

Package leaflet: Information for the user

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

1. What Levosert SHI is and what it is used for

Levosert SHI 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 SHI is an effective, long-term and non-permanent (reversible) method of contraception. Levosert SHI 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 SHI should be removed after 6 years of use when used for contraception.

Treating heavy menstrual bleeding

Levosert SHI 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 SHI acts by thinning the lining of your uterus-so that there is less bleeding every month. Levosert SHI should be removed or exchanged after 6 years of use, or earlier if heavy or bothersome menstrual bleeding returns.

Children and adolescents

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

2. What you need to know before you use Levosert SHI

Do not use Levosert SHI if you

- are pregnant or suspect that you may be pregnant;
- have or have had pelvic inflammatory disease;
- have an unusual or unpleasant vaginal discharge, or vaginal itching, as this may indicate an infection;
- have or have had inflammation of the lining of your womb following delivery of your baby;
- have or have had an infection of the womb after delivery or after abortion during the past 3 months;
- have or have had inflammation of the cervix (neck of your womb);

- have or have had an abnormal smear test (changes in the cervix);
- have or have had liver problems;
- have liver tumour;
- have an abnormal womb, including uterine fibroids, especially those that distort the uterine cavity;
- have an abnormal vaginal bleeding pattern;
- have any condition which makes you susceptible to infections. A doctor will have told you if you have this;
- have or have had hormone dependent cancer, such as breast cancer;
- have or have had any type of cancer or suspected cancer including blood (leukaemia) uterine and cervical cancer, unless in remission;
- have or have had trophoblastic disease. A doctor will have told you if you have this;
- 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 SHI fitted, your doctor or nurse will carry out some tests to make sure that Levosert SHI 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 SHI fitted.

If you have epilepsy, tell the doctor or nurse fitting Levosert SHI 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 SHI may not be suitable for all women.

Levosert SHI, 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 SHI if you:

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

Your doctor will decide if you can use Levosert SHI 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 SHI 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 SHI may also come out without you noticing. As Levosert SHI 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 SHI – 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 SHI 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 SHI 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 SHI.

Other medicines and Levosert SHI

The effect of hormonal contraceptives such as Levosert SHI 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 SHI should not be taken simultaneously with another hormonal contraceptive method.

Pregnancy, breast-feeding and fertility

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

Can I become pregnant whilst using Levosert SHI?

It is very rare for women to become pregnant with Levosert SHI 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 SHI in place, you should see your healthcare professional immediately to have Levosert SHI removed. The removal may cause a miscarriage. However, if Levosert SHI 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 SHI 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 SHI 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 SHI. Your usual level of fertility will return very quickly after the system is removed.

Can I breast-feed while using Levosert SHI?

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

Driving and using machines

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

Levosert SHI contains barium sulphate.

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

3. How to use Levosert SHI

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 SHI is fitted. If you have any concerns over its usage you should discuss it with them.

The device should be inserted either during your period or within seven days from the beginning of your period. If you already have the device and it is time to replace it with a new one, you do not need to wait until your period.

If you have just had a baby, you should wait at least 6 weeks before having Levosert SHI fitted.

Levosert SHI can sometimes be fitted immediately after you have had an abortion, provided that you have no genital infections.

How quickly should Levosert SHI work?

Contraception

You are protected from pregnancy as soon as the system is fitted.

Heavy menstrual bleeding

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

How will Levosert SHI 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 SHI 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 the system checked usually 6 weeks after it is fitted, again at 12 months and then once a year until it is removed.

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 SHI 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.

If you stop using Levosert SHI

Your doctor can remove the system at any time. The removal is very easy. Unless you plan to have a new system or an intra-uterine device fitted immediately, it is important to use another form of contraception in the week leading up to the removal. Intercourse during this week could lead to pregnancy after Levosert SHI is removed.

