EN

Instruction for use
Intrauterine contraceptive device “Yunona Multi”
Intrauterine contraceptive device “Yunona Multi Ag”

Instruction for physician

Field of application – contraception. Insertion and removal of an intrauterine contraceptive device (further IUD) is performed by a trained doctor specialist (obstetrician-gynecologist) in a medical facility.

Principle of action:

The mechanism of action of IUD consists in initiating chemical changes that inactivate the sperm and egg before they merge as well as in initiating changes that prevent implantation.

The contraceptive effect develops immediately after the insertion of IUD into the uterine cavity.

The fertility is restored immediately after the removal of IUD from the uterine cavity.

Description:

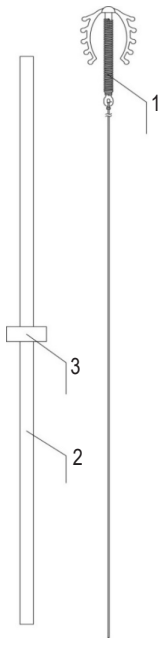
The anchor of IUD of Φ-shaped form “Yunona Multi”, “Yunona Multi Ag” is manufactured from inert polymeric material and has specified mechanical characteristics. Curved arms of the anchor have spurs for its additional fixation in the uterine cavity. On the anchor’s stem is wound copper wire (“Yunona Multi”) or copper wire with silver core (“Yunona Multi Ag”). There is a loop for fixation of monofilament transcervical thread of length not less than 100 mm at the end of the stem.

The length of the anchor is not over 36 mm, the width is not over 25 mm.

The degree of purity of copper in copper wire, of copper and silver in bimetallic wire is not less than 99,9%. The content of silver in bimetallic copper wire with silver core of IUD “Yunona Multi Ag” is not less than 9,3%.

The area of active copper-bearing surface is not over 380 mm².

IUD is supplied in paper-film pack coming with a polymeric insertion tube (of diameter not over 5 mm). There is an adjustable polymeric stopper on the insertion tube for the indication of insertion depth and the surface of anchor’s arms opening.



1 – IUD; 2 – insertion tube; 3 – stopper.

Duration (term) of use:

- IUD “Yunona Multi Ag” – not over 7 years;
- IUD “Yunona Multi” – not over 5 years.

Warnings

The product is supplied sterile and ready for use.

Gas sterilization – by ethylene oxide.

Expiry date of IUD in package is not over 5 years. It is forbidden to use IUD when the expiry date indicated on the label is exceeded. The expiry date is determined by the preservation of sterility of IUD in the final packaging.

It is forbidden to reuse the products.

It is forbidden to use IUD if the integrity of sterilization (final) packaging is damaged. In case of violation of the integrity of sterilization (final) packaging, the use of the product is prohibited and the product must be disposed of.

The products must be stored at the temperature from +5°C till +40°C, protected against direct sunlight and moisture.

The IUD must be used immediately after the removal from the final packaging.

Used products after disinfection must be disposed of in accordance with sanitary norms for infected and potentially infected waste.

IUD is not subject to technical, service maintenance and repair.

The IUD must be inserted and removed only by qualified medical personnel.

Intrauterine contraceptives do not protect against sexually transmitted infections and human immunodeficiency virus (STI/HIV).

Indications for use of IUD

Wish of a woman to prevent pregnancy.

Treatment and prevention of Asherman syndrome.

As a postcoital means IUD may be inserted within 5 days (120 hours) after unprotected sexual intercourse.

Contraindications for use of IUD

Intrauterine contraception is absolutely contraindicated (categories 3 and 4 according to the acceptance criteria of contraception methods WHO):

- in case of pregnancy (suspected or confirmed);
- in case of malignant diseases of female genital organs;
- in case of background/precancerous diseases of cervix uteri at the moment;
- in case of severe thrombocytopenia;
- in case of vaginal bleeding of unknown etiology (suspected serious disease);
- in case of gestational trophoblastic disease;
- in case of uterine myoma with deformation of the uterine cavity;
- in case of any congenital or acquired abnormalities of the uterine cavity, leading to deformation of its cavity incompatible with the insertion of IUD;
- in case of pelvic inflammatory disease at the moment;
- in case of sexually transmitted diseases (pyogenic cervicitis, chlamydial infection or gonorrhea at the moment), increased risk of sexually transmitted diseases;
- in case of AIDS (in the presence of antiretroviral therapy);
- in case of pelvic tuberculosis,
- in case of allergy to copper and silver (for silver-containing models of IUD);
- in case of Wilson disease.

