

Information for the user
Information destinée aux utilisatrices
Informatie voor de gebruikster
Information für die Frau
Informazioni per l'utilizzatrice
Información para la usuaria
Hasta için bilgi



MANUFACTURER - FABRICANT - FABRIKANT
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Contrel

*Controlled Release for the Enhancement
of Quality of Life of Women*

CONTREL EUROPE nv
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Information for the user

English

Whilst this information leaflet is intended to be helpful, we stress that this is not intended to and should not, replace the advice of a qualified medical professional.
www.wildemeersch.com

1. What is GyneFix®?

GyneFix® is an innovative contraceptive for women. GyneFix® is inserted in the wall of the uterus (womb). GyneFix® consists of 4 (GyneFix® 200) or 6 (GyneFix® 330) copper tubes which are threaded on a length of surgical suture. A tiny knot at the upper end of the thread keeps the IUD in place. This special characteristic of the device makes expulsion virtually impossible.

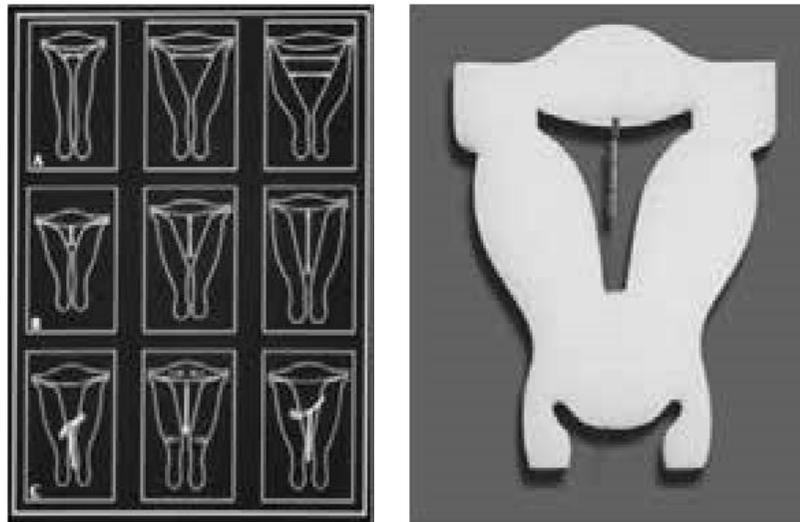
2. Why was GyneFix® developed?

Doctors have always considered the IUDs to be one of the most reliable forms of contraception. However older intrauterine devices (IUDs) were not favoured by women, many of whom complained of pain, discomfort, heavy bleeding and unintended expulsion in use. The new generation GyneFix® has been specially designed to be virtually trouble free whilst maintaining the superior levels of reliability, ease of use and spontaneity in relationships which women and their partners welcome.

The ideal IUD should possess the following characteristics:

- Highly effective in preventing pregnancy
- Easy to insert and remove
- Few side-effects
- Should not increase menstrual blood loss
- Rapid return of fertility on removal
- Not readily dislodged or expelled
- Usable for all women, also for young women

The dimensions and the shape of the uterine cavity differs from woman to woman (see figure). Conventional IUDs are less flexible and often too big, which will likely elicit uterine cramps and abnormal menstrual bleeding. GyneFix® differs from conventional IUDs by its very small size and because it has no frame which makes it completely flexible. In others words, it takes less space in the uterine cavity and its flexibility allows a perfect adaptation to all uterine cavities. These properties, including its fixation to the uterine fundus, makes expulsion very rare.



3. Advantages of GyneFix®

The main advantages of GyneFix® are:

- High efficacy (as high as the pill when taken correctly)
- Well tolerated and almost no side effects
- Small and flexible and, therefore very comfortable
- No increased menstrual bleeding especially with GyneFix® 200
- Can be used by women of all ages, also in young women with a small uterus (womb)
- Long duration of action (5 years)

- Easy to insert and remove*
- No effect on menstrual cycle and ovulation
- Non hormonal and, therefore, no disturbance of your hormonal cycle
- Rapid return to fertility

* GyneFix® should be inserted by a properly trained provider. Please contact: info@contrel.be.

