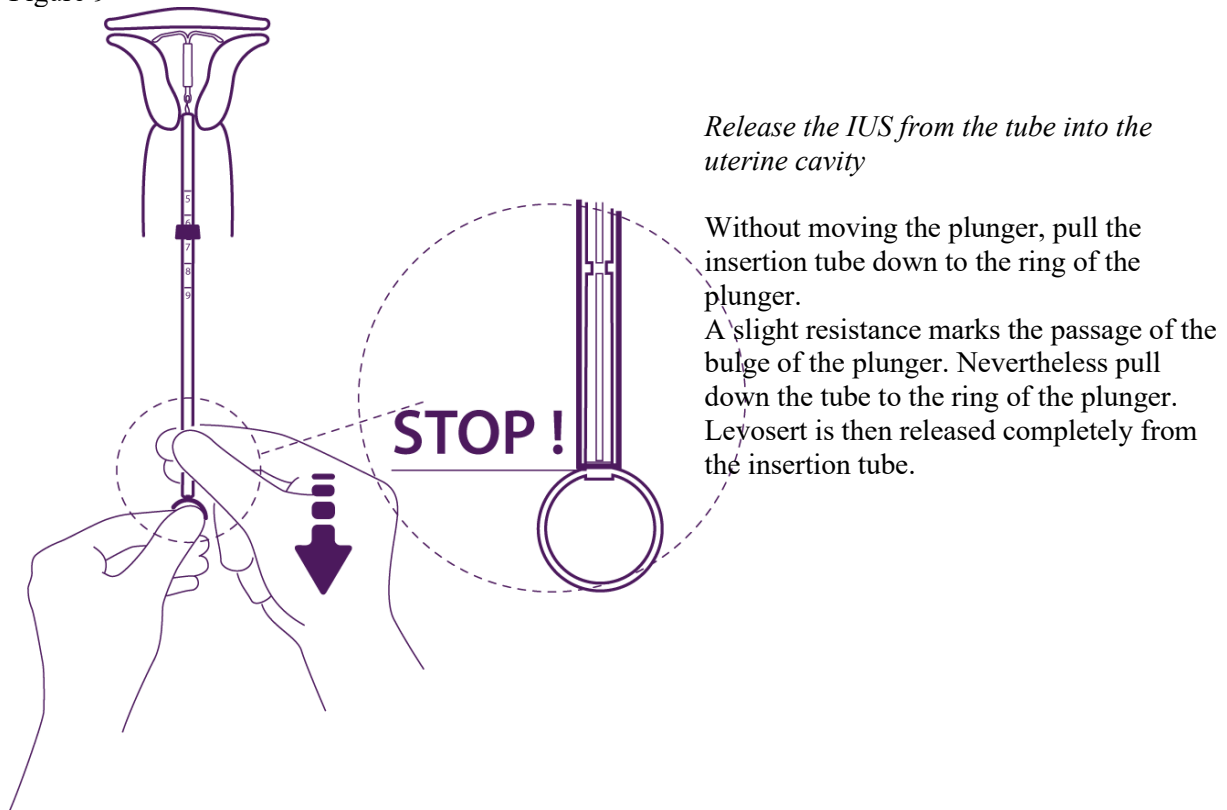
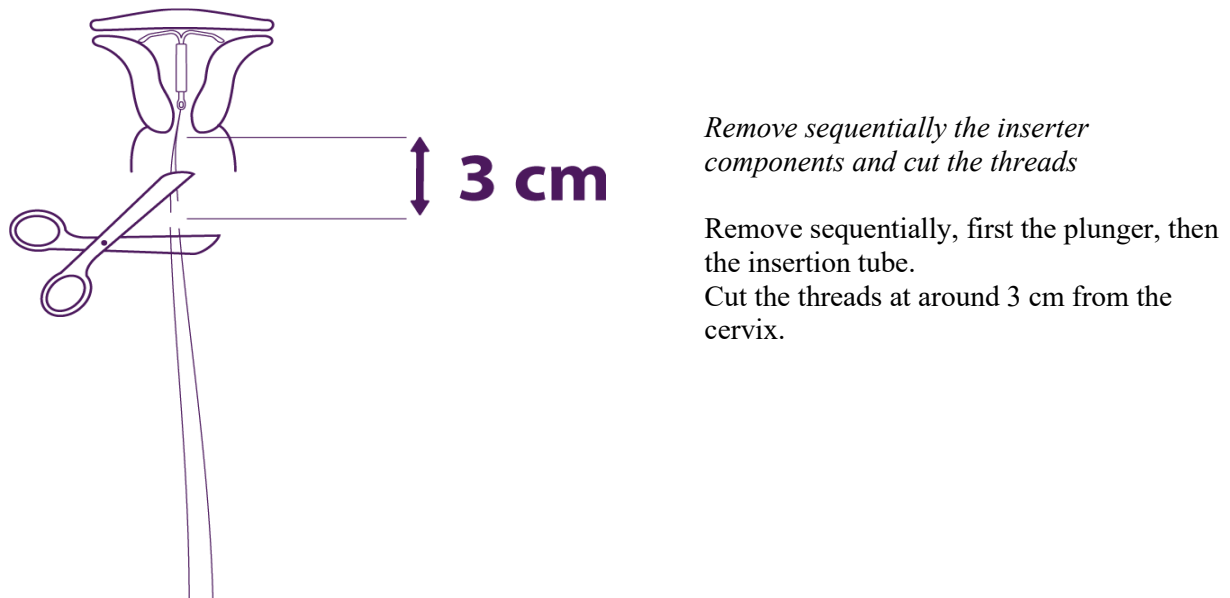


Figure 10



Insertion of Levosert is now complete.

*Important information to consider during or after insertion:*

- If you suspect the IUS is not in the correct position:
  - Check insertion with an ultrasound or other appropriate radiologic test.
  - If incorrect insertion is suspected, remove Levosert. Do not reinsert the same Levosert IUS after removal.

**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. Physical examination alone (including checking of threads) may not be sufficient to exclude partial perforation. If necessary remove the system and insert a new, sterile system.

After insertion, women should be re-examined after 4 to 6 weeks to check the threads and ensure that the device is in the correct position. Please report any case of uterine perforation or insertion difficulties via:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

**Removal/replacement**

Levosert is removed by gently pulling on the threads with forceps. The use of excessive force/sharp instruments during removal may cause breakage of the device.

If the threads are not visible and the system is found to be in the uterine cavity on ultrasound exam, it may be removed using a narrow forceps. This may require dilatation of the cervical canal or surgical intervention.

After removal of Levosert, the system should be examined to ensure that it is intact and has been completely removed. During difficult removals, single cases have been reported of the hormone cylinder sliding over the horizontal arms and hiding them together 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.