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 SHI, 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 SHI, although the perforation may not be detected until sometime later. A Levosert SHI 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 SHI 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 SHI 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 SHI users is low. However, when a woman becomes pregnant with Levosert SHI 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 (affects more than 1 in 10 women) side effects can include:

- absent, light or infrequent menstrual periods (see “How will Levosert SHI 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 SHI 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

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

5. How to store Levosert SHI

Store in the original package. This medicinal product does not require any special temperature storage conditions. Keep the sealed tray in the outer carton in order to protect from light. Do not open the Levosert SHI pack. Only your doctor or healthcare provider should do 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 SHI contains

- Levosert SHI 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 SHI looks like and contents of the pack

- Levosert SHI 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 SHI IUS with the inserter device is individually packed into a thermoformed plastic (PETG) tray with a peelable lid (TYVEK-Polyethylene). Sterile trays are packed into a folding carton.

Pack sizes:

One Intrauterine System with the inserter device.

Multipack containing five packs of one Intrauterine System with the 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 S.A.
Rue du Travail 16
4460 Grâce Hollogne
Belgium

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

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Levosert One
Cyprus	Levosert One
Germany	Levosert One
Denmark	Levosert One
Spain	LEVOSERT ONE 0,02MG CADA 24 HORAS SISTEMA DE LIBERACION INTRAUTERINO
Ireland	Levosert SHI
Iceland	Levosertone
Italy	Benilexa
Malta	Levosert One
Norway	Levosertone
Sweden	Levosertone
Slovenia	Levosert SHI
United Kingdom	Benilexa One Handed

This leaflet was last revised in March 2023.

The following information is intended for medical or healthcare professionals only

Instructions for use and handling

Prescriber Check List

Ask yourself the following questions before prescribing/inserting **Levosert SHI**:

I have checked that the patient's needs meet the **indications of contraception or heavy menstrual bleeding and for duration of use of up to six years?**

I have completed the patient card included in the pack and given this to the patient as a reminder?

Conditions for use

1. In women of fertile age, Levosert SHI 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 strongly recommended that Levosert SHI should only be inserted by physicians/health care professionals who have undergone sufficient training and have read carefully these instructions before Levosert SHI insertion.
3. Levosert SHI 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 contraindications.
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. If cervical dilatation is required, consider using analgesics and/or a paracervical block.
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

Figure 1a: Levosert SHI Intrauterine Contraceptive System (IUS)

