SMB®

CE 2460

Cu 375

Standard/Sleek

INTRAUTERINE CONTRACEPTIVE DEVICE

IUDs do not protect against sexually transmitted diseases/AIDS.

Instructions for use: (IFU)

SMB Cu 375 should be inserted and removed only by / under the supervision / training of a gynecologist/physician.

GENERAL INFORMATION :

SMB Cu 375 is an Intrauterine Contraceptive device made up of polyethylene with two flexible arms with spurs. A copper wire is wound around the stem, giving a total copper surface area of 375 mm2. The flexible side arms ensure that SMB Cu 375 remains in position as high as possible against the fundus, without the uterine cavity being stretched at all. A monofilament nylon thread is attached to the stem. The contraceptive action of the device is probably due to a number of foreign body reactions with the uterine endometrium and the presence of metallic copper.

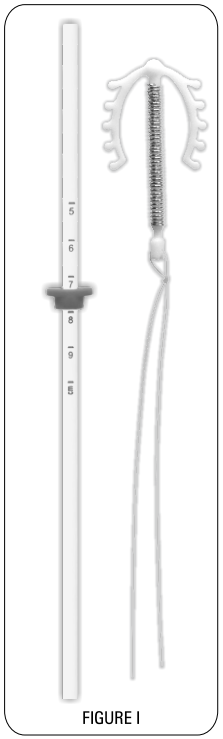


FIGURE I

Indications : Intrauterine contraception in women of child bearing age

Cu 375 can be inserted after a birth or abortion.

Cu 375 can be used as emergency contraception. In this case the risk of PID is higher.

Contraceptive Life : SMB Cu 375 can be left inserted for a maximum of 60 months(5 years). If continued, contraception is desired by the patient, a new SMB Cu 375 should be inserted at once.

Indicative selection criteria of the Sleek and Standard Models/sizes

SIZE/ Model	Horizontal Width	Vertical Length	Approx. Sound measuring Range
Sleek	19±0.3 mm	29.5±0.5 mm	5-8 cm
Standard	19±0.3 mm	35.5±1.0 mm	6-9 cm

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

The SMB Cu 375 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 Cu 375 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 Cu 375 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 Cu 375 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 :

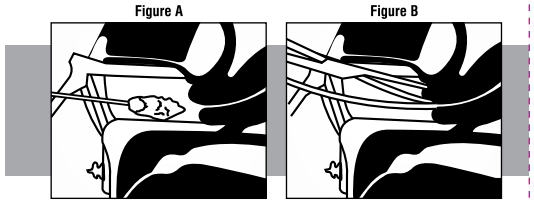
It is imperative that a no-touch technique is employed throughout the insertion procedure to ensure sterile handling. The intrauterine device should not be used in the event of the inner packaging being damaged.

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.



GENERAL INFORMATION :

The vertical stem of SMB Cu 375 is already preloaded in the introducer tube. The side arms do not require loading into the tube. They are sufficiently flexible to adapt to the shape of the cervical canal.

1. Peel the pouch open partially from the end marked OPEN.

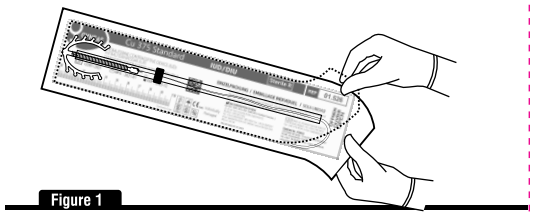


Figure 1

2. Peel the pouch back so far that the introducer tube (with IUD) can be picked up at its distal end, grasping the tube and the threads, but without taking Cu 375 out of the pouch (see Figure 2).

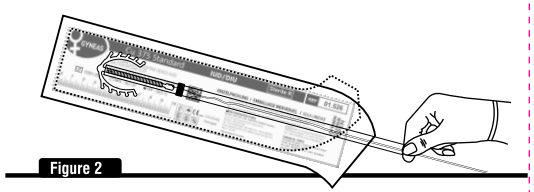


Figure 2

3. Hold the cervical stop with the thumb of one hand and adjust the position of the top of Cu 375 by moving the introducer tube with the other hand until it corresponds with the mark indicating, approximately, the sounded uterine length in centimeters (see Figure 3).

