Because clients may not always have exact information about these conditions, healthcare workers must know how to assess the accuracy of what clients tell them. If necessary, questions may need to be restated in several different ways. Also, the social, cultural or religious factors that might influence how a client (and her partner) responds should be taken into account.

Although clients with any of the following conditions may use Jadelle, they may require more frequent or special follow-up:

- diabetes,
- hypertension, and
- severe vascular or migraine headaches.

The findings from the client assessment determine whether a physical examination is necessary (i.e., if the client's response suggests a precaution for use of Jadelle, a brief physical examination or further questioning may be necessary).

Pelvic examinations are recommended as good healthcare, but are **not** a requirement for provision of Jadelle **unless pregnancy is suspected**, and then only if the client is thought to be more than 6 weeks from her last menstrual period (LMP).

Pregnancy testing is unnecessary except in cases where it is difficult to confirm pregnancy by a pelvic examination (i.e., 6 weeks or less from the LMP) or the results of the pelvic examination are equivocal (e.g., the client is overweight, making sizing the uterus difficult). In these situations a sensitive urine pregnancy test (i.e., detects < 50 mIU/ml of hCG) may be helpful, if readily available and affordable. If **pregnancy testing** is **not** available, counsel the client to use a temporary contraceptive method or abstain from intercourse until her menses occur or the possibility of pregnancy is confirmed.

How To Be Reasonably Sure A Client Is Not Pregnant

You can be reasonably sure a client is not pregnant if she has no signs or symptoms of pregnancy (e.g., breast tenderness or nausea) and:

- has not had intercourse since her last menses;

or

- has been correctly and consistently using a reliable contraceptive method;

or

- is within the first 7 days after the start of her menses (days 1-7);

or

- is within 3 weeks post-partum (for non-breastfeeding women);

or

- is within the first 7 days post-abortion;

or

- is fully breastfeeding, less than 6 months post-partum and has had no menstrual bleeding (see below).

Source: TGWG 1994.

Relying on the Lactational Amenorrhea Method (LMA)

The lactational amenorrhea method (LAM) is highly effective. It has a failure rate of less than 2% during the first 6 months post-partum (Labbok, Cooney and Coly 1994). A service provider can be reasonably sure that a fully or nearly fully breastfeeding woman is not pregnant if she is still within the first 6 months post-partum and has remained amenorrheic.

When a woman is more than 6 months post-partum, you still can be reasonably sure that she is not pregnant if:

- she has kept her breastfeeding frequency high,
- she has still had no menstrual bleeding (amenorrheic), and
- has no clinical signs or symptoms of pregnancy (Labbok, Cooney and Coly 1994; TGWG 1994).

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Chapter 5: Infection prevention[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.

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 micro-organisms 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 all, disease-causing micro-organisms from inanimate objects.
- **High-Level Disinfection** (HLD) by boiling, steaming or the use of chemicals eliminates **all** micro-organisms **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.

Protective barriers

Placing a physical, mechanical or chemical "**barrier**" between micro-organisms 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:

- handwashing;
- 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.

Handwashing and gloves

Thorough handwashing and use of protective gloves are key components in minimizing the spread of disease and maintaining an infection-free environment (Garner and Favero 1986). 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 handwashing is to have **physicians** or **other respected individuals** (role models) consistently wash their hands and encourage others to do the same.

Handwashing 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 handwashing, program managers should

[1] Adapted from: Tietjen L, W Cronin and N McIntosh. 1992. Infection Prevention for Family Planning Service Programs: A Problem-Solving Reference Manual. Essential Medical Information Systems, Inc.: Durant, Oklahoma.
[2] Throughout this manual, when hepatitis B virus (HBV) is mentioned, hepatitis C virus (HCV) and Delta hepatitis virus (HDV) also are referred to because their occurrence is worldwide and their modes of transmission/prevention are similar.

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.

When to wash hands

Handwashing 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.

Handwashing 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 handrub 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) (Garner and Favero 1986). 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 (Larson et al 1990; Rotter, Koller and Wewalka 1980).

- 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.

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 for 10 minutes,
- washed and rinsed, and
- sterilized (by autoclaving) or high-level disinfected (by steaming or boiling).

Which gloves to use

The glove requirements for providing Jadelle are presented in Table 5-1.

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.

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 micro-organisms 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 (Larson et al 1990). Preparing the client's skin with antiseptic solution helps prevent infection at the operative 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).

Table 5-1. Glove requirements for Jadelle

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

[a] This includes new "never used" individual or bulk-packaged gloves (as long as boxes are stored correctly).
[b] Reprocessed surgical gloves.
[c] When sterilization equipment (autoclave) is not available, HLD is the only acceptable alternative.

