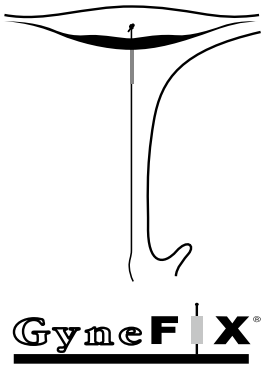

Developed by Dirk Wildemeersch MD, PhD

Information for Patients (PIP)

MANUFACTURER

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

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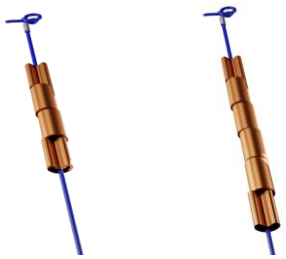
Contents

I. What is GyneFix®?....3
II. GyneFix® duration of action....3
III. Why was GyneFix® developed?....3
IV. How does GyneFix® prevent pregnancy?....4
IV. Advantages of GyneFix®....4
V. How effective is GyneFix®?....4
VII. What if I become pregnant while using GyneFix®?....4
VIII. Contraindications....4
IX. Are there side effects?....5
X. Who can use GyneFix®?....5
XI. Will GyneFix® interfere with sexual intercourse?....5
XII. Magnetic Resonance Image (MRI) with GyneFix®?....5
XIII. Important information....5

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.

I. What is GyneFix®?

GyneFix® is an innovative 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.



II. GyneFix® duration of action

GyneFix® 200 & **GyneFix® 330:** 4 or 6 copper tubes with a duration of action **up to 5 years.**

Once the full duration of action is reached, replace the device, or use a second method to prevent pregnancy!

III. 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.

IV. How does GyneFix® prevent pregnancy?

Available data indicate that the contraceptive effectiveness of contraceptive devices is enhanced by the addition of copper, from which minute quantities are 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.

V. Advantages of GyneFix®

- Easy to insert*.
- Easy to remove.
- High efficacy.
- Immediately active.
- Immediate return to fertility after removal.
- Long duration of action.
- Limited impact on menstrual bleeding.
- No impact on libido.
- No weight gain.
- Non hormonal and, therefore, no disturbance of your hormonal cycle.
- Position and retention easily monitored by ultrasound.
- Safe to be used while breastfeeding.
- Reduces the risk of ectopic pregnancy.
- Small and flexible, therefore very comfortable.
- Suitable for very small to large uterine cavities.
- Well tolerated and almost no side effects.

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

VI. How effective is GyneFix®?

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

VII. What if I become pregnant while using GyneFix®?

Although pregnancy has been rarely observed, you should **consult a doctor immediately** at the first signs of pregnancy (late period, abnormal spotting or bleeding, stomach pain, painful sex, offensive discharge, and/or fever).

VIII. Contraindications

- Anaemia (low red blood cell count).
- Condition of the uterus that changes the shape of the uterine cavity, such as large fibroids.
- Copper and/or polypropylene allergy (very rare).
- Multiple sexual partners or suspect that your partner has multiple sexual partners.
- Pelvic infection, pelvic inflammatory disease (PID).
- Problems with your immune system and susceptibility to infections.
- Sexually transmitted disease (STD).
- Suspect you might have cancer of the uterus or cervix.

- Wilson's disease.

IX. 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.

X. 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.

XI. Will GyneFix® interfere with sexual intercourse?

You and your partner should not feel GyneFix® during intercourse. In case needed, ask the doctor to shorten the thread.

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

MRI conditional.

XIII. Important information

- GyneFix® **must** only be inserted by a GyneFix® insertion trained doctor.
- 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.

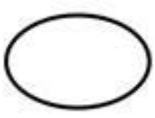
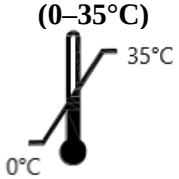
In case using tampons or menstrual cups, please, follow the manufacturer's instructions

- Check your pads for possible **GyneFix®** loss **during the first menstruation.**
- There may be spotting and/or **menstrual bleeding** may be heavier and last longer in the beginning. This usually settles down.
- The first follow up should be at **4-8 weeks** following insertion and **then annually at the minimum.**
- You should know that you have a **GyneFix®** device and **when it needs to be replaced**. Therefore, ask your doctor for your **GyneFix® implant card/pass.**

When reporting an event: a copy, scan, or picture of your GyneFix® implant card/pass is required to process your complaint adequately

- Although perforations with GyneFix® are rare, the possibility must be kept in mind. **In case of suspicion of perforation, you should contact the inserting doctor or a 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.
- Pain felt during the removal process is concentrated at the anchor point, which can be minimized by coughing at the instance of GyneFix® removal. The lack of horizontal arms that fold in during removal, as opposed to T-shaped IUDs, eliminates the most painful step of the removal procedure.
- If you do not have a long-term single partner sexual relationship, you should use additional protection, such as condoms.
- **Never try to remove the GyneFix® yourself!**

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**
Contains a medicinal substance (copper 99,99%)	**Single sterile barrier system with protective packaging outside**	**Keep safe from children**
GyneFix® 200 & GyneFix® 330 PIP code: W-10.04.2 ***Revision:*** *9th January 2024* ***Version:*** *14.2*		