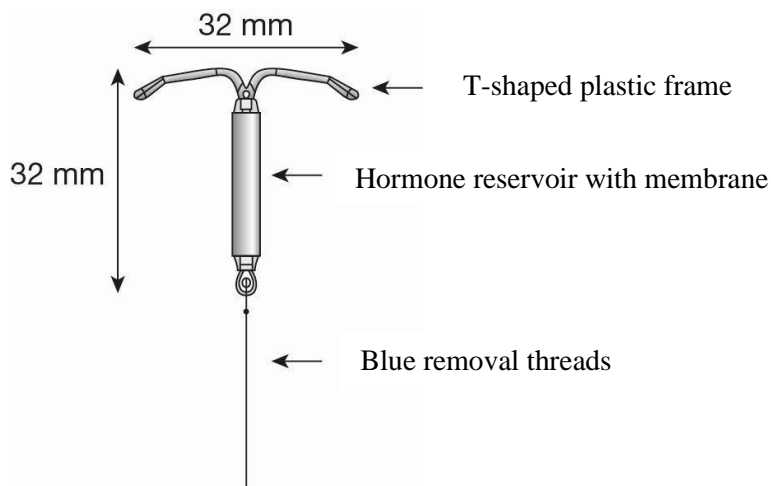


Figure 1b: Levosert SHI IUS with inserter

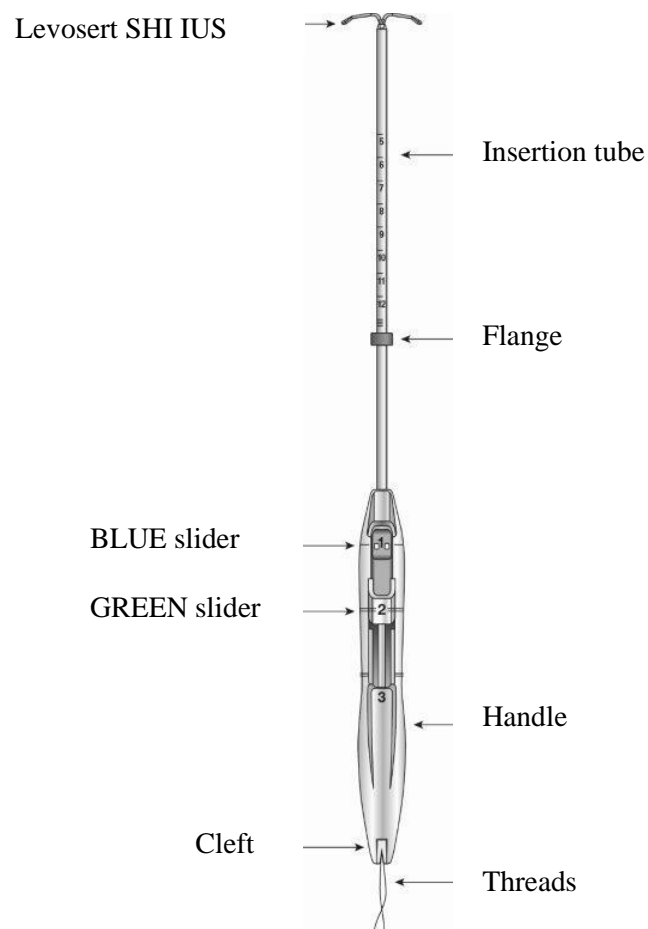
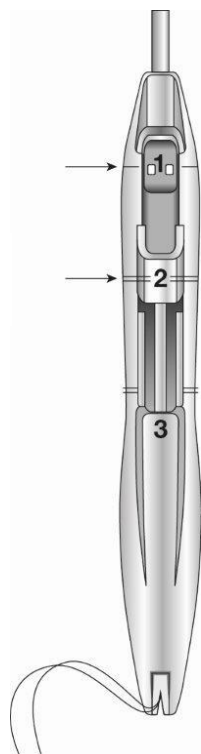


Figure 2: Inserter sliders



- Levosert SHI is packaged partially preloaded within the inserter. The threads are passed through the insertion tube, and exit through an opening in the handle at the cleft.
- The handle of the inserter contains a BLUE slider labelled with the number 1 and a GREEN slider labelled with the number 2, and the handle is labelled with the number 3 to assist with the insertion process.
- Moving the sliders achieves the positions required to complete the insertion process.

Preparation for insertion

Step 1: Opening the sterile Levosert SHI packaging

- Remove the sealed tray containing Levosert SHI from the box.
- Inspect the sealed tray and do not use the product if the packaging, inserter or IUS is damaged.
- Lay the tray on a flat surface with the peel-off lid side up.
- Remove peel-off lid.

Step 2: Removing inserter from tray (Figure 3)

Figure 3

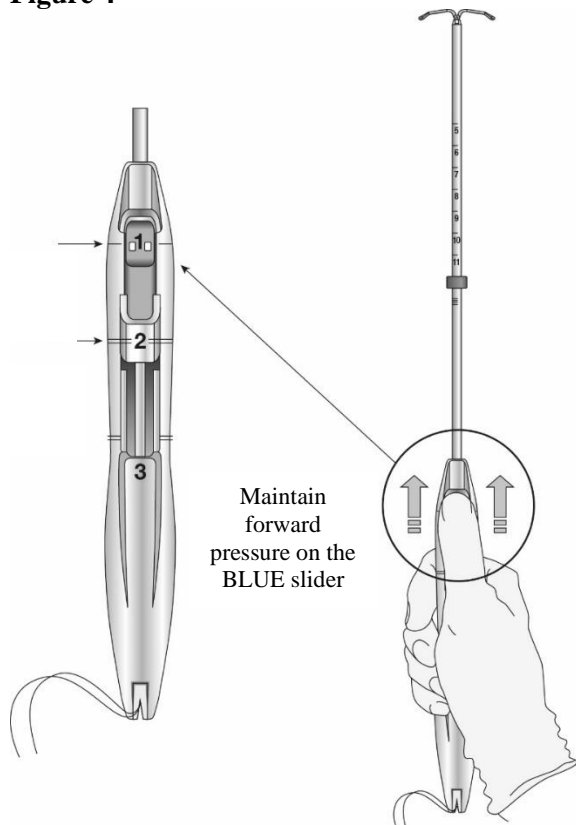


- To remove the inserter from the tray, grasp the handle below the sliders and twist gently (Figure 3).