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.

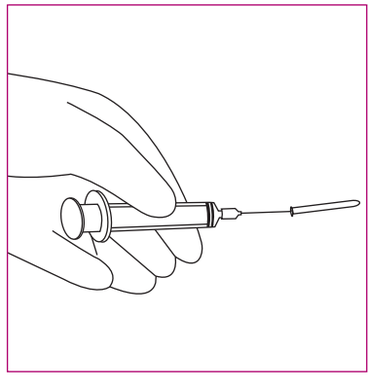
Many chemicals qualify as safe antiseptics. The following antiseptics are commonly available in different parts of the world:
- Alcohols (60-90% ethyl, isopropyl or "methylated spirit")
- Chlorhexidine gluconate (4%) (e.g., Hibiclens, Hibiscrub, Hibitane)
- Chlorhexidine gluconate and cetrimide, various concentrations (e.g., Savlon)
- Iodine (1-3%); aqueous iodine and alcohol-containing (tincture of iodine) products
- Iodophors, various concentrations (e.g., Betadine)
- Parachlorometaxylenol (PCMX or chloroxylenol), various concentrations (e.g., Dettol)

Safe work practices
Avoiding Needlestick Injuries
Accidental needlesticks will 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.

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 5-1.
One-handed recap method



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 handwashing facilities including a supply of clean water (i.e., clear, not cloudy or with sediment) and a toilet or latrine nearby.

[3] Where disposable needles are not available and recapping is practiced, use the "one-handed" recap method:
- First, place the cap on a hard, flat surface; then remove your hand.
- Next, with one hand, hold the syringe and use the needle to "scoop up" the cap.
- Finally, when the cap covers the needle completely, hold the needle at the base near the hub and use the other hand to secure the cap on the needle.

Infection prevention tips: Insertion and removal of Jadelle rods

To minimize the client's risk of infection after insertion or removal, clinic staff should strive to maintain an infection-free environment. To do this the clinician should:

- Have the client wash her entire arm thoroughly with soap and water and rinse well to be sure all traces of soap have been removed. (Residual soap decreases the effectiveness of some antiseptics.) This step is particularly important when client hygiene is poor.
- Wash hands thoroughly with soap and water. For insertion or removal of Jadelle rods, a brief handwashing with plain soap for about 10 to 15 seconds followed by rinsing in a stream of water is sufficient.
- Put sterile or high-level disinfected gloves on both hands. (A separate pair of gloves must be worn for each client to avoid cross-contamination.)
- Prep the insertion or removal site with an antiseptic by holding the cotton or gauze swab with a sterile or high-level disinfected sponge forceps. (If the swab is held with a gloved hand, care must be taken not to contaminate the glove by touching any unprepped skin.)

After inserting or removing both Jadelle rods and before removing gloves, decontaminate instruments by placing them in a container filled with 0.5% chlorine solution. Before disposing of or soaking the needle and syringe, fill with chlorine solution. (Following insertion, separate the plunger from the trocar. Dried blood makes them difficult to separate later.) Soak for 10 minutes; then rinse immediately with clean water to avoid discoloration or corrosion of metal items.

Remember: As the two Jadelle rods are removed, decontaminate them by placing in a small bowl containing 0.5% chlorine solution.

- The surgical drape (if used) must be washed before reuse. After using, place in a dry, covered container and remove to the designated area for washing.
- While still wearing gloves, dispose of contaminated objects (gauze, cotton and other waste items) in an appropriately marked leak-proof container with a tight-fitting lid or a plastic bag. Needles and syringes should be disposed of in a puncture-proof container if not being reused.
- 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.
- After completing the procedure, wash hands thoroughly with soap and water and dry with a clean, dry cloth or air dry.

