

# INSTRUCTIONS FOR INSERTION AND USE

The intrauterine contraceptive device GINETIK is indicated for contraception, used to prevent from pregnancy. It is made of polyethylene of the adequate quality. Contrast agents are also added, so that x-rays can monitor its position. A body of the device is coiled with copper wire in a total surface of 250 mm<sup>2</sup>, insuring a very reliable contraceptive protection. The probability of conception is less than 1%. The efficiency of the device lasts up to 5 years.

## INSERTION OF THE GINETIK:

Gynaecological examination should be performed before the insertion of this contraceptive device to determine suitability of the uterus for this type of contraception (position and shape of the uterus, possible anomalies and diseases).

The physician must introduce both, risks and benefits associated with the use of this contraceptive product to the patient prior to insertion.

The device can be inserted anytime during the menses cycle, the most convenient, however, are the last days of the menses. The device can be also inserted after an abortion.

In order to insert this contraceptive device properly, it should be pulled into the insertion tube with a string only so far as to enable the sides of the contraceptive device to be fully enclosed into the insertion tube, but the ends of each side should be left outside of the insertion tube and should form a rounded top to enable easier insertion through the cervical canal. Rounded top makes the insertion easier. Since the ends of each side of the contraceptive device may hide into the insertion tube, the device should therefore be retained with the flange during the insertion. The device can get damaged if it is ousted from the insertion tube before time. Device should not be released from the insertion tube with solid rod until it reaches the appropriate depth in the uterus. Insertion tube should be moved slowly from uterus simultaneously with the elimination of the device from the insertion tube. Otherwise the device could get damaged. This procedure will enable the placement of the device at the highest possible position within the endometrial cavity. The flange should be adjusted in order to indicate the depth to which the device should be inserted and the direction in which both sides of the device will open.

After the insertion of the device, the strings must be cut so far that they stretch into the vagina for about 2 cm. The strings facilitate the checking of the presence and position of the device and make its removal easier. The device can be removed by the slow traction of the strings.

**GINETIK** is sterilized with etilenoxid and intended for a single use only. It is made in two sizes:

- **GINETIK normal** is designed for women, who have given birth before
- **GINETIK mini** for women, who have not given birth yet

The device is convenient for women who are not planning pregnancy anymore.

## CONTRAINDICATIONS:

The only absolute contraindication is an acute or subacute inflammation of the true pelvis and possible existing pregnancy. Among the relative contraindications can be ranged congenital or acquired uterine malformations, larger myoms, menopause, metrorragia and anaemia.

## COMPLICATIONS:

After its insertion, the device may cause more or less expressed pain in the lower part of the abdomen and lumbago, usually not of long duration. The following menses can be somewhat stronger and longer. Intermediate bleedings can occur, usually stopping quickly. There's a possibility of extrauterus pregnancy. Certain inflammations may also occur that needs to be cured adequately.

## STORAGE AND HANDLING THE PRODUCT:

The items should be stored in dry, clean and suitable aired store. One should be careful that the basic package doesn't get damaged, otherwise the sterility is not assured.

## WARNING:

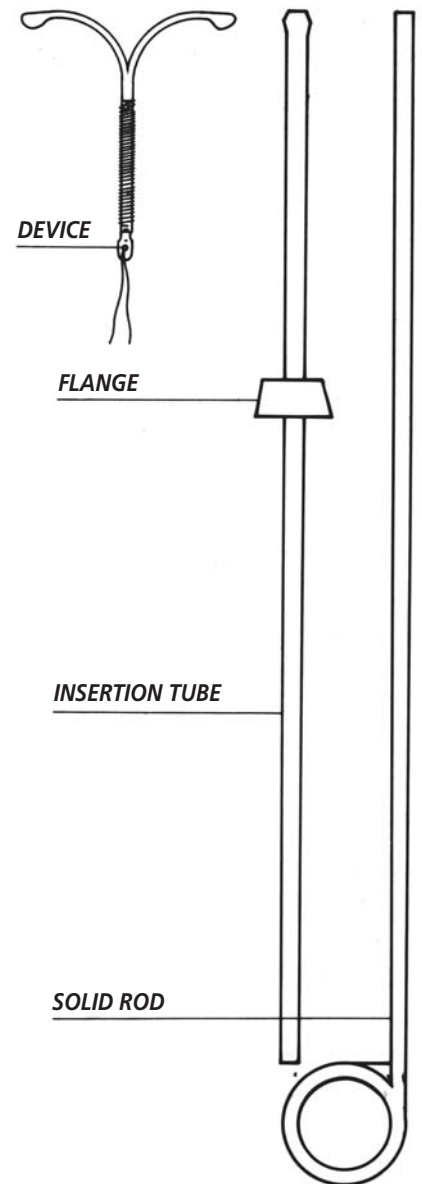
- Only a specialized physician should perform the insertion of the device. After the insertion of the contraceptive device a gynaecological checking after three, six and twelve months is recommended. And thereafter a gynaecological checking should be performed once a year, or if certain irregularities or troubles occur. It's recommended for the women to check the presence of the device after each menses by themselves.
- The batch code is used for traceability. The code needs to be registered after the insertion of a device.
- Re-sterilization is not allowed.
- Ginetik is not appropriate for women allergic to copper.

