INTRAUTERINE CONTRACEPTIVE DEVICE

SMB TCu 380Ag

MINI/NORMAL/MAXI

CE 2460

IUDs do not protect against sexually transmitted diseases / AIDS

LEAFLET INTENDED FOR THE HEALTHCARE PROFESSIONAL

SMB TCu 380Ag should be inserted and removed only by / under the supervision / training of a gynaecologist/physician.

DESCRIPTION

Tcu 380Ag Intrauterine device is ready-to-use in a sterile package and is composed of Y shaped two flexible arms and vertical stem made of low density polyethylene with barium sulphate, opaque to X-rays. It is wound with 0.40mm diameter copper -silver alloy wire providing a surface area of 380mm^2 ± 23mm^2. The frame is tied with Polyamide Monofilament thread for easy removal and is packed together with an Insertion Tube and Rod in a peelable pouch. The insertion tube is equipped with a movable flange to aid in gauging the depth to which the insertion tube should be inserted through the cervical canal and into the uterine cavity.

(FIGURE I)

The Copper-Silver alloy wire delays the fragmentation of the wire and prolongs the life span of the device.

The Sterile single unit pouch containing TCu380Ag IUD with its insertion components are **"For single use only"**.

FIGURE I

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

Indicative selection criteria of the Models Mini, Normal & Maxi

Size	Vertical Arm Length	Uterine Cavity Size	Approx. Sound Measuring Range
Mini	30.5 mm	36 mm	6-7.5 Cm
Normal	33 mm	45 mm	7-8.5 Cm
Maxi	38 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 Healthcare Professional.

STERILIZATION METHOD AND USE:

TCu 380Ag IUD is sterilized by Gamma Radiation or Ethylene Oxide. The Sterile single unit pouch containing TCu 380Ag IUD with its insertion components are **"For single use only"**.

CONTRACEPTIVE LIFE:

TCu 380Ag can remain inserted in the uterus for a maximum lifetime of 5 years. If continued contraception is desired by the patient, a new TCu 380Ag should be inserted at once.

INSERTION PERIOD

Insertion must take place during the first part of the menstrual cycle. It is recommended that insertion be carried out at the end of the menstrual period, which is the most suitable time.

TCu 380Ag IUD may be inserted during the first part of menstrual cycle, provided the woman is not pregnant and has been consistently using an effective contraceptive since her last menses.

Many clinicians prefer to insert the IUD within seven days of the onset of menstruation because the cervical opening is slightly dilated during this time, making insertion easier and pregnancy very unlikely. Insertion during these days also is likely to result in less discomfort, cramping and spotting for the patient. Given its small diameter, the insertion tube is easy to introduce and usually does not call for further dilation.

RECOMMENDED INSERTION TECHNIQUE

Insertion must absolutely be carried out by a qualified Healthcare Professional equipped with the appropriate instruments under aseptic conditions. It is imperative that a no-touch technique is employed throughout the insertion procedure to ensure sterile handling.

The inner packaging of the IUD must not have been opened or damaged. Insertion must not be carried out if the IUD or its accessories are damaged.

A. PREPARATION

1. Perform a careful bimanual examination to determine the version, flexion and uterine axis.
2. Insert a vaginal speculum to expose the cervix. Cleanse the cervix and vaginal walls with sterile cotton wool dipped in antiseptic solution, Wipe all secretion away from the external os.
3. Grasp the anterior lip of the cervix with a single-tooth tenaculum, taking a good bite through the cervical lip so that steady downward traction to straighten the uterine axis can be maintained without risk of cervical laceration.

   Reflex contraction, which causes cramp of the uterus when the tenaculum is applied, can be prevented by injection of a local anaesthetic into the anterior lip or a paracervical block.
4. Carefully sound the uterus to determine its depth and to confirm the direction of its axis. If the sound meets more than normal resistance at the internal os, it may be advisable to gently dilate the cervical canal to 4-5 mm, using sterile, tapered rather than cylindrical dilators. In the absence of other instruments for measurement of the internal dimensions of the uterine cavity, the sound may be used to obtain an idea of its configuration.

The IUD should be loaded in to the insertion tube not more than five minutes before insertion.

REUSE

The IUD, its accessories and the hysterometer must not be reused. In case of reuse, the patient is exposed to multiple risks of infection and the IUD loses its claimed performance.

B. PROCEDURE FOR LOADING

As a general principle, TCu 380Ag should be inserted under aseptic conditions using sterile gloves. The following steps should be followed when inserting TCu 380Ag :

1. Partially open the package from the end marked OPEN, approximately halfway to the Flange. Without extracting the IUD from the pack pull on the threads to draw the horizontal arms of IUD into the tube up to olives. (Figure II & III).
2. Holding the threads stretched with one hand, Place the rod/plunger into the tube with the free hand. This will ensure that the threads are lying straight in the tube and are not disarranged by the rod. (Figure III)

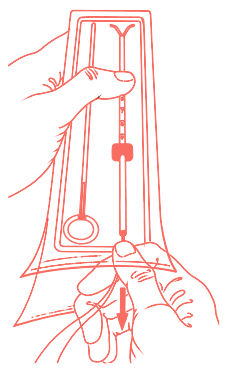

FIGURE II

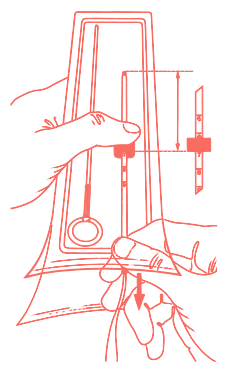

FIGURE III

3. Check the flange position using centimeter scale on Insertion tube so that it indicates the depth of uterus. The IUD is now ready for insertion.

C. INSERTING TCu 380Ag :

1. Swab the cervix with antiseptic.
2. Remove loaded insertion tube assembling from the pouch and gently introduce the loaded insertion tube assembling through the cervical canal until flange comes in contact with the cervix. This ensures that the folded arm is in contact with the fundus. (Figure IV).
3. Hold the rod stationary and withdraw the insertion tube up to the thumb grip of the rod, so as to release the arms of the T. (The arms of TCu 380Ag are now unfolded) (Figure V).
4. Gently push the insertion tube upwards until the flange touches the cervix again. TCu 380Ag is then in contact with the fundus. (Figure VI).
5. Withdraw the solid rod while holding the insertion tube stationary and gently withdraw the insertion tube (FigureVII).
6. Cut the threads so that they protrude only 2-3cms from the cervix.

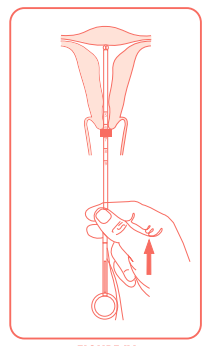

FIGURE IV

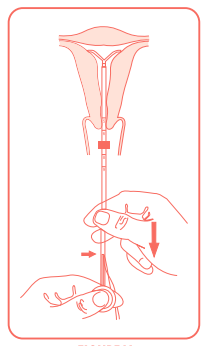

FIGURE V

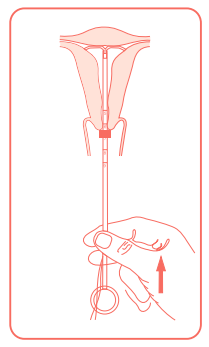

FIGURE VI

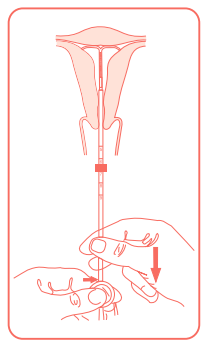

FIGURE VII

If you suspect that TCu380Ag IUD is not in the correct position, check placement (with ultrasound, if necessary), If it is not positoned completely within the uterus, remove it and replace it with a new TCu 380Ag IUD. Do not reinsert an expelled or partially expelled IUD.

REMOVAL TECHNIQUE

Removal can take place whenever the user would like to become pregnant or at the time of replacement.

Hold the threads with forceps as close as possible to the external orifice of the cervix.

Regular traction of the threads along with traction towards the bottom with the Pozzi forceps make it possible to remove the IUD without difficulty.

If it is very difficult, removal under general anaesthesia should be considered as per the most appropriate method.

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

WARNINGS

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 rate of expulsion and perforation of the uterus may be increased when insertions are made before the normal uterine involution occurs following delivery or abortion. It is recommended that TCu 380Ag be inserted not earlier than 6 weeks postpartum or post-abortion. If involution is substantially delayed, consider waiting 12 weeks to insert TCu 380Ag. In case of a difficult insertion and/or exceptional pain or bleeding during or after insertion, physical examination and ultrasound should be performed immediately to exclude perforation. Current data indicate that slightly higher expulsion, perforation and pregnancy rates may be anticipated with earlier insertion.

Perforation or penetration of the uterine wall or cervix by the IUD may occur most often during insertion. In a large prospective comparative non-interventional cohort study in IUD users (N = 61,448 women), the incidence of perforation was 1.3 (95% CI:1.1 – 1.6) per 1000 insertions in the entire cohort; 1.4 (95%CI: 1.1 – 1.8) per 1000 insertions in the LNG IUS cohort and 1.1 (95%CI: 0.7 – 1.6) per 1000 insertions in the copper IUD cohort.

