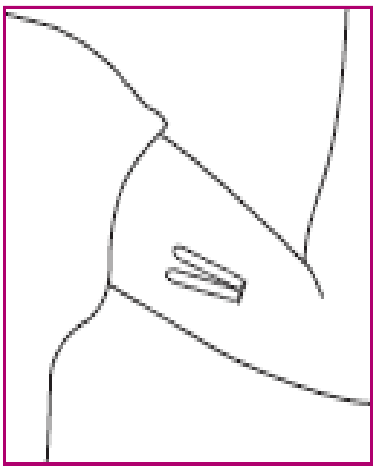
Guidelines For Service Providers on Implant (Jadelle) Insertion & Removal



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INTRODUCTION

Implant development began in 1966 with the pioneering research of Segal and Croxatto. They showed that steroid hormones could be released continuously for more than a year from silicone (Silastic) capsules implanted just under the skin.

Implants are small flexible rods or capsules that are placed just under the skin of the upper arm. Levonorgestrel (LNG) implants are the first new contraceptive to be made available since the 1960s when the oral contraceptive pill was developed, it provides safe, highly effective reversible contraception. Levonorgestrel implants are a progestin-only product; they contain no estrogen.

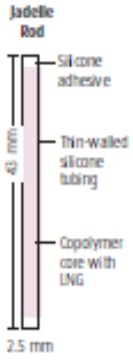
Jadelle, the latest second generation LNG implant system, has been found to be equally effective and acceptable as Norplant, the initial first generation sub-dermal implant system. Like Norplant, it provides safe, highly effective reversible contraception. Because Jadelle consists of only two rods, rather than the six capsules in Norplant, insertion and removal are easier and take less time.

1.1 Description of the Jadelle implant

Levonorgestrel implants are a progestin-only product; they contain no estrogen. A set of Jadelle implants consists of two small, flexible rods that have a core consisting of an equal mixture of levonorgestrel and silicone elastomer. The rods are covered with thin-walled silicone tubing and are sealed at the ends with silastic medical grade adhesive.

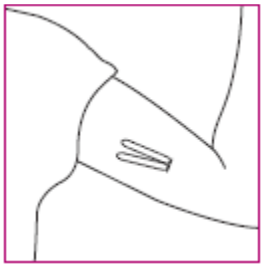
Levonorgestrel implants are a progestin-only product; they contain no estrogen. Each rod is 43 millimeters (mm) long, 2.5 mm in diameter and contains 75 mg.

Figure 1-1.
Jadelle rod, actual size



The rods are inserted just under the skin (subdermally) on the inner side of a woman's upper arm (Figure 1-2) using a minor surgical procedure with local anesthetic.

Figure 1-2. Jadelle insertion site



The rods are inserted just under the skin (subdermally) on the inner side of a woman's upper arm (Figure 1-2) using a minor surgical procedure with local anesthetic. The active contraceptive steroid in Jadelle is the progestin levonorgestrel, a chemical derivative of 19-nortestosterone. Levonorgestrel has potent progesterone-like activity, weak androgenic properties and no significant estrogen activity.

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1.2 Mechanism of action

With LNG implants, pregnancy is prevented through a combination of mechanisms. The two primary means are:

- Production of thick cervical mucus which prevents sperm penetration, and
- Inhibition of ovulation – in about 50% of menstrual cycles.

Other secondary actions, which may add to these primary contraceptive effects, include:

- Decreased natural progesterone production by the ovary during the postovulatory (luteal) phase even in those cycles in which ovulation occurs, and
- Suppression of endometrial growth (hypoplasia).

1.3 Effectiveness

One of the most effective and long - lasting methods:

Less than 1 pregnancy per 100 women using implants over the first year (5 per 10,000 women). This means that 9,995 of every 10,000 women using implants will not become pregnant.

1.4 Storage & Shelf life

The sterile packs of Jadelle rods should be stored away from excessive heat (temperatures higher than 30°C) and moisture. An unopened, undamaged sterile pack of Jadelle rods, if properly stored, has a shelf life of 5 years. The last date for insertion (expiration date) is stamped on each box.

1.5 Effective Period

If inserted any time before the expiration date (shelf life), a set of Jadelle rods is effective for 5 years.
The rods should be removed by the end of the fifth year.
If desired, a new set of rods may be inserted in the same location immediately following removal.

1.6 Advantages

- Highly effective
- Long-term method (5 years of protection)
- No daily action required
- Easy to use and requires no further action other than follow-up visits and return for removal; does not interfere with normal daily activities
- Comfortable – once the insertion site has fully healed (about 1 week), the rods should not cause any pain and are not noticeable in most women
- One of the lowest doses of any hormonal contraceptive and contains no estrogen
- A major advantage of Jadelle is that insertion and removal are easier and take less time because there are only two rods instead of the six Norplant capsules

1.7 Disadvantages

- Changes in the menstrual bleeding pattern are common (counseling should prepare the woman adequately for this)
- Insertion and removal are minor surgical procedures and may therefore be associated with bruising (discoloration of the arm), infection or bleeding
- A woman cannot discontinue the method on her own (counseling should, however, prepare her for this)
- The outline of the rods may be visible under the skin of some women, especially when the skin is stretched
- Jadelle does not protect a woman from GTIs and other STDs, including HBV and HIV/AIDS

2. COUNSELLING

Counselling is a crucial component of family planning services. It is an interactive process which is done in a systematic way to help someone to make a decision, through counselling providers help clients make informed choices of their reproductive options including pregnancy and family planning. Good counselling also helps clients select the appropriate family planning method voluntarily and use it longer and more effectively. Moreover, clients who have made an informed choice of the method are more likely to be satisfied with it too.

Box 2.1 Aspects to be covered in counselling

1. What the method is
2. How it works
3. Safety
4. Effectiveness & duration
5. Contraindications
6. Side effects and complications
7. When to use
8. How to use
9. Who will provide the method
10. Where to obtain the method
11. When to return/follow up
12. How to stop the method
13. Reuse of the method
14. Return of fertility
15. Additional information relevant to each method (e.g. myths)

Box 2.2 Tips on good counselling

- Listen effectively
- Answer questions objectively and clearly in simple language
- Reinforce important information on side effects, danger signs etc
- Let the client make his/ her own decision

2.1 Steps in family planning counseling

In a practical sense the elements of counseling fit into the three major phases of providing family planning services, namely: initial counseling at reception, individual counseling prior to service provision and follow-up counseling.

Counseling should, however, be part of every interaction with the client. Because information and counseling preferably may come from more than one source, clinic staff needs to work as a team. In addition, staffing patterns as well as client load may require shifting counseling activities to other staff or locations to meet varying needs.

2.2 Initial counseling

At the time of client reception, initial counseling (or education) may be provided by any clinic staff trained in family planning counseling. It is intended to provide the client with general information on all methods and other services offered by the clinic. Such education can be provided effectively in a group setting. Initial counseling helps the client identify an appropriate method for herself and her spouse.

Counseling in waiting areas with individuals or groups provides:

- an explanation about what the client should expect during the clinic visit,
- education about all available contraceptive methods,
- information that can help clients decide which methods they are interested in,
- education about the effectiveness of fully breastfeeding as a contraceptive method for clients up to 6 months postpartum, and
- information that may help the decision making.

Ask the client which method(s) interests her and what she knows about the method(s). This gives the service provider the opportunity to correct false rumors and misinformation, and to provide true information.

Tell the client about and discuss in greater detail how the method(s) in which she is interested works, its effectiveness, benefits, and limitations.

- Help the client choose a method. Based on the client's needs and history, the service provider should advise the client on the suitability of any method in which the client expresses an interest. This process leads to selection of a contraceptive.

- Advise the client on the possible need for further medical assessment depending on the method selected. Note: At this time the service provider conducts any physical and laboratory investigations, if indicated, to confirm the suitability of the chosen contraceptive method.

After completing the client assessment, the selected contraceptive method is provided to the client. If it is not possible to start the method at this time, she should be given an alternative method or instructions on what to do in order not to become pregnant in the interim. If the method can be provided at this time, the service provider should:
Explain simply and clearly how to use the method (or in the case of Jadelle, explain how it will be inserted) and possible problems.

After providing the method: Discuss with the client the need for return visit(s). Depending on the method, emphasis should be placed on the continuing need for supplies and their availability, advice about adverse effects, detecting problems early (warning signs) and the availability of removal services for implants.

- Ask the client to repeat all instructions to be sure she understands them. It is important for the service provider to recognize that:
- Clients are less likely to stop practicing family planning if they have frequent contact with providers.
- When appropriate reassurance is given, expected symptoms and minor adverse effects do not lead to discontinuation.

2.3 Pre-insertion counseling

Pre -insertion counseling is given at the time the rods are inserted. Any questions the woman may have regarding the insertion procedure and what she can expect (e.g. post-insertion bruising of the arm, how long it will last, etc.) should be answered. The woman should be given clear instructions on how to care for the insertion area (incision).

2.4 Post-insertion counseling

Usually is provided immediately after insertion, this is a good time to reinforce information given earlier (e.g. care of the insertion site).

Post-insertion counseling should focus on those problems (continued pain, redness or bleeding at the insertion site, fever immediately after insertion, or expulsion of a rod) that indicate the need for a quick return to the clinic.

In addition, the client should be:

- told that bruising is common and is part of the healing process; it does not require a return to the clinic;
- told whom to contact if she develops any problems or has any concerns; and
- given written information (if appropriate) telling her the date, in 5 years' time, by which she should have the rods removed and where she can go for removal.

2.5 When to return

The woman should be asked to come to clinic right away if she has;

1. Severe lower abdominal pain
2. Heavy vaginal bleeding
3. Arm pain
4. Pus or bleeding at the insertion site
5. Indicating infection
6. Expulsion of Jadelle
7. Episodes of migraine
8. Repeated severe headache or blurred vision
9. Delayed menstrual cycle after a long time of having regular cycles

2.6 Follow-up counselling

Follow-up counseling should reinforce information given post-insertion.

Service providers need to listen attentively and be prepared to answer questions about any problems the client has had. Answering questions helps clients cope with any problems or adverse effects.

At each follow-up visit, the following points should be covered:

- The woman should be asked if she is satisfied with the method and if there have been any problems since her last visit. She should be reminded that Jadelle rods need to be removed after 5 years but can be removed at any time before that time if she desires.

- The warning signs (e.g. missed menstrual period or blurred vision) that indicate the need to return to the clinic should be reviewed (see Chapter 7).

3. MEDICAL ELIGIBILITY CHECKLIST FOR JADELLE IMPLANT USERS

If, all of these conditions are negative (NO), and pregnancy is not suspected, the client may go directly for pre-insertion counseling and insertion of rods. Any positive response (YES), however, means that she may need further counseling and possible evaluation before making a final decision.

Conditions	**Yes**	**No**
Breastfeeding a baby less than 6 weeks old		
Bleeding/spotting between periods or after intercourse		
Jaundice (abnormal yellow skin or eyes)		
Severe headaches or blurred vision		
Breast cancer or suspicious (firm, non-tender or fixed) lump in the breast		
Current venous thrombosis or pulmonary embolism		
Taking drugs for epilepsy (phenytoin and barbiturates) or tuberculosis (rifampin)		

When can a woman get Implant inserted?

3.1	For a woman who is having menstrual cycle (monthly bleeding) or switching from a non-hormonal method	
		Any time of the month, • If she is starting within 7 days after the start of the menstrual cycle (monthly bleeding). No need for a backup method. • If it is more than 7 days after the start of menstrual cycle (monthly bleeding) she can get Jadelle inserted any time if it is reasonably certain she is not pregnant she will need a backup method for the 1st 7 days after insertion. If she is switching from an IUD, she can have Jadelle inserted immediately. it is recommended that the IUD be kept in place until her next monthly bleeding.
3.2	Switching from a hormonal method	• Immediately. If she has been using the method consistently & correctly or it is reasonably certain she is not pregnant. No need to wait for her next monthly bleeding. No need for a backup method. If she is switching from DMPA injectables, she can have the Jadelle inserted when next DMPA would have been given. No need for a backup method.

