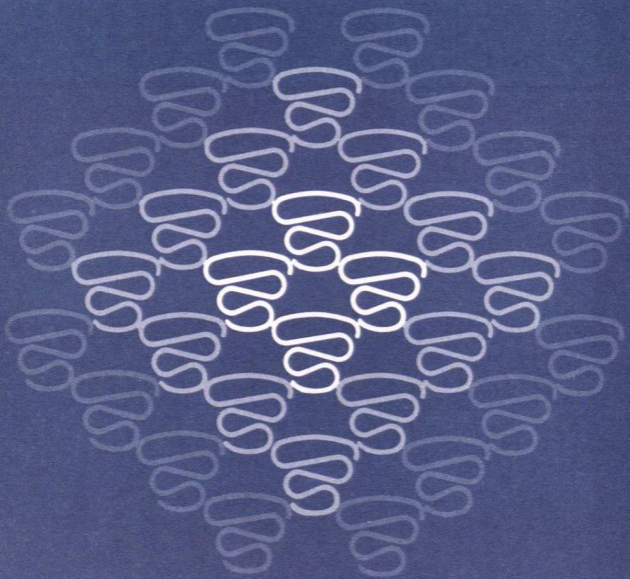


LIPPES LOOP

TRADEMARK



**your
intrauterine
contraceptive**

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LIPPES LOOP

Patient Information

This brochure provides information on the use of Intrauterine Contraceptive Devices (IUD's). There are other birth control methods that may be suitable. Before deciding which type of birth control method to use, you should read this brochure and have the opportunity to discuss fully with your doctor any questions you may have about the IUD and other methods of contraception.

Preinsertion Information

IUD's are small articles of various sizes and shapes which are inserted into the uterus (womb). The purpose of the IUD is to prevent pregnancy.

How the IUD prevents pregnancy is not completely understood. Several theories have been suggested. IUD's seem to interfere in some manner with the implantation of the fertilized egg in the lining of the uterine cavity. The IUD does not prevent ovulation.

The effectiveness of the IUD is measured by the pregnancy rate of women who use it and by the rate of adverse reactions and side effects requiring removal of the IUD.

Use-Effectiveness

Different pregnancy and adverse reaction rates have been reported with the use of different IUD's. Because these rates are usually derived from separate studies conducted by different investigators in several population groups, they cannot be compared with precision.

Since LIPPES LOOP Intrauterine Double-S Devices are marketed in four different sizes, the information obtained during clinical trials is presented in tabular form as follows:

LIPPES LOOP Size	Woman Months of Use		No. of Unplanned Pregnancies Per 100 Woman Years		No. of Medical Removals Per 100 Woman Years	
	First Year After Insertion	Second Year After Insertion	First Year After Insertion	Second Year After Insertion	First Year After Insertion	Second Year After Insertion
A	8,751	4,702	5.3	5.9	12.2	10.3
B	9,660	2,803	3.4	3.8	15.1	11.6
C	31,032	19,743	3.0	2.3	14.3	10.2
D	72,046	49,520	2.7	2.0	15.2	10.6

Some Things You Should Tell Your Doctor

Before you have an IUD inserted, you should tell your doctor if you have ever had, or suspect you have ever had, any of the following conditions which might make the IUD unsuitable as a method of contraception for you:

- Abnormalities of the uterus (womb).

- Allergy to copper.

- Anemia.

- Bleeding between periods.

- Cancer of the uterus (womb) or cervix.

- Fainting attacks.

- Heart disease.

- Heart murmur.

- Heavy menstrual flow.

- Infection of the uterus (womb) or cervix.

- Pelvic infection (Pelvic Inflammatory Disease (PID); pus in fallopian tubes).

- Prior IUD use.

- Prior uterine surgery.

- Recent abortion or miscarriage.

- Recent pregnancy.

- Severe menstrual cramps.

- Suspected or possible pregnancy.

- Suspicious or abnormal "Pap" smear.

- Unexplained genital bleeding.

- Vaginal discharge or infection.

- Venereal disease.

Adverse Reactions

The following adverse reactions and side effects have been reported and may occur after the IUD is inserted:

Anemia.

Backache.

Blood poisoning (septicemia).

Bowel obstruction.

Cervical infection.

Complete or partial expulsion.

Cysts on ovaries and tubes.

Delayed menstruation.

Difficult removal.

Embedment.

Fainting at the time of insertion or removal.

Fragmentation of the IUD.

Intermenstrual spotting.

Internal abdominal adhesions.

Migration resulting in perforation.

Pain and cramps.

Painful intercourse.

Pelvic infection.

Perforation of the uterus (womb) or cervix.

Pregnancy.

Pregnancy outside the uterus (womb) (tubal or ovarian).

Prolonged or heavy menstrual flow.

Septic abortion (infected miscarriage) followed in some cases by blood poisoning (septicemia) which can lead to death.

Spontaneous abortion (miscarriage).

Vaginal discharge and infection.

If you decide on the IUD as your method of birth control, read the following information and instructions carefully. Please keep this brochure so that you may refer to it. If you have any questions, consult your doctor.

