


Jadelle®

Contraceptive Implants up to 5 years

Insertion and Removal

 Bayer HealthCare
Pharmaceuticals

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HealthCare Programs
Family Planning 

Jadelle® – Contraceptive Independence

- »» Reversible contraception long-acting: up to 5 years usage with one single administration not requiring daily, weekly, monthly or quarterly remembering or action
- »» Effective: as reliable as sterilization but reversible
- »» Convenient and discreet: Jadelle® goes wherever she goes unnoticeably
- »» Cost-effective in long term use¹

Reference 1: Trussel J. in Hatcher H.A. Contraceptive Technology 17th Ed NY, Ardent media Inc. 1998



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Jadelle®

Contraceptive Implants up to 5 years Insertion and Removal

First Implants WHO-prequalified*

2 x 75mg Implants



* September 2009



Jadelle®

Contraceptive Implants up to 5 years

Introduction

On the following pages you will find the corresponding descriptions for the parts “Insertion” and “Removal” of the film.

Introduction for doctors

The package of Jadelle® implants contains two levonorgestrel-releasing implants to be inserted subdermally into the inside of the upper arm. The basis for successful use of Jadelle® implants is correct and carefully performed insertion. During insertion, special attention should be paid to the following:

- »» **asepsis**
- »» **correct placement of the implants just beneath the skin**
- »» **careful technique to minimize tissue trauma.**

This will help to avoid infections and scarring of the insertion area on one hand and, on the other hand, to keep the implants from being inserted too deep in the tissue, in which case they may be displaced. If the implants are placed too deep or displaced, they will be clearly more difficult to remove than correctly placed subdermal implants. Jadelle® implants provide 5 years of highly effective contraceptive protection. Since the method is new and intended for long-term use, it is worthwhile spending more time than usual in explaining the method to the patient and in performing the insertion.

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Insertion and Removal

Insertion

Insertion should preferably be performed during the first few days of menstrual bleeding, and not later than on the 7th day from the onset of menses.

A gynaecological examination should be performed before the insertion of Jadelle® implants as always before starting to use hormonal contraceptives. If the patient has no contraindication to progestin-only contraception and no allergy to the antiseptic or anaesthetic to be used, the implants can be inserted according to the following procedure.

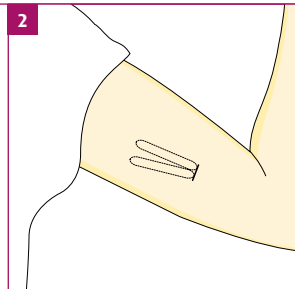
Picture 2 Ask the patient to lie down on the examination table with her non-dominant arm extended on a sterile cloth on the other table, at right angles to her body. The implants will be inserted subdermally through a small 2-mm incision, in the shape of a narrow V, opening towards the armpit.

1

Picture 1 The following equipment is needed for the insertion:

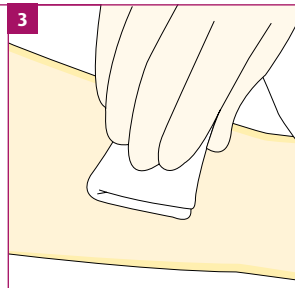
- a table for the patient to lie on and another table or rest for her arm
- sterile surgical cloths, sterile tray for the equipment, sterile gloves (free of talc), antiseptic solution for the skin.
- local anaesthetic, anaesthetic needle (5-5.5 cm long) and 5 ml syringe
- trocar, tweezers
- skin closure, sterile gauze and compresses.

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Picture 3 Clean the patient's upper arm with an antiseptic solution, and cover the arm with either two sterile clothes or a sterile fenestrated drape. The optimal insertion area is in the medial aspect of the upper arm about 6-8 cm above the fold of the elbow.



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Picture 4 Open the Jadelle pouch by pulling apart the films of the pouch and let the two implants drop on a sterile cloth. Do not touch the inside of the package or its contents with bare hands. There should be two implants.