3.3	For a woman who is fully or nearly fully breast feeding	
	3.3.1 Less than 6 months after giving birth	• If she gave birth less than 6 weeks ago, delay insertion at least 6 weeks after giving birth. • If her menstruation has ***not*** returned, she can have the Jadelle inserted any time between 6 weeks and 6 months after giving birth. No need for a backup method. • If her menstruation has returned, she can have the Jadelle inserted as advised for women having menstrual cycles (see 4 .1)
	3.3.2 More than 6 months after giving birth	• If her menstruation has ***not*** returned, she can have the Jadelle inserted any time it is reasonably certain she is not pregnant. She will need a backup method for the first 7 days after insertion. • If her menstruation has returned, she can have the Jadelle inserted as advised for women having menstrual cycles (see 4 .1)
3.4	For a woman who is partially breast feeding	
	3.4.1 Less than 6 weeks after giving birth	• Delay inserting implants until at least 6 weeks after giving birth.
	3.4.2 More than 6 weeks after giving birth	• If her menstruation has ***not*** returned, she can have the Jadelle inserted any time it is reasonably certain she is not pregnant. She will need a backup method for the first 7 days after insertion • If her menstruation has returned, she can have the Jadelle inserted as advised for women having menstrual cycles (see 4.1)
3.5	For a woman who is not breast feeding	
	3.5.1 Less than 4 weeks after giving birth	• She can have the Jadelle inserted at any time. No need for a backup method.
	3.5.2 More than 4 weeks after giving birth	• If her menstruation has ***not*** returned, she can have the Jadelle inserted any time it is reasonably certain she is not pregnant. She will need a backup method for the first 7 days after insertion • If her menstruation has returned, she can have the Jadelle inserted as advised for women having menstrual cycles (see 4.1)

3.6	For a woman who has no monthly bleeding (not related to childbirth or breast feeding)	• Any time if it can be determined that she is not pregnant*. • She will need a backup method for the first 7 days after insertion
3.7	After taking emergency contraceptive pills (ECPs)	• Jadelle can be inserted within 7 days after the start of the menstrual cycle (monthly bleeding) or any other time it is reasonably certain she is not pregnant. Give her a backup method, or oral contraceptives to start the day after she finishes taking the ECPs, to use until the Jadelle is inserted.

4. BASIC STEPS OF IMPLANT INSERTION

4.1 Background

Insertion of Jadelle takes little time because there are only two rods. An experienced healthcare provider can insert a set of 2 rods in 3 to 5 minutes.

Remember: Correct insertion – with the rods inserted just beneath the skin (sub dermally) – makes removals relatively trouble-free.

Most problems associated with removal have been due to improper or careless insertion; therefore, only service providers trained in both insertion and removal should perform these procedures. To further minimize post-insertion problems (e.g. infection or spontaneous expulsion), all phases of the insertion process must be performed carefully and gently, using recommended infection prevention practices.

The material presented in this chapter is intended to reinforce practical training and to serve as a ready reference for any problems or questions. It cannot substitute for actual practice, which is absolutely necessary if a clinician is to become proficient in insertion of Jadelle rods.

4.2 Timing of insertion

Jadelle rods may be inserted at any time during the menstrual cycle when it is reasonably certain that the client is not pregnant or at risk of being pregnant (see Chapter 3).

Optimal times for inserting implants are:

- During menstruation (days 1-7 of the menstrual cycle)
- Post-partum after 6 weeks if breastfeeding
- Immediately or within 3 weeks if not breastfeeding
- Post abortion (immediately or within the first 7 days)

4.3 Preparation

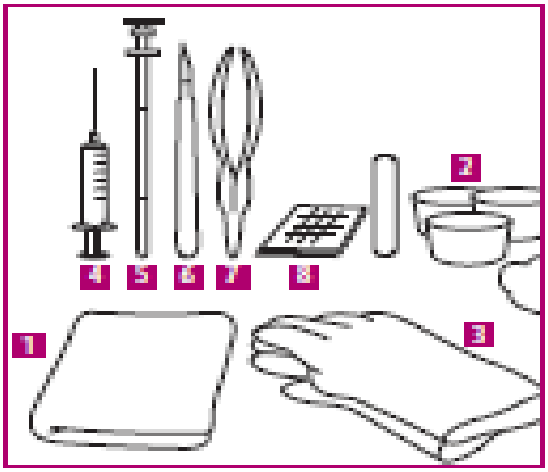
Jadelle rods are packed in sterile, heat-sealed, paper-backed pouches. They will remain sterile for the duration of the labeled 4–5-year shelf life as long as they are not damaged and are stored away from moisture and excessive heat.

Figure 4-1 Basic material for insertion, non-sterile items

The following supplies are recommended for each insertion (Figures 4-1):

1 Examining table for the woman to lie on;
2 Arm support or side table (optional);
3 Soap for washing the arm;
4 Ballpoint pen or marker;
5 Set of two rods in sterile pouch;
6 Antiseptic solution;
7 Local anesthetic (1% Lignocaine without adrenaline)

Figure 4-2 Basic material for insertion, sterile items



The sterile instruments and supplies necessary for insertion of Jadelle rods (Figure 4-2) include:

1. Sterile (or clean), dry surgical drape;
2. Three bowls (one for the antiseptic solution, one for cotton balls soaked with boiled or sterile water to remove talc from gloves and one to hold rods);
3. pair of surgical gloves;

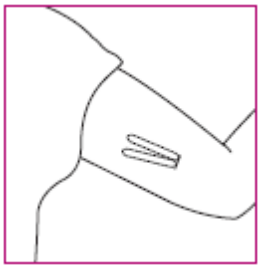
4. Syringe (5 or 10 ml) and 5 cm (2 inch) long needle (22 gauge)
5. Disposable trocar (with markings for Jadelle) with plunger
6. Ordinary Band-Aid or gauze with surgical tape;
7. Gauze and compresses; and
8. Adrenaline for anaphylactic shock (readily available for emergency use).

4.4 General procedure

The rods should be inserted beneath the skin on the inner aspect of the upper arm (Figure 6-3) about 8 cm from the elbow fold. (Usually, the arm that the woman uses less should be selected.) First have the client wash her entire arm with soap and water. Then swab the inner upper arm with an antiseptic and inject the local anesthetic.

Make a small, shallow incision, which just penetrates the skin, about 8 cm (3 inches) above the elbow fold. The rods are introduced through the incision by a specially designed 10-gauge trocar. The rods are fed through the trocar and placed just beneath the skin (subdermally) one at a time in a "V" shape. The V should open away from the elbow so that the two rods form an angle of about 15° (Figure 4-3). Sutures are not required to close the incision; a simple Band-Aid with a pressure dressing will do.

Figure 4-3 Insertion site



Remember: The rate of infection following both insertion and removal of LNG implants is low - less than 1% (Diaz et al 1991); therefore, use of prophylactic antibiotics is not recommended (Siswosudarmo 1992).

Figure 4-4 Transverse section through the left upper arm (middle third)

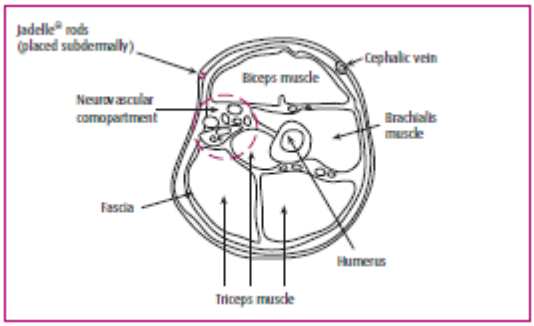


Figure 4-5 Neurovascular compartment, expanded view

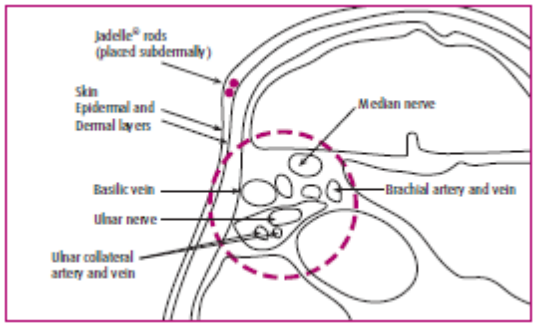


Figure 4-4 shows a cross section of the upper arm and Figure 4-5 shows a close-up view of the neurovascular compartment with the major blood vessels and veins identified. As shown in these figures, when Jadelle rods are placed correctly, they are well away from major blood vessels and nerves.

Remember:
It is important that the rods be placed sub-dermally. Deep placement will make removal much more difficult.

4.5 Step-by-step instructions for insertion

Before starting the procedure, again check to be sure whether the client:

- is taking any drugs that would decrease the effectiveness of the Jadelle rods,
- has ever had a local anesthetic before, and
- is allergic to any antiseptic solutions or local anesthetics.

Getting ready:

Step 1: Check to be sure the client has washed her entire arm with soap and water and rinsed it thoroughly, being sure to remove all traces of soap. (Residual soap
Decreases the effectiveness of some antiseptics) This step is particularly important when client hygiene is poor.

Step 2: Help position the client on the table. Her arm should be well supported and able to be comfortably extended straight or slightly bent, as the clinician prefers.

Step 3: Place a clean, dry cloth under her arm.

Step 4: Determine the optimal insertion area by measuring 8 cm (3 inches) above the elbow fold. Use the template (pattern) and mark where the incision will be made and the points for the upper end of each rod. (If an antiseptic containing alcohol will be used to prep the arm, a pen with permanent ink must be used.)

Step 5: Prepare an instrument tray and open the sterile instrument pack or high-level disinfected container without touching the instruments and other items.

Step 6: Carefully open the sterile pouch containing the 2 rods by pulling apart the sheets of the pouch and allowing the two rods to fall into a sterile bowl or onto a sterile tray. If a sterile bowl or tray is not available, the rods can be dropped into a high-level disinfected bowl or onto the tray containing the instruments.

Note: Contact with cotton or other cloth makes the rods more reactive (i.e., more apt to cause adhesions or scarring because minute particles of the cotton adhere to the rods).

If a rod falls on the floor, it is contaminated. Open a new package and continue with the procedure. (Never attempt to sterilize or high-level disinfect contaminated rods.)

4.6 Pre-insertion tasks

Step 1: Wash hands thoroughly with soap and water and dry them with a clean, dry cloth or air dry. For insertion or removal of Jadelle rods, a brief hand washing with plain soap for about 10 to 15 seconds followed by rinsing in a stream of water is sufficient.

Step 2: Put sterile or high-level disinfected surgical gloves on both hands (A separate pair of gloves must be worn for each client to avoid cross-contamination).

Note: Do not use powder with gloves. The tiny powder (talc) granules may fall into the insertion site and cause scarring (fibrous reaction). If gloves are powdered, wipe powder off gloved fingers with sterile gauze soaked in sterile or boiled water.

Step 3: Arrange instruments and supplies so that they are easily accessible. Make sure there are two rods and that they are separated. If they are stuck together, separate them with gloved fingers.

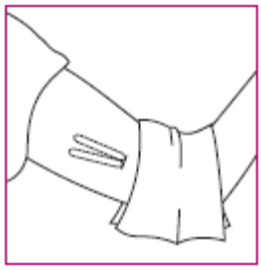
Step 4: Apply antiseptic solution to the incision area two times. Use the tissue forceps to hold a cotton or gauze swab soaked with antiseptic. (If prepping is done with a gloved hand, care must be taken not to contaminate the glove by touching any unprepped skin.)

Begin by wiping at the insertion site and move outward in a circular motion for 8 to 13 cm (3 to 5 inches). If an iodophor (e.g., povidone iodine) is used, allow to air dry for about 2 minutes before proceeding. (Iodophors require up to 2 minutes contact time to release free iodine.) Wipe off excess antiseptic only if necessary to see the template marks.

