

Leaflet for Patients

-If there is abdominal pain or pain during intercourse or infection such as gonorrhoea, abnormal discharge, fever, chills or not feeling well report to the clinic.Return to the clinic for check up or for the replacement of the TCu 380Ag.

- Abnormal discharge
- A menstrual period more than 7 days late
- Disappearance of the IUD threads when palpated for after the menstrual period
- Unexplained fever

Following the insertion of the IUD, experiencing short term mild cramps are normal, these cramps can be managed by taking analgesic tablets or applying warm compresses on the abdomen.

4-6 weeks after the insertion of the IUD, arrange to make the initial visit to your doctor.

During the first month following the insertion of the IUD, check the threads following menstruation. If the threads cannot be found and if they are longer or shorter than usual, visit your clinic.

If the threads cannot be found, the plastic part of the IUD can be felt with hand if IUD has been expelled or if you missed a period then visit your clinic without delay.

Following the first 3 months of the insertion of the IUD some intermenstrual spotting, bleeding, prolonged or increased menstrual flow may occur. If they continue, report to the clinic.

-If the period delayed for 10 days and have symptoms of pregnancy such as nausea, tender breasts etc. report immediately to the clinic.

-Pregnancy with the Tcu 380Ag in place occurs at rates of less than one per 100 women per year. If a woman using an IUD becomes pregnant the IUD should be removed immediately.

-Lactation can be continued during the use of the TCu 380Ag IUD.

Presence Of DEHP :

The Flange of the insertion tube is composed of PVC which contains DEHP as a Plasticizer However since the contact time of the Flange with the mucosal surface is extremely low hence no risk is posed to the woman

Classification and packaging

The TCu 380Ag is class III medical device as per the European Directive 93/42/EEC on Medical Devices as amended.

Labelling: since 2012

Each sterile package contains a single, single-use device, the Insert before date of which is indicated on the box.

I FILL IN MY PERSONAL FOLLOW-UP TABLE AND KEEP IT

Last name:

First name:

Date of insertion:

Type of IUD

+ TCu 380 Ag

Lot No.:

First check-up after the first menstrual period following insertion:

Regular follow-up visits:

- + Every year
- + Every 6 months
- + Other

I will consult my healthcare professional in principle in case of:

- + persistent abdominal pain
- + bloody and/or nauseating abnormal discharge
- + a menstrual period more than 7 days late
- + disappearance of the IUD threads
- + unexplained fever

I can keep my IUD TCu 380Ag safely for a maximum of 5 years.

The planned replacement date is.....

MADE WITH PRIDE IN INDIA
SMB CORPORATION OF INDIA
(An ISO 14001 : 2015 / ISO 13485 : 2016 Certified Company)
13, 33-36, Prem Industrial Estate, Jogeshwari (E), Mumbai 400 060, India.
E-mail : sales@smbcorp.com • Website : www.smbcorp.com
Mfg. Lic. No. : MFG/MD/2020/000278
CE REP Obelis S.A, Boulevard Général Wahnis 53, 1030 Brussels, Belgium
Tel : +(32) 2.732.59.54 • Fax : +(32) 2.732.60.03 • E-Mail : mail@obelis.net

MD **i** **☂** **☹** **☼** **☼** **☼** **CE** **2460** **STERILE R**

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INTRAUTERINE CONTRACEPTIVE DEVICE

SMB TCu 380Ag
MINI/NORMAL/MAXI

CE
2460

IUDs do not protect against sexually transmitted diseases / AIDS

LEAFLET INTENDED FOR THE USER

Dear Madam,

A healthcare professional has just prescribed you a TCu 380Ag IUD This leaflet, which has been written for you, will answer some of your questions. Please keep it, as it will serve as a reminder of insertion, consultation and replacement dates.

This information is intended to provide general information and should not serve as a substitute for a Physician's advice.

What is TCu 380Ag Model?

The TCu 380Ag IUD is ready-to-use in a sterile pouch, for single-use bearing the EC mark as per the European Directive 93/42/EEC on Medical Devices as amended.

The TCu 380 Ag is "Y" shaped IUD composed of two flexible arms made of polyethylene branching with a vertical stem, opaque to X-rays, around which a 380 mm" copper- silver alloy wire is wound and a monofilament nylon thread attached to the base of the device. Based on the clinical examination and the size of your uterus, your healthcare professional will choose the Model which will be the most suited to your anatomy.