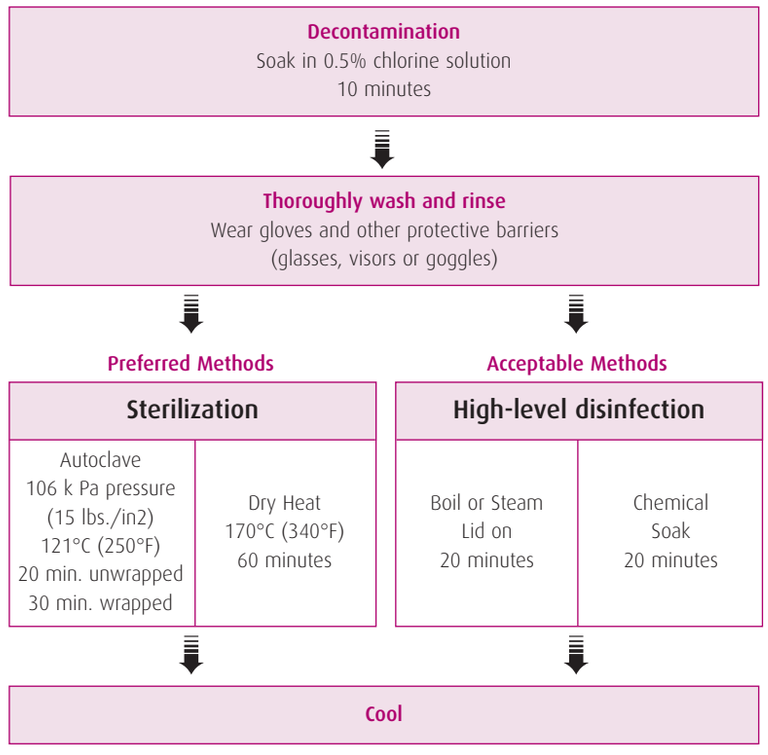
Processing instruments, gloves and other items

In working to create an infection-free environment, it is important that the rationale and limitations for each of the following recommended IP processes be clearly understood by clinic staff at all levels – from service providers to cleaning and maintenance staff. After completing either insertion or removal, and while still wearing gloves, dispose of contaminated objects (gauze, cotton and other waste items) in a leak-proof container or plastic bag. (Do not allow waste items to touch the outside of the container or bag.)

As illustrated in **Figure 5-2, decontamination** is the first step in processing soiled surgical instruments, gloves and other items. For example, soaking contaminated items briefly in 0.5% chlorine solution rapidly kills HBV and HIV, thereby making instruments and other items safer to be handled during cleaning (AORN 1990). Larger surfaces such as examination and operating tables, laboratory bench tops and other equipment that may have come in contact with blood or other body fluids should also be decontaminated. Wiping them down with a suitable disinfectant (e.g., 0.5% chlorine or 1-2% phenol) is a practical, inexpensive way to decontaminate these items.

After instruments and other items have been decontaminated, they

Figure 5-2.
Key steps in processing Instruments, Gloves and Other Items



Remember: For either sterilization or HLD to be effective, decontamination and thorough cleaning of instruments and other items must be done first.

Table 5-2.
Effectiveness of methods for processing instruments

	Effectiveness (kill or remove micro-organisms)	**End point**
Decontamination	Kills HBV and HIV and most micro-organisms	10 minute soak
Cleaning (water only)	Up to 50%	Until visibly clean
Cleaning (detergent and rinsing with water)	Up to 80%	Until visibly clean
Sterilization	100%	Autoclave, dry heat or chemicalfor recommended time
High-Level Disinfection	95% (does not inactivate some endospores)	Boiling, steaming or chemical for 20 minutes

need to be **cleaned** and then final processed by either **sterilization** or **HLD** (Tietjen and McIntosh 1989). The effectiveness of each of these processes for killing or removing micro-organisms is listed in **Table 5-2.**

As outlined in **Table 5-3**, the method used for final processing (i.e., either sterilization or HLD) usually depends on whether the the instruments and other items will touch only intact (unbroken) skin, intact mucous membranes or broken skin, or tissue beneath skin which is normally sterile.

When is HLD an acceptable alternative?
Most authorities recommend that the final step in processing instruments, surgical gloves and other items used for insertion and removal of Jadelle rods should be sterilization. When correctly performed, sterilization is the safest and most effective method for processing these items. If sterilization equipment (autoclave or dry heat sterilizer) is neither available nor suitable, then HLD is the **only acceptable** alternative.

See **Appendices C, D** and **E** for detailed information on processing surgical instruments and other items.

Maintenance of a safe environment

Maintaining a safe, infection-free environment is an ongoing process which requires frequent retraining and close supervision of clinic staff. With diligent application of recommended IP practices, infections following insertion and removal of Jadelle and transmission of diseases, such as hepatitis B and AIDS, can be avoided. The practices and processes described in this chapter, however, must be conscientiously applied before, during and after each procedure. Laxity at any point in the routine can have disastrous results for the safety of the procedure.