Step 5: If a sterile surgical drape with a hole in it is available, it should be used to cover the arm. The hole should be large enough to expose the area where the rods will be inserted. A second option is to cover the arm just below the insertion area with a sterile cloth.

Alternatively, a decontaminated, washed and machine-or air-dried drape or cloth can be used Figure 4-6.

Figure 4-6 Covering the arm



Step 6: After checking again to be sure the client is not allergic to the local anesthetic agent or related drugs, fill a syringe with about 2 ml of local anesthetic (1% without adrenaline). This is enough to numb the area while inserting the two rods. Explain to the client that the injection of the anesthetic will be slightly painful but that she should not feel any pain while the Jadelle rods are being inserted.

Step 7: Insert the needle just under the skin at the incision site (point closest to the elbow). Inject a very small amount of anesthetic to raise a small wheal (raised area). Then, without removing the needle, gently advance it under the skin for about 5 cm (2 inches) between where the two rods will be inserted (Figure 4-7). This will raise the skin up from the underlying soft tissue. If the needle is less than 2 inches long, push the hub of the needle against the skin so that the tip of the needle reaches between the marks on the skin nearest the shoulder.

Pull back on the plunger to be sure the needle is not in a blood vessel. As you withdraw the needle, slowly inject 1 ml of local anesthetic in a track. Experience has shown that injecting anesthetic between where the rods will be inserted provides adequate numbing and reduces the amount of local anesthetic needed. About 1 ml (cc) is needed for the track.

Place the needle in a safe area to prevent accidental needle sticks. Finally, gently rub the area injected to spread the anesthesia around; this will increase its effectiveness.

Note: To prevent local anesthetic toxicity, the total dose should not exceed 10 ml (10 grams/liter) of a 1% local anesthetic without adrenaline.

Figure 4-7. Injecting the anesthetic

4.7 Inserting the rods

Before starting, gently touch the incision site with the tip of the forceps to be sure the anesthetic is working. If the client can feel the forceps, wait 2 more minutes and retest the incision site.

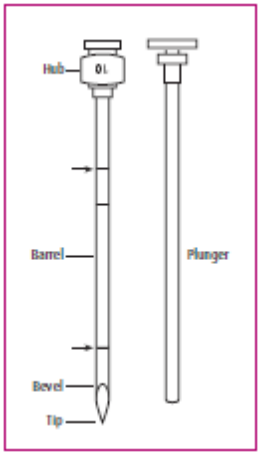
Step 1: The disposable trocar can be inserted directly through the skin without making an incision.

Step 2: The trocar should be held so that the bevel on the tip faces upward (Figure 4-8). There are three marks on the trocar; the middle mark is not used for insertion of Jadelle rods. The mark which is closest to the hub indicates how far the trocar should be subdermally inserted before loading each rod. The mark which is nearest to the tip indicates how much of the trocar should be left under the skin following the insertion of each rod.

Step 3: Insert the trocar and plunger through the incision at a shallow angle with the beveled tip of the trocar facing up. Move the trocar forward, stopping as soon as the tip is completely beneath the dermis (2 to 3 mm past the end of the bevel (Figure 4-9, upper). Never force the trocar. If resistance is met, try another angle.

Step 4: To keep the rods on a superficial plane, tilt the trocar upward while tenting the skin. Slowly and smoothly advance the trocar and plunger toward one of the marks on the skin (Figure 4-9), lower). The trocar should be positioned shallow enough so that it can be felt with a finger. It should visibly raise (tent) the skin at all times. The trocar will move easily if it is in a proper, shallow plane.

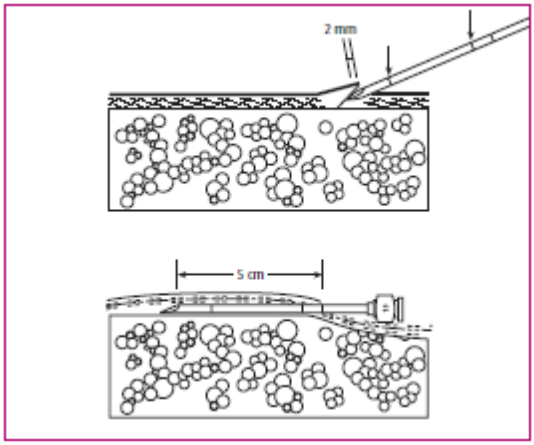
Figure 4-8 Trocar



Step 5: When the trocar has been advanced as far as the mark nearest the hub, remove the plunger from the trocar. Note: To avoid contaminating the trocar when inserting and pulling back on it, try not to touch it with your gloved fingers, especially the part of the barrel that goes under the skin.

Step 6: Load the first rod into the trocar. Use either the gloved thumb and forefinger of one hand or a forceps to pick up the rod and insert it in the trocar. Keep the other hand cupped under the trocar in order to catch the rod if it falls (Figure 4-10). Note: If the rod is picked up by hand, be sure the gloves are free of powder.

Figure 4-9. Inserting the trocar at a shallow angle



Slide the rod into the top of the trocar and reinsert the plunger (Figure 4-11).

Step 7: Use the plunger to gently advance the rod toward the tip of the trocar until you feel resistance –but never force the plunger (Resistance should be felt when the plunger is inserted about halfway into the trocar). Because the rods are soft, they will bend if pushed too hard with the plunger.

Tip: If you are not certain whether the plunger has been inserted far enough, drop the trocar to the skin and check for resistance.

Figure 4-10 Loading the rod

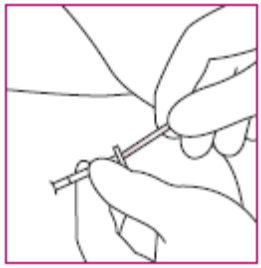


Figure 4-11 Inserting the plunger

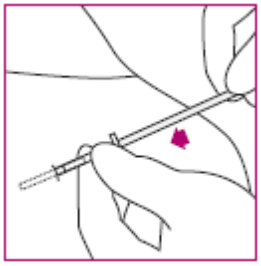


Figure 4-12 Sliding the trocar back

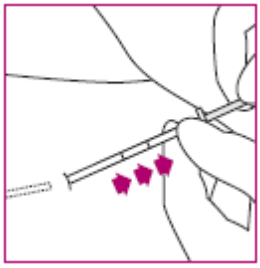
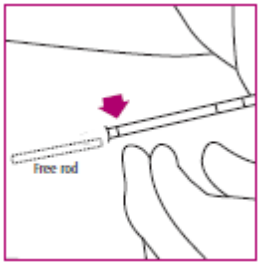


Figure 4-13 Releasing the rod

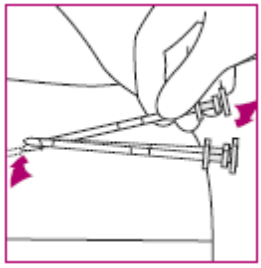


Step 8: Hold the plunger firmly in place with one hand to stabilize it. Check to be sure the trocar is still inserted to the mark nearest the hub. Then, with the thumb and forefinger, slide the barrel of the trocar back out of the incision until the mark nearest the tip just clears the incision, and the hub touches the handle of the plunger (Figure 4-12). It is important to keep the plunger steady so as not to push the rod into the tissue.

Step 9: When the hub of the trocar touches the handle of the plunger, the mark nearest the tip should be visible in the incision and the rod should now be lying beneath the skin, free of the trocar (Figure 4-13). Feel the end of the rod with a finger to make sure it is free of the trocar tip.

Step 10: Without completely removing the trocar, move the tip of the trocar laterally away from the end of the first rod (Figure 6-14) to be sure the end is completely free.

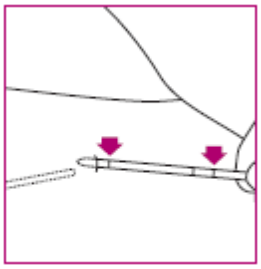
Figure 4-14 Rotating the trocar



Note: To minimize tissue trauma, decrease the chance of infection and shorten insertion time, try not to remove the trocar from the incision. Then redirect the trocar about 15°, following the "V" shape marked on the arm. Next fix the position of the first rod by placing the forefinger of the free hand over the end of the first rod (Figure 4-15).

Then slowly advance the trocar along the side of this finger toward the mark nearest the hub. Doing this will ensure a suitable distance between the rods and will keep the sharp tip of the trocar from cutting the first rod. When the mark nearest the hub is reached, load the second rod into the trocar and place it using the same technique (repeat Steps 5-9).

Figure 4-15. Fixing the position of the first rod



Step 11: Palpate the ends of the rods nearest the shoulder to be sure the rods are placed correctly.

Step 12: In order to minimize the risk of spontaneous expulsion of a rod palpate the incision area to be sure that the ends of the rods are about 5 mm away from it. The ends of the rods closest to the incision should be no farther apart than the width of a rod, 2-3 mm.

Step 13: Carefully withdraw the trocar and press down on the incision with a gauzed finger for a minute or so to stop any bleeding. Remove the drape. Clean the area around the insertion site with a small amount of sterile or high-level disinfected water or alcohol ("spirits") applied to a cotton or gauze swab.

4.8 Procedure to follow after insertion of rods

Covering the incision

- Bring the edges of the incision together and use a Band-Aid or surgical tape with sterile gauze or cotton to close the incision. Sutures are not necessary and may increase scarring.

- Check for any bleeding. Cover the insertion area with a dry piece of gauze (pressure dressing) and wrap gauze snugly around the arm to be sure there is no bleeding and to minimize the bruising (subcutaneous bleeding).

4.9 Waste disposal and decontamination

- Before removing gloves, place instruments into a container filled with 0.5% chlorine solution for decontamination (see Appendix C for how to make a solution from commercially available household bleach). Dispose of the needle and syringe by placing in a puncture-proof container. Separate the plunger from the trocar (dried blood makes it difficult to separate them later). Immerse and soak for 10 minutes. After soaking, rinse metal items immediately with clean water to avoid discoloration or corrosion of metal items.

- The surgical drape (if used) must be washed and sterilized before reuse. Place the drape in a dry covered container and remove to the designated washing area.
- While still wearing gloves, place all contaminated objects (gauze, cotton and other waste items) in a properly marked, leak-proof container with a tight-fitting lid or in a plastic bag. If the scalpel blade will be discarded, re-move the scalpel from the chlorine solution. Then take the blade off the scalpel using forceps and place it in a puncture-proof container.
- Immerse both gloved hands in 0.5% chlorine solution. Remove gloves by turning inside out.
- If disposing of gloves, place in a leak-proof container or plastic bag.
- If reusing gloves, submerge them in the 0.5% chlorine solution for 10 minutes for decontamination.
- Wash hands thoroughly with soap and water and dry with a clean, dry cloth or air dry.
- All waste material should be disposed of by burning or burying.

4.10 Client care

- Place a note in the client's record indicating the location of the rods and specifying any unusual events that may have occurred during insertion. A simple drawing showing the approximate location of the two rods in the client's arm is helpful.

- Instruct client regarding wound care (see below) and make a return visit appointment, if needed.
- Observe the client for at least 15 to 20 minutes. Check for bleeding from the incision and ask her how she feels before sending her home. She should be given written, post insertion care instructions if available and appropriate.

4.11 Client instructions for insertion site

- Keep the area around the insertion site dry and clean for at least 48 hours. The incision could become infected if the area gets wet while bathing.
- Leave the gauze pressure bandage in place for 48 hours and the Band-Aid or surgical tape in place until the incision heals (normally 3 to 5 days).
- There may be bruising, swelling or tenderness at the insertion site for a few days. This is normal.
- Routine work can be done immediately.
- Avoid bumping the area, carrying heavy loads or applying unusual pressure to the site.
- After healing, the area can be touched and washed with normal pressure.
- If the incision site becomes inflamed (red with increased heat or tenderness) or there is pus at the site, return to the clinic.

