Leaflet for Healthcare Professionals

INTRAUTERINE CONTRACEPTIVE DEVICE

Cu 375

STANDARD/SLEEK

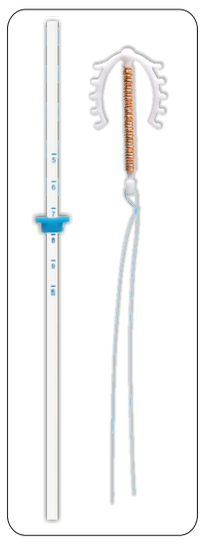
CE 2460

IUDs do not protect against sexually transmitted diseases / AIDS

LEAFLET INTENDED FOR THE HEALTHCARE PROFESSIONAL

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

DESCRIPTION



SMB Cu 375 Intrauterine Contraceptive device is ready to use in a sterile package and is composed of Ω shaped device with two flexible arms having spurs, made of low density polyethylene with barium sulphate, opaque to X-rays. It is wound with 0.40 mm diameter copper wire providing a surface area of 375 mm^2. The flexible side arms ensure that Cu 375 remains in position as high as possible against the fundus, with a nylon monofilament thread attached to the stem.

The single unit pouch containing Cu 375 IUD with its insertion components is a sterile medical contraceptive device for Single Use Only.

INDICATIONS

The Cu 375 IUD, is indicated for Intrauterine Contraception in women of child bearing age.

- Cu 375 can be inserted after a birth or abortion.
- Cu 375 can also be used as emergency contraception, however the risk of pelvic inflammatory disease is higher in this case.

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

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 Wilson's disease or a known allergy to copper
- Has genital actinomycosis

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

Indicative selection criteria of the Sleek and Standard Models/sizes

Size/ Model	Horizontal Width	Vertical Length	Approx. Sound measuring Range
Sleek	19 mm	29.5 mm	5-8 cm
Standard	19 mm	35.5 mm	6-9 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

Cu 375 IUD is sterilized by Gamma Radiation or Ethylene Oxide. The Sterile single unit pouch containing Cu 375 IUD with its insertion components are **"for single use only".**

CONTRACEPTIVE LIFE

Cu 375 can be left inserted for a maximum of 60 months (5 years). If continued contraception is desired by the patient, a new Cu 375 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.

Cu 375 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.

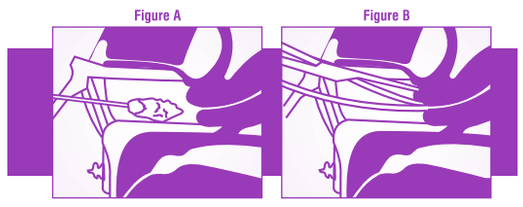
The inner packaging of the IUD must not have been opened or damaged. Insertion must not be carried out if the IUD or its accessories are damaged or insert before date has passed.

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.



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

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. (see Figure 1).

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).

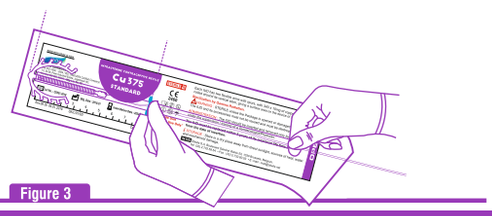
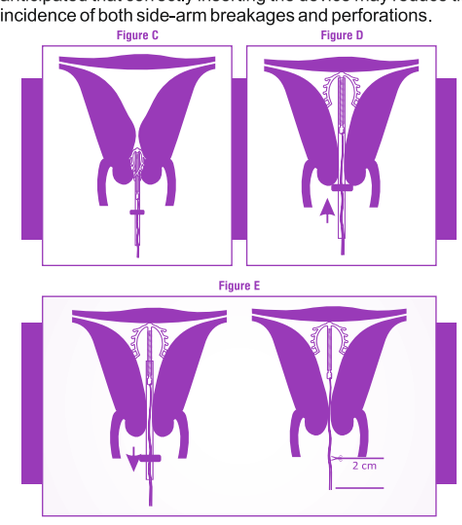


Figure 3

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 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.

If you suspect that Cu 375 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 Cu 375 IUD. Do not reinsert an expelled or partially expelled IUD.

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.



REMOVAL TECHNIQUE

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.

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 Cu 375 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 Cu 375 be inserted not earlier than 6 weeks postpartum or post-abortion. If involution is substantially delayed, consider waiting 12 weeks to insert Cu 375. 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. Cu 375 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 contraceptive effectiveness, side effects, health benefit, health risk and complication associated with Cu375 to the user.

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 strings to make sure that the IUD has not been expulsed.

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 WIRE

Copper 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 2008

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°C to 30°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	7	8
LOT					STERILE R		CE 2460
Lot No./ Batch No.	Manufacturing Date	Insert Before Date	Do not Reuse	Warning	Sterile and Method of sterilization,"R" states Sterilization by Radiation Method	Manufactured by	CE mark

9	10	11	12	13	14	15
					UDI	MD
Protect from rain or water	Do not use if carton is damaged	Protect from Sunlight	Do not re sterilize	Temperature Limit	UDI	Medical Device

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