USER PACKAGE LEAFLET

Implanon®

Please read this leaflet carefully before you decide to have Implanon inserted.
- This leaflet provides information that may help you in your decision to start using Implanon. It will also advise you how to use Implanon properly and safely. Read the leaflet also regularly while using Implanon, since it is important to stay alert on matters that do not affect you now, but may affect you in the future.
- This leaflet will provide information about the benefits and risks of Implanon. It will also advise you when to tell your doctor about health-related conditions. If you have further questions, please ask your doctor, professional health care provider or your pharmacist.

In this leaflet:

The name of your contraceptive implant is:
Implanon®, Implant for subdermal use

Composition in full
- The active substance is: etonogestrel (68 mg)
- The other ingredients are: ethylene vinylacetate

1. WHAT IS IMPLANON AND WHAT IS IT USED FOR?

Implanon is a small, flexible plastic rod, 4 cm in length and 2 mm in diameter (the implant), which contains 68 milligrams of the active substance etonogestrel, preloaded in an applicator. The rod is preloaded in the needle of the applicator, which allows the medical or health care professional to insert the implant just under the skin of your upper arm. Etonogestrel is a synthetic female hormone resembling progesterone. A small amount of etonogestrel is continuously released into the bloodstream. The rod itself is made of ethylene vinyl acetate copolymer, a plastic that will not dissolve in the body.

Implanon is used to prevent pregnancy

How does Implanon work?
The implant is inserted just below the skin. The active compound, etonogestrel, works in two ways:
- It prevents the release of an egg cell from the ovaries.
- It causes changes in the cervix that make it difficult for sperm to enter the womb.

As a result, Implanon protects you against pregnancy for a period of three years, but if you are overweight the doctor may advise you to replace the implant earlier. Implanon is one of several means of preventing pregnancy. Another frequently used birth control method is the combined Pill. In contrast to combined Pills, Implanon can be used by women who may not, or do not want to use oestrogens. When you use Implanon you do not have to remember to take a pill every day. Therefore, Implanon is very reliable, but as for all contraceptive methods protection is never 100%. When Implanon is correctly used, the chance of becoming pregnant is very low (less than 1%). In rare cases it has been reported that Implanon was not inserted correctly or was not inserted at all. This may lead to pregnancy. When you are using Implanon, your vaginal bleeding may change and become absent, irregular, infrequent, frequent, prolonged, or rarely heavy. Painful periods may improve.
You may stop using Implanon at any time (See also '*When you want to stop using Implanon*').

2. WHAT DO YOU HAVE TO KNOW BEFORE IMPLANON IS INSERTED

Hormonal contraceptives, and thus also Implanon, do not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not use Implanon
Do not use Implanon if you have any of the conditions listed below. If any of these conditions apply to you, tell your doctor before Implanon is inserted. Your doctor may advise you to use a non-hormonal method of birth control.
- if you are allergic to etonogestrel or any of the other ingredients of Implanon;
- if you have a thrombosis. Thrombosis is the formation of a blood clot in a blood vessel [for example in the legs (deep venous thrombosis) or the lungs (pulmonary embolism)];
- if you have jaundice (yellowing of the skin) or severe liver disease (when the liver is not functioning properly);
- if you have (had) or if you may have cancer of the breast or of the genital organs;
- if you have any unexplained vaginal bleeding;
- if you are pregnant or think you might be pregnant.

If any of these conditions appear for the first time while using Implanon, consult your doctor immediately. Take special care with Implanon

If Implanon is used in the presence of any of the conditions listed below, you may need to be kept under close observation. Your doctor can explain to you what to do. If any of these apply to you, tell your doctor before Implanon is inserted. **Also if the condition develops or gets worse while you are using Implanon you must tell your doctor.**
- you have or have had cancer of the breast;
- you have a liver disease;
- you have ever had a thrombosis;
- you have diabetes;
- you are overweight;
- you suffer from epilepsy;
- you suffer from tuberculosis;
- you have high blood pressure;
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so avoid too much exposure to the sun or ultraviolet radiation.