If infection occurs

- Treat infections with appropriate therapy for local wound infections (see Chapter 8).
- If there is an abscess (with or without expulsion of either rod), remove both rods.

Note: Giving antibiotics before (prophylactically) or after insertion does not reduce the risk of infection and is not necessary (Siswosudarmo 1992).

4.12 Key points for successful insertions

- Select the arm the client uses less for insertion of the rods.
- Use recommended infection prevention practices to avoid infections.
- The insertion incision should be small, just penetrating the skin.
- Use a scalpel tip or sharp trocar to make the incision.
- Make sure that the rods are placed at least 8 cm (3 inches) above the elbow fold, in the inner aspect of the arm.
- Insert the trocar with plunger in place through the incision at a shallow angle, superficially and just beneath the skin
- Never force the trocar.
- To ensure subdermal placement, the trocar should visibly raise (tent) the skin at all times.

- Make sure the first rod is completely free of the trocar before inserting the second one. (To avoid damaging the first rod, fix its position with the forefinger of the free hand and advance the trocar slowly along the side of this finger.)
- After insertion, if a rod tip protrudes from or is too close to the incision, it should be carefully repositioned in the correct position (i.e., 5 mm from the incision).
- Do not remove the tip of the trocar from the incision until both rods have been inserted and their position checked. This will help ensure that the rods are positioned correctly and inserted in a superficial plane.
- The two rods should form an angle of about 15°.
- Draw the location of the rods in the client's record and write a note if anything unusual happened during the insertion.

4.13 Record keeping

1. Complete the following records –
   - ☞ Family Planning Record- (H 1153)
   - ☞ Family Planning Client Record- (H 1155)

2. Ensure that client waits 15 minutes in the clinic before she leaves.

5. POST-INSERTION AND FOLLOW-UP CARE

5.1 Background

Long-term success, as defined by satisfied clients and high continuation rates, will occur only if clinic staff recognize the importance of providing follow-up care (including counseling) and prompt management of adverse effects as well as other problems, should they occur (WH0 1990). Most clients will not experience problems following insertion of Jadelle rods. When they do occur, however, immediate problems may include:

- pain at the insertion site that may require a mild analgesic (e.g., aspirin or ibuprofen), and
- bleeding from the incision.

Because of these potential problems, it is recommended that all clients remain at the clinic for at least 15 minutes before being discharged.

In addition, instructions for use of Jadelle should be reviewed with all clients before they leave. These include information on:

- how to care for the insertion site;
- when to come back to the clinic;
- how soon the method is effective;
- what to do if there are changes in menstrual periods or other minor adverse effects; and
- how to protect against GTIs and other STDs, including the AIDS virus.

The client should also be given specific information such as:

- the number of rods inserted (two rods),
- how long Jadelle is effective (5 years), and
- when and where to return for removal (latest after 5 years).

Finally, the client should be given a last opportunity to ask any questions she might have.

Remember: To help the client better understand and remember the most important points, be sure to explain them to her clearly and simply in her native language and to be certain she understands them clearly.

5.2 Care of insertion site

- Leave the gauze pressure bandage in place for 2 days and the Band-Aid or surgical plaster in place until the incision heals (normally 3 days).

- Keep the area around the insertion site dry and clean for at least 5 days. The incision could become infected if the area gets wet while bathing. There may be bruising, swelling or tenderness at the insertion site for a few days. This is normal
- Routine work can be done immediately. Avoid bumping the area, carrying heavy loads or applying unusual pressure to the site.
- After healing, the area can be touched and washed with normal pressure.
- If the incision site becomes inflamed (red with increased heat or tenderness) or there is pus at the site, return to the clinic.

5.3 Follow-up care

Follow up should be in the clinic as well as in the field setting. In the clinic follow up should be 6 weeks and one year after insertion and there after annually. In the field, the PHM should visit the client once a month for three months and thereafter once in 6 months. A Family Planning Field Record H-1154 should be maintained for each client.

The client should be instructed to come to the clinic because she:

- thinks she might be pregnant,
- wants to have a baby,
- wants to switch to another contraceptive methods, or
- has started any new medication that might decrease the effectiveness of Jadelle.

When possible, the client should return to the same clinic where the Jadelle rods were inserted if she has any worries or questions about the method or if she has any of the following warning signs:

- Delayed menstrual period (> 6 weeks) after several months of regular cycles (may be a sign of pregnancy)
- Severe lower abdominal pain (may be a symptom of ectopic pregnancy)
- Heavy bleeding (twice as long or twice as much as normal)
- Pus or bleeding at the insertion site
- Expulsion of a rod
- Migraine (vascular) headaches, repeated very painful headaches or blurred vision

6. REMOVAL

6.1 Background

Unlike insertion, removal of Jadelle rods can be done at any time in the menstrual cycle. As has been stressed throughout other sections of this manual, correct insertion – with the Jadelle rods placed subdermally and properly spaced – makes the removal procedure much easier.

While service providers can be trained to insert and remove Jadelle rods, a clinician skilled in removal should be consulted if difficulty in removing the rods is anticipated. Service providers need to work gently, carefully and patiently when removing the rods.

As with insertion, use of the recommended infection prevention practices is essential to minimize post-removal infections as well as the risk of disease transmission.

6.2 Preparation

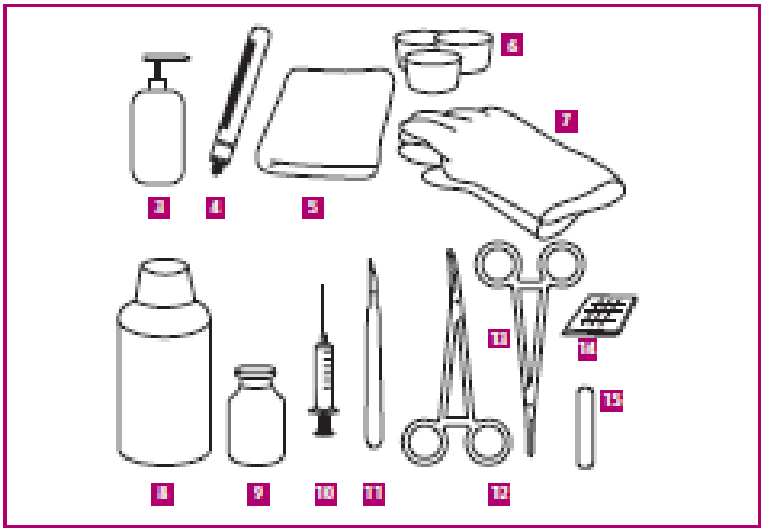
It is important that the instruments be in excellent condition (e.g., the scalpel must be sharp and the forceps should have a tight grasp). In addition, check that all instruments and other items have been sterilized or high-level disinfected.

The following items are needed for removal (Figure 6-1):

1. Examining table for the woman to lie on (optional);
2. Arm support or side table (optional);
3. Soap for washing the arm;
4. Ballpoint pen or marker;
5. Sterile (or clean) dry surgical drape;
6. Three bowls (one for the antiseptic solution, one for cotton balls soaked in boiled or sterile water to remove the talc from gloves and one containing 0.5% chlorine solution for decontaminating removed rods);
7. Pair of sterile (or high-level disinfected) surgical gloves;
8. Antiseptic solution;
9. Local anaesthetic (1% concentration without epinephrine);
10. Sterile or high-level disinfected syringe (5 or 10 ml) and 2.5 to 4 cm (1-11/2 inches) long needle (22 gauge);
11. Scalpel with #11 blade;
12. 1 curved mosquito forceps and
13. 1 Crile forceps; 1 tissue forceps (optional);
14. Ordinary Band-Aid or sterile gauze with surgical tape;
15. Sterile gauze and compresses; and

16. Adrenaline for anaphylactic shock (readily available for emergency use).

Figure 6-1. Additional equipment for removal



6.3 Pre-removal counselling

- Before removing the rods, talk with the client about her reason for removal and answer any questions.
- Ask the client about her present reproductive goals (e.g., Does she want to continue spacing or limiting births?).
- Briefly describe the removal process and what she can expect both during the removal and afterwards.

6.4 General procedure

An easy removal depends on correct insertion. Routinely, removals take slightly longer than insertions – usually from 5 to 10 minutes for Jadelle. If the rods are placed correctly – subdermally in the middle third of the upper arm, they will be easier to remove. If they are placed too deep (in the fascia muscle), removal could be difficult and could potentially damage the nerves or blood vessels in the neurovascular compartment.

It is helpful to locate the rods first with ungloved fingers. Most clinicians choose to mark the position of each rod with a ballpoint or marking pen. (When tissue swells during a difficult removal, these marks

help identify the location of the rods.) Then, the client's arm is swabbed with an antiseptic before the local anaesthetic is injected. The anaesthetic should be injected under the ends of the rods nearest the incision site; anaesthetic applied over the rods makes them difficult to feel (palpate).

Note: If all capsules or rods cannot be palpated, a provider inexperienced in removal should not begin the procedure. An experienced provider should be consulted.

Generally, only one small incision will be needed through which both rods will be removed. The incision should be no longer than 4 mm. If removal of either rod is difficult (i.e., both rods are not removed in 30 minutes), it may be better to stop the procedure for the client's comfort. In the event that one rod is left in the arm, the client should be provided with a backup contraceptive method. She should be asked to return when the area is fully healed (in about 4 to 6 weeks)
and a second attempt can be made. At that time, hard-to-find rods can be located by soft-tissue x-ray or ultrasound.

6.5 Step-by-step instructions for removal of Jadelle rods

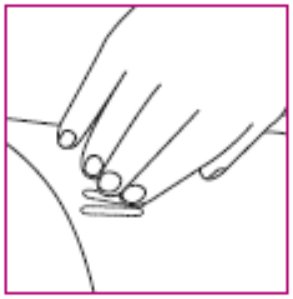
a. Getting ready

Step 1: Before starting the procedure, check to be certain the client is not allergic to antiseptic solutions or local anaesthetics.

Step 2: Check to be sure the client has washed her entire arm with soap and water, and rinsed it thoroughly, being sure to remove all traces of soap. (Residual soap decreases the effectiveness of some antiseptics.) This step is particularly important when client hygiene is poor.

Step 3: Help position the client on the table. Ask her to lie down on the table so that the arm with the rods rests on the table or arm support. Her arm should be well-supported and able to be comfortably extended straight or slightly bent, as the clinician prefers.

Figure 6-2. Palpating the rods



Tip: To make locating the rods easier, moisten fingertips with a small amount of soapy water or antiseptic solution, such as Povidone Iodine or Savlon. Doing this decreases friction between the clinician's fingertips and the client's skin and allows the rods to be more easily felt.

Step 4: Place a clean, dry cloth under her arm.

Step 5: Locate the two rods by palpation (Figure 6-2). To gauge where to make the incision, palpate the ends of the rods with bare (ungloved) fingers. (If it is difficult to find the rods, refer to the client's file where the original rod placement should be noted and a diagram may be available.)

Step 6: Confirm the position of each rod by making a mark at both ends of the rods using a ballpoint or marking pen (Figure 6-3). If an antiseptic containing alcohol will be used to prep the arm a pen with permanent ink must be used.

Figure 6-3. Marking the Skin over the Rods

Step 7: Prepare an instrument tray and open the sterile instrument pack without touching the instruments and other items.

b. Removal of Jadelle rods

Step 1: Wash hands thoroughly with soap and water and dry them with a clean, dry cloth or air dry.

Step 2: Put sterile or high-level disinfected surgical gloves on both hands. (A separate pair of gloves must be worn for each client to avoid cross-contamination.)

Note: Do not use powder with gloves. The tiny granules (talc) may fall into the removal site and cause scarring (fibrous reaction). If gloves are powdered, wipe powder off the glove fingers with sterile gauze soaked in sterile or boiled water.

Step 3: Arrange instruments and supplies so that they are easily accessible.