Table 5-3.
Final processing sterilization and HLD for instruments, gloves and other items

Tissue	**Final Processing**	**Examples**
Intact mucous membranes or broken skin	**High-Level Disinfection** destroys all micro-organisms except some endospores.[a] (HLD should be preceded by decontamination and cleaning.)	Uterine sounds and vaginal specula
Tissue beneath the skin which is normally sterile	Sterilization destroys all micro-organisms, including endospores. (Sterilization should be preceded by decontamination and cleaning.)	Surgical instruments such as needles and syringes, scalpels and trocars for insertion/removal of Jadelle and surgical gloves

[a] Bacterial endospores are forms of bacteria which are very difficult to kill because of their coating; types of bacteria which can produce endospores include the bacteria causing tetanus (Clostridia tetani) and gangrene (Clostridia sp.). Bacterial endospores can be killed reliably **only** by sterilization.

Adapted from: Spaulding et al 1968.

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Chapter 6: Insertion

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 (Peralta, Diaz and Croxatto 1995).

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

Most problems associated with removal have been due to improper or careless insertion; therefore only clinicians (physicians, nurses and midwives) 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 (see Chapter 5).

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.

Client assessment

In many countries (Jadelle rods are inserted at the first clinic visit. Under these circumstances, to minimize the risk of problems, particularly the possibility of the client being pregnant, a brief assessment of the woman's health should be conducted (see Chapter 4 and Appendix B).

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 4).

Optimal times for inserting implants are:

- During menstruation (days 1-7 of the menstrual cycle)
- Post-partum:
  - after 6 weeks if breastfeeding but not using LAM
  - immediately or within 3 weeks if not breastfeeding
  - after 6 months if using LAM
- Postabortion (immediately or within the first 7 days)

If the client has been using no contraception and insertion is done **after** day 7 of the menstrual cycle, either the couple should consider not having intercourse for up to 7 days or a backup method should be used. If the client is using **another contraceptive method** and wants to switch to Jadelle, the best time to do so is shown in **Table 6-1**. Inserting the rods at these recommended times will minimize the possibility of pregnancy.

Table 6-1. Current contraceptive users: optimal times for switching to Jadelle

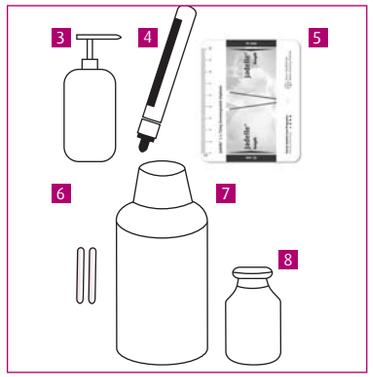
Current method	when to insert
Natural family planning or barrier methods	Before day 7 of the menstrual cycle
Combined Oral Contraceptives	After the last (21st) active pill and for the next 7 days
Norplant	At the same time that Norplant rods are removed, Jadelle can be inserted
Progestin-Only Pill (minipill)	On the day the last pill in the pack is taken
Progestin-Only (or estrogen and progestin) Injectables	Any time up to the time of the next scheduled injection
IUD	Any time, but do not remove IUD for 7 days after insertion
Levonorgestrel-IUS	On the day the IUS is removed

Preparation

It is important that the instruments be in excellent condition (e.g., the trocar and scalpel must be sharp). In addition, check that all instruments and other items have been sterilized or high-level disinfected (see **Chapter 5** and **Appendix C**).

Jadelle rods are packed in sterile, heat-sealed, paper-backed pouches. They will remain sterile for the duration of the labeled 3-year shelf life as long as they are not damaged and are stored away from moisture and excessive heat.

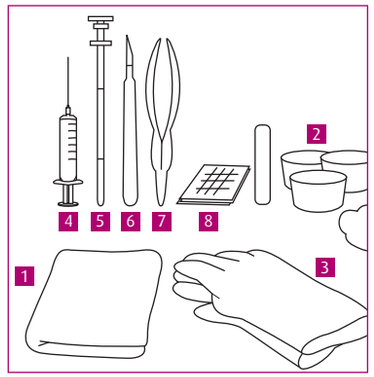
Figure 6-1. Basic materials for insertion, non-sterile items



The following supplies are recommended for each insertion **(Figures 6-1)**:

1 examining table for the woman to lie on;
2 arm support or side table (optional);
3 soap for washing the arm;
4 a ballpoint pen or marker;
5 plastic template for marking position of rods in "V" shape;
6 set of two rods in sterile pouch;
7 antiseptic solution;
8 local anesthetic (1% concentration without epinephrine);

Figure 6-2. Basic materials for insertion, sterile items



The sterile instruments and supplies necessary for insertion of Jadelle rods **(Figure 6-2)** include:

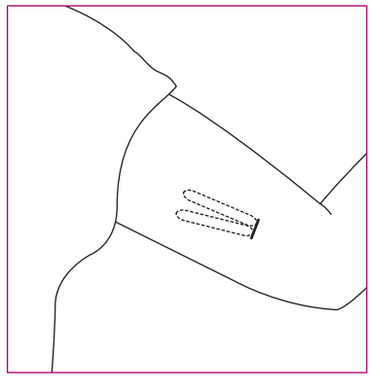
1 sterile (or clean), dry surgical drape;
2 three bowls (one for the antiseptic solution, one for cotton balls soaked with boiled or sterile water to remove talc from gloves and one to hold rods);
3 pair of surgical gloves;
4 syringe (5 or 10 ml) and 5 cm (2 inch) long needle (22 gauge)
5 #10 trocar (with markings for Jadelle) with plunger;
6 scalpel with #11 blade;
7 tissue forceps (optional);
8 ordinary Band-Aid or gauze with surgical tape;
9 gauze and compresses; and
10 epinephrine for anaphylactic shock (readily available for emergency use).

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 6-3)**. Sutures are not required to close the incision; a simple Band-Aid with a pressure dressing will do.

Figure 6-3. 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 6-4.
Transverse section through the left upper arm (middle third)

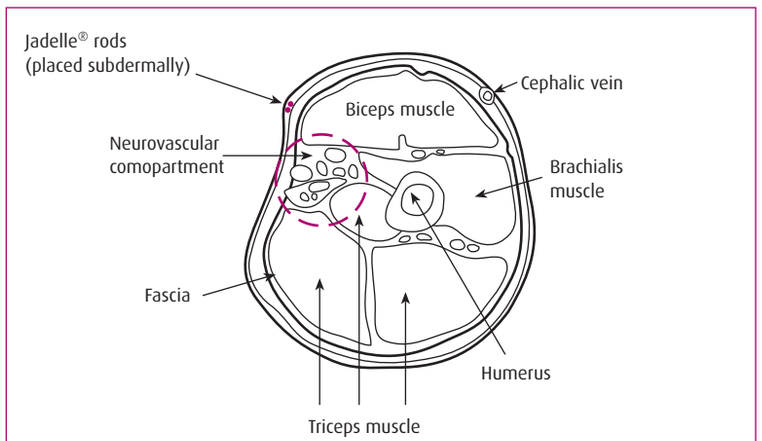


Figure 6-5.
Neurovascular compartment, expanded view

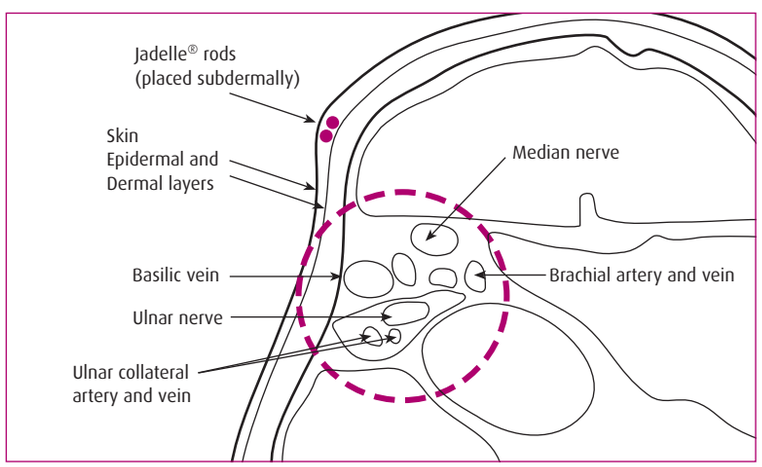


Figure 6-4 shows a cross section of the upper arm and Figure 6-5 shows a close-up view of the neurovascular compartment with the major blood vessels and veins identified. As shown in these figures, when Jadelle rods are placed correctly, they are well away from major blood vessels and nerves.

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

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.[1]

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).

Note: 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.)

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 handwashing 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 theyare stuck together, separate them with gloved fingers.

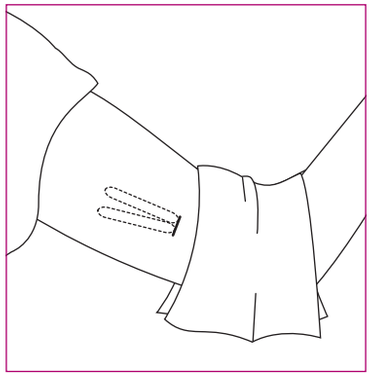
[1] If there is a specific history of allergic reaction to local anesthetics, the client should be advised that insertion and removal of Jadelle will need to be done using a short-acting, intravenous general anesthetic (Gbolade 1997).

Attach the scalpel to the blade using tissue forceps, not your fingers.