Possible serious conditions
Cancer
The information presented below has been obtained in studies with women who daily take an oral combined contraceptive containing two different female hormones ("the Pill"). It is not known whether these observations are also applicable to women who use a different hormonal contraceptive, such as implants containing only a progestogen.
Breast cancer has been found slightly more often in women using oral combined pills, but it is not known whether this is caused by the treatment. For example, it may be that tumours are found more in women on combined pills, because they are examined by the doctor more often. The increased occurrence of breast cancer becomes gradually less after stopping the combined pill. **It is important to regularly check your breasts and you should contact your doctor if you feel any lump in your breasts.** You should also tell your doctor if a close relative has or ever had breast cancer.

In rare cases, benign and even more rarely malignant liver tumours have been reported in women using the Pill. **If you experience severe abdominal pain, you should contact your doctor immediately.**

Thrombosis
A blood clot in a vein (known as a 'venous thrombosis') can block the vein. This can happen in veins in the leg, the lung (a lung embolus), or other organs.
Using any combined hormonal contraceptive increases a woman's risk of developing such clots compared with a woman not taking any combined hormonal contraceptive. The risk is not as high as the risk of developing a blood clot during pregnancy. The risk with progestogen-only methods like Implanon, is believed to be lower than in users of Pills that also contain oestrogens. **If you notice suddenly possible signs of a thrombosis, you should see your doctor immediately.** (See also "*When should you contact your doctor?*").

Vaginal bleeding
Like with other progestogen-only contraceptives, vaginal bleeding may change when using Implanon. In most women the bleeding may become unpredictable, and you may experience a change in frequency (absent, less, more frequent or continuous), intensity (reduced or increased) or in duration. Absence of bleeding was reported in about 1 of 5 women while another 1 of 5 women reported frequent and/or prolonged bleeding. Occasionally heavy bleeding has been observed. In clinical trials, bleeding changes were the most common reason for stopping treatment with Implanon (about 11 %). The bleeding pattern experienced during the first three months is broadly predictive of future bleeding patterns for many women. A changing bleeding pattern does not mean that Implanon does not suit you or is not giving you contraceptive protection. In general, you do not need to take any action. You should consult your doctor if vaginal bleeding is heavy or prolonged.

Insertion and removal related events
The implant may migrate from the original insertion site, if not correctly or too deeply inserted and/or due to external forces (e.g. manipulation of the implant or contact sports). In these cases localization of the implant may be more difficult and removal may require a larger incision. If Implanon cannot be found, and there is no evidence it has been expelled, contraception and the risk of progestogen-related undesirable effects may last longer than you want.

Ovarian cysts
During the use of all low-dose hormonal contraceptives, small fluid-filled sacs may develop in the ovaries. These are called ovarian cysts. They usually disappear on their own. Sometimes they cause mild abdominal pain. Only rarely, they may lead to more serious problems.

Using other medicines
Please tell your doctor if you are taking or have recently taken any other medicines or herbal products, including medicines obtained without a prescription. Some medicines may stop Implanon from working properly. These include medicines used for the treatment of
- o epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate),
- o tuberculosis (e.g. rifampicin),
- o HIV infections (e.g. ritonavir, nelfinavir, nevirapine),
- o other infectious diseases (e.g. griseofulvin),
- o depressive moods (the herbal remedy St. John's wort)

Implanon may also interfere with the working of other medicines; e.g. increase the activity of ciclosporin and decrease the effect of lamotrigine.
Always tell the doctor, who prescribes Implanon, which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use Implanon. They can tell you if you need to take additional non-hormonal contraceptive precautions and if so, for how long since the interaction may last up to four weeks after stopping with the medicine. They may also advise that Implanon is removed. If you want to use herbal products containing St. John's wort while you are already using Implanon you should consult your doctor first.

Using Implanon with food and drink
There are no indications of any effect of food and drink on the use of Implanon.

Pregnancy and Breast-feeding
You must not use Implanon when you are pregnant, or think you may be pregnant. In case you doubt whether you are pregnant or not, you should perform a pregnancy test before starting using Implanon.
Implanon may be used while you are breast-feeding. Implanon does not influence the production or the quality of breast milk. However, a small amount of the active substance of Implanon passes over into the breast milk. The health of breast-fed children whose mothers were using Implanon has been studied up to three years of age. No effects on the growth and development of the children were observed.
If you are breast-feeding and want to use Implanon, please contact your doctor.

