

MULTILOAD ®

^{cu}250 / ^{cu}375

CE

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Read all of this leaflet carefully before you decide to have Multiload Radiopaque inserted.

This leaflet provides information that may help you in your decision to start using Multiload. It will also advise you how to use Multiload properly and safely. Keep this leaflet and read it also regularly while using Multiload, since it is important to stay alert on matters that do not affect you now, but may affect you in the future. If you have further questions, please ask your doctor, professional health care provider or pharmacist.

In this leaflet:

1. What is Multiload Radiopaque and what is it used for
2. Manufacturer
3. What does Multiload do
4. When should you not use Multiload
5. What do you need to know before using Multiload
 - 5.1 General notes
 - 5.2 Multiload and other medicines
 - 5.3 Multiload and other treatments
 - 5.4 Multiload and breast feeding
 - 5.5 Multiload and pregnancy
 - 5.6 Multiload and the ability to drive and use machines
6. When should you contact your doctor
7. How should Multiload be used
 - 7.1 How should Multiload be inserted
 - 7.2 How can you check whether Multiload is still in place
 - 7.3 How long may Multiload be left in place
8. What side effects might you have while using Multiload
 - 8.1 Possible complications in the beginning
 - 8.2 Infections of the sex organs or urinary tract
 - 8.3 Breakage
 - 8.4 A shifting IUD
9. Storage and shelf-life
10. Package

11. Customer services
12. Last revision of this package leaflet
13. Explanation of symbols used on the package and user card

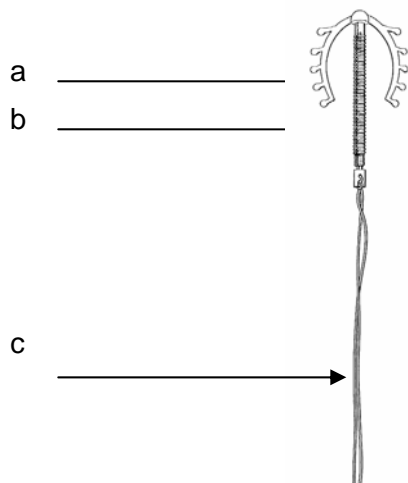
1. WHAT IS MULTILOAD RADIOPAQUE AND WHAT IS IT USED FOR

Multiload is an IUD, an intra uterine device, used for contraception (Please see: 'What does Multiload do'). It is a small plastic rod, called stem, with two small flexible side-arms. The plastic is a mixture of high density polyethylene, ethylene vinyl acetate copolymer and barium sulphate in a weight ratio 44/36/20. A copper wire is wound around the stem. A nylon thread with two ends is attached to the bottom end of the stem (Figure 1).

Multiload is intended for single use only.

Figure 1

- a. flexible plastic arms
- b. small plastic rod with copper wire wound around it
- c. nylon thread



Three different Multiloads are available. Your doctor will decide which one suits you best. It depends on how long you want to use Multiload, and the size of your womb.

Multiload-cu 250 has a copper wire with a surface of 250 square millimeters. It works for three years.

Multiload-cu 375 has a thicker copper wire, with a surface of 375 square millimeters. It works for five years.

The Multiload-cu 250 comes in a standard length; the Multiload-cu 375 comes in a standard and short length, to suit the size of your womb.

2. MANUFACTURER

Multilan AG, P.O. Box 2857, Drynam Road, Swords, Co. Dublin, Ireland.

3. WHAT DOES MULTILOAD DO

Multiload is an IUD. IUD stands for 'intra-uterine (contraceptive) device': an object in the womb. An IUD does not guarantee absolute protection against pregnancy, but it is very effective. It works as soon as it is fitted.

The IUD your doctor advised you to use is *Multiload*.

In order to explain how Multiload works we first would like to point out a few things.

A short lesson in anatomy

Figure 2

The womb or uterus (c) is located in the lower part of the abdomen ('tummy'), just above the pubic bone. The womb is a pear-shaped, muscular organ, slightly smaller than your fist.

