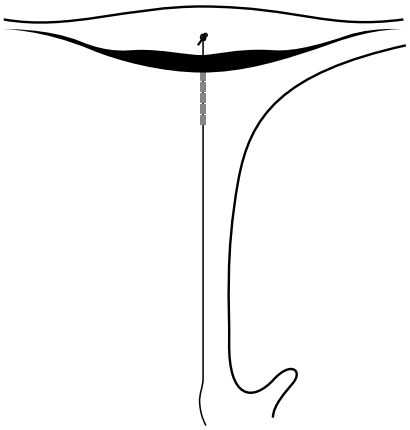

GyneFIX®

Information for Patients

MANUFACTURER

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

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Contents

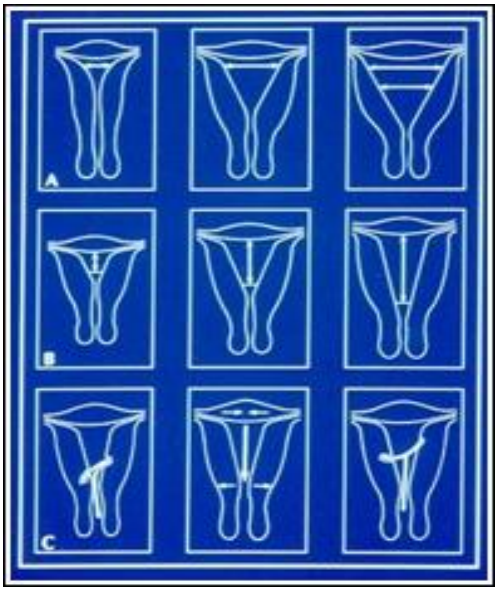
Whilst this information leaflet is intended to be helpful, we stress that this is not intended to and should not replace the advice of a qualified medical professional.

1. What is GyneFix®?

GyneFix® is contraceptive device. GyneFix® is inserted in the fundus of the uterus. GyneFix® consists of 4 (GyneFix® 200) or 6 (GyneFix® 330) copper tubes which are threaded on a surgical suture. A tiny knot at the upper end of the thread keeps the GyneFix® in place. This special characteristic makes expulsion virtually impossible. GyneFix® has a duration of action of 5 years.

2. Why was GyneFix® developed?

Doctors have always considered intrauterine devices (IUDs) to be one of the most reliable forms of contraception. However, conventional IUDs are not favoured by all patients, many of whom complain of pain, discomfort, heavy bleeding, expulsion and/or perforation. 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 patients and their partner welcome.
The dimensions and the shape of the uterine cavity differs significantly between individuals (see figure). Conventional IUDs are less flexible and often too big, which will likely elicit uterine cramps and increase menstrual bleeding. GyneFix® is different from conventional IUDs by its small size, and because it is frameless and therefore completely flexible. In other 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 adverse events rare, when correctly inserted by a GyneFix® trained and certified doctor.



3. Advantages of GyneFix®

- Very effective contraceptive device.
- Well tolerated and almost no side effects.
- Small and flexible, therefore very comfortable.
- No increased menstrual bleeding with GyneFix® 200.
- Suitable for small to large uterine cavities.
- Long duration of action.
- Easy to insert*.
- Easy to remove.
- No effect on menstrual cycle and ovulation.
- Non hormonal and, therefore, no disturbance of your hormonal cycle.
- No weight gain.
- Safe to be used while breastfeeding.
- Positioning and retention easily monitored by ultrasound.
- Immediate return to fertility after removal.

** GyneFix® should **ONLY** be inserted by a properly trained and GyneFix® certified doctor.*

4. How effective is GyneFix®?

The pregnancy rates with GyneFix® are similar or lower compared with the most effective high-load copper devices, oral contraceptives, and surgical sterilization procedures.