Driving and using machines
There are no indications of any effect of the use of Implanon on alertness and concentration.

When should you contact your doctor?

Regular check-ups
Before Implanon is inserted, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure, and depending on your personal situation, may also carry out some other tests. When you are using Implanon, your doctor will tell you to return for a medical check-up three months after insertion of Implanon. The frequency and nature of further check-ups will depend on your personal situation.

Contact your doctor as soon as possible if:
- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also "Do not use Implanon" and "Take special care with Implanon"; do not forget about the items related to your immediate family);
- you notice possible signs of a thrombosis (e.g. severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially when if you cough up blood);
- you have a sudden, severe stomach ache or look jaundiced (indicating possible liver problems);
- you feel a lump in your breast; This symptom may indicate breast cancer (see also "*Cancer*");
- you have a sudden or severe pain in the lower part of your belly or stomach (possibly indicating an ectopic pregnancy, this is a pregnancy outside the womb);
- you have unusual, heavy vaginal bleeding; This symptom may indicate cervical cancer;
- you are to be immobilized (for example being confined to bed) or are to have surgery (consult your doctor at least four weeks in advance);
- you suspect that you are pregnant.

3. HOW TO USE IMPLANON?

Please tell your doctor if you are pregnant or think you might be pregnant before Implanon is inserted (e.g. if you had unprotected intercourse during the current menstrual cycle).

How to use
Implanon should be inserted and removed only by a doctor or a healthcare professional who is familiar with procedures as described on the other side of this leaflet. The doctor or a healthcare professional will decide in consultation with you the most suitable time for insertion. This depends on your personal situation (for example on the birth control method that you are currently using). Unless you are switching from another hormonal contraceptive method, the insertion should be performed on day 1-5 of your spontaneous menstrual bleeding to rule out pregnancy. Your doctor will advise you (for more information see overleaf Section 7.2 "When is Implanon inserted").
Before inserting or removing Implanon, your doctor will give you a local anaesthetic. Implanon is inserted directly under the skin, on the inside of your upper arm (the arm that you do not write with, See also: section 6 "Further Information"). A detailed description of the insertion and the removal procedure of Implanon is shown in section 6. **Implanon should be removed or replaced no more than 3 three years after insertion.** To help you remember when and where Implanon was inserted, and when Implanon must be removed at the latest, your doctor will give you a User card that shows this information. Store the card in a safe place!
At the end of the insertion procedure, we advise you to try to verify the presence of Implanon by feeling it (palpation). A correctly inserted implant should be clearly palpable by the medical healthcare professional as well as by you, certainly if both ends can be lifted between thumb and finger. It should be realized that palpation is not suitable for 100% verification of the presence of Implanon. In case of the slightest doubt you have to use a condom until the doctor and you are absolutely sure that the implant has been inserted. In rare cases the doctor may have to use ultrasound or magnetic resonance imaging, or may have to take a blood sample, to make sure that the implant is inside your arm.
In case you would like to have Implanon replaced, a new implant may be inserted immediately after the old implant is removed. The new implant may be inserted in the same arm and at the same site as the previous implant. Your doctor will advise you.

When you want to stop using Implanon
You can ask your doctor to remove the implant at any time you want. If the implant cannot be localized by palpation, the doctor may use ultrasound or magnetic resonance imaging to locate the implant. Depending on the exact position of the implant removal may be a little difficult and may require minor surgery.
If you do not want to become pregnant after removal of Implanon, ask your doctor about other reliable methods of birth control.
If you stop using Implanon because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Implanon can cause side effects, although not everybody gets them.
Vaginal bleeding may occur at irregular intervals during the use of Implanon. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period and requires sanitary protection. You may also not have any bleeding at all. The irregular bleedings are not a sign that the contraceptive protection of Implanon is decreased. In general, you need not take any action. If, however, bleeding is heavy or prolonged consult your doctor.

