

THE MULTILOAD-cu375 RADIOPAQUE

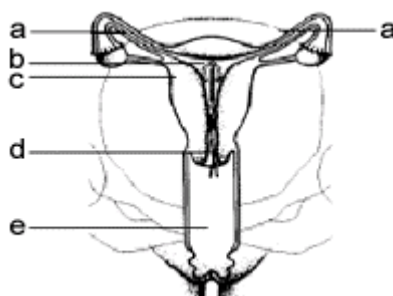
Consumer Medicine Information

PRE-INSERTION INFORMATION FOR PATIENTS

It has been known for centuries that pregnancy could be prevented by inserting an inert object (such as stone, a metal ring, fine wire or silk threads) into the cavity of the uterus. During the 20th century doctors have carried out extensive research in order to develop a modern, reliable and safe means of contraception based on this age-old knowledge. Evidence suggests that IUDs work by reducing the chances of the male and female reproductive cells uniting. The early devices were made of metals such as gold, silver and stainless steel. In the 1940's and 50's pliable plastics were used to create devices such as the 'Loop' and 'Coil'. In the mid-60's it was discovered that the addition of a layer of copper greatly increased the effectiveness of IUDs. Copper carrying IUDs such as the Multiload devices are highly effective at a smaller overall size than IUDs without copper.

The Multiload in the uterus

- a) Fallopian tube
- b) Multiload
- c) Uterus
- d) Cervix
- e) Vagina



Who can use an IUD?

An ideal method of contraception has not yet been discovered. Like the other methods available at present the IUD is not suitable for every woman. If you wish to use an IUD, some important matters must be considered.

Your past health

Your doctor will take a thorough medical and gynaecological history. It is important to answer all questions accurately, as some previous or existing conditions may indicate that an IUD may not suit you.

Women most likely to have problems with IUDs are those with

1. A history of painful or heavy periods.
2. A history of previous infection of the uterus or tubes.
3. A history of problems during previous IUD use.

An IUD cannot be inserted:

1. If there is suspicion or possibility of pregnancy.

2. If there is any existing infection in the reproductive system or a history of recurrent pelvic infection.
3. If there is any undiagnosed abnormal bleeding from the uterus.
4. If there is a history of persistent severe pain around the time of menstruation.
5. If there has been a previous ectopic pregnancy (pregnancy outside the uterus).
6. If there has been a septic abortion in the last 3 months.
7. If there has been in the previous 12 months a sexually transmitted disease such as chlamydia.
8. If there is an uninvestigated suspicion of or an existing cancer of the reproductive organs.
9. Until the uterus has returned to normal after delivery or abortion.
10. If there is allergy to copper or Wilson's disease (hereditary syndrome which may result in the accumulation of copper in various organs).
11. In some cases of valvular heart disease.
12. If there is any abnormality of the shape of the cavity of the uterus or cervical canal.

Your doctor will perform a thorough general and gynaecological examination to rule out any conditions of the uterus or other organs which may indicate that an IUD would be unsuitable for you.

What problems can occur with an IUD?

The majority of women have no problems.

However, there are some possible side effects and complications of IUD use.

Possible side effects

1. Menstrual problems

Periods may be heavier, more painful or more prolonged while wearing an IUD.

These problems may occur in the early months of use, or may develop after an interval of trouble-free use. In general, most women are not disturbed by slight increases in amount and duration of menstruation. If period problems are distressing or if there is a change in menstrual pattern, the device should be checked and removed if necessary.

2. Spotting

Light spotting or blood stained discharge may occur between periods, especially in the early months after insertion. This usually settles down. If not, or if bleeding between periods develop as a new symptom, the device should be checked and removed if necessary.

Possible complications

1. Pregnancy

Copper IUDs have a low failure rate, but if a pregnancy occurs with an IUD in place, the device should be removed as soon as possible.

If an IUD remains in the uterus during pregnancy, there is an increased risk of miscarriage and other complications, which may cause serious illness, reduced fertility and rarely, death.

2. Infection

Women wearing IUDs may develop more pelvic infections than women without IUDs, particularly during the first 20 days following insertion where there is an increased risk of pelvic infection which is attributed to contamination of the uterine cavity during insertion. Pelvic infection that develops more than 20 days after insertion of the IUD is likely to be due to other factors. Any pelvic infection which is not treated promptly may spread to the tubes and ovaries and cause serious illness. Scarring which occurs as the infection heals may block the tubes, causing reduced fertility or infertility. Scarring of tubes also increases the risk of ectopic pregnancy (pregnancy outside the uterus) in the future.

3. Anaemia

Women who continue to have heavy menstrual loss with an IUD may become anaemic. Continued heavy periods may mean that the device should be removed.

4. Expulsion

Sometimes the muscular contractions of the uterus will partly or wholly expel an IUD. If the device is displaced its contraceptive effectiveness is reduced or lost.

5. Fainting at time of insertion

Some women feel faint after insertion or removal of an IUD, even if the procedure has been painless. This is a reflex phenomenon. If you decide on an IUD, you will be asked to rest laying down for ten minutes after insertion and to remain in the surgery for a further 30 minutes.