NOTE: Do not attempt to remove the inserter by pulling on the tube

Step 3: Sliders completely forward for loading Levosert SHI (Figure 4)

Figure 4

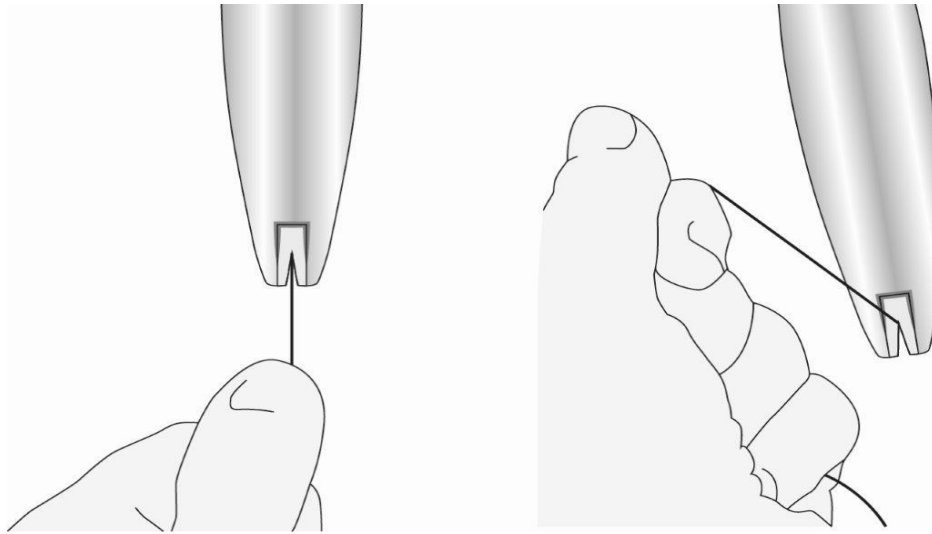


- The BLUE slider (labelled with the number 1) has a single line marking that will align with the handle's single line marking.
- The GREEN slider (labelled with the number 2) has a double line marking that will align with the handle's double line marking.
- Grip the handle keeping your thumb or finger in the groove of the BLUE slider (over the numeral 1) and apply **forward pressure** while ensuring both sliders are **fully forward**.

Step 4: Load Levosert SHI into the inserter

- Ensure the arms of the IUS are horizontal (aligned to the horizontal plane of the handle and flange); adjust the rotation of the IUS as needed using the flat sterile surface of the tray.
- While maintaining **forward pressure** on the blue slider, gently pull the threads **straight** back to load Levosert SHI into the insertion tube. Ensure even tension is applied to both threads when pulling. Pull the threads upward or downward to **lock the threads** into the cleft at the bottom end of the handle (Figure 5); you must lock the threads in the cleft to prevent the IUS from moving out of the top of the insertion tube. Once the threads are locked in the cleft, **stop holding the threads**.

Figure 5: Locking the threads in cleft



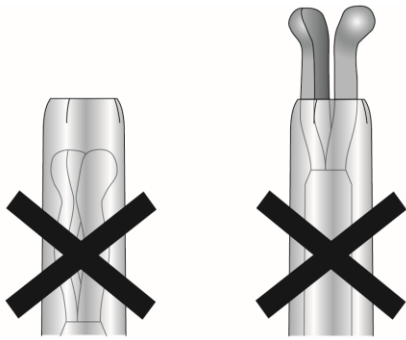
- After the IUS is loaded, continue to sustain forward pressure on the BLUE slider to maintain the correct position of the IUS.
- When correctly loaded, the IUS is completely within the insertion tube with the tips of the arms forming a hemispherical dome at the top of the tube (Figure 6, Zoom 1).

Figure 6: Position of the IUS in the insertion tube
Zoom 1



The knobs of the lateral arms must be closely opposed to each other, slightly above the upper extremity of the insertion tube (Zoom 1).