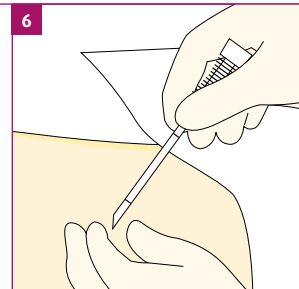
Note: Always use sterile gloves or forceps when handling the rods. If an implant is contaminated, e.g. falls on the floor, leave it for later disposal. Open a new package and continue with the procedure.

5

Picture 5 First determine the absence of known allergies to the anaesthetic agent or related drugs. Fill the syringe with 2-4 ml of local anaesthetic. Anaesthetize the insertion area by inserting the needle just under the skin about 5 to 5.5 cm in the directions where you are planning to introduce the trocar.

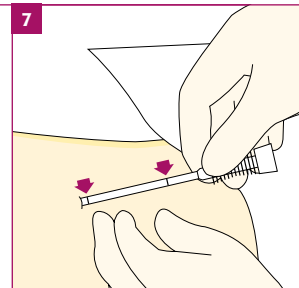
Picture 6 Jadelle is provided with a disposable trocar that is sharp enough to penetrate the skin directly. Thus the disposable trocar can be used to puncture the skin and insert the rods, without the need for an incision.

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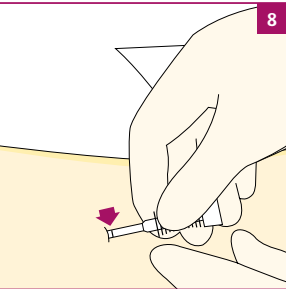
7

Picture 7 The trocar has two marks. One mark is close to the handle and one close to the tip. When inserting Jadelle implants, the mark closest to the handle indicates, how far the trocar should be introduced under the skin before the loading of each implant. The mark closest to the tip indicates how much of the trocar should be left under the skin after the insertion of the first implant. When inserting the trocar, avoid touching the part of the trocar that will go under the skin.



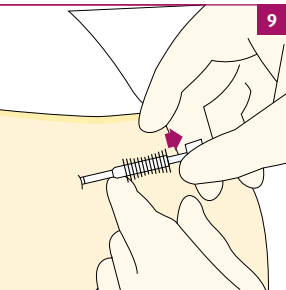
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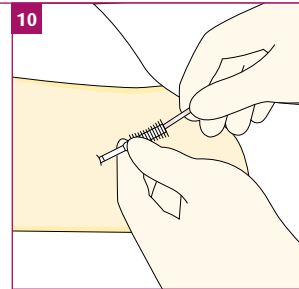
Picture 8 Once the tip of the trocar is beneath the skin it should be directed along the skin horizontally by pointing slightly up-wards toward the raising the skin (tenting) to keep the implant in the subdermal plane. Throughout the insertion procedure, the trocar should be oriented with the bevel up. It is important to keep the trocar subdermal by tenting the skin with the trocar, as failure to do so may result in deep placement of the implants causing a more difficult removal. Advance the trocar beneath the skin about 5.5 cm from the incision to the mark closest to the handle of the trocar. Do not force the trocar, and if you feel any resistance, try another direction.



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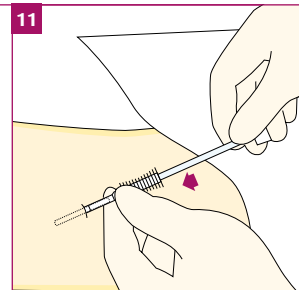
Picture 9 Remove the plunger when the trocar is advanced to the correct mark.

Picture 10 Load the first implant into the trocar either with tweezers or fingers.



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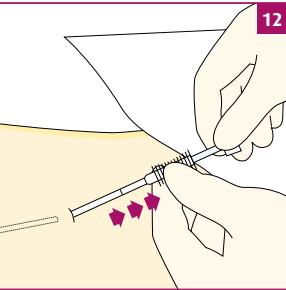
Picture 11 Push the implant gently with the plunger to the tip of the trocar until you feel resistance. Never force the plunger.



