

PATIENT CONSENT FORM - Copper IUD

Dear Patient,
you decided to use a copper IUD for contraception. Subsequent information should be part of the consultation by your physician to clarify all open questions.

Mode of action

There are different types of intrauterine contraceptive devices. Wide-ranging international studies still verify that copper-IUDs are not only safe but also effective over long periods. In addition, it is also generally recognized that copper IUDs are one of the most effective means of contraception. Copper IUDs are shaped in such a way as to prevent irritation of the uterus. It is usually inserted during menstruation. The insertion is normally painless. The opening of the uterus is examined, the length of the uterine cavity is determined and the IUD is carefully inserted into the uterine cavity, until it is in the correct position and touches the fundus. As soon as the copper IUD has been inserted, you are protected against pregnancy. The copper IUDs are highly effective and can only be compared with the oral contraceptive pill for the prevention of pregnancy. No contraceptive method offers 100% safety. However, in practical terms, with a copper IUD you are protected.

It is not fully known how copper IUDs work. However, nowadays it is assumed that the most probable effect is that it disrupts the normal function of the male gametes (sperm), which become incapable of fertilizing the female egg. It is also assumed that copper ions influence the development of the egg so that fertilization does not take place: IUDs are no longer considered a method of abortion.

Insertion and removal

Before the insertion, you must be informed on the efficacy, risks and side effects of a copper IUD. A gynecological examination including pelvic examination and a cervical smear should be performed. Pregnancy, genital infections and sexually transmitted diseases should be excluded. The position of the uterus and the size of the uterine cavity should be determined.

The instructions for insertion should be carefully taken into account and the patient card be filled out together with the attending doctor. You should return for check-up 4 to 12 weeks after insertion and once a year there after or more frequently if clinically indicated.

Insertion is recommended during or shortly following menstruation. If pregnancy is excluded, a copper IUD may be inserted at any time of the cycle. It can be also inserted immediately after first trimester abortion. After having a baby, insertion should be postponed until six weeks after delivery, as this is associated with greater rates of perforation and expulsion.

There are no problems about breast feeding with an IUD, but the risk of perforation for insertion while breastfeeding is increased.

A copper IUD is removed by gently pulling on the threads. If the threads are not visible, and the device is in the uterine cavity, removal should be postponed until after the next menstrual bleeding since the threads usually become visible immediately after menstruation. If they are still not visible, the device may be removed using a narrow forceps. This may require dilatation of the cervical canal. After removal, pregnancy is immediately possible.

If you wish to continue using the method, a new device can be inserted at the same time. If pregnancy is not desired, the removal should be carried out during the menstruation.

Insertion and removal may be associated with some pain and bleedings. Occasionally, the procedure may precipitate fainting or a seizure if you suffer from epilepsy.

It is recommended that you visit your doctor for a check-up one month after a IUD was inserted to make sure the IUD is still in your uterus and is positioned correctly. An annual visit is recommended thereafter. You should also check to make sure that the IUD is still in your uterus by reaching up to the top of your vagina, while in a squatting position, with clean fingers to feel the threads. Do not pull on the threads.

If you cannot feel the threads or you can feel more of the IUD than just the threads, consult your doctor immediately. This suggests that your copper IUD is not in the uterus or is incorrectly positioned which would increase your chances of getting pregnant. It is recommended that you use an additional birth control method until you have seen your doctor. It is good practice to check that the IUD is in place once a month.

Possible complications and precautions

The first three cycles following insertion are usually different from your normal cycles. Periods can be heavier, cramps and spotting may occur both before and afterwards. Three to four cycles after insertion of the IUD menstruation normally resumes as before insertion.

Sometimes these changes are experienced between the menstrual periods during the cycle.

The absolute risk of ectopic pregnancy is extremely low due to the high effectiveness of intrauterine devices. However, when a woman becomes pregnant during intrauterine contraceptive use, the relative likelihood of ectopic pregnancy is greatly increased, and should be excluded.

Due to the risk of infections and a possible higher risk of expulsion, the insertion of an IUD in nulliparous women may be reconsidered and the advantages and possible therapeutic risks should mutually be weight up carefully.

You should contact your doctor if:

- you cannot feel the threads of the IUD,
- you or your partner are able to feel the lower end of the IUD,
- you think you are pregnant,
- you experience abdominal pain, fever or unusual vaginal discharge,
- you or your partner feel pain or discomfort during sexual intercourse,
- your menstruation is delayed, since rarely a pregnancy outside the uterine cavity, e.g. in a fallopian tube (ectopic pregnancy) may occur,
- you wish to have the IUD removed and / or want to become pregnant.

Cases of expulsion of the IUD have been reported in women using a menstrual cup but there is no certainty whether the expulsion is caused by the cup. There is a possibility of a suction effect on the IUD when the menstrual cup is removed incorrectly. Please ask your doctor for advise on the correct use of the menstruation cup.

Interactions

The available experience indicates that, in general, drugs do not interfere with the contraceptive efficacy of a copper IUD. However, there are published reports which appear to show diminished efficacy with long-term use of non-steroidal anti-inflammatory drugs (especially acetylsalicylic acid) and corticosteroids. Short-term use in the treatment of dysmenorrhea with non-steroidal anti-inflammatory drugs does not appear to reduce contraceptive efficacy.

Side effects

In rare cases pain or dizziness may occur after insertion. If these complaints don't abate within half an hour of resting, the position of the IUD should be checked and the copper IUD may have to be removed. The IUD may rarely cause allergic skin reactions.

Consent form:

In a detailed consent conversation I was informed about the advantages and disadvantages of copper IUDs and I agree with the insertion of the following copper IUD:

- | | | |
|--|--|---|
| <input type="checkbox"/> T-Safe CU 380A QL | <input type="checkbox"/> Neo-Safe T CU 380 | <input type="checkbox"/> Neo-Safe T CU 380 Mini |
| <input type="checkbox"/> Multi-Safe CU 375 | <input type="checkbox"/> Multi-Safe CU 375 short | <input type="checkbox"/> CU-Safe T 300 |
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I am aware about the above mentioned problems and possible complications. Open questions were answered to my complete satisfaction. I am also aware of the necessity of regular check-ups.

date / signature patient

date / signature physician