Step 4: Apply antiseptic solution to the removal site two times. Use the tissue forceps to hold a cotton or gauze swab soaked with antiseptic solution. (If prepping is done with a gloved hand, care must be taken not to contaminate the glove by touching any unprepped skin.)
Begin wiping at the incision site and move outward in a circular motion for 8 to 13 cm (3 to 5 inches). If an iodophor (e.g., Povidone Iodine) is used, allow to air dry for about 2 minutes before proceeding. (Iodophors require up to 2 minutes contact time to release free iodine.) Wipe off excess antiseptic only if necessary to see the pen marks.

Step 5: If a sterile surgical drape with a hole in it is available, it should be used to cover the arm. The hole should be large enough to expose the area where the rods are located. A second option is to cover the arm below where the rods have been inserted with a sterile cloth (Alternatively, a decontaminated, washed and machine or air-dried drape or cloth can be used).

Figure 6-4 Palpating the rods

Step 6: Again, locate the two rods by palpation. (Figure 6-4)

Step 7: 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.

Figure 6-5 Making an incision

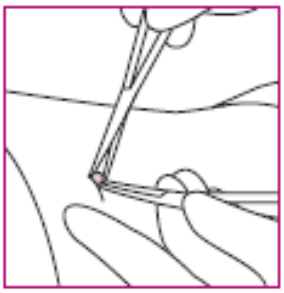
Step 8: Make a 4-mm incision with the scalpel close to the ends of the implants. Keep the incision small. (Figure 6-5)

Step 9: Push each implant gently with your fingers 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. (Figure 6-6)

Figure 6-6. Grasping the rod with mosquito forceps and opening the fibrous sheath with the scalpel

Step 10: Grasp the end of the implant with the second forceps (Crile). (Figure.6-7)
Remember: If additional anaesthetic is required, inject it under the ends of rods; anaesthetic applied over the rods makes them difficult to feel (palpate).

Figure 6-7 Grasping the rod with crile forceps



Step 11: Remove the implant gently.
Repeat the procedure for the second implant. (Figure 6-8) Measure the length of the removed implants. The length of Jadelle implants is 43 mm. This will ensure that the patient has had two Jadelle implants and not other contraceptive implants.

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

Figure 6-8. Removing the rod

If the client wishes to continue using Jadelle, see section on Insertion after Removal.

6.6 Procedure to follow after removal of rods

a. Covering the incision

- Press down on the incision with a gauzed finger for a minute or so to stop any bleeding. Remove the drape.
- If the client does not want another set of rods, clean the area around the incision site with a small amount of sterile or high level disinfected water or alcohol ("spirits") applied to a cotton or gauze swab. Use gauze covered fingers to hold the edges of the incision together briefly (10 to15 seconds). This will help reduce bleeding from the incision.
- Bring the edges of the incision together and close with a Band-Aid or surgical tape with sterile gauze or cotton. Sutures are not necessary and may increase scarring.
- Check for any bleeding. Cover the insertion area with a dry piece of gauze (pressure dressing) and wrap gauze snugly around the arm to be sure there is no bleeding and to minimize the bruising (subcutaneous bleeding).

b. Waste disposal and decontamination

- Before removing gloves, place instruments into a container filled with 0.5% chlorine solution for decontamination (see Appendix C for how to make a solution from household bleach). Fill syringe (with needle attached) with 0.5% chlorine solution and either place in solution or dispose of needle and syringe by placing in a puncture-proof container. Soak for 10 minutes. After soaking, rinse metal items immediately with clean water to avoid discoloration or corrosion.
- If the scalpel blade will be discarded, remove the scalpel from the chlorine solution. Then take the blade off the scalpel using forceps and place it in a puncture proof container.
- The surgical drape (if used) must be washed and sterilized before reuse. Place in a dry covered container and remove to the designated washing area.
- While still wearing gloves, place all contaminated objects (gauze, cotton and other waste items) in a properly marked, leak-proof container with a tight-fitting lid or in a plastic bag.
- Immerse both gloved hands in 0.5% chlorine solution. Remove gloves by turning inside out.
- If disposing of gloves, place in a leak-proof container or plastic bag.

- If reusing surgical gloves, submerge them in the 0.5% chlorine solution for 10 minutes for decontamination.
- Wash hands thoroughly with soap and water and dry with a clean, dry cloth or air dry.
- All waste material should be disposed of by burning or burying.

c. Client care

- Place a note in the client's record indicating the date of removal and specifying any unusual events that may have occurred during removal.
- Instruct the client regarding wound care (see below) and make a return visit appointment, if needed.
- Observe the client for at least 15 to 20 minutes. Check for excessive bleeding from the incision and ask how she feels before sending her home. She should be given written, post-removal care instructions if available and appropriate.

6.7 Removal tips

a. Rods That Are Difficult to Remove

Occasionally the rods cannot be removed readily at the first visit. If removal of either rod is difficult (i.e., both rods are not removed in 30 minutes), it may be better to stop the procedure for the client's comfort. In the event that one rod is left in the arm, the client should be provided with a backup contraceptive method. She should be asked to return when the area is fully healed (in about 4 to 6 weeks) and a second attempt can be made. Usually the remaining rod will be readily located and removed at the second visit.

Remember: The client should be given a backup contraceptive method to use while waiting to have the remaining rod removed if she does not wish to become pregnant.

b. Rods that cannot be palpated

There are two ways to locate rods that have been inserted too deep to feel with the fingers: x-ray and ultrasound. By using a radiopaque object to mark the original incision site, the rods, which are also radiopaque, usually can be detected by x-ray (set at 50-55 kilovolts and 4-5 milliamperes, exposure time 0.03 seconds). Their depth usually cannot be determined by a single x-ray. Thus, further examination may be required to establish their exact location. With ultrasound, the image caused by the rods can also be detected (i.e. a shadow – echo-free area – will be present under each rod). Special adjustments (positioning of the ultrasound probe) may be necessary to focus the ultrasound image.

c. Rods that are broken

Removal of the rods is more difficult if they are broken during attempts to get them out. Once the rod is damaged, it may break again with each attempt to grasp it with the Norplant-holding or curved forceps. Rarely, removal of a broken rod may require an additional incision at the proximal end of the rod (end

nearest the shoulder) so that the remaining piece can be removed more easily. Because Jadelle rods are highly elastic and do not immediately return to their original length after being stretched, it may be difficult to determine if all pieces of a broken rod have been removed. To remove remaining pieces of a broken rod through the original incision:

- Repalpate the arm to locate the missing piece(s).
- Inject more anaesthesia if necessary.
- Grasp the end of the rod with curved (mosquito or Crile) forceps and gently bring it into the incision.

6.8 Client instructions for wound care at home

- Keep the area around the insertion site dry and clean for at least 48 hours. The incision could become infected if the area gets wet while the client is bathing.
- Leave the gauze pressure bandage in place for 48 hours and the Band-Aid or surgical tape in place until the incision heals (about 3 to 5 days).
- There may be bruising, swelling or tenderness at the insertion site for a few days. This is normal.
- Routine work can be done immediately. Avoid bumping the area, carrying heavy loads or applying unusual pressure to the site.
- After healing, the area can be touched and washed with normal pressure.
- If signs of infection develop, such as inflammation (redness plus heat and increased tenderness) or pus at the site, or persistent arm pain for several days, return to the clinic.
- The fibrous tissue envelopes that surrounded the rods (tracks where the rods were located) may be felt for some time. This sensation will disappear within a few months. If infection occurs
- Treat infections with appropriate therapy for local wound infections

Note: Giving antibiotics before or after removal does not reduce the risk of infection and is not necessary.

6.9 Key points for successful removals

- An easy removal depends on correct insertion. If the rods were placed correctly, they will be easier to remove. If they were placed too deep, problems can occur.
- Routine removals should take only slightly longer than insertions – usually from 3 to 5 minutes.
- Palpate the area to identify the location of each rod and mark the position of both rods with a pen.
- Use recommended infection prevention practices to avoid infections.
- Inject small amounts of the local anaesthetic (usually not more than 1 ml total) under the rod ends nearest the original incision site. If anaesthetic is applied over the rods, it will obscure them and make removal more difficult.
- If the rods are positioned correctly, only one small incision (up to 4 mm) should be necessary for removal of both rods.

- Remove the rod that is nearer the point of the incision or closer to the surface of the skin first.
- Add incremental amounts of anaesthetic only under the rod ends.
- Control bleeding by applying pressure.
- If removal of either rod is difficult (i.e., both rods are not removed in 30 minutes), it may be better to stop the procedure for the client's comfort. In the event that both rods are not removed, ask the client to return when the incision site is fully healed (in about 4 to 6 weeks) and try again or refer to a more experienced clinician.

  Finally, and most important, the clinician should work gently, carefully and patiently to avoid injuring the client's arm.

6.10 Insertion of Jadelle after removal of Jadelle or Norplant

If the client wants to continue using Jadelle, a new set of rods can be inserted at the time the current set is removed. The rods may be placed through the incision used for removal and inserted in the same general direction as the previous set or rotated slightly to the left or right (Figure 6-9).

In the unlikely event that the removal site is unsuitable, or at the client's request, the new set can be inserted in the other arm. When levonorgestrel levels following the first insertion were compared with those following the insertion of a second set of implants, no significant difference was observed after placement in the same site or in the opposite arm (Figure 6-10). To reduce the risk of infection, after completing the removal procedure – including decontaminating instruments, gloves and other items and disposing of waste materials:

- cover the incision with a sterile gauze pad;
- remove gloves and wash hands thoroughly with soap and water;
- put on a new pair of sterile or high-level disinfected gloves;
- prep the incision area again, and put a drape on the arm (if required).

Note: Hands should be washed after removing gloves because the gloves may have invisible holes or tears. In this instance, washing hands protects the provider from any contact with blood. Because the local anaesthetic for removal is injected only in the incision area (i.e., under the ends of the rods), additional anaesthetic is needed for an insertion.

7. INFECTION PREVENTION

7.1 Background

The two primary objectives of infection prevention in family planning facilities are:

- To prevent infections when providing surgical contraceptive methods such as Jadelle
- To minimize the risk of transmitting serious infections such as hepatitis B 2 and AIDS not only to clients but also to service providers and staff, including cleaning and housekeeping personnel

Although insertion and removal of Jadelle rods are minor surgical procedures, good surgical technique, including aseptic technique, must be followed to prevent infections. Such infections are usually mild, but following insertion they are one of the reasons for early removal. Infection also may result in spontaneous expulsion of one or both rods.

To reduce the risk of infection, contaminated waste must be properly disposed of and instruments and other items should be decontaminated, thoroughly cleaned, and sterilized by autoclaving (high-pressure steam) or dry heat. If sterilization is not possible, high-level disinfection (by boiling or steaming) is the only acceptable alternative. The infection prevention (IP) practices described in this chapter are intended for use in all types of medical and healthcare facilities – from large urban hospitals to small rural clinics. They are designed to minimize costs and the need for expensive and often fragile equipment while at the same time assuring a high degree of safety.

7.2 Definitions

Micro-organisms are the causative agents of infection. They include bacteria, viruses, fungi and parasites. For infection prevention purposes, bacteria can be further divided into three categories: vegetative (staphylococcus), mycobacteria (tuberculosis) and endospores (tetanus), which are the most difficult to kill.

The terms asepsis, antisepsis, decontamination, cleaning, disinfection and sterilization are often confusing. For the purpose of this manual, the following definitions will be used:

- Asepsis and aseptic technique are general terms used to describe the combination of efforts made to prevent entry of micro-organisms into any area of the body where they are likely to cause infection. The goal of asepsis is to reduce to a safe level, or eliminate, the number of microorganisms on both animate (living) surfaces (skin and tissue) and inanimate objects (surgical instruments and other items).

- Antisepsis is the prevention of infection by killing or inhibiting the growth of micro-organisms on skin and other body tissues using a chemical agent (antiseptic).