Side effects

• Increased menstrual blood loss. With the use of IUD an increase in the duration of menstrual bleeding by 1-2 days and an increase in menstrual blood loss by 50-55% can be observed.

In patients with a tendency to iron-deficiency anemia, laboratory parameters must be monitored for timely diagnostics and correction of this condition. It may be necessary to remove the IUD.

• Pre- and intermenstrual spotting. In case of persistent menstrual cycle disorder it is necessary to exclude partial expulsion of IUD or other conditions requiring the removal of contraceptive. In case of absence of indications for contraceptive removal, medication therapy is possible (NSAID group of drugs).

Complications

• Pain syndrome during insertion/removal of IUD. This condition is observed rarely. In patients with a low pain threshold it is advisable to use local anesthesia means. Pain syndrome is more often observed when using IUD in nulliparous women. In case of development of pain syndrome with the use of IUD, it is necessary to exclude the development of pelvic inflammatory disease, pregnancy and partial expulsion of IUD. It may be necessary to remove the contraceptive.

• Perforation of uterus during the insertion of IUD. The cases of uterine perforation when inserting IUD are rare (less than 1 per 3,000 insertions). Great care should be taken in case of extreme posterior position of the uterus. If there is a suspicion of perforation it is necessary to clarify the location of IUD. The contraceptive must be removed (uterine perforation is an indication for contraceptive removal). Surgery may be required. Delayed detection of perforation can lead to IUD migration, commissures, erosion of adjacent internal organs, severe pelvic inflammatory disease.

• Pregnancy against the background of IUD. The frequency of unplanned pregnancy during the use of IUD is less than 1 case per 100 women using this method during the first year (6-8 cases per 1000 women). An insignificant risk of unplanned pregnancy remains throughout the entire period of IUD use (about 2 cases per 100 women over 10 years of use). In this situation in most cases a uterine pregnancy is diagnosed but it is necessary to exclude an ectopic pregnancy. Women who become pregnant while using IUD should be informed about the increased risk of septic miscarriage, the increased risk of premature birth and infection if the IUD remains in the uterus. Women who wish to maintain pregnancy should be informed that removing an IUD (in case of presence of conditions for this procedure) will reduce the possible risks of an unfavourable course of pregnancy. However, the IUD removal procedure itself increases the risk of miscarriage.

• Development of pelvic inflammatory disease. Currently, it is believed that the development of pelvic inflammatory disease in the first several months after the insertion of IUD can be associated with the contamination of the uterine cavity with endogenous vaginal and cervical microflora when inserting the contraceptive. As with other gynecological or surgical procedures, a severe infection or sepsis can occur after the insertion of IUD, although this is extremely rare. IUD should be used with caution in patients at high risk of infectious endocarditis. Such patients should be prescribed antibiotic prophylaxis during the insertion/removal of IUD.

• The reason for the development of pelvic inflammatory disease 3-4 months after the insertion of the contraceptive are sexually transmitted diseases, and not the procedure of insertion of contraceptive. To reduce the risks it is necessary to exclude infectious contraindications to the use of intrauterine contraceptives and carefully adhere to aseptic and antiseptic during the insertion of IUD. There was found a higher risk of development of sexually transmitted diseases in women with several sexual partners.

• IUD expulsion is rare. An increased risk of expulsion occurs when an IUD is inserted before the end of uterine involution after childbirth or abortion. IUD expulsion may be connected with the incorrect contraceptive insertion. Partial expulsion of IUD increases the risk of pregnancy and other complications development. Identified expulsion is an indication for contraceptive removal.

Interaction with drug products

No interaction with drug products was reported. In case of necessity of diagnostic (MRT) and therapeutic exposure medical personnel should be informed about the presence of IUD.

In some cases it may be necessary to remove the contraceptive.

Indications for IUD removal

IUD must be removed:

- at woman's will at any day of menstrual cycle;
- it is obligatory to remove the IUD after the ending of period of use;
- in case of absence of confidence in the correct position of IUD (uterine perforation) immediately after the insertion it is necessary to remove the contraceptive and if meeting the criteria, insert a new contraceptive device;
- the contraceptive must be removed in case of development of pelvic inflammatory diseases (PID);
- in case of development of constant menstrual disorders in the presence of IUD, in case of development of vaginal bleeding of unknown etiology (suspected serious disease);
- in case of development of anaemia;
- in case of partial expulsion of IUD;
- in case of pain syndrome connected with the presence of IUD in the uterine cavity.

