Post Delivery IUD
Copper T 380A
(TCu 380A)

INTRAUTERINE CONTRACEPTIVE DEVICE

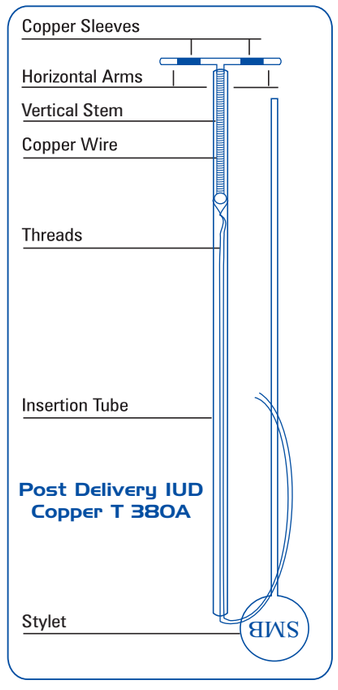
IUDs do not protect against sexually transmitted diseases/AIDS

INSTRUCTIONS FOR USE: (IFU)

PD IUD TCu 380A SHOULD BE INSERTED AND REMOVED ONLY BY / UNDER THE SUPERVISION / TRAINING OF A GYNAECOLOGIST / PHYSICIAN

GENERAL INFORMATION

Each unit wound with approximately 176±11 mg of copper wire in addition, a copper sleeve containing approximately 68.7± 3 mg of copper is swaged on each of the transverse arms. The total surface area of copper on device is 380mm^2 ± 23mm^2.



INDICATION

The Post Delivery IUD TCu 380A is indicated for Intrauterine Contraception in women just after delivery

Vertical Width	Horizontal Width
36 ± 0.5 mm	32 ± 0.5 mm

The PD IUD TCu 380A is recommended for women
- Post Delivery
- Have no history of pelvic inflammatory disease (PID)
- Choose not to use hormonal contraceptives.

The PD IUD TCu 380A should not be inserted in woman who:
- 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. Prior to Pregnancy
- Has Wilson's disease or a known allergy to copper
- Has genital actinomycosis

Shelf Life: Seven years shelf life

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.

TIMING OF INSERTION

- **PD IUD** may be inserted within 48 hours of delivery

INSERTION TECHNIQUE

- **Explaining the procedures** to the client. This helps the client relax, making insertion easier and less painful.

- **Infection- prevention procedure** including use of high level disinfected instruments, sterile hand gloves and cleaning of the cervix with a water based antiseptic such as chlorhexidine gluconate or an iodophor (for e.g Betadine). This minimizes the chances of uterine infection following insertion using No Touch Technique

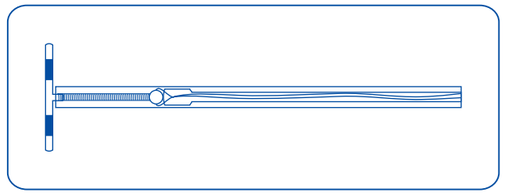
- **Speculum examination and bimanual pelvic examination**. The speculum examination is done to check for signs of genital tract infection. The bimanual examination determines the size, position, consistency, and mobility of the uterus and identifies any tenderness.
  After inserting a vaginal speculum to expose the cervix, the cervix and vaginal walls are cleansed with sterile cotton wool dipped in antiseptic solution. All secretion is wiped away from the external os.

- **IUD placement high in the uterus** (i.e. at the fundus). This minimizes expulsions, accidental pregnancies, and possibly bleeding.

- **Following the manufacturer's instructions** for insertion. Most IUDs are inserted by the withdrawal technique. The insertion tube loaded with the IUD, is inserted to the depth indicated. Then the insertion tube is withdrawn while the inner stylet is held steady. This leaves the IUD in position. Then the stylet is withdrawn.

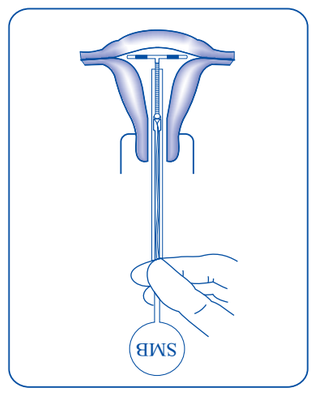
PROCEDURE FOR LOADING

1. Partially open the package from the end marked OPEN, approximately halfway.
2. Put the stylet into the insertion tube to almost touch the bottom of the T.

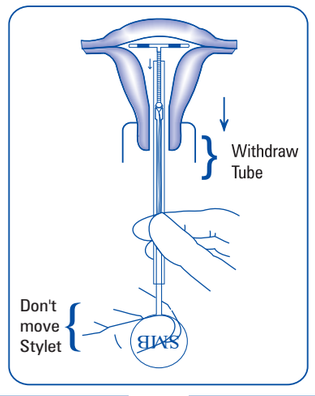


PROCEDURE FOR INSERTION

1. Swab the cervix with antiseptic.
2. Grasp the anterior lip of the cervix with sponge holder
3. Gently introduce the loaded inserter assembly through the cervical until the T reaches the fundus.