Description

The LIPPES LOOP is made of a type of flexible plastic (polyethylene) in the shape of a double S. Four different sizes are manufactured to allow for the variability in the size of the uterus. (See below.) A fine double, plastic thread (monofilament) or “tail” is attached to the lower end to facilitate removal. The color of the thread assists the doctor in determining the size of the LIPPES LOOP. In addition, feeling of the tail through the mouth of the womb (cervix) by the patient, or visualization by the physician, can help in determining whether or not an undetected ex-



A

290 mg



B

526 mg

pulsion has occurred. A LIPPES LOOP comes prepackaged in a polyethylene/paper pouch with an introducer, together with an insertion tube. This unit is sterilized. The insertion tube should be inserted through the mouth of the womb and into the womb (uterine cavity). The four available sizes are as follows:

Loop A — Blue tail thread.

Loop B — Black tail thread.

Loop C — Yellow tail thread.

Loop D — White tail thread.



C

615 mg



D

709 mg

Postinsertion Information

Directions for Use.

1. Checking your IUD. A tail or thread is attached to the IUD so that you can check to see if it has not been expelled since the IUD can come out of the uterus (womb) without your knowing it. This occurs most often during or right after a menstrual period but may occur at any time. (Presence of the string does not insure that perforation has not occurred.)

Follow these steps to make sure your IUD is in place:

- a. Wash your hands.
- b. Assume the squatting position or seat yourself on the toilet.
- c. Insert the index or middle finger high into the vagina and locate the cervix (mouth of the uterus [womb]). The cervix feels firm like the tip of your nose.
- d. Feel for the tail or thread of the IUD which should be in the cervix high in your vagina.
- e. If you can feel the tail or thread it is likely that the IUD is in place and working. You should not pull on the tail or thread because this may displace the IUD.
- f. You should check the tail or thread as often as possible but at least after each menstrual period.
- g. If you think the IUD has come out or has been displaced (i.e., you cannot feel the tail or thread or you can feel the IUD itself), use another birth control method, such as contraceptive vaginal foam, cream, or jelly, or condoms (rubbers), until you can be checked. (These alternative methods may not be as effective as IUD's.) Call your doctor for an examination.

h. You should return to see your doctor as soon as possible after your next menstrual period following insertion of your IUD, preferably within one month, but no later than three months after insertion. This will allow the doctor to make sure that the IUD is in the correct position.

i. After your first checkup, you should be checked at least once a year by your doctor.

2. Continuation and removal. While you are wearing the IUD, you may use tampons and use douches, if this is your usual practice. Check with your doctor concerning this. You should return to your doctor if you wish to have the IUD removed.

Side Effects

The following may occur during or after the IUD is inserted:

1. Some bleeding occurs following insertion in most women. Because of this, your doctor may choose to insert your IUD during or at the end of your menstrual period. This also reduces the possibility that you are pregnant at the time of IUD insertion.

2. Bleeding between menstrual periods, usually in the form of spotting, may occur during the first two or three months after insertion. The first few menstrual periods after the insertion may be heavier and longer. If this persists for longer than two or three months, consult your doctor.

3. Pain, usually in the form of uterine cramps or low backache, may occur at the time of insertion and last for a few days. Simple pain medication usually relieves the cramping or backache.

4. Fainting may occur at the time of insertion or removal of an IUD. This passes quickly and is not usually serious.

5. The IUD may be expelled at any time, but most often this occurs during the first two or three menstrual cycles following insertion. Expulsion increases the risk of an unplanned pregnancy. The use of a second contraceptive method, such as a contraceptive vaginal foam, cream, or jelly, or condoms (rubbers), is recommended although these methods may not be as effective as the IUD.

Warnings

1. Call your doctor for any of the following reasons:

a. Severe or prolonged bleeding. If your menstrual flow is heavier and lasts much longer than usual, you may need to have the IUD removed to prevent the development of anemia.

b. Pelvic pain and cramps. This could mean an infection has developed requiring treatment.

c. Exposure to venereal disease (VD). If exposure to venereal disease is suspected, report for examination and treatment promptly. Failure to do so could result in serious pelvic infection because use of an IUD in itself does not prevent venereal disease.

d. Tail or thread disappearance. If you cannot feel the tail or thread coming through the cervix, it is possible that the IUD has been expelled or displaced or that perforation has occurred. If any of these has occurred, you should consult your doctor immediately, and remember, you are no longer protected from becom-

ing pregnant. Use another birth control method, such as contraceptive vaginal foam, cream, or jelly, or condoms (rubbers), until you can be checked. (These alternative methods may not be as effective as the IUD.)

2. Do not undergo medical diathermy (including short-wave or microwave) treatments to the abdomen or lower back areas if you are wearing a metal IUD. These treatments may cause heat injury to the surrounding tissues.

[LIPPES LOOP contains no metals. This section does not apply to LIPPES LOOP.]

Special Warning About Pregnancy with an IUD in Place

Some women become pregnant while using an IUD. If you miss your menstrual period, or if you have a scanty flow during your period, or if you suspect that you might be pregnant, see your doctor right away. Serious complication of sepsis (severe infection), septic abortion (infected miscarriage), and death have occurred when a pregnancy continues with an IUD in place. Most of the occurrences of these serious complications have been reported in the middle third of pregnancy.

If your doctor confirms that you are pregnant, he should remove the IUD if the tail is visible.

If removal of your IUD proves to be difficult, you and

your doctor should discuss at that time the question of continuing the pregnancy in view of the serious complications that may occur. In reaching a decision as to whether or not to have an abortion, it should be remembered that the risks associated with terminating a pregnancy increase with the length of time you are pregnant.

I have received a copy of "LIPPES LOOP—
Your Intrauterine Contraceptive."

I have read and fully understand the
information contained in this booklet. I
also understand that my doctor is available
to answer any questions I may have
concerning the LIPPES LOOP.

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patient's signature

date

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