The contraceptive device GINETIK has been tested by the Gynaecological Clinics of Ljubljana. The permission to use CE sign was acquired in 2004.

## INTRAUTERINE CONTRACEPTIVE DEVICE

# GINETIK

(STERILE)



**METALOPLAST** d.o.o. Kobarid  
Staro selo 47a  
5222 Kobarid  
tel/fax: 05 38 48 043  
05 38 93 039

# NAVODILA ZA VSTAVITEV IN UPORABO

Intrauterini kontracepcijski vložek GINETIK je kontracepcijsko sredstvo za preprečevanje nosečnosti. Izdelan je iz polietilena ustrezne kakovosti, z dodatkom kontrastnih sredstev, da je možno njegovo lego kontrolirati z rentgenom. Steblo vložka je ovito z bakreno žico skupne površine 250mm<sup>2</sup>, kar zagotavlja zelo zanesljivo kontracepcijsko zaščito. Verjetnost zanositve je manj kot 1%. Vložek je učinkovit do 5 let.

## VSTAVITEV GINETIK-a:

Pred vstavitvijo vložka mora zdravnik žensko pregledati, da ugotovi primernost maternice za tovrstno zaščito (pozicijo in obliko maternice, morebitne nepravilnosti ali bolezni).

Zdravnik mora pred vstavitvijo vložka žensko seznaniti z dobrimi in slabimi lastnostmi tovrstne zaščite.

Vstavimo ga lahko katerikoli dan menstruacijskega ciklusa, najprimernejši pa so zadnji dnevi menstruacije. Vložek je možno vstaviti tudi po opravljenem splavu.

Da bi vložek čim lažje vstavili, ga je potrebno z nitkama povleči v vstavljalno cevko le toliko, da se kraka vložka » skrijeta « v cevki, glavici - na koncu vsakega kraka - pa ostaneta zunaj cevke in s tem tvorita zaokrožen vrh, ki omogoči lažji prehod cevke skozi maternični vrat. Brez zaokroženega vrha je vložek težje vstaviti.

Med vstavljanjem vložka v maternico obstaja možnost, da se glavici vložka pomakneta (skrijeta) v vstavljalno cevko, zato je vložek, med vstavljanjem, potrebno pridržati s potisnim trnom. Pri tem pa je treba paziti, da se ga predčasno ne izrine iz vstavljalne cevke, ker bi se poškodoval. Iz cevke se ga s potisnim trnom izrine šele tedaj, ko le - ta doseže ustrezno globino v maternici. Sočasno z izrivanjem vložka iz cevke, je potrebno tudi cevko počasi izvleči iz maternice, da bi se kraka vložka lahko neovirano sprostila na ustrezno mesto. V nasprotnem primeru se vložek lahko poškoduje (zmaliči) ali celo zlomi.

Globino vstavitve vložka nastavimo z drsnim nastavljalcem, ki obenem služi tudi za pravilno usmeritev krakov vložka.

Po vstavitvi vložka v maternico, je potrebno nitki toliko odrezati, da molita v nožnico približno 2 cm. Nitki služita za preverjanje lege vstavljenega vložka in njegovo odstranitev. S počasnim vlekrom za nitki, je vložek možno varno odstraniti.

