



How to Use

The IUD Kit should be used by or under the supervision of a physician / Gynecologist

SMB IUD Insertion / Removal kit

SMB IUD Kit offered are instruments that are designed to quickly as well as safely perform involved medical procedures in a highly sterile and safe environment. These kits allow IUD Insertion / Removal in form of single time usage and contain in it options like Pozzi Tenaculum Forcep, Cheron / Sponge Forceps, Thread Cutting Scissors, Thread Cutting Scissors.

Composition

| Element | Material | Composition |
|-----------------------------|---------------|--------------------|
| Pozzi Tenaculum | Polycarbonate | 100% Polycarbonate |
| Cheron Forceps | Polycarbonate | 100% Polycarbonate |
| IUD Thread Cutting Scissors | Polycarbonate | 100% Polycarbonate |
| Clean Forceps | Polycarbonate | 100% Polycarbonate |

Procedure:

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 indophenol. This minimizes the chances of uterine infection following insertion / removal of IUDs.

Stabilizing the Cervix :

The healthcare professional / doctor will hold open the vagina by using a speculum, which resembles a metal beak of a duck. The instrument is inserted into the vagina, then its blades are separated and held open by a special action device on the handle. Once this is accomplished, due to the importance of having a completely sterile environment to reduce the likelihood of infections, the cervix and the adjacent anterior (front) and posterior (back) recesses in the vagina will be cleansed with an antiseptic sterile gauge held by Pozzi Tenaculum solution. Some healthcare professional / doctor may apply a local anesthesia, such as 5 percent lidocaine gel, into the cervical canal to reduce discomfort.

For Insertion of IUD:

Once the IUD is in place, the tenaculum, and the speculum are then removed from the vagina. The intrauterine device will stay in place. The IUD will have suture attached to it that the doctor / Healthcare provider will leave intact. They hang down through the cervix into the vagina. At this point, the doctor will cut the ends of the suture / strings with the help of Thread Cutting Scissor but will allow about one to two inches to hang out of the cervix. The strings are not able to be seen from outside of the vagina but are long enough to be felt by a finger inserted in the vagina (this is how a woman can check if her IUD is still in place).

Table

| Attribute | Intended Use |
|-----------------------------|--|
| Pozzi Tenaculum | To holds the cervix during the gynecological procedure |
| Cheron Forceps | To hold the swab/sponge and dressings in gynecological procedures |
| IUD Thread Cutting Scissors | To cut the extra length of the suture protruding out the cervical canal after insertion of intrauterine contraceptive device |

For Removal of IUD :

The IUD strings are usually readily visualized. Grasp the IUD strings with the Pozzi Tenaculum Forceps and apply steady gentle outward traction, and the IUD should easily appear in the vagina. Remove the speculum.

Table

| Attribute | Intended Use |
|-----------------|---|
| Pozzi Tenaculum | To holds the cervix during the gynecological procedure. |
| Cheron Forceps | To hold the swab/sponge and dressings in gynecological procedures |
| Clean Forceps | To pull the thread while extracting / removing IUD |

Contraindications:

A. Absolute Contraindications

- The procedure is contraindicated in suspected pregnancy or in woman with acute pelvic inflammatory disease
- It is also contraindicated in woman with chronic cervical infections or any conditions which contraindicates an outpatients surgical procedure
- A patient with an intrauterine device (IUD) currently in place

B. Warning

- Do not exert pressure during use.
- Do not reuse the instruments. It may cause the infection.
- Use only if the package is not opened or damaged

C. Precautions

- The decision of analgesia or anesthetic to be made by the clinician or Healthcare professional to the patient.
- Adequate visualization of the entire cervix with sufficient lighting should be achieved to ensure proper placements of the SMB Devices
- Take care not to perforate the uterine cavity by exerting too much pressure with the SMB Device. If resistance does occur, the patient must be observed to ascertain whether laparoscopy or laparotomy needs to be performed.

D. Adverse Effect

- Patients should be carefully watched for evidence of unusual pallor, nausea, vertigo or weakness. Any cervical manipulation may cause a vasovagal reaction. These symptoms typically subside in about 15 minutes of rest and/or a mild analgesic
- In some cases there may be spot bleeding or mild cramps after this procedure has been performed. The patient should be instructed to notify the physician if spotting

Patient population : Women of child bearing age

Storage Condition :

Store properly to protect from heat, direct sunlight, water and mechanical damage. Store under cool, dry condition and away from light.

Reuse :

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

Shelf Life : 5 years

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|----------------|---|--|-------------------------------|-------------------------------|--|--------------|
| LOT | MM | DD | XX | AA | RR | YY |
| Batch Code | Date of Manufacture | Use - by Date | Do not Reuse | Caution | Shelfs and Method of sterilization "R" Method of sterilization by Radiation Method | Manufacturer |
| 8 | 9 | 10 | 11 | 12 | 13 | 14 |
| CE 2862 | Keep Dry | Do not use if package damaged and consult instructions for use | Keep away from sunlight | Do not re sterilize | Temperature Limit | UDI |
| MD | EC REP | | | | | |
| Medical Device | Authorized Representative in the European Community | Consult Instructions for Use | Single sterile barrier system | presence of phthalates (DEHP) | Medical Substance | |

MADE WITH PRIDE IN INDIA

Legal Manufacturer

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