**Lydia T Cu 380 A - SafeLoad IFU:** SPE/QA/6539/D  Size 285 x 210 mm

**INDICATION**
Lydia T Cu 380A Safe Load IUD is indicated for contraception.

**INTENDED USE**
Lydia T Cu 380 A SafeLoad IUDs offer almost complete protection against pregnancy, having a shelf life of 7 years and it remains effective for a period of 10 years.

Lydia is very delighted to offer customer friendly and innovative unique Safe Load with Preloaded Solid Rod for ease in loading Lydia T Cu 380 A SafeLoad. Preloaded Solid Rod in the insertion tube will help the doctor from losing its sterility by avoiding its touching or brushing against another surface. The loading is performed without human touch to the Lydia T Cu 380A SafeLoad resulting in aseptic loading.

**ADVANTAGES**
- Convenient for a woman who has one or more children and who wants to space their children.
- This is an effective contraception up to ten years.
- Very effective. Little to remember.
- No hormonal side effects.
- No interactions with any medicines.
- Immediately reversible.
- Easy, quick and aseptic T loading.

**PROCEDURE FOR INSERTION**

**CAUTION**
- Do not pick up and use any component that has fallen on the floor or table.
- Do not pour the contents of the pouch in the instrument tray.
- Do not use the white solid rod to measure uterine cavity length.

**A) PREPARING THE USER**
- Operator should wear sterile gloves and use aseptic technique. He/She should gently explain to the client what he/she is doing.
- Prior to insertion the vagina and cervix should be cleansed with an antiseptic solution.
- The cervix should be visualized by means of speculum and its anterior lip grasped with a tenaculum. Gentle traction on the tenaculum will tend to reduce the angle between the cervical canal and endometrial cavity and will greatly facilitate introduction of the uterine sound. The tenaculum should remain on the cervix, throughout the insertion of the T Cu 380A SafeLoad so that gentle traction on the cervix can be maintained.
- The uterine sound should then be introduced in the endocervical cavity until it reaches the fundus. As soon as the direction and length of the cervical canal and endometrial cavity have been determined, the T Cu 380A SafeLoad may be prepared for insertion.

**B) LOADING THE T CU 380A SAFELOAD WITH PRELOADED SOLID ROD**
Loading of T Cu 380A SafeLoad should be done just before the time of insertion. The T Cu 380A SafeLoad can be prepared with the help of SafeLoad for insertion inside the sterile package as per the instructions given below:

**STEP 1**
Place the package on a clean, hard, flat surface with the clear plastic side up. Partially open the package from the end marked OPEN, approximately half way to the blue flange.

**STEP 2**
Through the plastic clear cover, hold the Safe Load by your thumb and index finger. Use your other free hand to push insertion tube with ‘T’ into the Safe Load as shown in Fig. 1. Ensure proper bending of horizontal arms of ‘T’ in the designed profile of Safe Load (fig. 2).

**STEP 3**
Pull the insertion tube backwards till it comes of the Safe load (fig. 3).

**STEP 4**
Lift the insertion tube upward (fig. 4), and push it towards the ‘T’. Ensure that both arms fit into the insertion tube.

**STEP 5**
Turn the tube 90 degrees (either way) and withdraw the insertion tube along with loaded Copper ‘T’ to remove it from the SafeLoad (fig. 5 & 6).

**STEP 6**
Adjust the movable flange depth of the uterus (figs. 6 & 7). The flange should be positioned so that it is on the same plane as the arms of the ‘T’.

**STEP 7**
The T Cu 380A SafeLoad is now ready for insertion. Peel the remaining cover of the package and lift the loaded insertion tube just before insertion. Do not let insertion assembly touch any unsterile surface that may contaminate it. (The SafeLoad with preloaded Solid Rod is for single use only)

**C) INSERTING THE LOADED T CU 380 A SAFELOAD**

**STEP 1**
Gently introduce the loaded insertion assembly through the cervical canal and advance upwards until the ‘T’ lies in contact with the fundus and flange comes in contact with the cervix. Ensure that the flange is in the horizontal plane as shown in Fig. 8.