The womb is joined to the cervix(d) , and the vagina (e). The fallopian tubes (a) extend from both sides of the upper part of the womb to the ovaries (b).

Together the ovaries, fallopian tubes, womb and vagina form the female sex organs. They are not functional until puberty.

Figure 2

- a. fallopian tubes
- b. ovaries
- c. womb
- d. cervix
- e. vagina

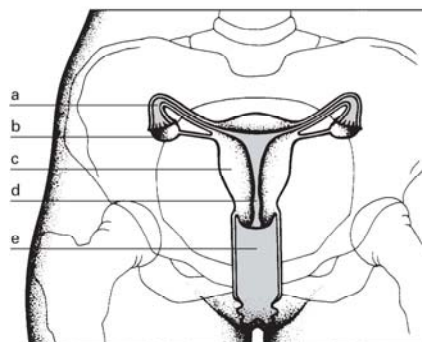


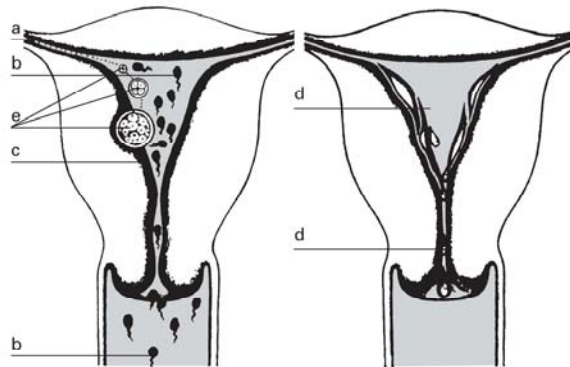
Figure 3

When a woman starts having periods (menstruating) she is sexually mature. Around every four weeks a tiny egg cell (which is smaller than this . dot) ripens in one of the ovaries.

This egg cell (a) travels through the fallopian tube where it may be fertilized by a male seed cell (sperm, b in Figure 3).

While the egg cell travels through the fallopian tube, the womb prepares to receive a fertilized egg. The inside of the womb is lined with mucous membrane (c) (just like the inside of your mouth). At about the time when an egg cell is ready to be fertilized, this membrane - the endometrium - becomes twice as thick as normal, and tiny blood vessels supply it with an extra quantity of blood.

Figure 3:



If the egg cell is *not* fertilized, a part of the endometrium is shed after fourteen days, together with a quantity of blood and : menstruation (d) takes place.

If the egg is fertilized, it travels from the fallopian tube into the womb. Here, it attaches to the mucous membrane (e), usually high up in the womb. If this happens, the mucous membrane is not shed and: no menstruation takes place.

An age old method rediscovered

For more than 2000 years it has been known that pregnancy can be prevented by inserting objects into the womb, such as a pebble, a ring or a wire.

Doctors have developed a modern and reliable way of contraception based on this age-old method. An important discovery was that the reliability of IUDs is greatly improved by adding copper.

How an IUD prevents pregnancy is not exactly known yet, but it is generally believed that an IUD prevents the sperm meeting and fertilizing an egg cell.

4. WHEN SHOULD YOU NOT USE MULTILOAD

Your doctor will take a thorough look at your medical records to find out if there is any reason why you should not use an IUD. In addition, you must tell your doctor all about your state of health.

You should not use Multiload if any of the following applies to you:

1. tumors of the womb or cervix;
2. vaginal bleeding with an unknown cause;
3. pregnancy or suspected pregnancy;
4. an increased risk of extra-uterine (or 'ectopic') pregnancy. That is a pregnancy in which a fertilized egg does not implant in the womb, but for instance in a fallopian tube.