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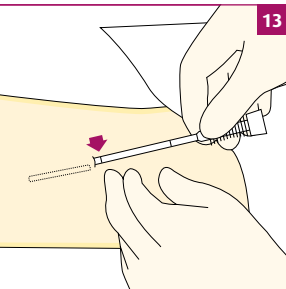
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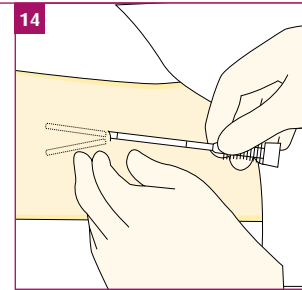
Picture 12 Hold the plunger steady and pull the trocar back along it until it touches the handle of the plunger. It is important to keep the plunger steady and not to push the implant into the tissue. Do not completely remove the trocar until both implants have been placed. The trocar is withdrawn only to the mark closest to its tip.



13

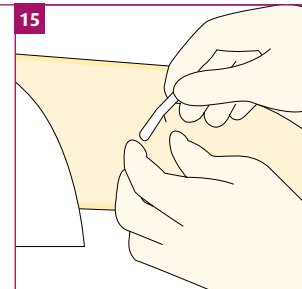
Picture 13 When you can see the mark near the tip of the trocar in the incision, the implant has been released and will remain in place beneath the skin. You can check this by palpation.

Picture 14 Insert the second implant next to the first one, to form a V shape. Fix the position of the first implant with the left fore-finger and advance the trocar along the side of the finger. This will ensure a suitable distance between implants. To prevent expulsions leave a distance of about 5 mm between the incision and the ends of the implants. You can check their correct position by cautious palpation of the insertion area.

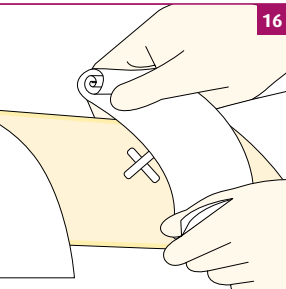


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Picture 15 After the insertion, press the edges of the incision together and close the incision with a sterile skin closure. Suturing the incision is not necessary and may even increase scarring.



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Picture 16 Cover the insertion area with a compress and wrap enough gauze around the arm to ensure haemostasis. Observe the patient at the clinic for a few minutes for signs of syncope or bleeding from the incision before she is discharged.

Advise the patient to keep the insertion area dry for three days and give her a copy of the Jadelle patient information leaflet in which you have noted the date of insertion.

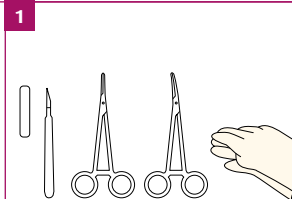
The gauze and the bandages may be removed as soon as the incision has healed usually after 3-4 days.

Removal

The removal procedure described below has been used in clinical trials. Similarly to many other surgical procedures, various techniques of removal have been published. No particular removal procedure appears to have any advantage over the others. For optimal readiness, implant removal should preferably be done on certain scheduled days. The implants shall be removed very gently, and this will usually take more time than their insertion. Implants may sometimes be nicked, cut or broken during removal. If removal proves difficult, close the incision and bandage the wound, and have the patient return for another attempt. The remaining implant(s) will be easier to remove after the area is healed. A nonhormonal method of contraception shall be used until both implants have been removed.

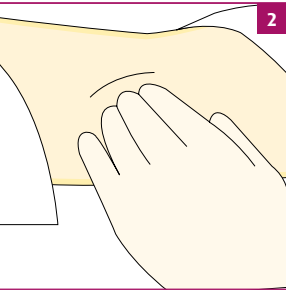
Picture 1 The following additional equipment is needed for removal:

- local anaesthetic, an anaesthetic needle and a syringe
- a scalpel
- two different types of forceps (Mosquito and Crile)
- a skin closure, gauze and compresses.