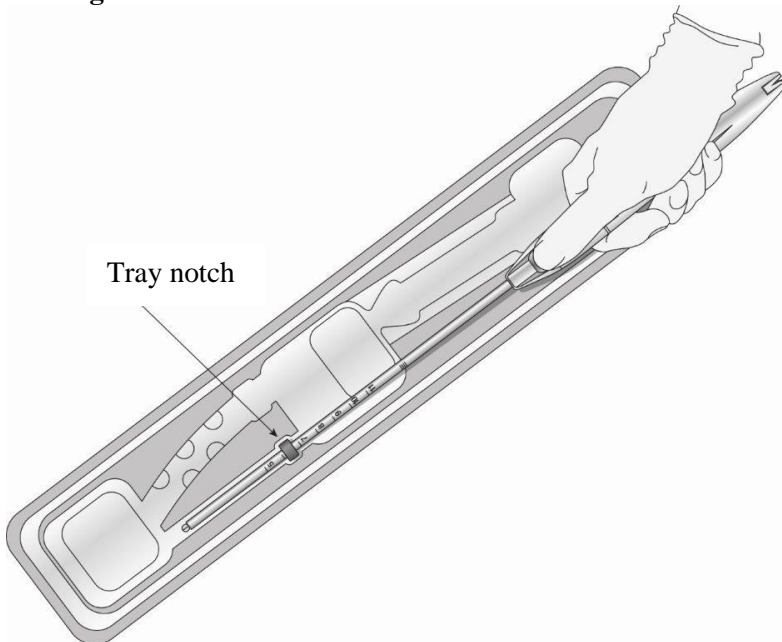
Zoom 2



- If the IUS is not correctly loaded (Zoom 2), do not attempt insertion.
- To re-load Levosert SHI:
 - Pull the BLUE slider back with your thumb until the groove becomes aligned with the GREEN slider to release the IUS.
 - Manually pull the threads out of the cleft.
 - Return the BLUE slider to the forward position and repeat the loading steps.

Step 5: Adjusting the flange (Figure 7)

Figure 7



- Adjust the flange to the measured uterine depth based on sounding. To adjust, place the flat side of the flange in the tray notch (Figure 7) or against a sterile edge inside of the tray. Slide the insertion tube as necessary to move the flange to the correct measurement. Ensure the flat sides of the flange are in the same horizontal plane as the handle.

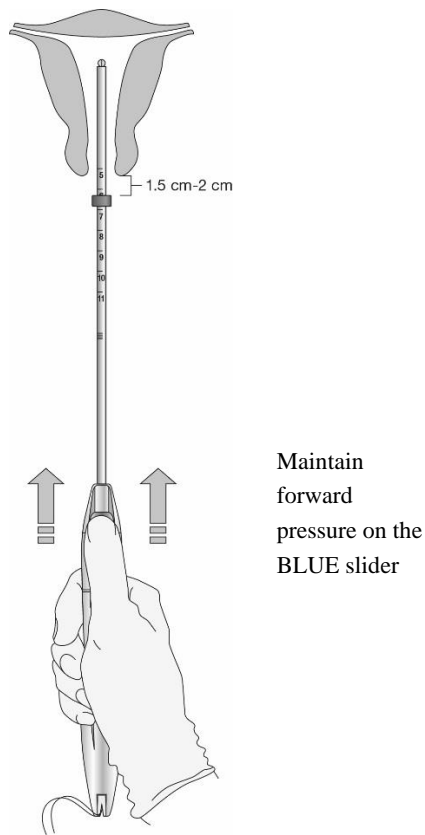
- If an adjustment to the curvature of the insertion tube is required to accommodate the anatomical orientation of the uterus, you may bend or straighten the insertion tube. When bending the tube, avoid sharp bends to prevent kinking.

- Once the flange has been properly positioned, avoid contact with flange against objects that can change its position (e.g. tray, speculum, tenaculum, etc.).

Note: If, at any step, there is a need to touch the flange or another sterile surface, sterile gloves should be used.