The risk is higher if you have had an ectopic pregnancy before, or if you have ever had an infection of the womb or the fallopian tubes (pelvic inflammatory disease, PID);

5. abnormalities of the womb or the cervix; many or large fibroids (benign growths of the uterine wall) together with very heavy menstrual periods; endometriosis (growth of uterine tissue outside the womb or fallopian tubes);
6. an infection of the reproductive organs, with the exception of candidiasis (the latter is an infection caused by the skin fungus *Candida albicans*);
7. a sexually transmitted disease during the past 12 months (with the exception of vaginal infections caused by bacteria, candidiasis, or infections caused by the herpes virus, the hepatitis B virus, or the cytomegalovirus);
8. an infected miscarriage or abortion in the past 3 months;
9. PID (pelvic inflammatory disease, infection of the womb or the fallopian tubes), or if you suffer repeatedly from PID;
10. an allergy to copper.

5. WHAT DO YOU NEED TO KNOW BEFORE USING MULTILOAD

IUDs DO NOT protect against HIV infection (AIDS) or any other sexually transmitted disease.

5.1 General notes

You should be informed by your doctor on all aspects of Multiload including those concerning your health and future fertility.

Your doctor should arrange regular check-ups for you.

Contact your doctor about any changes in your state of health, which you think may be due to the use of Multiload.

Tell any doctor you consult that you are using an IUD.

5.2 Multiload and other medicines

Some medicines may prevent Multiload from working properly. This can lead to decrease in contraceptive efficacy. This is the case for medicines that suppress the immune system (for instance given to prevent rejection of a graft after transplantation), corticosteroids, and 'nonsteroidal anti-inflammatory drugs' (NSAIDs) including painkillers such as aspirin. If you need long-lasting intensive treatment with any of these medicines, another method of contraception might be more appropriate.

If you have to undergo intensive treatment with any of these medicines on occasion, during these periods you should take additional protective measures (for example by using a condom).

There are also indications that tetracycline antibiotics may hinder the working of an IUD.

Always tell your doctor or dentist who prescribes another medicine that you use Multiload. He/she can tell you if need to take additional contraceptive precautions and if so, for how long.

5.3 Multiload and other treatments

When you have microwave, shortwave or diathermy treatment of the lower abdomen or back, inform your (physio)therapist that you use a copper-bearing IUD.

Magnetic Resonance Imaging (MRI) does not negatively influence the working of Multiload. Multiload does not impair the scan obtained with MRI.

5.4 Multiload and breast feeding

Multiload may be used while you are breast feeding. However, as there may be an increased risk that Multiload may pass the uterine wall during breast feeding,

particular care should be taken. Therefore, if you wish to use Multiload while breastfeeding, please seek the advice of your doctor.

5.5 Multiload and pregnancy

Even when using an IUD, there is still a very slight chance that you become pregnant. If this happens, pregnancy could lead to serious complications. So you should contact your doctor if your period is two weeks or more late. The IUD should be removed as soon as pregnancy is established. Sometimes, removing the IUD leads to a miscarriage.

If you insist on continuing the pregnancy without removal of the IUD, you ought to be referred to a gynaecologist. This because such a pregnancy requires a good medical support. You must tell your doctor immediately if you have complaints such as flu, fever, cramping or pain in your tummy, pain during intercourse and vaginal bleeding or discharge.

If you do get pregnant with the IUD in place, there is a chance of having an extra-uterine pregnancy (a fertilized egg not implanting in the womb, but for instance in a fallopian tube). Although a copper loaded IUD protects also against extra-uterine (ectopic) pregnancies, it protects better against a normal pregnancy. An extra-uterine pregnancy is a serious condition, which needs urgent medical attention.

Some signs of an ectopic pregnancy are:

- your period is two or more weeks late;
- severe one-sided lower abdominal pain with or without vaginal bleeding;
- shoulder tip pain;
- dizziness or fainting.

You must tell your doctor immediately if you have any of these signs.

5.6 Multiload and the ability to drive and use machines

It is unlikely that Multiload affects the ability to drive and the capability to use machines.