- Decontamination is the process that makes objects safer to be handled by staff before cleaning (i.e., reduces, but does not eliminate, the number of micro-organisms on instruments and other items). Objects to be decontaminated include large surfaces (e.g. pelvic examination or operating tables) and surgical instruments, gloves and other items contaminated with blood or body fluids.

- Cleaning is the process that physically removes all visible blood, body fluids or any other foreign material such as dust or dirt from skin or inanimate objects.

- Disinfection is the process that eliminates most, but not al disease-causing micro-organisms from inanimate objects.

- High-Level Disinfection (HLD) by boiling, steaming or the use of chemicals eliminates all microorganisms except some bacterial endospores from inanimate objects.

- Sterilization is the process that eliminates all micro-organisms (bacteria, viruses, fungi and parasites) including bacterial endospores from inanimate objects.

7.3 Protective Barriers

Placing a physical, mechanical or chemical "barrier" between microorganisms and an individual, whether a client or health worker, is an effective means of preventing the spread of disease (i.e., the barrier serves to break the disease transmission cycle).
The following actions create protective barriers for infection prevention:

- hand washing;
- wearing gloves (both hands) either for surgery or when handling contaminated waste materials or soiled instruments;
- wearing appropriate attire (e.g. protective goggles, face mask or apron) when contact with blood or body fluids is possible;
- using antiseptic solutions to prepare the skin prior to inserting or removing Jadelle rods;
- using safe work practices such as not re-capping or bending needles, safely handling surgical instruments, and properly disposing of waste materials; and
- processing surgical instruments, gloves and other items after use by decontamination, cleaning and either sterilization or HLD.

7.4 Hand washing and gloves

Thorough hand washing and use of protective gloves are key components in minimizing the spread of disease and maintaining an infection- free environment. In addition, understanding when sterile or high-level disinfected surgical gloves are required and, equally important, when they are not, can reduce costs while maintaining safety for both clients and staff.

Experience has shown that the most effective way to increase hand washing is to have physicians or other respected individuals (role models) consistently wash their hands and encourage others to do the same.

Hand washing may be the single most important procedure in preventing infection. The vigorous rubbing together of all surfaces of lathered hands mechanically removes and inactivates most organisms. To encourage hand washing, program managers should make every effort to provide soap and a continual supply of clean water, either from a tap or bucket, and single use towels. Do not use shared towels to dry hands.

a. When to wash hands

Hand washing is indicated before:

- examining (direct contact with) a client, and
- putting on sterile or high-level disinfected surgical gloves for inserting or removing LNG implants.

Hand washing is indicated after:

- any situation in which hands may be contaminated, such as:
- handling soiled instruments and other items, or
- touching mucous membranes, blood or other body fluids (secretions or excretions), and
- removing gloves.

Micro-organisms grow and multiply in moisture and in standing water.

Therefore:

- If bar soap is used, provide small bars and soap racks that drain.
- Avoid dipping hands repeatedly into basins containing standing water. Even with the addition of antiseptic agents such as Dettol or Savlon, micro-organisms can survive and multiply in these solutions.
- Choose from several options when running water is not available:
- Use a bucket with a tap which can be turned off to lather hands and turned on again for rinsing, or a bucket and pitcher.
- Use an alcoholic hand rub that does not require water.

Note: A non-irritating alcohol solution can be made by adding either glycerine, propylene glycol or Sorbitol to the alcohol (2 ml in 100 ml 60-90% alcohol solution). Use 3 to 5 ml for each application and rub the solution over the hands for about 2 minutes, using a total of 6 to 10 ml per scrub.

- Dry hands with a clean, dry towel or air dry; shared towels quickly become contaminated. (Carrying one's own small towel or handkerchief is a good way to avoid using dirty towels.)
- Collect used water in a basin and discard in a toilet or latrine if a drain is not available.

b. When to wear gloves

Gloves should be worn by all staff prior to contact with blood and body fluids from any client.

Wear gloves:

- When performing a procedure, such as inserting or removing Jadelle rods, in the clinic
- When handling soiled instruments, gloves and other items
- When disposing of contaminated waste items (cotton, gauze or dressings)

A separate pair of gloves must be used for each client to avoid cross contamination.

Using disposable gloves is preferable but where resources are limited, surgical gloves can be reused if they are:

- decontaminated by soaking in 0.5% chlorine solution for10 minutes,
- washed and rinsed, and
- sterilized (by autoclaving) or high-level disinfected (by steaming or boiling).

Table 7-1. Glove requirements for Jadelle

Task or activity	Are gloves needed?	Preferred gloves	Acceptable gloves
Pelvic Examination (if necessary)	yes	Exam	HLD Surgical
Jadelle Insertion and Removal	yes	Sterile Surgical	HLD Surgical
Handling and Cleaning Instruments	yes	Utility	Exam or Surgical
Handling Contaminated Waste	yes	Utility	Exam or Surgical
Cleaning Blood or Body Fluid Spills	yes	Utility	Exam or Surgical

c. Clients and staff attire

Because insertion and removal of Jadelle rods are minor surgical procedures

(i.e., only a small skin incision is required and only superficial tissues entered):

• Clients can wear their own clothing provided it is clean.

• Staff, including the clinician, do not have to wear a cap, mask or gown.

7.5 Antisepsis

Although skin cannot be sterilized, pre-operative cleaning of the surgical site with soap and water followed by antiseptic preparation minimizes the number of microorganisms on the client's skin. Both steps are important in reducing the risk of infection following insertion or removal of Jadelle.

Infection following minor surgical procedures, such as Jadelle insertion or removal, may be caused by micro-organisms from the skin of the client or from the hands of the health-care worker. Preparing the client's skin with antiseptic solution helps prevent infection at the operative site.

a. Selection of antiseptics

Antiseptics do not have the same killing power as the chemicals used for HLD. Thus, antiseptic solutions should never be used to high-level disinfect objects such as instruments or surgical gloves. Many chemicals qualify as safe antiseptics. The following antiseptics are commonly available in different parts of the world:

- Alcohols (60-90% ethyl, isopropyl or "methylated spirit")
- Chlorhexidine gluconate (4%) (e.g., Hibiclens, Hibiscrub, Hibitane)
- Chlorhexidine gluconate and cetrimide, various concentrations (e.g., Savlon)
- Iodine (1-3%); aqueous iodine and alcohol-containing (tincture of iodine) products
- Iodophors, various concentrations (e.g., Povidone Iodine)
- Parachlorometaxylenol (PCMX or chloroxylenol), various concentrations (e.g., Dettol)

b. Safe work practices

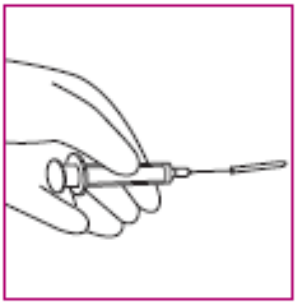
Avoiding needle stick Injuries. However, accidental needle sticks may occur.

- Surgeons and assistants are most often stuck by needles during procedures.
- Cleaning staff are most often stuck by needles when processing soiled instruments.
- Housekeeping staff are most often stuck by needles when disposing of waste material.

c. Safety tips when using hypodermic needles and syringes

- Use each needle and syringe only once.
- Do not disassemble needle and syringe after use.
- Do not recap, bend or break needles prior to disposal.3
- Decontaminate needle and syringe prior to disposal.
- Dispose of needle and syringe in a puncture-proof container if not reusing them.
- Make hypodermic needles unusable by burning them.

Figure 7-1 One-handed recap method



d. How to withdraw medication from a sterile multidose bottle

- Wipe the top of the bottle with a cotton swab soaked in 60-90% alcohol or other locally available disinfectant. Allow to dry.
- If using a new disposable needle and syringe, open the sterile pack.
- If using a sterile or high-level disinfected needle and syringe, remove from covered container using dry, sterile or high-level disinfected forceps.

Never use a syringe for more than one injection. Studies have shown that changing only the needle, not the syringe, between clients can result in transmission of HBV, and presumably HIV/AIDS.

- Attach a needle to the syringe by holding the hub (base) of the needle and the barrel of the syringe.
- Turn the bottle containing the drug upside-down and draw the fluid into the syringe using the same needle you will use for the injection.
- Withdraw the needle from the bottle.

Do not leave a needle inserted in the rubber stopper of a multiple dose bottle. This practice is dangerous because it provides a direct route for bacteria to enter the drug bottle and contaminate the fluid between each use.

Waste disposal medical waste may be non-contaminated or contaminated. Non contaminated waste (e.g., paper from offices, boxes) poses no infectious risk and can be disposed of according to local guidelines. Proper handling of contaminated waste (blood- or body fluid-contaminated items) is required to minimize the spread of infection to clinic personnel and to the local community.

Proper handling means:

- Wearing utility gloves
- Transporting solid contaminated waste to the disposal site in covered containers
- Disposing of all sharp items in puncture-resistant containers
- Carefully pouring liquid waste down a utility drain or flushable toilet or latrine
- Burning or burying contaminated solid waste
- Washing hands, gloves and containers after disposal of infectious waste area for Jadelle insertion and removal.

Any outpatient clinic or minor surgery room is a suitable area for insertion or removal of Jadelle rods. If possible, the room should be located away from heavily used areas of the clinic or hospital and should:

- have adequate lighting,
- have tile or concrete floors to make cleaning easier,
- be kept free of dust and insects, and
- be well ventilated. (If windows need to be open for ventilation, they should have tight-fitting screens.)

There should be adequate hand washing facilities including a supply of clean water (i.e., clear, not cloudy or with sediment) and a toilet or latrine nearby.

7.6 Decontamination and disinfect ion of instruments and reusable gloves

a) Place used instruments in 0.5% chlorine solution for 10 minutes for decontamination prior to cleaning and disinfecting.
b) Wipe contaminated surfaces with 0.5% chlorine solution before removing gloves.
c) Dispose waste material (gauze swabs, gloves).
d) If reusing surgical gloves immerse both gloved hands in 0.5% chlorine solution, then remove by inverting and place gloves in chlorine solution. Soak for 10 minutes (see Annex 2 for steps removing surgical gloves).
e) Wash, clean and rinse instruments and gloves, and disinfect by sterilization or High Level Disinfection (HLD)-See Annex 6.
f) Wash hands thoroughly, with soap and water.

8. MANAGEMENT OF ADVERSE EFFECTS AND OTHER PROBLEMS

8.1 Background

Most adverse effects and other problems associated with the use of LNG implants are not serious. As mentioned previously, changes in menstrual bleeding patterns are by far the most common adverse effect. In addition to menstrual bleeding changes, women using LNG implants occasionally develop enlarged ovarian follicles. Fortunately they rarely cause symptoms and are usually discovered only incidentally at pelvic examinations. In addition, they generally shrink and disappear spontaneously and rarely require treatment.

Although ectopic pregnancies have occurred in LNG implant users, clinical studies have shown that Jadelle is extremely protective against ectopic pregnancies, ranking with the most effective contraceptive methods in its protection. The risk of pregnancy (both intrauterine and ectopic) and the ratio of ectopic to intrauterine pregnancies, however, increase after 5 years of Jadelle use. Finally, several adverse conditions, which may or may not be associated with use of LNG implants, have been reported. They include headache, breast tenderness and/or discharge, weight gain, vaginal discharge, genital itching, cervicitis, nervousness, dizziness, pelvic pain, nausea and benign intercranial hypertension (pseudotumor cerebri).

In this chapter, additional information for assessing and managing the most common adverse effects and other problems is provided.

8.2 Menstrual bleeding changes

The most frequently reported adverse effect of LNG implants is a change in the menstrual bleeding pattern. Because the changes vary widely, the kind of change a particular client may experience cannot be predicted. If increased frequency of bleeding occurs, the quantity of blood lost is rarely enough to cause anemia, but there have been a few cases that required treatment with iron tablets. Fortunately these bleeding problems gradually diminish over time, becoming less frequent and bothersome after 9 to 12 months.