Step 4: Apply antiseptic solution to the in-cision 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., Betadine) 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 **(Figure 6-6)**. (Alternatively, a decontaminated, washed and machine- or air-dried drape or cloth can be used.)

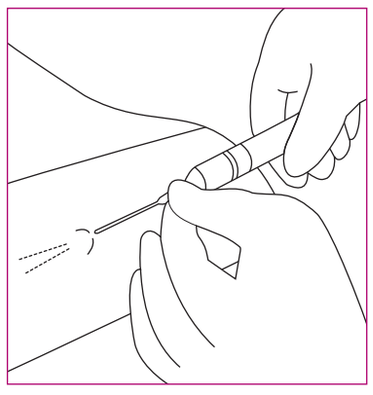
Figure 6-6.
Covering the arm



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** epinephrine). 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 shouldn't 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 6-7)**. 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.

Figure 6-7.
Injecting the anesthetic



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 epinephrine.

Inserting the rods

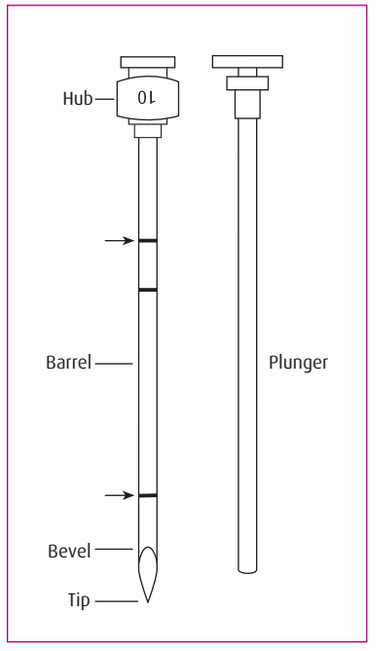
Before starting, gently touch the incision site with the tip of the forceps to be sure the anesthetic is working. If the client can feel the forceps, wait 2 more minutes and retest the incision site.

Step 1: Holding the scalpel at about a 45° angle, make a small (2 mm), shallow incision which just penetrates the skin. **Do not make a wide or deep incision.** Alternatively, if the trocar is new it can be inserted directly through the skin without making an incision (Diaz et al 1991).

Step 2: The trocar should be held so that the bevel on the tip faces upward **(Figure 6-8)**. 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 6-9, upper)**. Never force the trocar. If resistance is met, try another angle.

Figure 6-8.
Trocar, actual size



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 6-9**),

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.

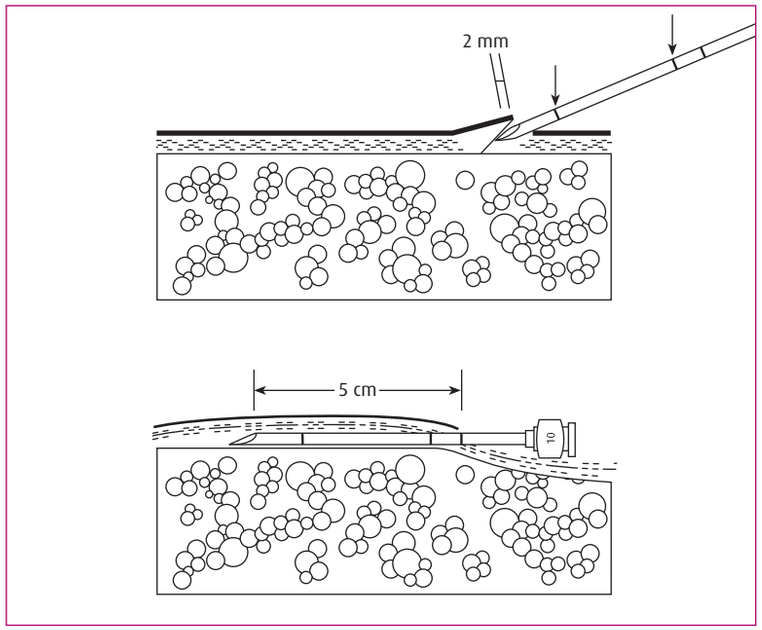
Step 5: When the trocar has been advanced as far as the mark nearest the hub, remove the plunger from the trocar.

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 6-10).

Note: If the rod is picked up by hand, be sure the gloves are free of powder.

Figure 6-9.
Inserting the trocar at a shallow angle



Slide the rod into the top of the trocar and reinsert the plunger (Figure 6-11).