**STEP 2**
Holding the white solid rod stationary by one hand withdraw the insertion tube by your free hand not more than half inch. This releases the arms of the ‘T’ as shown in Fig. 9.

**STEP 3**
Once the arms have been released, carefully push the insertion tube upwards, towards the top of the uterus until you feel a slight resistance as shown in Fig. 10. This step ensures that the arms of the ‘T’ are as high as possible in the uterus. Excessive force could cause perforation of the fundus.
Lydia T Cu 380A Safe Load

MECHANISM OF ACTIONS

Copper IUDs act by greatly reducing the likelihood of fertilization. Data and analysis indicate that the main antifertility effect of copper bearing IUDs involve inhibition of egg or sperm transport and/or the capacity of sperm to fertilize egg. Reduced gamete transport and capacitation inhibits fertilization and occurs before the ovum reaches the uterine cavity. Continuous copper release in uterine cavity from the copper wire and copper sleeves enhances the contraceptive effect of Lydia T Cu 380A Safe Load.

FOLLOW UP GUIDELINES FOR HEALTHCARE PROVIDERS

- The healthcare provider should encourage the user to come for a follow up visit in case of any problem or doubt regarding usage of T Cu 380A SafeLoad. During follow up the physician should pay particular attention to the following points:
  - Heavier bleeding indicates the possibility of anemia.
  - If pregnancy has occurred, the T Cu 380A SafeLoad should be removed, if possible
  - If a woman gets pregnant with IUD in place, there is a chance of having an ectopic pregnancy, which should be evaluated.
  - Removal of the T Cu 380A SafeLoad is advisable if user is exposed to conditions that substantially increase the risk of pelvic inflammatory disease.

DIRECTIONS FOR IUD USERS

- Longer and heavier menstrual periods, or bleeding or spotting between periods may occur during the first weeks after insertion. If they continue or are severe, report to the clinic.
- Cramping may occur following insertion usually short time, but could last for several hours to even days. This can be relieved by taking mild analgesic tablets, using hot compresses or abdomen, and/or exercising moderately.
- Check periodically and particularly after menstruation, to make certain that the threads still protrude from the cervix. If threads are missing, shorter or longer, return to the clinic.
- If Lydia T Cu 380A SafeLoad is expelled, return to the clinic. There is no continuing protection after expulsion.
- Return to the clinic for check-up or for replacement of the Lydia T Cu 380A SafeLoad (end of ten years after insertion), as instructed by physician.

- If there is abdominal pain, pain during intercourse, infections (such as gonorrhea), abnormal discharge, fever, chills, consult your physician.

CONTRAINDICATIONS (ABSOLUTE)

- Malignant diseases of the genital tract
- Undiagnosed vaginal bleeding
- Pregnancy
- Past history of ectopic pregnancy or predisposing factors
- Infections of the genital tract
- Sexually transmitted diseases during the last 12 months except: bacterial vaginosis, repeated herpes infections, Hepatitis B
- Abortion with infection during the last 3 months, pelvic inflammatory disease
- Uterine malformations (congenital or acquired)
- Allergy to copper

CONTRAINDICATIONS (RELATIVE)

- Anemia
- Valvular heart disease
- Coagulation disorders
- Anti-inflammatory treatment
- Wilson's disease
- Multiple exposures to different sexual partners

This device is for single use only.

Lydia T Cu 380A Safe Load

Intrauterine Contraceptive Device

Manufactured by PREGNA INTERNATIONAL LTD.

INDIA
Email: pregna@taparia.com
Website: www.pregna.com

Imported and Marketed by:
Deep K. Tyagi Foundation Nigeria
2 Iwaya Road, Onike Yaba
Lagos, Nigeria
info@dktnigeria.org
www.dktnigeria.org

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