Step 6: Inserting Levosert SHI into the uterus (Figure 8)

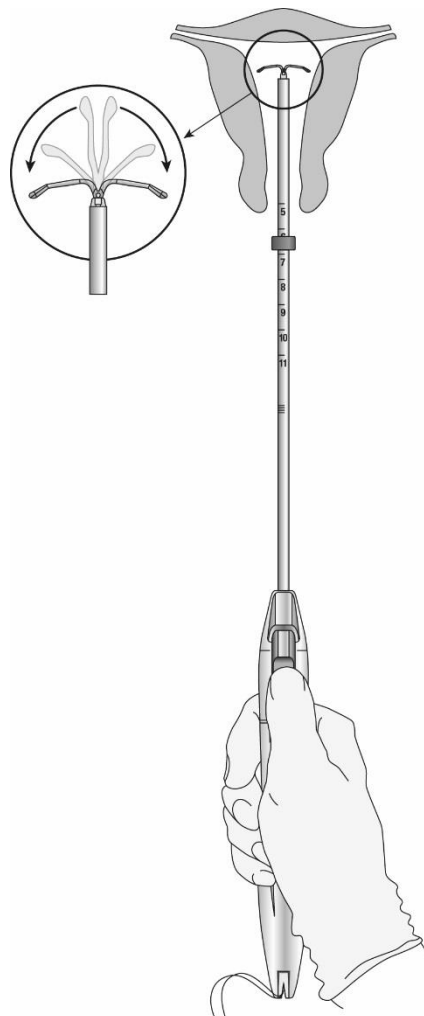
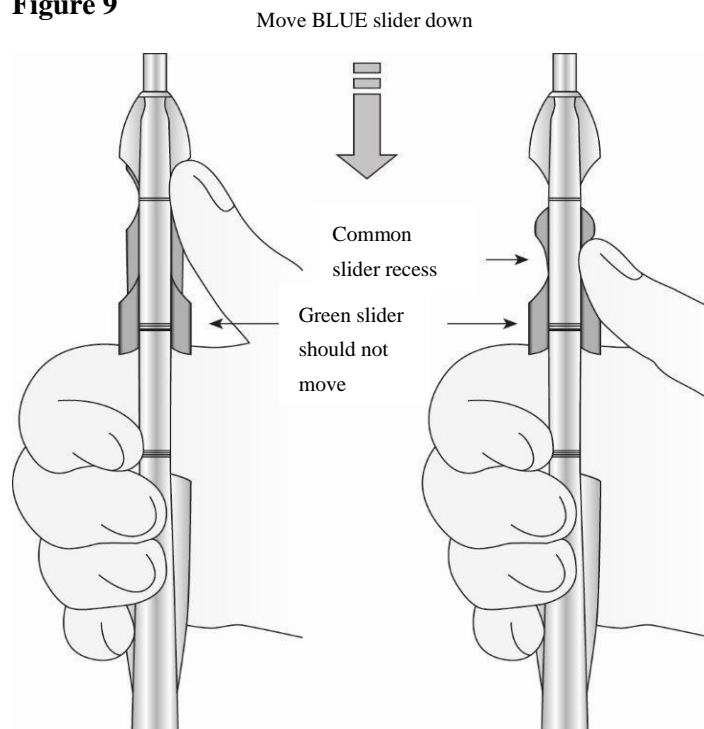
Figure 8



- Apply gentle traction on the tenaculum and continue to apply **forward pressure** on the BLUE slider while inserting the loaded insertion tube through the cervical os. Advance the tube until the upper edge of the flange is 1.5-2 cm from the external cervical os (Figure 8). Maintain forward pressure on the BLUE slider throughout the insertion process.
- DO NOT advance flange to the cervix at this time.
- DO NOT force the inserter. If necessary, dilate the cervical canal.