Possible serious side effects
Serious undesirable effects associated with the use of Implanon are described in the paragraphs of section 2 "Cancer" and "Thrombosis". Please read this section for additional information and consult your doctor at once where appropriate.
Users of Implanon have reported the following side effects:

Very Common (>1/10)	Common (1/10-1/100)	Uncommon (1/100-1/1000)
acne; headache; increase in body weight; breasts tenderness and pain; irregular bleeding; infection of the vagina.	hair loss; dizziness; depressive moods; emotional lability; nervousness; decreased sexual drive; increased appetite; abdominal pain; nausea; gas in stomach and intestines; painful menstruation; decrease in body weight; influenza-like symptoms; pain; fatigue; hot flushes; implant site pain; implant site reaction; ovarian cyst.	itching; itching in the genital area; rash; excessive hair growth; migraine; anxiety; sleeplessness; sleepiness; diarrhoea; vomiting; constipation; urinary tract infection; vaginal discomfort (e.g. vaginal secretion); breast enlargement; breast secretion; back pain; fever; fluid retention; difficult or painful urination; allergic reactions; inflammation and pain of the throat; rhinitis; joint pain; muscle pain; skeletal pain.

Apart from these side effects, a rise in blood pressure has occasionally been observed. You should see your doctor immediately if you experience symptoms of angioedema, such as (i) swollen face, tongue or pharynx; (ii) difficulty to swallow; or (iii) hives and difficulties to breath. During the insertion or removal of Implanon, some bruising, pain or itching may occur and in rare cases infection. A scar may be formed or an abscess may develop at the implantation site. A numb feeling or sensation of numbness (or lack of feeling) may occur. Expulsion or migration of Implanon is possible, especially if the implant has not been inserted properly. Surgery might be necessary when removing Implanon.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE IMPLANON

Keep out of the reach and sight of children.
Do not use after the expiry date which is stated on the blister and carton.
Implanon does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Implanon contains
One applicator containing one implant with
- The active substance is: etonogestrel (68 mg)
- The other ingredients are: ethylene vinyl acetate copolymer.

What Implanon looks like and the content of the pack
Implanon is a subdermal long acting hormonal contraceptive. It consists of a progestagen-only implant preloaded in a user-friendly disposable applicator. The off-white implant 4 cm in length and 2 mm in diameter contains etonogestrel. The applicator has been designed to facilitate the insertion of the implant just below the skin of your inner upper (non dominant) arm. The implant is to be inserted and removed by a physician or healthcare professional who is familiar with the procedures. For uncomplicated removal it is necessary that the implant is inserted just below the skin (see other side of the leaflet). Local anaesthetic should be used before inserting or removing the implant. The risk of complications is small if the provided instructions are followed.

These pictograms are only meant to illustrate the insertion and removal procedures *for the woman*.
NB The exact procedures for the insertion and removal of Implanon by the qualified doctor or health care professional are described in section 7 of this patient leaflet

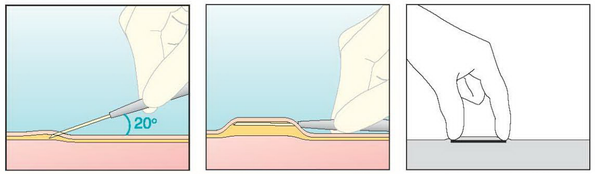

Fig. 1

Fig. 2

Fig. 3

- Stretch the skin around the insertion site with thumb and index finger (Figure 1).
- Insert first only the tip of the needle, slightly angled (~ 20°) (Figure 2).
- Release the skin.
- Lower the applicator to a horizontal position (Figure 3).
- The skin is stretched and the needle is inserted, **directly** under the skin. Once the tip is inside the skin the needle is completely inserted in a movement parallel to the skin.
- The obturator will be fixed with one hand parallel to the arm and with the other hand the physician or health care professional will slowly retract the needle out of the arm. The implant will remain in the upper arm when the needle is withdrawn.
- **We advise to try to verify the presence of the implant by feeling it (palpation) immediately following insertion. A correctly inserted implant should be clearly palpable by the medical health care professional as well as by you. It should be realized that palpation is not suitable for 100% verification of the presence of Implanon.**
- **In case the implant can not be palpated or when its presence is doubtful other methods must be used to confirm the presence of the implant.**
- **Until the presence of the implant has been verified you may not be protected against pregnancy and a contraceptive barrier method (e.g. condoms) must be used.**
- You will be given sterile gauze with a pressure bandage to minimize bruising. You may remove the pressure bandage in 24 hours and the small bandage over the insertion site in 3-5 days.
- After insertion of the implant, the doctor or health care professional will give you an User card with on it the insertion site, insertion date and the latest date on which the implant has to be removed or replaced. Put it in a safe place, since the information on the card may facilitate removal later on.

