

GyneFIX[®]

**GyneFix[®] 10
Information for Patients**

MANUFACTURER



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

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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® 10?

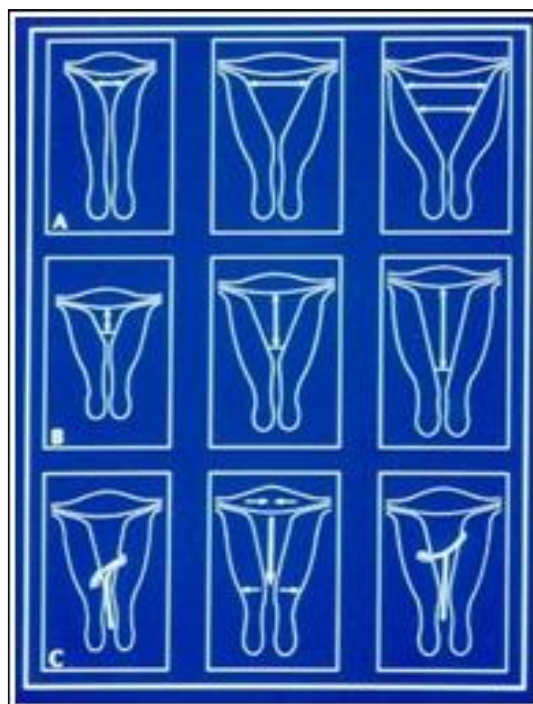
GyneFix® is an innovative contraceptive for women. GyneFix® is inserted in the wall of the uterus. GyneFix® 10 consists of 6 copper tubes which are threaded on a length of surgical suture. A tiny knot at the upper end of the thread keeps the GyneFix® in place. This special characteristic of the device 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 traditional intrauterine devices (IUDs) were not favoured by women, many of whom complained of pain, discomfort, heavy bleeding, and/or expulsion. 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 partner welcome.

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 increase menstrual bleeding. GyneFix® differs 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 expulsion rare.



3. Advantages of GyneFix®

- High efficacy (as high as the pill when taken correctly).
- Well tolerated and almost no side effects.
- Small, flexible, and therefore very comfortable.
- Can be used by women of all ages irrespective of cavity size, also in young women with a small uterus.
- Long duration of action (up to 10 years).
- 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.
- Retention and positioning 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.

GyneFix® can also be used as emergency contraception up to 5 days following sexual contact.

5. How does GyneFix® prevent pregnancy?

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

Copper leads to decreased sperm and egg viability. In the unlikely event that fertilization does occur, the same inflammatory actions are directed against the blastocyst, and the endometrium is transformed into a hostile site for implantation. With copper IUD, copper levels increase in the mucus of users and lower sperm motility and viability (*Cunningham F. G., Leveno K. J., Bloom S. L., Hauth J. C., Rouse D. J., Spong C. Y. 2010. "Williams Obstetrics, 23rd Edition". McGraw-Hill Companies, Inc. Medical. 1835pp.*). Ectopic pregnancy can occur although it is a rare event. The use of GyneFix® reduces the risk of ectopic pregnancy.

If you present pregnancy symptoms, please contact your doctor immediately.

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 including oral pills.

GyneFix® is suitable as emergency contraception (**up to 5 days** following intercourse).

GyneFix® can be used by adolescent women.

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 6 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 traditional IUDs.

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

- **No sex or self-gratification in the first 14 days following insertion.**
- **Do not touch or pull the thread.**
- **Do not use tampons or menstrual cups in the first 2 months after insertion.**

<p>In case using tampons or menstrual cups, please, change in time according to the manufacturer's instructions</p>
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- Check your pads for possible loss, **during the first menstruation** to ensure that GyneFix® has not been expelled.
- **Menstrual bleeding** may be heavier and last longer, in the beginning. There may be spotting, especially 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.

<p>When reporting an event, a copy, scan, or picture of your GyneFix® Pass is required to process your complaint adequately</p>
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- **GyneFix® should only be inserted by a GyneFix® insertion trained doctor.**
- 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, the possibility of perforation must be kept in mind. In case of perforation or 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**.
- Although PID (Pelvic Infection Disease) is rare, you should **visit a doctor immediately** at the first signs of pelvic infection (stomach pain, painful sex, offensive discharge, fever).
- You should know that **GyneFix® offers no protection against sexual transmitted diseases** (HIV, hepatitis B, others) and if you do not have a long-term, single partner sexual relationship, you should use additional protection, such as condoms.

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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.

CE marking

CE 1639

Sterilized using ethylene oxide



Do not reuse



Do not resterilize



Manufacturer



Control Europe nv
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9052 Gent (Zwijnaarde), Belgium

Consult electronic instructions for use

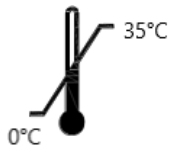


eIFU indicator: www.gynefix.be, www.control.be

Do not use if package is damaged



Store at room temperature (0-35°C)



Lot number



Caution

Do not insert unless properly trained!



Expiry date



MR conditional