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 6-10.
Loading the rod

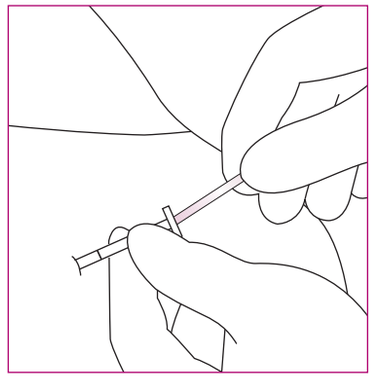
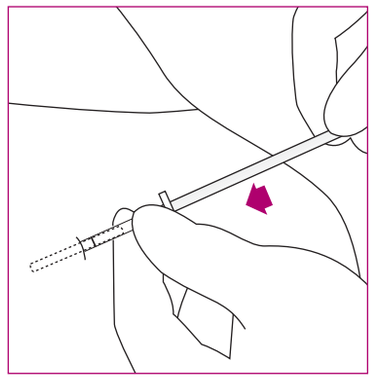


Figure 6-11.
Inserting the plunger



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 6-12). It is important to keep the plunger steady so as not to push the rod into the tissue.

Figure 6-12.
Sliding the trocar back

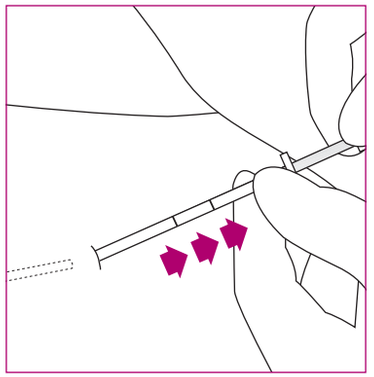
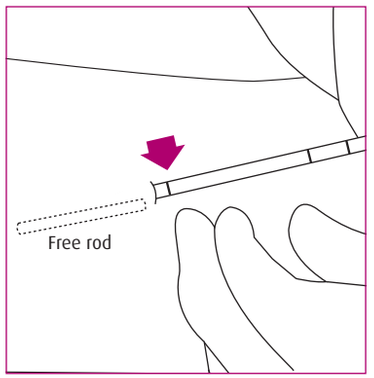


Figure 6-13.
Releasing the rod



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 6-13). Feel the end of the rod with a finger to make sure it is free of the trocar tip.

Note: Repeated sharpening shortens the trocar, lessening the distance to the mark nearest the tip. Therefore, when using trocars that have been sharpened, be careful not to pull the trocar too far back or it will come out of the incision.

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 6-14.
Rotating the trocar

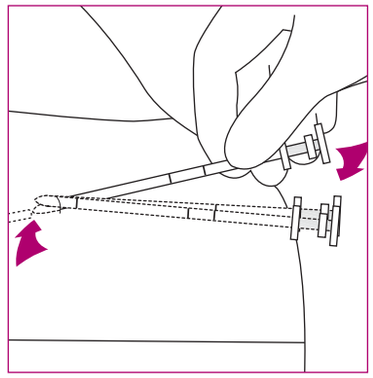
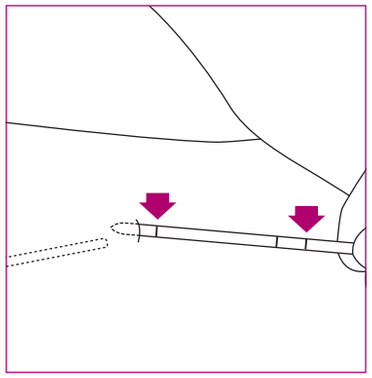


Figure 6-15. Fixing the position of the first rod



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 6-15**).

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**).

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. Th 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.

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).

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). Fill syringe and attached needle with 0.5% chlorine solution and place in the solution or 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 scal-pel 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.

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, postinsertion care instructions if available and appropriate.

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).

Key points for successful insertions

- Select the arm the client uses less for insertion of the rods.
- Use recommended IP 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.

Tips for keeping a trocar sharp

- Repeated use will cause the trocar to become dull; therefore, it should be examined carefully after every 10 insertions.
- After use, separate the plunger from the trocar. This helps keep the trocar sharp.
- If it appears that the trocar is becoming dull, it may be sharpened in the same way that a knife or pair of scissors is sharpened, using a smooth grindstone.
- When sharpening a trocar, avoid excessive grinding that could change the angle of the point, thereby making the trocar unusable. Repeated grinding will shorten the trocar, lessening the distance to the mark nearest the tip of the trocar **(Figure 6-8)**.
- Another problem due to repeated grinding is that the blunt end of the plunger, when fully inserted, may protrude beyond the point of the trocar. This makes insertion of the trocar under the skin more difficult. If this happens, pull back slightly on the plunger until it no longer protrudes beyond the trocar's point.
- After approximately 50 to 100 insertions, the trocar should be **replaced**, not **resharpened**.