6.2 How should Implanon be removed?
- Implanon should only be removed by a qualified healthcare professional who is familiar with the procedure.
- Implanon is removed at your request or **-at the latest- three years after insertion.**
- The precise location of the insertion site of the implant is indicated on the User card.
- The healthcare professional will locate the implant. If the implant can not be located the doctor may have to use ultrasound or magnetic resonance imaging techniques.

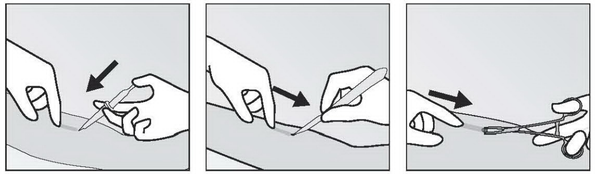
Fig. 4

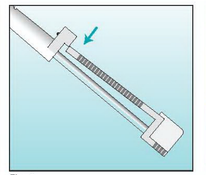
Fig. 5

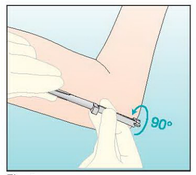

Fig. 6

- Your upper arm will be desinfected and anaesthetized.
- A small incision will be made along the arm just below the tip of the implant.
- The implant is gently pushed towards the incision and removed with a forceps.
- Occasionally, the implant may be surrounded by hard tissue. If this is the case, a small cut needs to be made into the tissue before the implant can be removed.
- If you want your doctor or health care professional to replace Implanon with another implant, the new implant may be inserted using the same incision.
- The incision will be closed by a butterfly closure.
- You will be given sterile gauze with a pressure bandage to minimize bruising. You may remove the pressure bandage in 24 hours and the small bandage over the insertion site in 3-5 days.

The following information is intended for the medical or healthcare professional

7. INFORMATION FOR THE MEDICAL OR HEALTHCARE PROFESSIONAL

7.1 How to insert Implanon
- Insertion of Implanon should be performed under aseptic conditions, and only by a physician or healthcare professional who is familiar with the procedure.
- Insertion of Implanon is performed with the specially designed applicator. The use of this applicator differs substantially from that of a classical syringe.
- The procedure used for insertion of Implanon is **opposite to giving an injection**. When inserting Implanon the **obturator** must remain fixed while the **cannula** (needle) is retracted from the arm. For normal injections the **plunger** is pushed and the **body** of the syringe remains fixed.
- Allow the subject to lie on her back with her non-dominant arm (the arm which the woman does not use for writing) turned outwards and bent at the elbow.
- To minimize the risk of neural or vascular damage, Implanon should be inserted at the inner side of the non-dominant upper arm about 8-10 cm above the medial epicondyle of the humerus.
- **Implanon should be inserted subdermally, i.e. just under the skin (subcutaneously).**
- **When Implanon is inserted too deeply (intramuscular or in the fascia) this may cause neural or vascular damage. Too deep insertions have been associated with paraesthesia (due to neural damage) and migration of the implant (due to intramuscular or fascial insertion), and in rare cases with intravascular insertion. Moreover, when the implant is inserted too deeply, it may not be palpable and the localization and/or removal can be difficult later on.**
- Mark the insertion site.
- Clean the insertion site with a disinfectant.
- Anaesthetize with an anaesthetic spray, or with 2 ml of lidocaine (1%) applied just under the skin along the 'insertion canal'.
- Remove the sterile disposable applicator carrying Implanon from its blister.
- While keeping the shield on the needle, visually verify the presence of the implant, seen as a white body inside the needle-tip. If the implant is not seen, tap the top of the needle shield against a firm surface to bring the implant into the needle tip. Following visual confirmation, the implant should be lowered back into the needle by tapping it back into the needle tip. The needle shield can now be removed.
- Please note that the implant can fall out of the needle prior to insertion. Therefore, always hold the applicator in the upward position (i.e. with the needle pointed upwards) until the time of insertion. This is to prevent the implant from dropping out. Keep the needle and the implant sterile. If contamination occurs, a new package with a new sterile applicator must be used.

