



Cu 380
Standard - Mini

YANAE® Cu 380 standard and YANAE® Cu 380 mini
Intrauterine devices (IUD)

PATIENT INFORMATION LEAFLET

Your healthcare professional has prescribed the YANAE® Cu 380 IUD for your contraception. This leaflet, for your own use, will provide you with the necessary information and will answer some of your questions. Fill the associated card with the help of your healthcare provider and keep it, you can use it as a reminder of the date of IUD insertion and of the follow-up and replacement visits. The information contained in this leaflet does not replace the advice of your healthcare professional.

What is Yanae®?

Yanae® is a Y-shaped, copper, non-hormonal IUD providing reversible contraception for 5 years. It is associated with an inserter that facilitates its insertion. It is a medical device with CE marking, in compliance with European Directive 93/42/EEC on medical devices. Its manufacture meets very strict requirements with regards to quality and sterility. Yanae® is available in two sizes, standard and mini. Your healthcare professional will choose the model most adapted to the size and anatomy of your uterus.

How does a copper IUD work?

Copper provides the contraceptive effect of the IUD. It creates a nonviable environment for sperm cells and modifies the uterine mucosa making it less adapted to pregnancy.

How effective is Yanae®?

The World Health Organisation indicates that with a copper IUD, the risk of unwanted pregnancy in the first year of use is less than 1%⁽¹⁾.

Yanae® Cu 380 does not provide protection against sexually transmitted infections.

What are the indications for Yanae®?

Yanae® is a non-hormonal intrauterine contraceptive device that allows preservation of natural cycles. Yanae® is indicated for all women of childbearing age, including adolescents and women who have never been pregnant. Apart from the contraindications described below, it can be introduced after childbirth or a termination of pregnancy and can also be used as emergency contraception.

What are the contraindications to the use of Yanae®?

Absolute contraindications⁽¹⁾:

- Any suspected or proven pregnancy
- Post-partum puerperal infection
- Immediately after a septic abortion
- Ongoing pelvic inflammatory disease
- Ongoing purulent cervicitis, or ongoing chlamydia or gonorrhoea infection.

- Proven genitourinary tuberculosis
- Unexplained vaginal bleeding (suspected serious pathology)
- Malignant gestational trophoblastic disease
- Cervical cancer
- Endometrial cancer
- Any congenital or acquired malformation leading to a deformation making IUD insertion impossible
- Uterine fibroids with deformation of the uterine cavity
- Hypersensitivity to copper or to one of the components of the device

Insertion of an IUD is not recommended:

- In the post-partum period between 48 hours and 4 weeks after childbirth
- In the event of an increased risk of sexually transmitted infections.

How is Yanae® inserted?

The Yanae® insertion procedure must be performed by a healthcare professional trained in the insertion of IUDs.

Yanae® can be inserted at any time in the cycle: you will choose the most appropriate moment for you with your healthcare professional. The insertion is performed in a few minutes, in the common gynaecologic position, using a speculum which allows good visualisation of the cervix. After disinfection, the IUD is introduced into the uterine cavity using the inserter. The inserter will then be removed and the strings cut a few centimetres away from the cervix. The speculum will also be removed.

What happens after insertion of Yanae®?

The contraceptive efficacy of Yanae® starts from the first day after insertion. It is possible that you may feel some pelvic pain (similar to menstrual pain) or that you experience mild bleeding for a few days following insertion. These symptoms should disappear rapidly. However, if they persist beyond the first cycles, do not hesitate to contact your healthcare professional. Menstrual bleeding may be heavier after insertion of a copper IUD. This is a non-serious common event.

Are there specific precautions to be observed after insertion of Yanae®?

It is recommended that the position of your IUD be checked regularly, for example at the end of each cycle. You can do it yourself. For this, using two fingers inserted in the vagina, in a crouching position, check that you can feel the strings of the Yanae® device, which indicates it is present and in the right position. In case of doubt, you must not hesitate to have the position of the IUD checked by your healthcare professional.

In the event of pain or discomfort for yourself or your sexual partner, the strings of your IUD can be readjusted by your healthcare professional.

The appearance of an abnormal vaginal discharge should lead to a visit aimed to detect and treat a possible infection, especially if it is accompanied by fever and pain.

Any menstrual delay requires that a rare but possible risk of pregnancy be ruled out.

Main adverse effects⁽¹⁾

IUDs expose users to problems associated with insertion (pain, uterine contractions and bleeding), to risks of expulsion and of uterine perforation and, more commonly, to changes in the menstrual cycle (heavy menstrual bleeding, irregular bleeding, pain and cramps during menstruation).

Inflammatory pelvic pain and extra-uterine pregnancy are possible but rare.

Are there possible interactions with treatments?

When anticoagulants or non-steroidal anti-inflammatories are prescribed, it is necessary to inform your doctor that you are fitted with an IUD.

Radiotherapy or high frequency electrotherapy (diathermy or short wave) is contraindicated in women fitted with an IUD in particular if applied to the pelvic and sacroiliac regions. The use of direct current and low frequency (ionization) therapies is not contraindicated in women fitted with a copper IUD.

When should I consult my health professional and replace my IUD?

Gynaecological follow-up visits are generally scheduled 1 to 3 months after insertion and then annually. Your follow-up will be adapted on a case by case basis by your healthcare professional. The aim of the first follow-up consultation is to ensure that the IUD is well tolerated, that it has not been expelled and that its insertion has not caused uterine inflammation.

The maximum duration of Yanae® contraception is 5 years. If you wish to be pregnant or if you wish to change your contraceptive method, it can be withdrawn at any time during a visit.

Withdrawal of Yanae must be performed by a healthcare professional. He/she will put a speculum in place and will pull gently with a forceps on the strings of the IUD.

Classification and packaging

Yanae is a class III medical device.
CE 2460 marking since 2021

Each package contains a single, sterile, single use device. Insertion expiration date is indicated on the packaging.

⁽¹⁾ HAS sources (www.HAS-sante.fr)

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