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Chapter 7: Post-Insertion and Follow-up Care

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 name of the service center or clinic,
- 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).

If possible, this information should be provided in writing. A simple reminder card, such as the one illustrated in Figure 7-1, is provided by the manufacturer together with Jadelle.

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

Figure 7-1.
Sample Patient Reminder Card

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 have her repeat them to be certain she understands them clearly.

Care of 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.

Answers to common questions

Answering client questions about Jadelle, as well as telling clients what to do if certain other problems occur, promotes continued use (Population Council 1992).
In particular, clients should know the answers to these common questions:

When should the client return to the clinic?
The follow-up schedule depends on the clinic or program from which the woman receives Jadelle. Some clinics may ask the woman to return for periodic health check-ups or to report on her experience with Jadelle. She should be encouraged to return to the clinic if she:
- thinks she might be pregnant,
- wants the Jadelle rods removed for any reason,
- wants to have a baby,
- has any problems with the method that worry her,
- wants to switch to another contraceptive method,
- is moving and needs the address of a clinic in her new area that provides Jadelle services, or
- has started any new medications that might decrease the effectiveness of Jadelle (e.g., rifampin and most anti-epileptic drugs).

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.

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.

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.

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).

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.

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?
Several studies have reported no long-term effects on a woman's fertility, regardless of age or parity (i.e., young women with no previous pregnancies can safely use Jadelle). Once the two rods are

removed, the contraceptive effect of Jafelle is gone within a few days. Return to previous fertility is usually prompt. In one study of women who had Jadelle re-moved and wished to become pregnant (Buckshee et al 1995), 20% conceived within 1 month of removal, 63% by 6 months, 80% by 1 year and 88% by 2 years (see **Table 1-5**). In another study, 58% of women who had been using Jadelle conceived within 3 months of removal (Sivin et al 1992). These rates of conception are similar to those for women using Norplant or no contraception (Sivin 1988).

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.

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.

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.

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; griseofulvin[1] 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.

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 doesn't 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.

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 concommittant 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, FeSO4, daily for 1 to 3 months) if hemoglobin is ≤ 9 g/dl or hematocrit ≤ 27.

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

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

[1] Because griseofulvin, which increases progestin metabolism, usually is used only for a short period of time (2 to 4 weeks), women taking it for funga infections can use Jadelle. They should use a backup method while taking griseofulvin and until the start of the next menstrual period after stopping the antibiotic.

a new set of rods in the same arm immediatel after the old set is removed.

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.

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.

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.

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.

Table 7-1. Ten most frequently reported adverse conditions over a 3-year period

Condition[a]	Percentage of women Jadelle (n=600)
Vaginal Discharge	24.3
Headache	23.5
Pelvic Pain	16.7
Weight Increase	12.0
Dizziness	10.7
Breast Pain	8.3
Genital Itching	8.2
Nervousness	7.7
Cervicitis	7.5
Nausea	6.7

[a] Women reported more than one condition.

Source: Sivin et al 1997a.a

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).

Follow-up care

When to return to the clinic
The client does not need to return until 5 years after insertion unless she has decided to have the rods removed because she:

- thinks she might be pregnant,
- wants the Jadelle rods removed for any reason,
- wants to have a baby,
- has any problems with the method that worry her,
- wants to switch to another contraceptive methods, or
- has started any new medication that might decrease the effectiveness of Jadelle.

While annual preventive healthcare visits are not necessary for continued safe use of Jadelle, they are recommended.

When possible, the client should return to the same clinic or service center 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
- Unilateral leg pain or swelling, sudden severe pain in the chest or breathlessness (may be a symptom of thrombosis)

Finally, at any follow-up care visit, she should be told that she can return anytime there is a problem or she has questions.

In summary:
As mentioned earlier, successful programs require well-trained staff who exhibit:

- good clinical judgment in selecting acceptors;
- care, sensitivity and thoroughness

in informing the user about common adverse effects and other problems;

- skill in inserting and removing Jadelle rods;
- knowledge of and ability to recognize real or potential problems; and
- capability to take appropriate clinical action in response to these problems, including knowing when (and where) to refer clients with serious problems.

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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 im-plants 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.

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.

Evaluation of hormonal regimens

Alvarez-Sanchez et al (1996) reported that use of a COC containing 50 pg EE and 250 pg LNG for 20 days provided excellent treatment for bleeding irregularities in LNG implant users. This COC stopped the bleeding in 91% of women in fewer than 3 days (mean 2.6 +-1.45 days) and provided a bleeding-free interval of more