

Model TCu 380 Plus

Model : Mini, Normal & Maxi

CE
2460

INTRAUTERINE CONTRACEPTIVE DEVICE

IUDs do not protect against sexually transmitted diseases/AIDS.

Instructions for use: (IFU)

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

GENERAL INFORMATION :

Each modified T shaped SMB TCu 380 Plus is made from compound of Low Density Polyethylene and Barium Sulphate wound with 0.40mm diameter copper wire providing a surface area of 380mm² ± 23 mm². The modified T is equipped with Polyamide Monofilament thread (suture) for easy removal. It 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.

Indications : Intrauterine contraception in women of child bearing age

Contraceptive Life : SMB TCu 380 Plus can be left inserted for a maximum of 60 months(5 years). If continued, contraception is desired by the patient, a new SMB TCu 380 Plus should be inserted at once.



FIGURE I

Indicative selection criteria of the Mini, Normal, Maxi Models

SIZE	Vertical arm length	Uterine Cavity Size	Approx. Sound measuring Range
Mini	30.5±0.5 mm	36 mm	6-7.5 cm
Normal	33±0.5 mm	45 mm	7-8.5 cm
Maxi	38±0.5 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 Gynecologist/Physician.

The SMB TCu 380 Plus 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.

The SMB TCu 380 Plus 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 genital actinomycosis

SMB TCu 380 Plus 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

TIMING OF INSERTION :

SMB TCu 380 Plus IUD may be inserted at any time during the menstrual cycle, provided the woman is not pregnant and has been consistently using an effective contraceptive since her last menses. Given its small diameter, the insertion tube is easy to introduce and usually does not call for further dilation.

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.

RECOMMENDED INSERTION TECHNIQUE :

It is imperative that a no-touch technique is employed throughout the insertion procedure to ensure sterile handling. The intrauterine device should not be used in the event of the inner packaging being 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.

B. PROCEDURE FOR LOADING

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

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)
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 SMB TCu 380 Plus :

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 SMB TCu 380 Plus are now unfolded). Figure V.
4. Gently push the insertion tube upwards until the flange touches the cervix again. SMB TCu 380 Plus is then in contact with the fundus. Figure VI
5. With draw the solid rod while holding the insertion tube stationary. Gently withdraw the insertion tube. Cut the threads so that they protrude only 2-3 cms from the cervix. Figure VII

CONTRAINDICATIONS :

A. ABSOLUTE

- Pregnancy
- Acute pelvic inflammatory disease or a history of pelvic inflammatory disease (PID)
- Post partum endometritis or abortion

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Information to the user (ITU)

This Information is intended to provide General Information and should not Serve As a Substitute for a Physician's Advice

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- 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 genital actinomycosis
- Has Wilson's disease or a Known allergy to Copper

SMB TCu 380 Plus should not be the method of first choice for a woman who has :

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

CONTRAINDICATIONS :

Absolute

- Pregnancy
- Acute pelvic inflammatory disease or a history of pelvic inflammatory disease (PID)
- Post partum endometritis or abortion
- Sexually transmitted diseases (STD) including a lower genital tract infection, such as gonorrhoea 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.

Relative

- Severe Dysmenorrhoea
- Vascular Cardiac disease.
- Disorders of blood coagulation

Secondary Effects

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

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
- Painful periods
- Pain or cramps at insertion or following insertion.
- Vaginal discharge & infection
- Backache
- Allergic skin reaction due to the IUD
- Heavy or prolonged periods
- Anemia
- Leg pain & soreness

Contraceptive Life

International bibliography recommends not to surpass five years of insertion in the active copper IUDs



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CITY NAME :

THE CLINIC WHERE THE IUD WAS INSERTED :

NAME OF THE USER :

NEXT APPOINTMENT FOR CHECK UP :

..... FAMILY PLANNING CLINIC

THE DATE WHEN THE IUD WAS INSERTED :

THE DATE WHEN THE IUD WAS REMOVED :

INSTRUCTIONS FOR CLIENT

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 SUTURES REGULARLY ESPECIALLY AFTER YOUR PERIOD. THEN CHECK THE SUTURES FOLLOWING MENSTRUATION. IF THE SUTURES CANNOT BE FOUND AND IF THEY ARE LONGER OR SHORTER THAN USUAL, VISIT YOUR CLINIC.