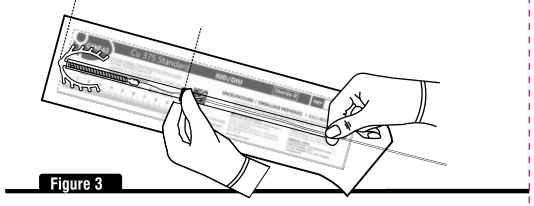


Figure 3

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INTRAUTERINE CONTRACEPTIVE DEVICE

IUDs do not protect against sexually transmitted diseases/AIDS.

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

The SMB Cu 375 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 Cu 375 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
- Has Wilson's disease or a Known allergy to Copper

SMB Cu 375 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 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.

Relative

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

Contraceptive Life

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

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INTRAUTERINE CONTRACEPTIVE DEVICE

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 Cu 375

PREGNANCY WITH THE SMB Cu 375 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 Cu 375 IUD

MADE WITH PRIDE IN INDIA

SMB CORPORATION OF INDIA

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REF: 46107
ART: 01.526

4. The distal end of the introducer may be held without risk of contaminating the device. Holding the threads together with the tube ensures that the device does not fall out of the introducer tube. Cu 375 can now be taken out of the pouch.

5. Carefully insert Cu 375 into the uterus (Figure C) until it touches the fundus and the cervical stop rests against the external os (Figure D) while maintaining steady downward traction with the tenaculum to straighten the uterine axis. No attempt should be made to force insertion.
Insufficient axial straightening may, on occasion, result in a sub-endometrial insertion. This risk may be reduced by exerting an adequate downward pulling force on the cervix, thereby fully straightening the axis of the uterus against its ligamentous supports.

6. When Cu 375 touches the fundus, it is released into the uterine cavity by simply withdrawing the introducer tube (Figure E). During this procedure continue to apply downward traction with the tenaculum. No push rod is required to insert SMB Cu 375. Check the cervical canal with the sound to ensure that the tail of IUD is entirely within the uterine cavity. Trim the threads of Cu 375 to 2 to 3 cm measured from the external os.

7. It is imperative to follow precisely the recommended insertion procedure in order to minimize the risk of a sub-endometrial insertion, which may, in turn, lead to full or partial endometrial embedding of the IUD. Should this occur, a higher than normal force may need to be applied to remove the IUD from this incorrect location, which may increase the risk of side-arm breakages. Furthermore, it may be clinically difficult to confirm the IUD's sub-endometrial location, since this is usually not obvious to the doctor during insertion of the device and the patient probably experiences no pain. It is anticipated that correctly inserting the device may reduce the incidence of both side-arm breakages and perforations.

Figure C

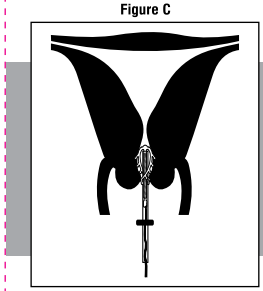


Figure D

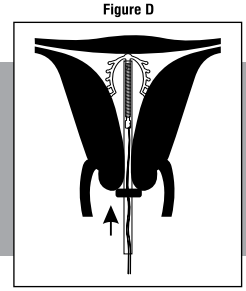
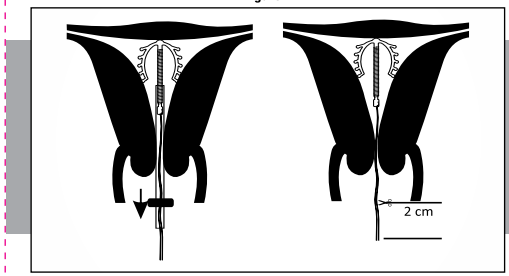


Figure E



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- Missed or late periods
- Heavy or prolonged periods
- Painful periods
- Anemia
- Pain or cramps at insertion or following insertion.
- Vaginal discharge & 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 vaginea 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 Cu 375 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.

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

MADE WITH PRIDE IN INDIA
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