6. WHEN SHOULD YOU CONTACT YOUR DOCTOR

You should have extra check-ups by your doctor if any of the following apply to you:

1. valvular heart disease. The use of an IUD may increase the risk of a bacterial inflammation of the inside lining of the heart (endocarditis). To prevent this, treatment with antibiotics should be given on inserting or removing the IUD;

2. anaemia, or a history of severe uterine bleeding;
3. if you have a blood clotting disorder, or if you are using medicines that interfere with blood clotting (anti-coagulants);
4. painful or irregular menstruation;
5. uterine scars from perforation, or from surgery (other than caesarean section);
6. small fibroids (benign growths of the uterine wall), polyps (benign growths of the uterine mucous membrane), or endometriosis (growth of uterine tissue outside the womb or fallopian tubes);
7. a disorder of the copper metabolism (that is the way in which your body takes up and excretes copper), for instance Wilson's disease;
8. an infection of the lower genital tract (cervix and vagina), or if you suffer from that repeatedly;
9. sexual contact with multiple partners and unsafe sexual habits do increase the risk of PID. So tell your doctor if you or your partner have other sexual partners.

7. HOW SHOULD MULTILOAD BE USED

7.1 How should Multiload be inserted

Multiload has to be inserted by a doctor. After examining your womb to determine its position, size and condition, an instrument called 'speculum' is inserted into your vagina (as for a smear test) and the cervix and vagina are cleaned with antiseptic lotion.

The womb is held steady while its length is measured.

Your doctor uses a thin plastic tube to insert Multiload into your womb. After insertion of Multiload, the two threads reach into the top of the vagina (see Figures 4 and 5) so that you can check if Multiload is still in place. Your doctor will show you how to do this.

Figure 4:

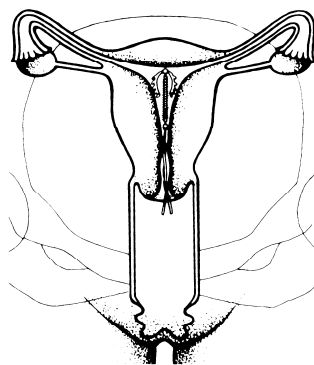
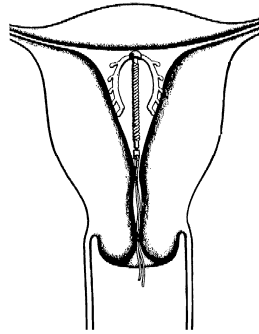


Figure 5:

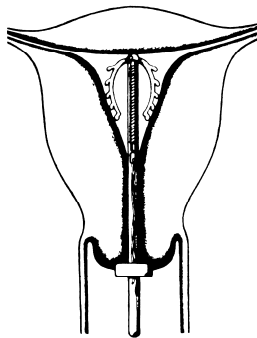
These pictures show how Multiload is inserted

- A. The flexibility of Multiload allows it to go through the cervix easily.
- B. This picture shows Multiload when completely inserted into the womb.
- C. After the removal of the insertion tube Multiload is left high in the womb.

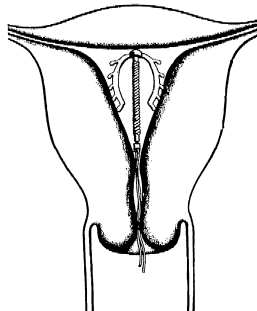
A:



B:



C:



7.2 How can you check whether Multiload is still in place

Neither you nor your partner should feel Multiload during intercourse. If you do, tell your doctor.

Sometimes an IUD is pushed out of the womb into the vagina ('expulsion'). Your womb remains slightly open during your menstrual period, so the chance of expulsion is somewhat higher during these days. Always check your sanitary towel or tampon before disposing of it. (Menstrual tampons can be freely used.)

Make sure after each period and at any time you have an unusual pain in your abdomen during your period, that you do feel the *threads* deep down in the vagina, and that you do not feel the *rod* sticking out of the cervix. Always wash your hands carefully before and after this examination.