Step 7: Releasing and opening the arms of the IUS

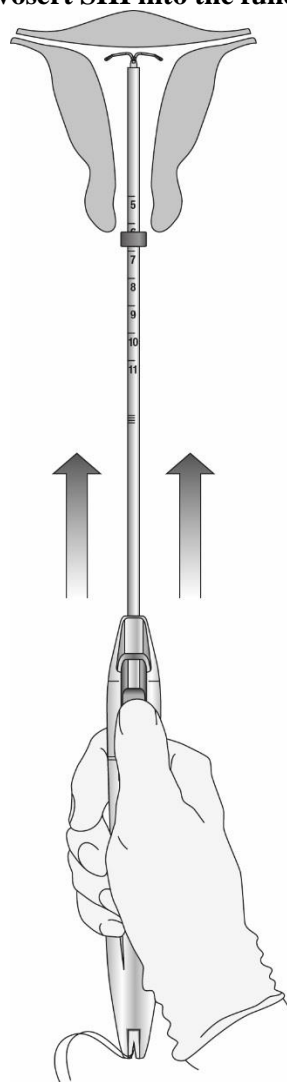
Figure 9



- Using your thumb or finger, gently slide only the BLUE slider back until you feel resistance. The BLUE and GREEN sliders will merge together to form a common slider recess. Do not move the BLUE slider any more than is necessary to create the recess. Maintain the GREEN slider so that the double line markings on the slider and the insertion handle remain aligned (Figure 9). This will allow the IUS arms to open in the lower uterine segment. Do not pull the sliders back any further as this could result in premature release of the IUS at the incorrect location.

Wait 10-15 seconds to allow for the arms of the IUS to fully open.

Figure 10: Move Levosert SHI into the fundal position



- Without moving the sliders, advance the inserter until the flange touches the cervix. If fundal resistance is encountered, do not continue to advance. Levosert SHI is now in the fundal position (Figure 10).

Note: Fundal position is important to prevent expulsions.