Despite the fact that medical treatment for prolonged or irregular bleeding is usually not necessary, the inconvenience caused by more or less continual bleeding or spotting interferes with the daily and sexual life of women. Any treatment that can quickly and reliably stop the bleeding contributes to comfort and satisfaction of LNG implant users. Therefore, clinicians should be sensitive to the importance of treating this problem if counseling and reassurance are not sufficient.

8.3 Management of vaginal bleeding problems

Irregular (< 15 day interval) bleeding as well as prolonged spotting or bleeding (8 days or more) are common and expected in LNG implant users — over 65% experienced this during the first year. In addition, moderate menstrual bleeding more than twice as long as a normal menses occurs in 20-30% of implants users during the first 3 to 6 months. For a woman with prolonged spotting or moderate bleeding, the first approach should be counseling and reassurance. It should be explained that in the absence of other causes (e.g., cervicitis or cervical polyp) this type of bleeding is not harmful, even if prolonged for several weeks. Furthermore, these prolonged bleeding or spotting episodes typically become lighter and shorter in succeeding months. If, after reassurance, the woman is still unhappy with the irregular bleeding, but wants to continue using LNG implants, a short course (1 to 3 cycles) of COCs may be tried using:

- a low-dose COCs (30-35 pg EE) once daily for 21 days If COCs are not appropriate for personal or medical reasons, try:
- Ibuprofen (or another NSAID) up to 800 mg 3 times daily for 5 days

Combined oral contraceptives control or stop bleeding by rebuilding the endometrium while ibuprofen, which blocks prostaglandin synthesis, decreases uterine contractions and blood flow to the endometrium.

Heavy bleeding (twice as long or twice as much as normal) is very uncommon with LNG implants. But usually can be managed with low-dose COCs (with or without ibuprofen).
If the bleeding is not reduced in 3 to 5 days or is much heavier (1 to 2 pads or cloths per hour):

- Determine whether there are other causes for the uterine bleeding.
- Give 2 low-dose COC pills per day for the remainder of the cycle (at least 3 to 7 days), followed by 1 cycle (1 pill per day) of COCs.

Note: Check to be sure vaginal bleeding has decreased within 3 days.

If COCs or estrogens fail to correct the bleeding problem, the implants may need to be removed for medical reasons (excessive bleeding) or due to the client's wishes.
Do not perform a D&C unless another medical condition (e.g., endometrial polyp or incomplete abortion) is suspected. (If uterine evacuation is necessary, manual vacuum aspiration, not D&C, is the preferred method for emptying the uterine cavity.)

For anemia, give nutritional advice on the need to increase iron intake. Use oral iron treatment (one tablet containing at least 100 mg elemental iron, $FeSO_4$, daily for 1 to 3 months) if hemoglobin ≤ 9 g/dl or hematocrit ≤ 27

8.4 Management of most common adverse effects

The steps in evaluating and managing adverse effects associated with use of the LNG implants Jadelle are outlined below:

Adverse effects	Assessment	Management
Amenorrhea (absence of vaginal bleeding or spotting)	Check for pregnancy (intrauterine or ectopic) by history, checking symptoms and performing a pelvic examination (speculum and bimanual) or a pregnancy test, if indicated and available (see Chapter 4).	Amenorrhea occurs in about 7% of LNG implants users in the first year and decreases thereafter. Amenorrhea for 6 weeks or more, especially after a pattern of regular menses, may signal pregnancy and should be evaluated. If intrauterine pregnancy is confirmed, counsel client regarding options. If the pregnancy will be continued, remove rods and assure her that the small dose of LNG to which she was exposed will have no harmful effect on the fetus. If miscarriage (spontaneous abortion) occurs (or pregnancy will not be continued), it is not necessary to remove the LNG implants. If ectopic pregnancy is suspected, refer at once for complete evaluation. Do not give hormonal treatment (COCs) to induce withdrawal bleeding. It is not necessary and usually is not successful unless 2 or 3 cycles of COCs are given.
Bleeding/Spotting (prolonged spotting or moderate bleeding) Prolonged spotting: > 8 days	Perform pelvic examination (speculum and bimanual) to be sure bleeding is not due to other causes (i.e. genital tract problems such as vaginitis, cervicitis, cervical polyps or uterine fibroids).	If an abnormality of the genital tract is found, after counseling, treat the problem or refer for further evaluation. Do not remove rods. Advise client to return for additional counseling after management of problem(s).
Moderate bleeding: ≥ normal menses, 50-80 ml	If pregnancy (intrauterine or ectopic) or incomplete abortion is suspected, examine and perform pregnancy test if indicated and available.	See Amenorrhea (above) for management of pregnancy-related conditions. Reassure client that light, intermenstrual bleeding or spotting occurs in a large percentage of women using LNG implants (50-80% of women during the first few months of use). It is not serious and usually does not require treatment. Most women can expect the altered bleeding pattern to become more regular after 6 to 12 months (Population Council 1990). If the client is not satisfied after counseling and reassurance, but wants to continue using implants, two treatment options are: • a cycle of COCs (30-35 pg EE), or • ibuprofen (up to 800 mg 3 times daily for 5 days) or other NSAID

		(TGWG 1994). Be sure to tell the client to expect bleeding during the week after completing the COCs (21-pill pack) or during the last 7 pills if 28-pill pack.
Bleeding Prolonged or heavy bleeding Prolonged bleeding: > 8 days	Perform pelvic examination (speculum and bimanual) to be sure bleeding is not due to other causes (e.g., genital tract problems such as vaginitis, cervicitis, cervical polyps or uterine fibroids).	If an abnormality of the genital tract is found, treat the problem and counsel the client or refer for further evaluation. Do not remove rods. Advise client to re-turn for additional counseling after management of problem(s).
Heavy bleeding: twice as long or twice as much as normal	If pregnancy (intrauterine or ectopic) or incomplete abortion is suspected, examine and perform pregnancy test if indicated and available.	See Amenorrhea above for management of pregnancy-related conditions.
	If no genital tract abnormality noted, check for significant anemia (pale conjunctiva or nail beds, low hematocrit or hemoglobin)	For hemoglobin < 9 g/dl or hematocrit 27, give iron (FeSO4, 1 tablet containing at least 100 mg elemental iron, daily for 1 to 3 months) and nutritional counseling. If anemia persists or client requests, remove rods and help client choose another method. **Note:** Despite the increased frequency of bleeding in some women, the monthly blood loss in LNG implants users usually is less than with normal menses in non contracepting women. In some users, hemoglobin levels increase over time. More women have increases than have decreases in hemoglobin (Population council 1990)
Prolonged or heavy bleeding cont…	No other cause found, but client has prolonged bleeding or amount is more than normal menses	If the client is not satisfied after counseling and reassurance, but wants to continue using implants, two treatment options are: • a cycle of COCs (30-35 pg EE), or • ibuprofen (up to 800 mg 3 times daily for 5 days) or other NSAID. Be sure to tell the client to expect bleeding during the week after completing the COCs (21-pill pack) or during the last 7 pills if 28-pill pack.
	No other cause found, but bleeding is: • not reduced in 3-5 days, or • much heavier (1-2 pads per hour).	If client wants to continue using implants, give: • 2 COC pills per day for the remainder of the cycle (at least 3-7 days) followed by 1 cycle (1 pill per day) of COCs, or 1.25 mg conjugated estrogen for 14-21 days.
	Take history, perform abdominal and pelvic (speculum and bimanual) examinations. Check vital signs:	**Refer immediately** if the client has any of the following: • Moderate to severe lower abdominal tenderness (rebound)

	• Pulse • Blood pressure • Temperature Examine to rule out: • Ectopic pregnancy • PID • Appendicitis • Ovarian cysts Do lab tests for Hb/Hct and pregnancy test if indicated and available.	• Elevated resting pulse (> 100 BPM) • Decreased blood pressure (< 90/60 mm Hg) • Elevated temperature (> 38°C) • Suspected/confirmed pregnancy and acute anemia (e.g., Hb < 9 g/dl or Hct < 27) In some women with LNG implants, ovarian follicles develop and their shrinkage (atresia) is sometimes delayed. In these instances, the follicle may continue to grow beyond the size it would attain in a normal cycle. These enlarged follicles cannot be is distinguished from ovarian cysts. They usually occur during the first 6 months of use, generally are asymptomatic and often are palpable.
Lower abdominal/pelvic pain (with or without symptoms of pregnancy)		In most cases the enlarged follicles disappear spontaneously and should not require treatment or removal of rods. Rarely, they may twist or rupture, sometimes causing abdominal pain, and surgical intervention may be required.
	Check history for exposure to GTIs and other STDs (e.g., HBV, HIV/AIDS) and examine for vaginitis, purulent cervicitis or beefy red cervix. Examine saline and KOH wet mounts of vaginal discharge for trichomonas, monilia (Candida) and Gardnerella.	Obtaining an accurate history will facilitate diagnosis and treatment. If cervicitis (mucopus or beefy red cervix), check Gram's stain of cervical discharge. If saline or KOH wet mounts are positive, treat appropriately for specific organism.
Vaginal discharge	Observe for gram negative intracellular diplococci (GNIDs) and WBC (PMNs). If Gram's stain negative, obtain GC culture if available	If positive for GNIDs, treat for gonorrhea. If negative for GNIDs and purulent cervicitis or beefy red cervix, treat for chlamydia
Weight gain or loss (change in appetite)	Compare weight prior to implants use (if known) and current weight. Check for pregnancy. Check that the client is eating and exercising properly.	Counsel client that normal fluctuations of 1 to 2 kg (2 to 4 lbs) may occur. Review diet if weight change is excessive (• } 2 kg or more). If weight gain (or loss) is unacceptable, even after counseling, remove rods and help client choose another method

8.5 Management of health problems

Clients may present with other problems which may or may not be method-related. The assessment and management of these problems are presented below.

Adverse effect	Assessment	Management
Acne	Ask how and how often she cleans her face. Ask if she is currently under great stress	In some women, implants use can make acne worse. Recommend cleaning face twice a day and avoiding use of heavy facial creams. Counsel as appropriate. If condition is not tolerable, help client choose another (nonhormonal) method.
Breast fullness or tenderness (mastalgia)	Check for pregnancy.	**If pregnant**, manage as described in Amenorrhea. If **not pregnant**, do not remove rods unless client requests it after counseling.
	Check breasts for: • lumps or cysts, and • discharge or galactorrhea (leakage of milk-like fluid), if not breastfeeding.	If physical examination shows lump or discharge suspicious for cancer (e.g., firm, non-tender or fixed and which does not change during menstrual cycle), refer to appropriate source for diagnosis. If no abnormality, reassure.
	If she is breastfeeding and breast(s) is tender, examine for breast infection.	If breast(s) is not infected, recommend a bra that provides additional support. If breast infection, use warm compresses, advise to continue breast-feeding and give antibiotics as appropriate. For any of the above conditions, do not remove rods unless client requests it after counseling.
Chest pain (especially if it occurs with exercise	Assess for possible cardiovascular disease (CVD). Also, check: • Blood pressure • Heart for irregular beats (arrhythmias)	If evidence for CVD, refer for further evaluation. Low-dose progestins do not increase the risk of CVD but if acute venous thrombosis or pulmonary embolism is diagnosed, remove implants and help client choose another (nonhormonal) method.
Depression (mood changes or loss of libido)	Discuss changes in mood or libido.	Depression or loss of libido may be associated with progestins; therefore, if the client thinks her depression has worsened while using LNG implants, help her choose another method.