The study showed that both breast feeding at the time of insertion and insertion up to 36 weeks after giving birth were associated with an increased risk of perforation (see Table 1). These risk factors were independent of the type of IUD inserted.

Table 1: Incident of perforation per 1000 insertions for the entire study cohort, stratified by breast- feeding and time since delivery at insertion (parous women).

	Breastfeeding at time of insertion	Not breastfeeding at time of insertion
Insertion ⩽ 36 weeks after delivery	5.6 (95% CI 3.9-7.9; n=6047 insertions)	1.7 (95%CI 0.8-3.1; n=5927 insertions)
Insertion> 36 weeks after delivery	1.6 (95% CI 0.0-9.1; n=608 insertions)	0.7 (95% CI 0.5-1.1; n=41910 insertions)

Reference

Heinemann et al. Risk of uterine perforation with levonorgestrel-releasing and copper intrauterine devices in the European Active Surveillance Study on Intrauterine Devices, Contraception 2015; 91: 274-279.

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.

NSAIDS

The use of NSAIDS (including ASA, naproxen and ibuprofen) reduces the efficacy of all IUDs (as per WHO recommendations).

MAGNETIC RESONANCE IMAGING (MRI)

According to the literature MR-examinations of up to 1,5 Tesla in women who have a copper-intrauterine device for contraception (IUD) in place does not influence neither the results of the MR-examinations nor the functional efficacy of the IUD.

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.

PREGNANCIES DURING IUD USE

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

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.

PRECAUTIONS FOR USE

The company asks the healthcare professional to read the information in this package leaflet. Company cannot be held responsible if this information is not complied with.

Information for the users can be found in a package leaflet specially designed for users, which is to be given to them. Intrauterine devices must be used with caution in users receiving anticoagulant treatment or with a coagulation disorder.

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.

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.

An IUD should be tolerated well after two cycles. If this is not the case, the persistence of bleeding and/or pain are reasons to consider removing the IUD.

It is recommended that the user be seen again after the menstrual period following insertion, and then on a regular basis.

In case of suspected perforation during insertion, remove the IUD immediately. Perforation can also occur in women with an IUD. If this happens, the IUD should be located and its removal considered.

INFORMATION TO BE GIVEN TO THE USER BY THE HEALTHCARE PROFESSIONAL

The healthcare professional must inform the user of the benefits and risks of intrauterine contraception. He or she must give the package leaflet for the user to the user and have her read it completely.

It is especially important that the users be able to recognise the onset of a complication as quickly as possible.

Users must learn to feel for the threads to make sure that the IUD has not been expelled.

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

MECHANISM OF ACTION

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.

However, like all methods of contraception, intrauterine contraception does not guarantee absolute protection.

The contraceptive efficacy of the IUD is present starting from the first day of insertion.

TARNISHING OF COPPER - SILVER WIRE

Copper-Silver wire bearing IUDs may show discoloration in their sterile packaging, but this should not cause alarm because the copper tarnishes causing an oxide or sulfide film to form on the surface.

If the package is not damaged and the insert before date on the package has not expired. the IUD will be sterile even if the copper on the device is tarnished. Laboratory studies show the tarnishing does not affect the safety or effectiveness of the 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 IUDs are class III medical devices as per the European Directive 93/42/EEC on Medical Devices as amended.

Labelling: CE since 2012

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

The IUD, its accessories must be eliminated after use, as per the regulations in force for the handling of potentially infectious material.

Storage Conditions:

Store at 15^{0}C to 30^{0}C in a dry place away from direct sunlight, sources of heat, water and mechanical damage.

Shelf Life : 5 years

1	2	3	4	5	6
LOT					STERILE R
Lot No./ Batch No.	Manufacturing Date	Insert Before Date	Do not Reuse	Warning	Sterile and Method of sterilization: "R " states Sterilization by Radiation Method

7	8	9	10	11	12
	CE 2460				
Manufactured by	CE mark	Protect from rain or water	Do not use if carton is damaged	Protect from Sun light	Do not re sterilize

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SMB CORPORATION OF INDIA

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13, 33-36, Prem Industrial Estate, Jogeshwari (E), Mumbai 400 060, India

E-mail : sales@smbcorpn.com • Website : www.smbcorpn.com

Mfg. Lic. No. MFG/MD/2020/000278

EC REP Obelis S.A, Boulevard Général Wahis 53, 1030 Brussels, Belgium

Tel: +(32) 2.732.59.54 • Fax : +(32) 2.732.60.03 • E-Mail : mail@obelis.net

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