Step 8: Releasing Levosert SHI and procedure completion

Figure 11: Releasing Levosert SHI from the inserter tube

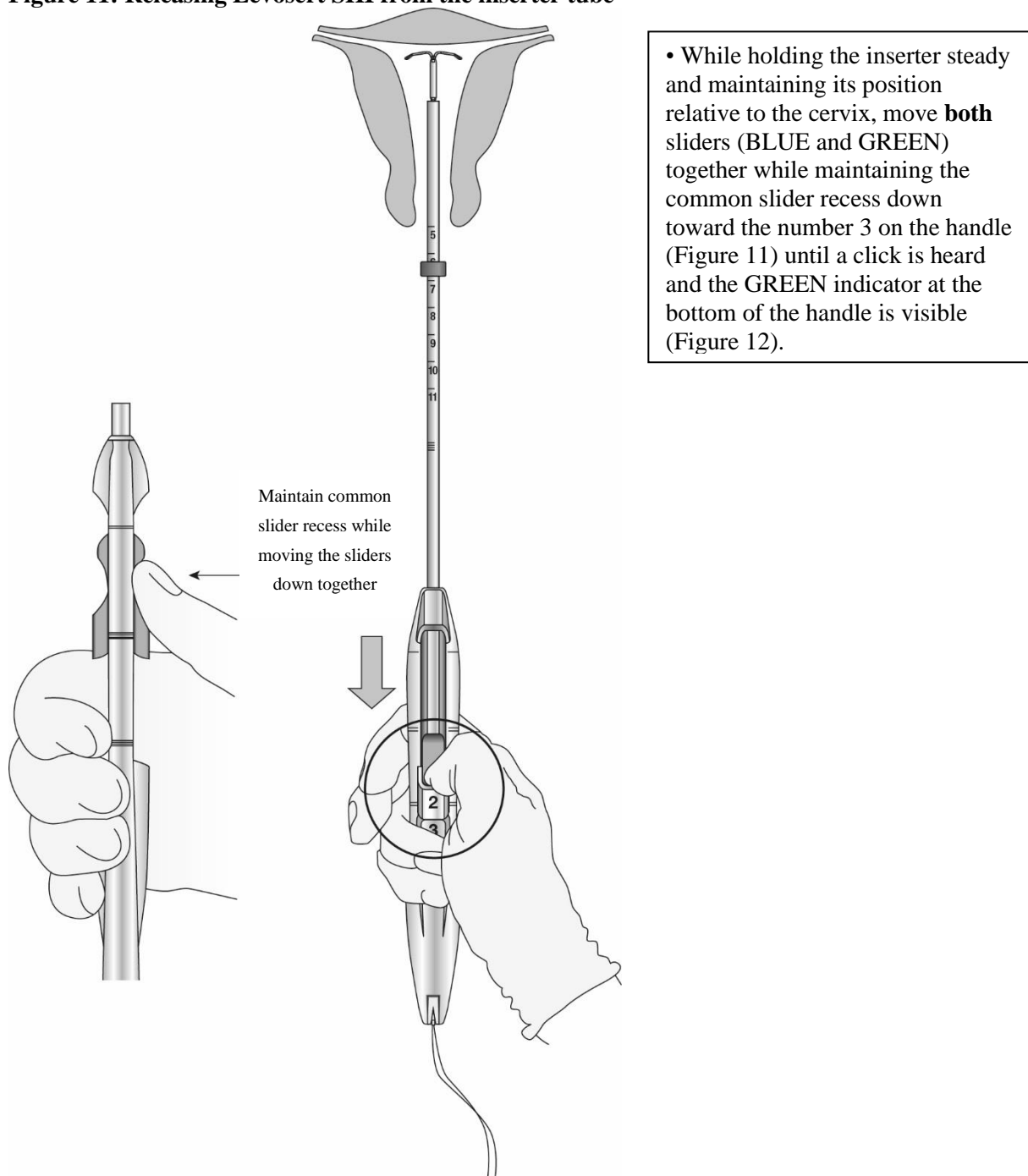


Figure 12: Green indicator visible and threads released from cleft

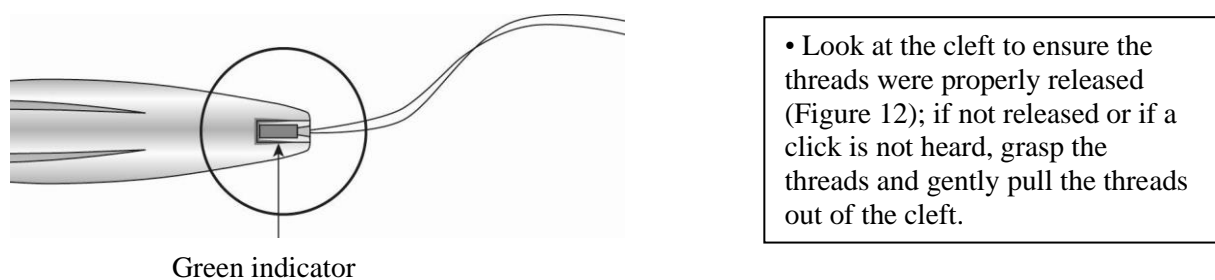
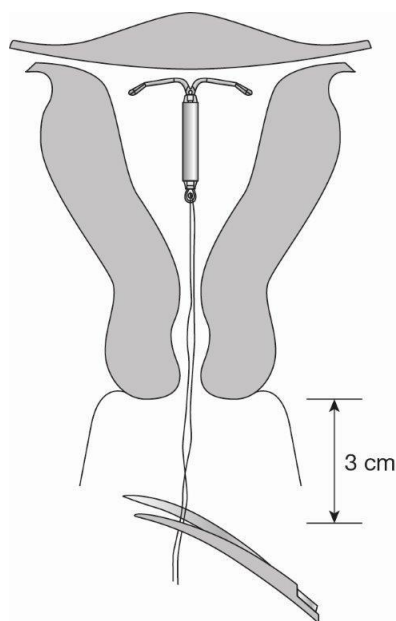


Figure 13: Cut the threads about 3 cm from the cervix



- Withdraw the inserter from the uterus.

- Use blunt-tipped sharp scissors to cut the IUS threads perpendicular to the thread length, leaving about 3 cm outside of the cervix (Figure 13).

Note: Do not cut threads at an angle as this may leave sharp ends.

- Do not apply tension or pull on the threads when cutting to prevent displacing the IUS.

Insertion of Levosert SHI 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 SHI. Do not reinsert the same Levosert SHI 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. If necessary remove the system and insert a new, sterile system.

Please report any case of uterine perforation or insertion difficulties via:

HPRA Pharmacovigilance

Website: www.hpra.ie

How to remove Levosert SHI

Levosert SHI is removed by gently pulling on the threads with forceps. If the threads are not visible and the device is in the uterine cavity, it may be removed using a narrow tenaculum or intrauterine thread retriever. This may require dilatation of the cervical canal.

If pregnancy is not desired, the removal should be carried out during the menstruation in women of fertile age, provided that there appears to be a menstrual cycle. If the system is removed in the mid-cycle and the woman has had intercourse within a week, she is at a risk of pregnancy unless a new system is inserted immediately following removal.

After removal of Levosert SHI, the device should be checked to ensure it is intact. 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.