Lydia Cu 375 Sleek IFU for DKT Nigeria: SPE/QA/8236/D, 255 x 210 mm

**INDICATION**
Lydia Cu 375 Sleek IUD is indicated for contraception control.

**INTENDED USE**
Lydia Cu 375 Sleek IUD offers almost complete protection against pregnancy, having a shelf life of 5 years, and it remains effective for a period of 5 years. Correctly inserted, Lydia Cu 375 Sleek IUDs are safe for women at low risk of sexually transmitted disease.

The Lydia Cu 375 Sleek is an intrauterine contraceptive device made of polyethylene. The stem is covered with copper wire, the total surface of the copper is approx. 375 mm². The side arms are flexible and shaped in such a way as to keep the Lydia Cu 375 Sleek IUD adjacent to the fundus, without stretching the uterine cavity or touching the cornua. 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.

**INSERTION**
How is Lydia Cu 375 Sleek Inserted?

After examining the uterus to determine its position, size and condition, a speculum is inserted into the vagina (as for a Pap smear) and the cervix. The vagina is cleansed with antiseptic lotion. The uterus is held steady while depth is sounded. The doctor uses a slender flexible transparent plastic tube to insert Lydia Cu 375 Sleek into the uterus.

Hysteroscopy should be carried out and the depth of stroma marked in the cervix around the Lydia Cu 375 Sleek inserter. The Lydia Cu 375 Sleek IUD is then gently inserted until the marker touches the cervix which means that the tip of the IUD has reached the fundus. The applicator is then pulled off, releasing the Lydia Cu 375 IUD in the uterus. After the insertion, the two strings attached to the device extend into the vagina so that the presence of the device is felt by the doctor or self-examination. The threads protruding from the cervical canal are then cut, leaving 3-4 cm outside the cervical os.

**INSERTING STEPS**
1. Lay the Lydia Cu 375 Sleek pack on the flat surface. Strip the wrapping from the device by lifting the transparent sheet of the pack from the end marked open.
2. The vertical stem of the device is already preloaded in the insertion tube. The side arms do not require loading into the tube. They are sufficiently flexible to adapt to the shape of the cervical canal.
3. Pick up the insertion tube (with preloaded IUD) gripping the tube at the indentation near its distal end and move the flange to the distance corresponding to the sound length in cm. Adjust the movable flange depth gauge with the help of the preprinted scale on the insertion tube so that it indicates the depth of uterine (as measured earlier by uterine sound).
4. Lift the insertion tube (with preloaded IUD) from its packet. Make sure that the tube is held with the Lydia Cu 375 Sleek upwards so that it does not fall out of the tube.
5. Carefully insert the Lydia Cu 375 Sleek into the uterus until it touches the fundus and the flange rests against the external os while maintaining the steady downward traction with the tenaculum to straighten the uterine axis. No attempt should be made to force insertion.
6. When Lydia Cu 375 Sleek touches the fundus, it is released into the uterine cavity by simply withdrawing the insertion tube. During this procedure continue to apply downward traction with the tenaculum. No inserter rod is required to insert the Lydia Cu 375 Sleek. Check the cervical canal with the sound to ensure that the tail of Lydia Cu 375 Sleek is entirely within the uterine cavity. Trim the threads of the Lydia Cu 375 Sleek to 3-4 cm measured from the external os.
7. It is imperative to follow precisely the recommended insertion procedure in order to minimize the risk of subadnimal perforation which will lead to partial embedding of the IUD and may increase the risk of perforation.

**PRECAUTIONS**
A thorough medical history and pelvic examination are mandatory to exclude women with contra-indications, i.e., vaginal and cervical infection. It is also advisable to take a vaginal and cervix culture before inserting the IUD to prevent PID. Finally, a pelvic examination to determine the position of the uterus will enable the IUD to be inserted correctly.

The Lydia Cu 375 Sleek is designed for women with a uterine cavity depth of 5-9 cm. One month after the insertion of an IUD the woman must be re-examined to determine whether the IUD is properly placed and if there are signs of infection.

Pelvic inflammatory diseases during IUD use should be treated without delay. For this reason the user must be instructed to report to her physician if there are suspicious signs or symptoms. This can be ascertained by gynecological examination and/or ultrasound (if available). If there is no response after 48 hours of antibiotic treatment, or if there are signs of PID, the Lydia Cu 375 Sleek IUD must be removed immediately.

Excessive bleeding or dysmenorrhoea during the first cycle after insertion should also be carefully assessed to see if it is caused by the IUD, in which case it might have to be removed.

If a woman gets pregnant with the IUD in place, there is a chance of having an ectopic pregnancy which should be evaluated.
The possibility of perforation of the uterus during insertion should always be considered, especially if the nylon thread is invisible or cannot be pulled out of the cervical canal. If there are any doubts (if the IUD is extremely difficult or painful to insert) the appropriate diagnostic techniques should be used (flat X-ray of the pelvis, ultrasonography, hysteroscopy, laparoscopy).

If the nylon thread appears to be longer than it was when it was inserted an ultrasonogram should be carried out to determine if the IUD has been displaced, which might decrease its contraceptive efficacy.

**Physician’s Instructions to IUD Users**

Users should be informed in detail as to the advantages and disadvantages of IUD contraception, not only so that they understand how it works but above all so that any complications can be detected early. The user must learn how to feel the thread emerging from the cervical canal.

**Removal Procedure**

Prepare the vulva, insert the speculum and cleanse the cervix as for insertion. To facilitate removal, a tenaculum should always be used to straighten the uterine axis, thereby also minimising side arm breaksages. Use forceps to grasp both the threads of Lydia Cu 375 Sleek. Using steady downward traction straighten the uterine axis so the device can be easily withdrawn from the uterus. On completion of shelf life or on removal after use, dispose of the items as per the local regulations governing disposal of non-recyclable waste/medical waste.

**Contraindications (Absolute)**

1. Malignant disease of the genital tract
2. Undiagnosed vaginal bleeding
3. Pregnancy
4. Past history of ectopic pregnancy or predisposing factors
5. Infections of the genital tract
6. Sexually transmitted diseases during the last 12 months (except bacterial vaginitis, repeated herpes infection, Hepatitis B)
7. Abortion with infection during the last 3 months, pelvic inflammatory disease
8. Uterine malformations (congenital or acquired)
9. Allergy to copper

**Contraindications (Relative)**

1. Anaemia
2. Valvular heart disease
3. Coagulation disorders
4. Anti-inflammatory treatment
5. Wilson’s disease
6. Multiple exposure to different sexual partners

The device is for single use only and should not be re-used. It may result in loss of efficacy and infections.