Indicative selection criteria of the model :

Mini, Normal, Maxi

| Size | Vertical Arm Length | Horizontal Width | Uterine Cavity Size | Approx. Sound Measuring Range |
|--------|---------------------|------------------|---------------------|-------------------------------|
| Mini | 30.5 mm | 24 mm | 36 mm | 6-7.5 cm |
| Normal | 33 mm | 31 mm | 45 mm | 7-8.5 cm |
| Maxi | 38 mm | 36.5 mm | 53 mm | 8-9 cm |

The above information is indicative only. The final decision of selection of the correct model for the patient is to be made by the Gynaecologist/Physician

What is intrauterine contraception?

The contraceptive activity of the IUD is mainly due to the presence of a foreign body in the intrauterine cavity. This action is reinforced in an ancillary manner by the presence of copper. After oxidation, the copper atoms are distributed locally in the cervical mucus and endometrium. The contraceptive efficacy of the IUD is present starting from the first day of insertion.

However, like all methods of contraception, intrauterine contraception does not guarantee absolute protection and a late menstrual period is a reason to consult your healthcare professional.

What will happen during the first cycle after insertion of TCu 380Ag?

The contraceptive efficacy of the IUD is present starting from the first day of insertion. Some abdominal pain may occur after insertion. If this happens, it should disappear rapidly. You may also have some minor bleeding. These are rare effects that are not cause for concern and that disappear on their own. However, do not hesitate to consult your healthcare professional if you are unsure of anything or if this continues beyond the first few cycles. Please note that women using IUDs generally have heavier menstrual periods. This is a known effect that is not serious. You can use tampons if you so choose you should check for the threads of the IUD at the back of the vagina after your menstrual period.

What are the Indications ?

•The TCu 380Ag IUD, is indicated for Intrauterine Contraception in women of child bearing age.

•Tcu 380Ag can be inserted after a birth or abortion.

•TCu 380Ag can also be used as emergency contraception, however the risk of pelvic inflammatory disease is higher in this case.

TCu 380Ag is recommended for women who :

- Women of child bearing age
- Are in mutually monogamous relationships
- Have no history of pelvic inflammatory disease (PID)
- Choose not to use hormonal contraceptives

TCu 380Ag should not be inserted in a woman who :

- Is pregnant
- Still retains a previously inserted IUD
- Has a known or suspected malignancy of the genital tract, including undiagnosed vaginal bleeding and an unresolved abnormal Pap smear, or a severe uterine abnormality

•Had a postpartum endometritis or postabortion infection in the past three months

•Has Wilson's disease or a known allergy to copper

•Has genital actinomycosis

TCu 380Ag should not be the method of first choice for a woman

who has :

- Painful or long menstrual periods
- Severe anemia
- Cervical stenosis or narrowing of the cervical canal
- No access to a health center for follow-up care
- A history of ectopic pregnancy

What are the contraindications?

A.ABSOLUTE

- Pregnancy
- Acute pelvic inflammatory disease or a history of pelvic inflammatory disease (PID)
- Postpartum endometritis or abortion
- Sexually transmitted diseases (STD) including a lower genital tract infection, such as gonorrhea or Chlamydia
- At high risk of STDs because she or her partner has multiple sexual partners
- Known or suspected malignancy of the genital tract, including undiagnosed dysfunctional uterine bleeding
- Congenital uterine abnormality
- Allergy to Copper
- Untreated acute cervicitis or vaginitis including bacterial vaginosis until infection is controlled
- Conditions associated with increased susceptibility to infections with microorganisms. Such conditions include, but are not limited to leukemia, acquired immune deficiency syndrome (AIDS), and intravenous drug abuse
- Wilson's disease
- Small uterine cavity
- To avoid burning/perforation, radiotherapy and diathermy should be contraindicated, especially if applied to the lower pelvic region
- Patients with uterine fibroids

B.RELATIVE

- Severe Dysmenorrhea
- Disorders of blood coagulation
- Vascular Cardiac disease

C.SECONDARY EFFECTS

- Spotting between menses
- Possible menstrual hemorrhages, more intense and/or prolonged
- Possible abdominal pain
- Partial or total Expulsion
- Pelvic inflammatory disease
- Uterine puncture

Are there any special precautions to take?

•The appearance of abnormal discharge is a reason to consult to screen for and treat any infections, especially if the discharge is accompanied by fever and pain.

•As with all IUDs, a late menstrual period is in principle a reason to consult your doctor to rule out a rare but possible risk of the development of a pregnancy. When a pregnancy is confirmed, the IUD must be removed as soon as possible, without an invasive procedure, from the pregnant woman A pregnancy that continues with an IUD in place is subject to complications (spontaneous abortion, septic abortion) and is associated with a high rate of at-risk pregnancy.