4. Hold the stylet stationary and withdraw the insertion tube



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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 PD IUD Copper T 380A is recommended for women
- Post Delivery
- Have no history of pelvic inflammatory disease (PID)
- Choose not to use hormonal contraceptives

The PD IUD Copper T 380A should not be used by a woman who:
- 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.
- Has Wilson's disease or a known allergy to copper
- Has genital actinomycosis.
- Follow up after six weeks necessary.

CONTRAINDICATIONS

- Acute pelvic inflammatory disease or a history of pelvic inflammatory disease.
- Sexually transmitted disease(STD) including a lower genital tract infection, such as gonorrhoea or chlamydia.
- Known or suspected malignancy of the genital tract, including undiagnosed dysfunctional uterine bleeding.
- 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.

ADVERSE REACTIONS

The following adverse reactions and side effects have been reported with IUDs and may occur after the Copper T is inserted.
- Pregnancy with the Copper T in the uterus or when it has been partially or completely expelled.
- Complete or partial expulsion
- Bleeding or spotting between periods
- Missed or late periods
- Heavy or prolonged periods
- Painful periods
- Anemia
- Vaginal discharge & infection
- Backache
- Leg pain & soreness
- Allergic skin reaction due to the Copper on the Copper T.

Post Delivery IUD

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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 USER

IMMEDIATE RESPONSE :

- Trimming of thread will be needed at 6 weeks of followup

LATE INSTRUCTION :

- 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.
- 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 Copper T (TCu 380A protects from preganancy for 10 years).
- Preganancy with the TCu 380A in place occurs at rates of less than one per 100 women per year. if a women using an IIUD becomes pregnant the IUD should be removed immediately.
- Lactation can be continued during the use of the TCu 380A IUD.

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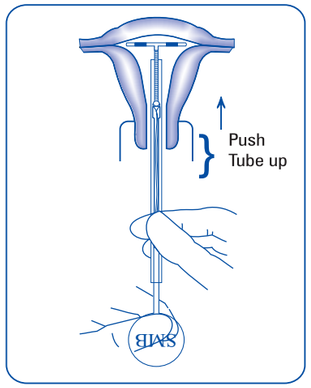
5. Gently push the insertion tube upwards,towards the top of the uterus until a slight resistance is felt. This ensures that the T is close to the fundus.



6. Withdraw the stylet while the insertion tube stationary. Gently withdraw the insertion tube with a rotation. Cut the threads so that they protrude only 2-3 cm into the vagina.
7. Remove the tenaculum and ask the woman to get down from the table slowly and instruct how and when to check the threads Invite question and instruct about return visit as well as what to do, whom to contact for help if needed.

CONTRAINDICATIONS

- Acute pelvic inflammatory disease or a history of pelvic inflammatory disease.
- Sexually transmitted disease (STD) including a lower genital tract infection,such as gonorrhoea or Chlamydia.
- Known or suspected malignancy of the genital tract, including undiagnosed dysfunctional uterine bleeding.
- Congenital uterine abnormality.
- Untreated acute cervicitis or vaginitis including bacterial vaginosis, until infection is controlled.
- Conditions associated with increased susceptibility to infections with micro- organisms. Such conditions included, but are not limited to leukemia, acquired immune deficiency syndrome (AIDS), and intravenous drug abuse.
- 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

WARNINGS

• 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 TCu 380A promptly. The use of an IUD in breastfeeding women increases the risk of uterine perforatioin

Table 1

Postpartum IUCD in Paraguay (2000-2003)[1] : Review of 3029 Cases

Complication	Number of Cases	Rate
Perforation	0	0.0%
Infection	4	0.1%
Removal (any reason)	102	3.4%
Spontaneous expulsion	43	1.4%

1. Unpublished data Presented in the Global Maternal Health Conference, 2010, New Delhi, by Jeffery M Smith, Team Leader, Maternal Health, MCHIP

- 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. Copper T 380A 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).

Removal
Remove TCu 380A with Forceps, pulling gently on the exposed threads. The arms of the IUD will fold upwards as the T is withdrawn from the uterus. If the thread is not seen the SMB IUD Thread Retriever can be used.
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 :
Store at 15^{0}C to 30^{0}C in a dry place away from direct sunlight, sources of heat, water and mechanical damage.

Reuse
Do not reuse the device. It may cause lower abdominal infection, risk of subsequent infertility.

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 Sun light	Do not re sterilize	Temperature Limit	UDI	Medical Device

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