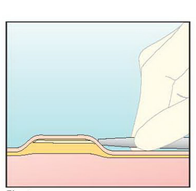
Fig. 7

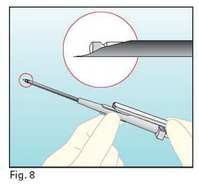
Fig. 8

- Fix the obturator with one hand parallel to the arm and with the other hand slowly retract the canula (needle) out of the arm (Figure 7).
- **Never push against the obturator.**
- Check the needle for the absence of the implant. After retraction of the canula, the grooved tip of the obturator should be visible (Figure 8).
- **Always verify the presence of the implant by palpation and also have the woman palpate it herself.**
- In case the implant can not be palpated or when the presence of the implant is doubtful, other methods must be applied to confirm its presence. Suitable methods to locate the implant are first of all ultrasound (USS) and secondly magnetic resonance imaging (MRI). In case these imaging methods fail, it is advised to verify the presence of the implant by measuring the etonogestrel level in a blood sample of the subject.
- **Until the presence of Implanon has been confirmed a contraceptive barrier method must be used.**
- Apply sterile gauze with a pressure bandage to prevent bruising.
- Fill out the User Card and hand it over to the subject to facilitate removal of the implant later on.
- The applicator is for single use only and must be adequately disposed of, in accordance with local regulations for the handling of biohazardous waste.

7.2 When to insert Implanon
No preceding hormonal contraceptive use

Implanon should be inserted between Day 1-5, but at the latest on Day 5 of the woman's natural cycle (Day 1 is the first day of her menstrual bleeding).
Changing from a combined hormonal contraceptive (combined oral contraceptive (COC), vaginal ring, or transdermal patch)
Implanon should be inserted preferably on the day after the last active tablet (the last tablet containing the active substance(s) of her previous COC, but at the latest on the day following the usual tablet-free interval or following the last placebo tablet of her previous COC. In case a vaginal ring or transdermal patch has been used, Implanon should be inserted preferably on the day of removal, but at the latest when the next application would be due.
Changing from a progestagen-only method (minipill, injectable, a different implant, or from a progestagen-releasing intrauterine system [IUS])
Implanon may be inserted any day when the woman is switching from a minipill, from another implant or an IUS on the day of its removal, from an injectable when the next injection would be due.
Following first-trimester abortion
Implanon should be inserted immediately.
Following childbirth or a second-trimester abortion
Implanon should be inserted on day 21-28 after delivery or second-trimester abortion. When the implant is inserted later, the woman should be advised to additionally use a barrier method on the first 7 days after the insertion. However, if intercourse has already occurred, pregnancy should be excluded or the woman's first natural period should be awaited before the actual insertion of the implant.

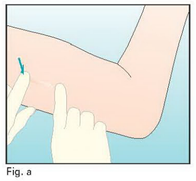
Fig. a

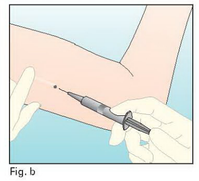
Fig. b

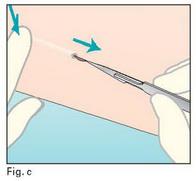
Fig. c

- Locate the implant by palpation and mark the distal end (Figure a).
- A non-palpable implant should always first be localized by either ultrasound (USS) or magnetic resonance imaging (MRI) before removal is attempted and subsequently be removed under the guidance of USS. In case of doubt, the presence of Implanon can be verified by etonogestrel determination. Exploratory surgery without knowledge of the exact localisation of the implant is strictly discouraged. Removal of deeply inserted implants should be conducted with caution in order to prevent damage to deeper neural or vascular structures in the arm and be performed by healthcare providers familiar with the anatomy of the arm.
- Wash the area and apply a disinfectant.
- Anaesthetize the arm with 0.5-1 ml lidocaine (1%) at the site of incision, which is just below the distal end of the implant. Note: Apply the anaesthetic **under** the implant. Application **above** the implant makes the skin swell, which may cause difficulties in locating the implant (Figure b).
- Push down the proximal tip to fix the implant; a bulge may appear indicating the distal end of the implant. Starting at the distal tip of the implant, make a longitudinal incision of 2 mm towards the elbow (Figure c).