•In women who have never had a baby, the expected benefits should be weighed against the possible risks of treatment. In young women, the main risk is related to sexually transmitted infections, especially if there are multiple partners.

Warnings

The complication rate is not very high, but the known side effects are as follows:

Ectopic Pregnancy

If a woman gets pregnant with IUD in place, there is a chance of having an extra-uterine pregnancy (a fertilized egg not implanting in the womb, but for instance in a fallopian tube) which should be evaluated.

Pelvic Infection

Although pelvic inflammatory disease(PID) in woman using IUDs is uncommon, IUDs may be associated with an increased relative risk of PID compared to other forms of contraception and to no contraception. The highest incidence of PID occurs within 20 days after insertion. It is therefore, important to promptly assess and treat any woman who develop signs or symptoms of PID.

PID can be a cause of sterility and requires the removal of the IUD and the administration of a suitable antibiotherapy.

Expulsion

Sometimes an IUD is pushed out of the womb into the vagina during the heavy flow of menses as womb remains slightly open during the menstrual period. If unnoticed, an unintended pregnancy could occur.

Perforation

Partial or total perforation of the uterine wall or cervix may occur rarely during placement, though it may be detected later. Spontaneous migration has also been reported. If perforation does occur, remove TCu 380Ag promptly. The use of an IUD in breastfeeding women increases the risk of uterine perforation.

The risk of perforation may be increased in women with abnormal uterine anatomy or with fixed retroverted uteri.

Perforation or penetration of the uterine wall or cervix may occur during insertion although the perforation may not be detected until sometime later. If perforation occurs, pregnancy may result. TCu 380Ag Intrauterine Contraceptive Device must be located and removed. Delayed detection of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses and erosion of adjacent viscera.

Possible interactions with other treatments :

•Tell your healthcare professional that you have an IUD if you are prescribed anticoagulants.

•Non-steroidal anti-inflammatories cannot be used during treatment During short-term treatment, they do not impact the contraceptive efficacy of IUDs.

•Radiotherapy or electrotherapy using high-frequency current (diathermy or short waves) is contraindicated, especially when it is applied on the area of the lower pelvis. With regard to the use of continuous low-frequency current (ionisation), it appears that it cannot have a harmful effect on women using a copper contraceptive IUD.

•The energetic state of the copper will not be modified by magnetic resonance imaging (MRI). We can therefore not take into account the effect of MRI on the intrauterine device. In addition, based on the non-ferric characteristics of copper, scintigraphy obtained by MRI is not considered to be impacted by the presence of an IUD.

How is the TCu 380Ag IUD Inserted & Removed?

TCu 380Ag is inserted during the last days of your menstrual period or right after. Your healthcare professional will insert a speculum. After having disinfected the cervix and vagina and measured the depth of the uterus, he or she will insert the IUD into the uterus using a thin tube that passes through the cervix. After insertion, which only lasts a few seconds, the inserter tube and plunger are withdrawn and your healthcare professional will cut the threads to a suitable length, thus ending the insertion. The IUD can be removed whenever you wish by your healthcare professional by simply pulling on the removal threads.

Procedure for periodically checking the presence of the IUD :

•During the first month following the insertion of the IUD, check the threads following menstruation. If the threads cannot be found and if they are longer or shorter than usual, visit your clinic.

•If the threads cannot be found, the plastic part of the IUD can be felt with hand; if IUD has been expelled or if you missed a period then visit your clinic without delay.

•After your menstrual period, it is necessary to check using two fingers inserted in the vagina while squatting down that you do in fact feel the threads of the IUD, which shows that it is present and in the proper position. If you do not feel the threads, consult your healthcare professional.

•Signs of movement or even expulsion of the IUD have been reported in women with a menstrual cup, but there is no certainty as to the link between the cups and the reported incidents. The possibility of a suction effect on the IUD when the menstrual cup is withdrawn has been suggested.

Adverse Reactions

The following adverse reactions and side effects have been reported with IUDs, and may occur after the IUD is inserted. Visit your doctor for any of the following reasons:

•Pregnancy with the IUD in the uterus or when it has been partially or completely expelled

•Bleeding or spotting between periods

•Missed or late periods

•Heavy or prolonged periods

•Painful periods

•Anemia

•Pain or cramps at insertion or following insertion

•Vaginal discharge(Leucorrhea) & infection

•Backache

•Leg pain & soreness

•Fever

•Allergic skin reaction due to the IUD

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

•The first consultation is a control consultation planned after the first menstrual period following the insertion of the IUD.

•Outside of regular visits, 5 symptoms should lead you to consult your doctor: