Jadelle®

Contraceptive Implants up to 5 years
First Implants WHO-prequalified

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Insertion
Jadelle®
Contraceptive Implants up to 5 years   First Implants WHO-prequalified®

Global HealthCare Programs
Family Planning

The implants will be inserted subdermally.
Anaesthetize the insertion area.
Use the new disposable trocar
Introduce the trocar just beneath the skin.
Advance to the ring mark, while “tenting”.

Jadelle®
Contraceptive Implants up to 5 years  First Implants WHO-prequalified®
Remove the plunger and load the first implant.
Hold the plunger steady and pull the trocar to the mark near the tip.
Advance again to the mark forming a narrow V.
Remove the plunger and load the second implant.
Hold the plunger steady while pulling the trocar back.
After the insertion close the incision with a sterile skin closure.
Removal
Locate the implants by palpation.
Inject a small amount of local anaesthetics under the narrow V-ends of the implants.
Make an incision.
Push each implant with your fingers gently towards the incision.
The implants will be inserted subdermally.

Mosquito forceps
Open the tissue capsule.
Grasp the end of implant with the crile forceps.
Release the mosquito forceps.
Remove the implant gently.
Repeat the procedure for the second implant.

After the insertion close the incision with a sterile skin closure.
Be sure that you remove both implants.
Insertion

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.

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.

Proper times for insertion are:
- within 7 days from the onset of menstrual bleeding
- immediately or within 7 days postabortion
- immediately or within 3 weeks postpartum if the woman is not breastfeeding
- from 6 weeks postpartum if the woman is breastfeeding
Insertion

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 incision by using the disposable trocar, in the shape of a narrow V, opening towards the armpit.
Insertion

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 disposable trocar.
**Insertion**

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.
Insertion

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.
Insertion

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.
Insertion

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

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

Push the implant gently with the plunger to the tip of the trocar until you feel resistance.

Never force the plunger.
Insertion

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.

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.
Insertion

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.
**Insertion**

Remove the plunger and load the second implant.
Insertion

Hold the plunger steady while pulling the trocar back.
Insertion

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.

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.
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.

The patient shall be in a similar position, and a similar aseptic technique shall be applied as for insertion.
Removal

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.
Removal

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.
Removal

Make a 4-mm incision with the scalpel close to the ends of the implants.

Keep the incision small.
Removal

Push each implant with your fingers gently towards the incision.
Removal

When the tip is visible in the incision, grasp it with the Mosquito forceps.
Removal

Use a scalpel to very gently open the tissue capsule around the implant.
Removal

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

Release the mosquito forceps.
Removal

Remove the implant gently.
Removal

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.
Removal

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.

After the procedure is completed, close the incision and bandage it as after insertion. The arm should be kept dry for a few days.
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 AG (local subsidiary).