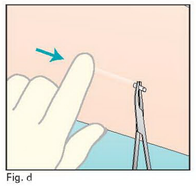
Fig. d

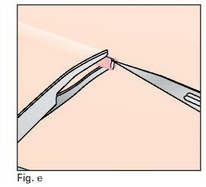
Fig. e

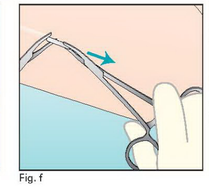
Fig. f

- Gently push the implant towards the incision until the tip is visible. Grasp the implant with forceps (preferably 'mosquito' forceps) and remove it (Figure d).
- If the tip of the implant is not visible, there might be formation of fibrotic tissue around the implant. The fibrotic tissue can be split by continuing to cut towards the distal tip, until the tip is clearly visible. Remove the implant with a forceps (Figures e and f).

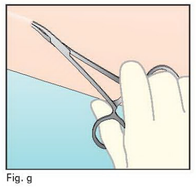
Fig. g

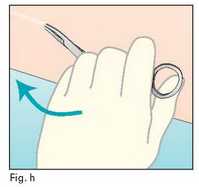
Fig. h

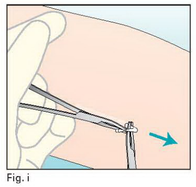
Fig. i

- If the tip of the implant is not visible, gently insert a forceps into the incision and grasp the implant (Figures g and h). With a second forceps carefully dissect the tissue around the implant. The implant can then be removed (Figure i).
- Close the incision with a butterfly closure.
- Apply sterile gauze with a pressure bandage to prevent bruising.
- There have been occasional reports of displacement of the implant usually this involves minor movement relative to the original position. This may complicate localisation of the implant by palpation, USS and/or MRI, and removal may require a larger incision and more time.
- If the woman would like to continue using Implanon, a new implant may be inserted immediately after the old implant is removed (see section 7.4 'How to replace Implanon').
- If the woman does not wish to continue using Implanon and does not want to become pregnant, another contraceptive method should be recommended.

7.3 How to remove Implanon
- Removal of Implanon should only be performed by a physician or healthcare professional who is familiar with the removal technique.
- The precise location of the insertion site of the implant is indicated on the User card.

7.4 How to replace Implanon
- Replacement of Implanon should only be performed under aseptic conditions and only by a physician who is familiar with the insertion and removal procedure.
- Immediate replacement can be done after removal of the previous implant as described in section 7.3 'How to remove Implanon'.
- The procedure to replace Implanon is similar to the insertion procedure described in section 7.1 'How to insert Implanon'. The new implant can be inserted via the same arm, and often through the same incision from which the previous implant was removed. If the same incision is being used, the instructions below must also be taken into account.
- The small incision of the removal procedure can be used as the entrance for the needle of the new applicator.
- Anaesthetize the insertion site with 2 ml lidocaine (1%) applied just under the skin commencing at the removal incision along the 'insertion canal'.
- During replacement inserting the needle to its full length is crucial; failure to do so will result in a partly visible implant in the removal incision in the skin.
- Close the incision with a butterfly closure.
- Apply a sterile gauze with a pressure bandage to prevent bruising. Let the woman keep the bandage in place for at least 24 hours to allow the removal incision to heal.

This leaflet was last approved in November 2009

CONSULT YOUR DOCTOR OR PHARMACIST IF YOU HAVE ANY QUESTIONS OR WHEN YOU WOULD LIKE TO RECEIVE THE COMPLETE PRESCRIBING INFORMATION

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THIS IS A MEDICAMENT
- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists

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