If you do not feel the threads, or if you do feel the firm part of Multiload, you should contact your doctor. Until you have been examined, use an additional form of contraception such as a condom.

7.3 How long may Multiload be left in place

Ask your doctor when Multiload should be replaced. With Multiload-cu 250 this is usually done after 3 years; with Multiload-cu 375 after 5 years. If necessary, remind your doctor of the need of replacement.

To help you remember when Multiload was inserted, and when Multiload must be removed at the latest, your doctor will give you a User Card that shows these data. Keep this card carefully. This card is also important in case you want to report any complaints about Multiload.

If you want to become pregnant, ask your doctor to remove Multiload.

8. WHAT SIDE EFFECTS MIGHT YOU HAVE WHILE USING MULTILOAD

8.1 Possible complications in the beginning

Soon after Multiload has been fitted, you may have lower abdominal pain or cramps, but these usually get better quickly. If you have serious or persistent abdominal complaints or heavy bleeding you must tell your doctor.

Your heart rate and/or blood pressure may change during, or after insertion or removal of an IUD.

Your first, and sometimes your second menstruation may come slightly earlier than expected. These periods may last longer and be a bit more painful than usual.

In the beginning some bleeding may occur between menstrual periods. This is nothing to worry about, but mention it to your doctor during your next visit.

After two or three months everything should be back to normal again.

Occasionally complaints are reported, such as; pain in the back or legs, pain during intercourse, or itching eruptions of the skin as a result of an allergic reaction. If you notice such signs, contact your doctor immediately.

8.2 Infections of the sex organs or urinary tract

During the first weeks to months after insertion of an IUD, there is a slightly higher chance of infection of the womb and the fallopian tubes (pelvic inflammatory disease, PID). The chances of getting an infection are greater if you or your partner have other sexual partners.

Having PID can seriously affect your fertility in the future. An infection should be treated until it is completely cured. Sometimes the IUD has to be removed to ensure complete healing of the infection.

Signs of an infection of the sex organs or urinary tract are:

- flu-like complaints with a high temperature (over 38°C/100°F);
- persistent lower abdominal tenderness or pain;
- pain during or after sexual intercourse;
- prolonged or heavy menstrual bleeding;
- unpleasant-smelling vaginal discharge.

You must tell your doctor immediately if you have any of these signs.

8.3 Breakage

There have been occasional reports of the thread breaking when removing Multiload. Very occasionally the plastic body broke. This mostly happened when Multiload got stuck (embedded) in the wall of the womb. Breakage or embedding may require an operation (curettage) to remove the device or pieces of it.

8.4 A shifting IUD

In rare occasions an IUD may pass the uterine wall. If this occurs an operation may be required to remove the IUD and the uterine wall may need to be repaired.

9. STORAGE AND SHELF-LIFE

Don't open or damage the pouch.

In an intact package Multiload may be stored for five years, if kept dry and below 30°C in the original carton box.

Multiload may be inserted until the expiry date printed on the package.

10. PACKAGE

Pouch containing one sterile Multiload-cu 250 (Standard) or one Multiload-cu 375 (Standard or SL).

11. CUSTOMER SERVICES

In order to maintain the high quality of this the manufacturer is very interested in all your complaints or remarks with respect to Multiload. If you have any complaint or remark, it is recommended to discuss these with your doctor, but you may also report these directly to your local distributor of Multiload (for address details see User Card). Please always report the Lot number of the Multiload you are using; the Lot number is mentioned on your User Card.

12. LAST REVISION OF THESE INSTRUCTIONS FOR USE:

November 2008

13. EXPLANATION OF SYMBOLS USED ON THE PACKAGE AND USER CARD:



: Attention: see instruction for use



: Sterile, sterilized by irradiation



: Single use



: Use by



: Batch number



: Manufacturer



: Date of insertion



: Date of removal