6. Perforation (of the uterus or cervix)

This is a very rare complication, which may occur at the time of insertion.

An IUD which is located outside the uterus should be removed to prevent damage to the bowel or other surrounding organs.

7. Breakage

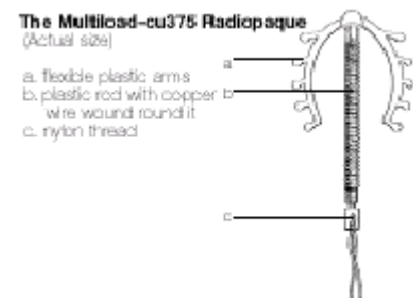
This is an uncommon complication which may or may not be associated with embedding (i.e. fixation of the device or part of it in the uterine wall). Embedding or breakage with retained fragments may require operative intervention to remove fragments (e.g. curettage).

This list of side effects and complications sounds formidable. But remember, it is estimated that over 58 million women have used the IUD and all serious complications are rare. However, it is important that you should be aware of possible adverse consequences, so that you can make a well informed decision before having an IUD inserted.

The Multiload-cu375 Radiopaque

The Multiload consists of a plastic stem 35 mm long with two small flexible side arms. The plastic is a mixture of high density polyethylene, ethylene vinyl acetate co-polymer and barium sulfate in a weight ratio of 44/36/20. The barium sulfate makes it radio opaque, so that it can be detected by ultrasound or by x-rays. Two flexible curved arms are attached to the top of the stem. A 29 cm length of fine pure copper wire is wound around the stem. A single filament nylon strand is threaded through a hole in the lower end of the stem and secured by a double-loop knot.

The Multiload-cu375 Radiopaque



How is the Multiload inserted?

After examining your uterus to determine its position, size and condition, a speculum is inserted into your vagina (as for a Pap smear) and the cervix and vagina are cleaned with antiseptic lotion.

The uterus is held steady while its depth is checked.

Your doctor uses a slender flexible transparent plastic tube to insert the Multiload-cu375 radiopaque into your uterus. After insertion, the two threads attached to the Multiload extend into the top of the vagina so that the presence of the device may be checked by you and your doctor.

Multiload-cu375 radiopaque, post-insertion information for users

Important

For 48 hours after insertion of the Multiload:

- 1. Do not put anything into your vagina - i.e. use pads instead of tampons and avoid sexual intercourse.**
- 2. You may feel some pain similar to menstrual cramps, especially on the evening of insertion. This pain should be slight and relieved by rest, a hot water bottle and mild pain killers. If otherwise, please contact your doctor.**
- 3. There may be slight bleeding.**

After this initial 48 hour period you may use tampons during menstruation without risk of disturbing the device. You may resume sexual relations knowing that you are protected against pregnancy with a high degree of certainty for the next five years. After this period, the Multiload must be removed. If you wish to continue contraception a new Multiload may be inserted, provided there are no contraindications to its continued use.

While you are wearing the Multiload

Menstrual periods

The first two or three periods after insertion may be heavier than usual, and may last longer. In most cases this settles down.

There may be slight spotting between periods during the first few months, especially just before menstruation is due.

This will also settle as your uterus becomes accustomed to the Multiload. If periods continue to be heavier or troublesome in any way, please contact your doctor.

Follow-up visits

You will usually be asked to return for your first check-up after your next period, i.e. about six weeks after insertion. Thereafter, you should be checked again at regular intervals until replacement of the Multiload is due (after 5 years).

Checking for the strings

Sometimes, muscular contractions of the uterus will displace or expel an IUD.

Check for the strings, as you have been instructed, once per week during the first month, and then after each period. If you cannot feel the strings, or if you feel anything unusual, arrange to see your doctor without delay. Until you have been examined, use an additional form of contraception, or avoid sexual intercourse.

To check for the strings

Wash your hands and squat so that you can insert one or two fingers into your vagina. At the far end you will feel your cervix, a firm knob about the size and consistency of the tip of your nose. It has a dimple in the middle which marks the beginning of the canal which leads into the uterus.

You should be able to feel the threads of the IUD emerging from this canal. You may need to rotate your finger around the cervix to feel the strings confidently. Take care not to pull on the strings, as this may displace the device. Many women find it convenient to perform this check while taking a shower.



Sexual intercourse

Neither you nor your partner should be aware of the presence of the Multiload during sexual intercourse. If otherwise, consult your doctor. Avoid further sex until the device has been checked.

Suspected pregnancy

If you miss a period or suspect pregnancy, make arrangements without delay for a pregnancy test and an examination.

Evidence has shown that if pregnancy occurs with an IUD in place it is important for the device to be removed as soon as possible.

Infection

If infection occurs while wearing an IUD, prompt treatment must be commenced to prevent any serious consequences. If you have any continuous lower abdominal pain, fever, pain on sexual intercourse or persistent, unusual discharge, contact your doctor at once.

Physiotherapy

Women using copper carrying IUDs, such as the Multiload, should not have microwave, short wave or diathermy treatment to the lower abdomen or back.

When you wish to become pregnant

Arrange to have your Multiload removed, do not attempt to remove it yourself.

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