IF THE SUTURES 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.

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 SMB TCu 380 Plus.


PREGNANCY WITH THE SMB TCu 380 Plus 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 SMB TCu 380 PLUS IUD

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REF: 46105 / ART: 01,520

REF: 46106 / ART: 01,521

- Sexually transmitted diseases (STD) including a lower genital tract infection, such as gonorrhoea 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.

B. RELATIVE

- Severe Dysmenorrhoea
- 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

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(leucorrhoea) & infection
- Backache
- Leg pain & soreness
- Fever
- Allergic skin reaction due to the IUD

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.

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 TCu380 Plus promptly.

Do not reuse the Device. It may cause lower abdominal infections, risk of subsequent infertility.

Removal

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

Hold the strings with forceps as close as possible to the external orifice of the cervix and apply steady force. Applying unsteady force/ pressure may cause breakage of arm

Regular traction of the strings 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. Sometimes partial penetration or embedment of the IUD in the myometrium can make removal difficult. Surgical removal may be necessary to remove the device.

Tarnishing of Copper

Copper bearing IUDs may show discoloration in their sterile packaging, but this should not cause alarm. The copper tarnishes because air passes through the sterile IUD package causing an oxide or sulfide film to form on the surface. The IUD packaging has to be permeable to sterilize the devices. If the package is not damaged and the expiration date on the package has not passed, 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.

Storage Conditions:

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

Shelf life :

5 years shelf life


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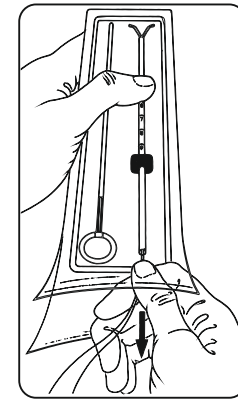


FIGURE II

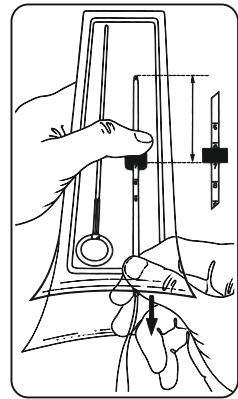


FIGURE III

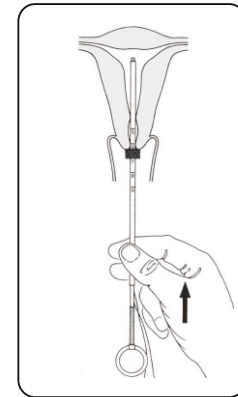


FIGURE IV

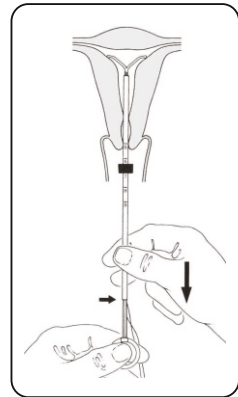


FIGURE V

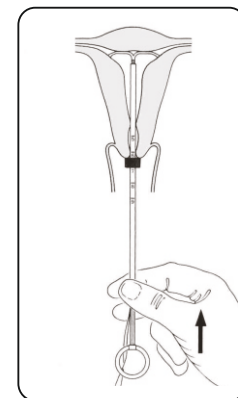


FIGURE VI

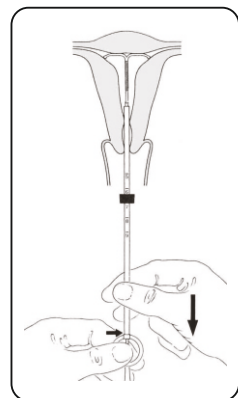


FIGURE VII

STERILE R

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