ASLxxxxx FAMILY CLINICS FAMILY CLINIC _____

INFORMED CONSENT TO THE APPLICATION OF INTRAUTERINE DEVICE / SYSTEM (IUD or IUS)

Mrs _____ born in _____

on____/____/_____ requests the application of an intrauterine device.

She states that she understood the under-mentioned information and recommendations, which were illustrated to her by Dr _____ Intrauterine devices and systems (IUD and IUS) are effective, safe, practical and reversible.
Intrauterine devices (IUD) consist in a biologically inert plastic material, polyethylene, with the addition of a copper or copper and silver filament aimed at enhancing its effectiveness.
Intrauterine systems (IUS) consist in plastic material that releases small doses of the progestin levonorgestrel into the uterine cavity. In addition to the contraceptive purpose, they can be used in women who have menstruations of a haemorrhagic nature or as endometrial protection in hormone replacement therapy during menopause. They are of two types, which release different doses of levonorgestrel: Mirena® releases 20 mcg a day for 5 years, Kyleena® 12.5 mcg a day and Jaydess® 6 mcg a day for 3 years.

1. EFFECTIVENESS. The percentage of failures stands, for the first year of use, at 0.8% for copper-medicated IUD and at 0.2% for IUS medicated with levonorgestrel. Pregnancy with IUD-IUS has a risk of abortion approximately 3 times above the average, with a slight increase in the risk of preterm delivery. There is no increased risk of foetal malformations.

2. COME FUNZIONA:

a. INTRAUTERINE DEVICES (IUD) The copper released into the uterus by the IUD is toxic to the oocyte and spermatozoa; it furthermore produces a foreign body reaction, with biochemical and cellular alterations of the uterine mucosa (endometrium), which obstruct the passage of spermatozoa and their maturation, and which can cause particularly long and intense menstrual flows. In addition, these alterations of the endometrial mucosa can obstruct the implantation of the fertilised egg. It must be reiterated that the committee for medical aspects of FIGO (International Federation of Gynaecology and Obstetrics), at the request of the WHO (World Health Organisation), has confirmed that pregnancy is deemed to start only after implantation of the fertilised egg; from this perspective, the IUD cannot be defined an abortion method.
b. INTRAUTERINE SYSTEMS (IUS) The levonorgestrel released by IUS thickens the cervical mucus, which becomes practically impenetrable to spermatozoa. The thickness of the uterine mucosa is considerably reduced, thereby giving rise, unlike copper-medicated IUD, to a more or less important reduction in menstrual bleeding, up to and including amenorrhea (absence of periods). The changes at endometrial level can additionally lead to the production of glycodelin A, a protein that inhibits the spermatozoa-egg cell interaction, and thus fertilisation.

3. REVERSIBILITY. The return to fertility after removal of the IUD-IUS is immediate; 80- 95% of women who remove the IUD-IUS to have a child obtain pregnancy within the first 12 months of removal.

4. ABSOLUTE CONTRAINDICATIONS: IUD-IUS are NOT contraindicated in women who have not had children or in adolescents. The following are instead absolute contraindications:

a. Pregnancy.
b. Infections: pelvic infection (PID) underway or diagnosed less than 3 months before,

sexually transmitted disease (STD) in progress, post-abortion or post-partum sepsis, purulent cervicitis, pelvic tuberculosis.
c. Uterine tumours.
d. Fibroids that alter the uterine cavity or uterine malformations.
e. Wilson's disease.
f. Contraindications specific to IUS medicated with levonorgestrel: Systemic Lupus Erythematosus (SLE) with antiphospholipid antibodies, deep vein thrombosis or pulmonary embolism underway, hormone-dependent malignancy (e.g. breast cancer).

5. POSSIBILE COMPLICATIONS:

a. VAGAL REACTION: the IUD-IUS must be inserted by a doctor. Vagal reaction is a rare occurrence, linked to stimulation of innervation in the uterus, which can cause a reduced heart rate, with sweating, and eventually loss of consciousness. The doctor has at his disposal and will use drugs to tackle any such rare complication.
b. PERFORATION: it is described with an incidence that varies in different studies, from 0.06 to 1.6 every 1000 women/year.
c. PELVIC INFECTION (PID): The risk of pelvic inflammatory disease (PID) is very low and concentrated in the 20 days after insertion. Since PID can be related to the application procedure, which must occur under sterile-aseptic conditions, recourse to a condom might be useful in the 20 days following insertion. The risk of PID is greater if the woman and/or her partner have multiple sexual partners. No vaginal swab is recommended, unless a clinical indication points to that at the time. The swab can also be collected simultaneously with insertion, postponing any therapy to such a time when the results thereof are available. Preventive use of antibiotics, on the other hand, is not recommended.
d. INFERTILITY-STERILITY: pelvic infection, with germs climbing back into the tubes, could result in infertility. However, the latest reviews of international scientific literature concur on the fact that there is no increase in the incidence of infertility-sterility in users of this type of contraceptives; on the other hand, women with multiple sexual partners are potentially at risk.
e. ECTOPIC PREGNANCIES: the risk of ectopic (extra-uterine) pregnancy is reduced among women using IUD-IUS compared to the general population; however, if the method fails, there is a high likelihood that the pregnancy is ectopic.
f**. ABUNDANT MENSTRUATIONS, MENOMETRORRAGIES** (only for copper IUD): in the first 3 months after insertion, menstruations can be particularly abundant and long, and although they decrease in the following months, menstrual bleeding with copper IUD is generally more intense and longer than normal menstruations.
g. EXPULSION OR DISLOCATION: it is more frequent in the 3 months after insertion, and can be unnoticed or cause pain and/or bleeding.
6. INTERACTIONS: caution is recommended in the event of thermotherapy of the sacral or abdominal region (for women carrying copper IUD, which could overheat). No risks of dislocation, perforation, expulsion or pregnancy can be linked to performance of a MRI, since copper and silver are not magnetisable, and the same is true of the material of IUS.

Having acknowledged the information she was provided with, Mrs _____ authorises the insertion of the IUC, undertaking to undergo a clinical or ultrasound check-up approximately one month after implant.

Roma, ____ / ____ / _____

Signature of the woman

_____

Signature of the doctor

_____