**GINETIK** je steriliziran z etilenoksidom in namenjen za enkratno uporabo.

Izdelujemo ga v dveh velikostih:

- **GINETIK normal** je primeren za ženske, ki so že rodile
  - **GINETIK mini** pa za ženske, ki še niso rodile.
- Vložek je primeren za ženske, ki ne načrtujejo več nosečnosti.

## KONTRAINDIKACIJE:

Edina absolutna kontraindikacija je akutno ali subakutno vnetje v mali medenici ter morebitna obstoječa nosečnost. Med relativne kontraindikacije štejemo prirojene malformacije maternice, večje miome, meno, metroragije in slabokrvnost.

## KOMPLIKACIJE:

Vložek po ustavitvi lahko povzroči bolj ali manj izražene bolečine v spodnje delu trebuha in v predelu križa, ki običajno hitro minejo. Naslednje menstruacije so lahko nekoliko močnejše in daljše. Možno je, da se pojavijo tudi vmesne krvavitve, ki običajno hitro minejo. Lahko se pojavijo vnetja, ki jih je potrebno primerno zdraviti. Obstaja tudi možnost zunajmaternične nosečnosti.

## SHRANJEVANJE IZDELKOV IN RAVNANJE Z NJIMI

Izdelke je potrebno hraniti v suhem, čistem in primerno prezračujem prostoru.

Paziti je potrebno, da se osnovna embalaža ne poškoduje, ker sicer sterilnost izdelka ni zagotovljena.

## OPOZORILO:

- Vstavitve vložka mora opraviti zdravnik-specialist za to področje. Po vstavitvi kontracepcijskega vložka priporočamo ginekološko kontrolo čez tri, šest in dvanajst mesecev, nato pa enkrat letno, oziroma ob vseh nepravilnostih ali težavah. Priporočamo, da ženske same kontrolirajo prisotnost vložka po vsaki menstruaciji.
- Številka serije izdelka služi za vzdrževanje sledljivosti pripomočka. Ob vstavitvi vložka je potrebno zabeležiti serijsko številko.
- Ponovna sterilizacija ni dopustna.
- Vložek ni primeren za ženske, ki so alergične na baker.

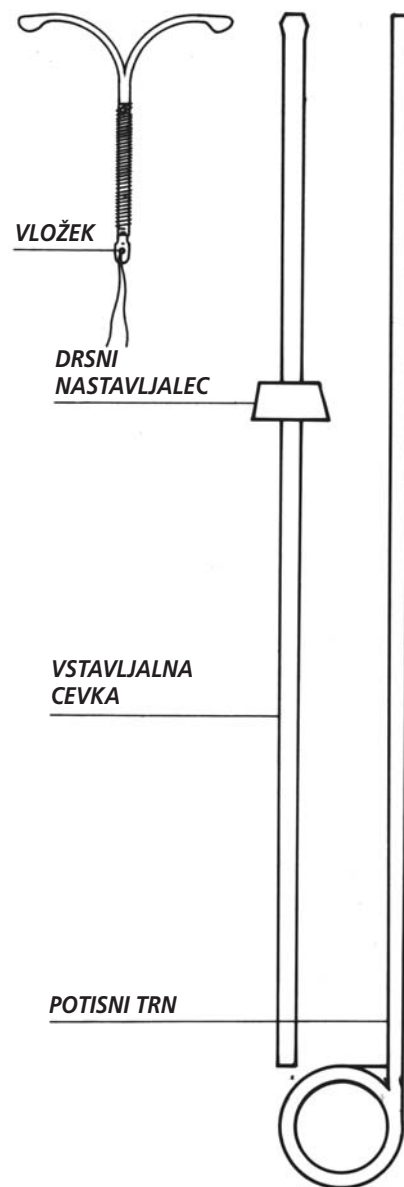
Kontracepcijski vložek GINETIK je bil testiran na Ginekološki kliniki v Ljubljani.

Dovoljenje za uporabo CE oznake je bilo pridobljeno v letu 2004.

## INTRAUTERINI KONTRACEPCIJSKI VLOŽEK

# GINETIK

(STERILNO)



**METALOPLAST** d.o.o. Kobarid

Staro selo 47a

5222 Kobarid

tel/fax: 05 38 48 043

05 38 93 039