Recommended terms of IUD insertion:

- any day of menstrual cycle (preferably from the 4 till the 19 day);
- immediately after **uncomplicated** medical abortion performed by vacuum-aspiration method or curettage;
- upon the finishing of involution of uterus (5 – 6 weeks after uncomplicated delivery) including in case of lactational amenorrhea;
- immediately after removing the IUD the period of use of which has expired, if a woman wants to continue intrauterine contraception and there are no contraindications to the use of IUD;
- with the aim of postcoital contraception IUD is inserted within 5 days (120 hours) after unprotected sexual intercourse.

Adaptation to IUD

During the period of adaptation of patient's organism to IUD (3 – 4 months) changes in menstrual cycle are possible. Menstruations may be accompanied by pain in the lower part of abdomen or sacral region which as a rule soon decreases.

In order to improve IUD acceptability and reduce the adaptation period it is recommended:

- to carry out careful examination of a woman to detect contraindications for IUD use;
- differentiated approach to the choice of IUD model taking into consideration the specific features of a woman's organism and plans for having children in future, the time of IUD insertion;
- using the recommended IUD insertion method and optimum terms for its insertion;
- preventive prescription of antibiotics;
- prescription of non-steroidal anti-inflammatory agent preparations during first days after IUD insertion and during first three menstruations.

Patient examination before IUD insertion

The patient must be advised of advantages, disadvantages and possible complications of intrauterine contraception method. The scope of the examination before the IUD insertion should allow excluding possible contraindications to the use of intrauterine contraception method.

Patient examination before IUD insertion (the scope of patient examination before IUD insertion is subject to national medical protocols and may be different in different countries):

- physical examination;
- bacteriscopic analysis of vaginal smears;
- Pap smear (smear for oncocytological examination).

Procedure of IUD insertion

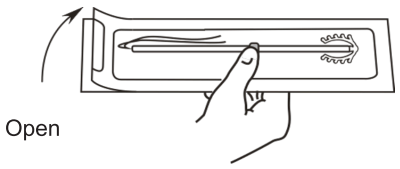
The procedure of inserting of IUD is carried out by a doctor obstetrician-gynecologist who is trained in the appropriate procedure, with observation of generally accepted rules of aseptics and antiseptics.

After gynecological examination and excluding contraindications to the use of intrauterine contraception method a speculum is inserted in aseptic conditions and cervix uteri and vagina are treated with antiseptic solution three times. Cervix uteri is fixed with the help of bullet forceps, pulled down a little bit, the direction of cervical canal axis and the length of uterine cavity are determined with the help of sterile probe.

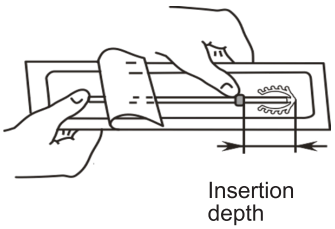
In some cases it may be necessary to dilate cervical canal instrumentally with the help of Hegar's dilatators till № 4 – 4,5.

Preparation of IUD for insertion

1. Open the pack from the side of trans-cervical threads.

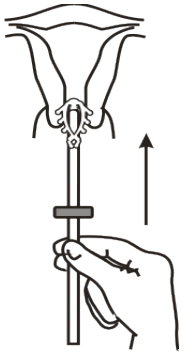


2. Fix the movable stopper at the distance corresponding to the length of the uterine cavity according to the probe. In order to control the alignment of IUD arms twist the stopper on the insertion tube until the flat surfaces of the stopper coincide with the presumed surface of opening of IUD curved arms. The anchor's arms are not inserted into the insertion tube.

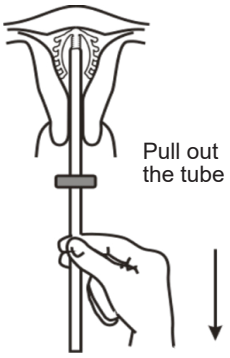


The procedure of IUD insertion (method of "retraction")

1. Keeping traction of bullet forceps as during probing of theuterine cavity, without forcing insert the IUD through the cervical canal up to the stopper.



2. Pull out the insertion tube. IUD anchor is released from the tube due to the contact of anchor's arms with endometrium during the withdrawal of the insertion tube from the uterus.



3. Cut the transcervical threads ends to leave about 2 – 3 cm outside the cervix.

Removal of IUD from the uterine cavity

To remove the IUD grasp the transcervical thread with the forceps and by traction towards yourself remove the IUD anchor from the uterine cavity. In case of breakage, "loss" of thread or impossibility of fixing it, instrumental removal of IUD may be necessary.

Manufacturer:
CJSC "Medical enterprise Simurg",
Generala Lyudnikova ave. 13, room 413,
210023, Vitebsk, the Republic of Belarus
www.simurg-mp.com

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