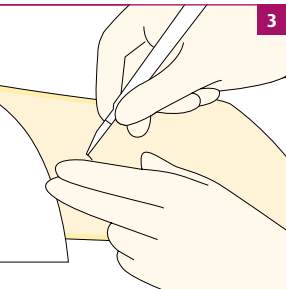
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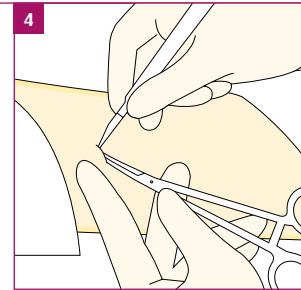
Picture 2 Locate the implants by palpation, possibly marking their position with a marker pen. If they cannot be palpated, they may be located by ultrasound or soft tissue X-ray. Inject a small amount of local anaesthetic under the ends of the implants that are closer to each other. Anaesthetic injected over the implants may obscure their position and make removal more difficult. If necessary, more anaesthetic can be given in small amounts at a time.



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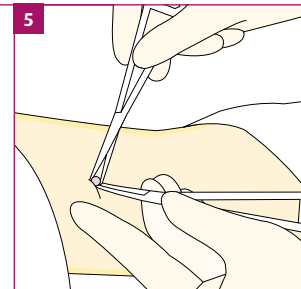
Picture 3 Make a 4-mm incision with the scalpel close to the ends of the implants. Keep the incision small.

Picture 4 Push each implant with your fingers gently towards the incision. When the tip is visible in the incision, grasp it with the Mosquito forceps. Use a scalpel to very gently open the tissue capsule around the implant.



4

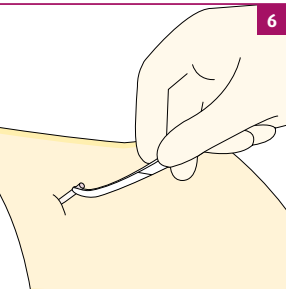
Picture 5 Grasp the end of the implant with the second forceps (Crile).



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Picture 6 Remove the implant gently. Repeat the procedure for the second implant. Measure the length of the removed implants to make sure the patient had two Jadelle implants and not other contraceptive implants. The length should be 43 mm. After the procedure is completed, close the incision and bandage it as after insertion. The arm should be kept dry for a few days.

If the patient wishes to continue using the method, a new set of Jadelle implants can be inserted through the same incision, in the same or the opposite direction.

Following removal pregnancy may occur at any time.

Abbreviated Prescribing Information:

This section is intended as general reference source on Jadelle for the international reader. For detailed information, please refer to the prescribing information of your national regulatory authority.

Jadelle 2x75mg implants

Composition: The product consists of two implants to be inserted subdermally. Each implant contains 75 mg levonorgestrel. The release rate of levonorgestrel is about 100 microgram/day at one month after insertion, declining to about 40 microgram/day within one year, to about 30 microgram/day within 3 years, and to about 25 microgram/day within five years. **Indication:** Contraception. **Method of administration:** For subcutaneous use for long-term (up to five years) contraception. The user must be informed that Jadelle can be removed at her request at any time. Training is required for the insertion and removal procedures, which should be done by a health care professional and the insertion instructions must be closely followed. Jadelle should be inserted within 7 days from the onset of menstrual bleeding. If the implants are inserted at any other time, pregnancy must be reliably excluded before insertion and an additional non-hormonal contraceptive method used for at least 7 days after the insertion. **Contraindications:** Hypersensitivity to levonorgestrel or any other component of Jadelle, Undiagnosed abnormal vaginal bleeding, Diagnosed or suspected sex hormone dependent neoplasia, Acute liver disease, Benign or malignant liver tumor, Thromboembolic disease. **Special precautions:** See full prescribing information. **Most common undesirable effects:** Headache, nervousness, dizziness, nausea, changed menstrual bleeding (frequent, irregular or prolonged menstrual bleeding, spotting, amenorrhea), cervicitis, vaginal discharge, genital pruritus, pelvic pain, breast pain, weight gain. For further details see the full prescribing information. **Marketing authorization holder:** Bayer Pharma AG (local subsidiary).



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