Excess hair growth (hirsutism) or hair loss	Review history, before and after insertion	Pre-existing conditions such as excess facial or body hair might be worsened by implants use. Changes usually are not excessive, may improve over time, and do not require rod removal unless client requests it after counseling
Headache (especially with blurred vision)	Ask if there has been a change in pattern or severity of headaches since insertion of implants. Perform physical examination, measure blood pressure. Examine as appropriate: • Eyes (fundoscopic) • Neurologic system	If headaches are mild, treat with analgesics and reassure. Re-evaluate after 1 month if mild headaches persist. If headaches have changed since starting implants (i.e., numbness or tingling accompanied by loss of speech, visual changes or blurred vision) remove implants and help client choose another (nonhormonal) method
High blood pressure (> 180/110 mm Hg)	Ask if this is the first time anyone has told her that she has high blood pressure. Allow 15 minutes rest, then repeat BP reading.	Counsel client that a mild increase in blood pressure (< 180/110) does not require removal of implants unless she requests it. If requested, help the client choose another method. In addition, tell her that high BP usually goes away within 1 to 3 months. Take BP monthly to be sure it returns to normal. If after 3 months it has not returned to normal, refer for further evaluation. If BP > 180/110 or she has arterial vascular problems (e.g., heart attack, stroke, kidney failure or retinopathy), the implants should be removed. Help her choose another method.
Idiopathic intracranial hypertension, **benign** (pseudotumor cerebri)	Review history for headache, dizziness or generalized weakness. Examine: • Eyes (fundoscopic) for retinal swelling (papilledema) • Neurological system	No cause and effect relationship has been established. Because of the seriousness of the condition, removal of implants is recommended. Help the client choose another method.
Rod coming out	Check for partial or complete expulsion of rod	Remove partially expelled rod. Check to determine if remaining rod is in place. • If area of insertion is not infected (no pain, heat and redness), replace rod. • If area of insertion is infected: • remove remaining rod • insert a new set in the other arm, or • help the client choose another method.
Infection at insertion site	Check area of insertion for infection (pain, heat and redness), pus or abscess.	If infection (not abscess), wash area with soap and water and give appropriate oral antibiotic for 7 days. Do not remove rods. Ask client to return after 1 week. If no improvement, remove rods

		and insert a new set in the other arm or help client choose another method. If abscess: • Prep with antiseptic. • Incise and drain. • Remove rods. • Perform daily wound care. • Give oral antibiotics for 7 days. Insert new set in the other arm or help client choose another method.
"Missing" rods	Usually due to rods being inserted too deep (not palpable) or, rarely, a rod spontaneously expelled and forgotten by the client.	Can almost always be detected by x-ray or sonography. If regular sonography is used, the focal length needs to be increased to about 15 cm to focus accurately. Rods are best seen in cross-section (transverse) as a shadow (echo-free area) underneath each rod.2 If both rods are present, note this in the client's chart. If removal will be difficult, an expert in LNG implants removal should be consulted.
Jaundice	Acute jaundice occurring after insertion is not method-related. Check for: • Active liver disease (hepatitis) • Gall bladder disease • Benign or malignant liver tumors	Levonorgestrel has little effect on liver function and does not increase the risk of liver tumors. If the client has jaundice due to viral hepatitis and does not want to stop using LNG implants, it is unlikely that they will worsen liver disease and their use is safer than pregnancy. If pregnant, manage as above. (See Amenorrhea).
Nausea/Dizziness/Vomiting	Check for pregnancy by checking symptoms, performing a pelvic examination (speculum and bimanual) and a pregnancy test (if indicated and available).	If not pregnant, reassure that this is not a serious problem(s) and usually disappears with time.
Thromboembolic disorders (including blood clots in legs, lungs or eyes)	Assess for **active** blood clotting problem.	Even if levonorgestrel implants do not increase the risk of blood clotting problems (WHO 1996), remove rods because of seriousness of these conditions. If there is strong evidence of blood clotting disorder, refer for further evaluation.

REFERENCES

1. Jadelle Training Manual for Family Planning, Social Health Care Programs
2. Family Planning a Global Hand Book for Providers, WHO, USAID, JHBSPH, 2008
3. Medical Eligibility Criteria Wheel for Contraceptive Use, WHO, 2008 Update
4. Family Planning: A Global Hand Book for Providers, 2008, page 110

Annex 1: Frequently asked Questions

1. How effective is Jadelle?

No contraceptive is 100% effective; however, Jadelle is one of the most effective contraceptives available. For every 100 women who use it for 5 years, 1 will become pregnant. That is a lower user failure rate than for the oral contraceptive pill, the Copper T 380A IUD, progestin-only injectables (DMPA), levonorgestrel-IUS and voluntary sterilization.

2. How quickly does Jadelle become effective?

Implants become effective within 24 hours after insertion. If they are not inserted by the seventh day of the menstrual period, however, use of a backup contraceptive method for 7 days is recommended.

3. How long will Jadelle be effective?

Jadelle is approved for 5 years of use, but the rods can be removed earlier if desired or necessary. Both rods are needed for protection, even if the method is used for less than 5 years.

4. Is the effectiveness affected by a woman's weight?

With Jadelle, annual pregnancy rates through four years were similar in all weight groups. In the fifth year, the annual pregnancy rate was 0.8 per 100 for all women and 1.1 per 100 for women weighting more than 60 kg (Sivin I, Nash H, and Waldman S 2002).

5. What is the most common adverse effect?

The most frequently reported adverse effect is a change in the menstrual bleeding pattern,
such as:

- Prolonged bleeding (> 8 days)
- Irregular bleeding or spotting (interval < 15 days)
- Delayed menses (> 6 weeks)
- Spotting
- Heavy bleeding (twice as much as normal menses)
- A combination of changes

The kind of bleeding pattern a woman will have with Jadelle cannot be predicted. Most women can expect an altered bleeding pattern to become more regular after 9 to 12 months. Despite the increased frequency of bleeding in some women, the monthly blood loss is usually less than with normal menses. In fact, in some studies, hemoglobin levels have been shown to rise in LNG implant users.
A follow-up visit to the clinic is recommended if a client experiences prolonged, heavy bleeding.

Remember: The more thoroughly a prospective Jadelle user is counseled about menstrual bleeding changes, the less likely it is that this adverse effect will lead to her becoming unhappy with the method and requesting removal.

6. Will Jadelle protect a woman from AIDS?

While use of progestin-only contraceptives, such as Jadelle, may decrease the risk of getting certain types of pelvic infections, LNG implants do not provide protection against STDs (e.g., HBV, HIV/AIDS). If either you have or your partner has other sexual partners, you should use an additional barrier method (condom) to minimize the risk of getting a STD. Does the use of Jadelle affect a woman's fertility?

7. How widely have LNG implants been researched and tested?

They have been studied since the 1960s and have been used by more than 6 million women in more than 50 countries, including over a million women in the US.
Levonorgestrel has been used for more than 30 years in oral contraceptive pills. The rods themselves are made of silicone tubing that does not cause any reaction (allergy) and has been used in various devices placed in the body, such as heart pacemakers, since the 1950s (Population Council 1990).
See Chapter 1 for additional information.

8. Can the rods be seen or felt?

Since the incision is small (2 mm), insertion does not leave a noticeable scar. The rods are not visible in most women but can be felt under the skin. When they are visible, the outline of the rods resembles veins underneath the skin.

In some women the scar may be darker (hyperpigmentation). This usually disappears following removal of the rods.
Will the rods move or migrate to some other place in the body? No.
The rods remain where they are inserted until they are removed. They are flexible and do not break inside the woman's arm.

After the incision has healed, the skin over the rods can be touched at any time. Also, the client does not have to be concerned if the rods are bumped or if pressure is put on the area, such as when a child is carried.

9. Can a woman who is breastfeeding use Jadelle?

A hormonal contraceptive is not considered the method of first choice for breastfeeding women. However, studies have shown no significant effects on the growth or health of infants whose mothers used levonorgestrel beginning 6 weeks after childbirth. The effects of LNG implants earlier than 6 weeks after childbirth in breastfeeding women have not been studied.

10. Do other drugs interact with the hormone in Jadelle?

Certain drugs increase the ability of the liver to break down the hormone (levonorgestrel), thereby making the method less effective in preventing pregnancy. Such drugs include: rifampin, used to treat tuberculosis; griseofulvin1 and drugs used for epilepsy (seizure disorders), such as barbiturates (e.g.: phenobarbital), phenytoin (e.g., Dilantin) and carbamazepine (e.g., Tegretol) but not valproic acid (Angle, Huff and Lea 1991).

Remember: Counsel the woman to tell the healthcare worker she is using Jadelle whenever a new drug is given to her.

11. Should a woman be concerned if her menstrual period is delayed?

Although Jadelle is highly effective, pregnancies occur occasionally. If a woman's period is delayed (> 6 weeks) after an interval of regular cycles, she should be evaluated for pregnancy (see Chapter 8). If she is not pregnant, counsel her that there is no harm to her health if she does not get her menstrual period (i.e., there is no "build up" of blood in the uterus) and that not having menses will have no harmful effect on her future fertility.

12. Should a woman with prolonged bleeding (with or without anemia) have the Jadelle rods removed?

Not usually. If the woman wants to continue using Jadelle, she should be checked to be sure there are no other causes for the bleeding. Following this, the first approach should be counseling and reassurance that prolonged spotting or moderate bleeding (equivalent to normal menstruation but longer in duration) are common and expected during Jadelle use. If reassurance is not sufficient for the woman, the concomitant use of a low-dose COC or ibuprofen can be tried. (See Chapters 1 and 8 for additional information and detailed instructions.) For anemia, give nutritional advice on the need to increase iron intake.

Use oral iron treatment (one tablet containing at least 100 mg of elemental iron, $FeSO_4$, daily for 1 to 3 months) if hemoglobin is ≤ 9 g/dl or hematocrit ≤ 27.

13. What are the warning signs of problems?

The client should return to the clinic if she has any of the following problems:

- Delayed menstrual period after several months of regular cycles (may be a sign of pregnancy)
- Severe lower abdominal pain (may be a symptom of ectopic pregnancy)
- Heavy bleeding (twice as long or twice as much as normal)
- Pus or bleeding at the insertion site
- Expulsion of a rod
- Migraine (vascular) headaches, repeated very painful headaches or blurred vision

14. When should Jadelle be removed?

Jadelle should be removed at the end of 5 years. The rods can, however, be removed before 5 years if the user wishes to stop the method for either a personal or medical reason. The rods should be removed by a service provider trained in removal.

If the client wants to continue using Jadelle, she may receive a new set of rods in the same arm immediate after the old set is removed.

15. Where should the client go to have the rods removed?

The client should return to the same clinic where the rods were inserted, or to another clinic where Jadelle is provided. The counselor should be sure that the client knows she has access to removal. If removals are not done every day, the clinic should post a schedule of the regular days of the week when removals are performed.

16. What should a woman do if she cannot or does not want to have the Jadelle rods removed at the end of 5 years?

Because of the increased risk of intrauterine and ectopic pregnancy, every effort should be made to help convince the woman to have the rods removed. In the interim, the woman should use a reliable contraceptive method (COCs, injectables or an IUD) until the rods can be removed.

17. What happens if Jadelle rods are left in longer than 5 years?

The effectiveness of Jadelle may decrease somewhat after 5 years and, therefore, the chance of becoming pregnant (either intrauterine or ectopic) may increase (see Chapter 1 for discussion). Moreover, after 5 years, those women who do become pregnant are more likely to have an ectopic pregnancy. Jadelle should be removed after 5 years and replaced with a new set if continued contraception with Jadelle is desired.

18. How long does removal take?

The removal process usually takes 5 to 10 minutes, but may take longer if the rods were not inserted correctly or are difficult to locate.

19. What other adverse conditions have been observed in Jadelle users?

A number of women using Jadelle have experienced the following conditions,
which may or may not be method-related (Table 7-1):

- Pre-existing acne or excessive growth of body or facial hair could also be worsened.
- Occasionally, an infection may occur at the insertion site.
- Enlarged ovarian follicles, detectable only during a physical examination, may occur in implants users. They usually disappear spontaneously within a few months without need for medical or surgical treatment (see Chapter 8)

• Rarely, women of all ages, but especially those in the childbearing years who are overweight, may develop benign intracranial hypertension (pseudotumor cerebri) (see Chapter 8).