4. How effective is GyneFix®?

The effectiveness of GyneFix® is superior than all other conventional copper IUDs. In use, GyneFix® is more effective than the pill (0,1 to 0.5% pregnancies with GyneFix® against 5% or more with typical use of the pill after one year of use).

GyneFix® can also be used as post-coital method and provides almost 100% protection against pregnancy up to 5 days after sexual contact. GyneFix® is even the first option intrauterine device for use in young women with a small uterus and for those who never gave birth. GyneFix® offers continued protection, whilst the morning after pill only prevents 3 out of 4 pregnancies.

5. How does GyneFix® prevent pregnancy?

The copper tubes of GyneFix® release copper ions that kill sperm and prevent fertilisation of the egg. GyneFix® also prevents ectopic pregnancy.

6. Are there side effects?

Following GyneFix® insertion slight bleeding, that lasts for a few days may occur. As your body accustoms itself to your GyneFix®, you will find that any increased bleeding or spotting will tend to lessen. After a few periods your bleeding patterns will steadily return to normal.

7. Who can use GyneFix®?

GyneFix® is an ideal contraceptive for many women, even for younger women because it is small, effective and well tolerated. Unlike the pill, it is genuinely ‘fit-and-forget’. In use, it is much more effective than pills in this age group.

GyneFix® is also suitable for women who do not have children yet as the small IUD fits in the small cavity of young women.

GyneFix® can even be used by adolescent women.

GyneFix® does not offer protection against STDs as AIDS and hepatitis B. Women who have several sexual partners should use a condom for additional protection.

Important information for the GyneFix® user:

- Although pregnancy and PID have been rarely observed, you should **see a doctor immediately** at the first signs of pregnancy (period late, abnormal spotting or bleeding) or of pelvic infection (stomach pain, painful sex, offensive discharge, fever).
- You should **not use tampons nor mooncup in the first 14 days** after insertion and you should **inspect your pads during the first menstruation** to ensure that GyneFix® has not been expelled.
- Partial or total perforation of the uterine wall or cervix has occurred with the use of conventional IUDs, most commonly during IUD insertion. Although perforations with GyneFix® are rare (approximately 0.5/1000), the possibility of perforation must be kept in mind. In case of perforation or suspicion of perforation, you should contact your healthcare provider.
- **You can have sex as usual (no sex for the first 7 days after insertion)**. If the thread bothers your partner, it can be shortened or looped in the cervical canal.
- **Menstrual bleeding** may be heavier and last longer, especially in the beginning. There may be spotting, especially in the beginning. This usually settles down.
- You should know that you have a GyneFix® IUD and **when it needs to be replaced**. Therefore ask your doctor for your GyneFix Pass.
- **If you get pregnant, the GyneFix® should be removed** if possible.
- You should know that **GyneFix® offers no protection against sexual transmitted diseases** and if you do not have a long-term, single partner sexual relationship, you should use additional protection, such as condoms.

A follow-up examination is compulsory after the first menstruation.

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Nothing in this leaflet should be construed as giving advice or making a recommendation, and it should not be relied on as the basis for any decision or action. It is important that you rely only on the advice of a healthcare professional to advise you on your specific situation or possible risks.

STERILE EO



STERILIZED USING ETHYLENE OXIDE

DO NOT REUSE



DO NOT RESTERILIZE



MANUFACTURER

CONTREL EUROPE

IIC UGent Technologiepark 82, 9052 Gent, België



INSTRUCTIONS FOR USE AND INSERTION TECHNIQUE



DO NOT USE IF PACKAGE IS DAMAGED



TEMPERATURE LIMITATION (0°C -35°C)

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