5. How does GyneFix® prevent pregnancy?

Available data indicate that the contraceptive effectiveness of copper devices is enhanced by a minute quantity of copper being released continuously into the uterine cavity. The exact mechanism by which copper enhances the contraceptive effect of an IUD has not been conclusively demonstrated. Various hypotheses have been advanced, the major one being that copper in the uterus interferes with enzymatic or other processes that regulate blastocyst implantation. Recent studies suggest that copper may play a role in reducing sperm transport within the uterine environment.

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 pattern will steadily return to your normal pattern.

7. Who can use GyneFix®?

It can be used in woman who have never been pregnant or in women with multiple births. It is suitable for use in adolescents because of its small size and flexible design. It is genuinely 'fit-and-forget' while being more effective than other means of contraception.
GyneFix® is suitable as emergency contraception (**up to 5 days** following sexual intercourse).
GyneFix® is even suitable for adolescents.
GyneFix® can be inserted immediately after a spontaneous or induced first trimester abortion of **less than 10 weeks** gestational age.
GyneFix® is **not suitable** for use in the immediate post placental period. A period of **at least 8 weeks** should be allowed until the uterus has **regained its normal size** and the patient has had at

least **one normal menstrual period**. In breastfeeding women, however, a period of **12 weeks** following full term delivery is recommended because of the higher risk of perforation reported in some studies with conventional IUDs. Breastfeeding patients must have had at least **one normal menstrual** period before insertion.

8. Will GyneFix® interfere with sexual intercourse?

You and your partner should not feel GyneFix® during intercourse. If the thread bothers your partner, it can be looped in the cervical canal or shortened.

9. Magnetic Resonance Image (MRI) with GyneFix®?

MRI conditional.

10. Important information

- **Do not have sexual intercourse in the first 14 days following insertion.**
- **Do not grab or tug the thread (which could remove the GyneFix®).**
- **Do not use tampons or menstrual cups in the first 2 months following insertion.**

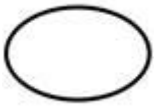
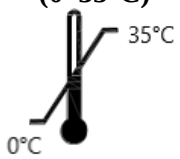
In case using tampons or menstrual cups, please, follow the manufacturer's instructions

- Check your pads for possible loss **during the first menstruation** to ensure that **GyneFix®** has not been expelled.
- There may be spotting and/or **menstrual bleeding** may be heavier and last longer in the beginning. This usually settles down.
- **A follow-up examination is required 4 to 8 weeks following insertion and thereafter yearly.**
- You should know that you have a **GyneFix®** device and **when it needs to be replaced**. Therefore, ask your doctor for your **GyneFix® Pass.**

When reporting an event, a copy, scan, or picture of your GyneFix® Pass is required to process your complaint adequately

- **GyneFix® should only be inserted by a GyneFix®certified trained doctor.**
- Although perforations with GyneFix® are rare, the possibility must be kept in mind. **In case of suspicion of perforation, you should contact your healthcare provider**.
- Although pregnancy is rare, you should **visit a doctor immediately** at the first signs of pregnancy (period late, abnormal spotting or bleeding). If you get **pregnant**, your doctor should advise you to **remove the GyneFix® or not**.
- Ectopic pregnancy can occur although it is a rare event. The use of a copper intrauterine device reduces the risk of an ectopic pregnancy.
- Although Pelvic Infection Disease (PID) is rare, you should **visit a doctor immediately** at the first signs of pelvic infection (stomach pain, painful sex, offensive discharge, fever).
- **GyneFix® offers no protection against sexual transmitted diseases** (HIV, hepatitis B, others). Be advised to use additional protection, such as condoms.

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.

Manufacturer  Contrel Europe nv IIC, UGent Technologiepark 82, 9052 Gent (Zwijnaarde), Belgium	**Medical device** 	**Consult electronic instructions for use**  eIFU indicator: https://www.contrel.be/IFU/GyneFix
Caution **Do not insert unless properly trained!** 	**Do not use if package is damaged** 	**Sterilized using ethylene oxide** 
Do not resterilize 	**Single sterile barrier system** 	**Store at room temperature (0–35°C)** 
Do not reuse 	**MR conditional** 	**Protect against humidity** 
Avoid direct sunlight 	**Expiry date** 	**Lot number** 

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