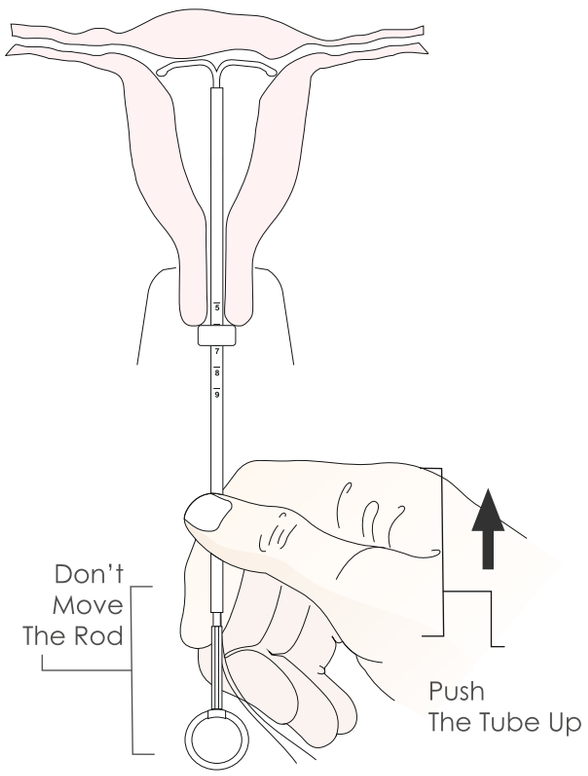
**Step 3**

Advance the insertion tube until the flange is touching the cervix again. The ELOIRA is now in contact with fundus as shown in Fig. 5.

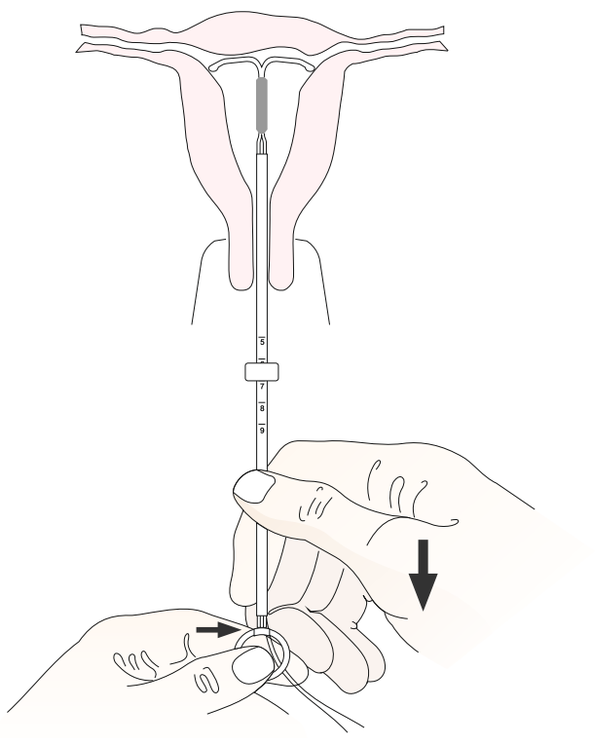
**Fig. 5**




**Step 4**

To release the device entirely from the insertion tube, hold the white solid rod firmly and draw the tube back as far as the ring of solid rod, as shown in Fig. 6.

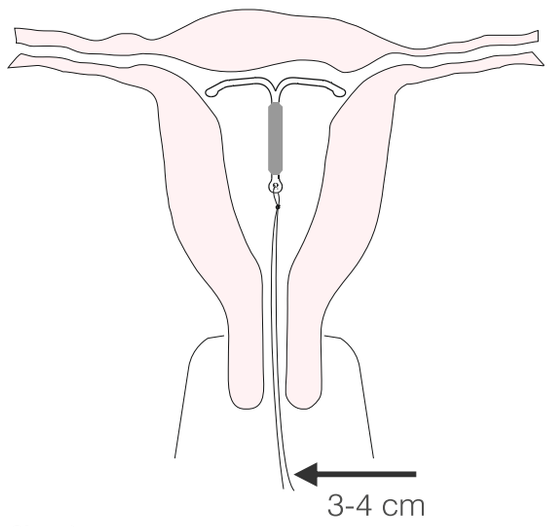
**Fig. 6**



**Step 5**

Gently withdraw the white solid rod first,(hold the insertion tube stationery while removing the white solid rod) and then the insertion tube from the cervical canal. Cut the threads so that they protrude only 3-4 cm into the vagina as shown in Fig. 7.

**Fig. 7**




**Step 6**

Assist the woman from the table slowly (be alert to possible dizziness) and instruct her how and when to check the threads. Have her check the threads. Invite questions and instruct about return visit as well as what has to be done, whom and how to contact for help if needed.

**D) Removal Instruction for ELOIRA**

ELOIRA must be removed by a trained healthcare provider. This can be done easily and safely in the clinic and takes only a few minutes. Removal is effected by gently pulling one of the exposed threads. Excessive force in pulling the threads could result in breakage of threads. Some cramping or bleeding may be experienced during removal.

**E)** The sterile ELOIRA is for single use only and should not be reused

**F)** On completion of shelf life or removal after use, dispose the items as per the local regulations, governing the disposal of non-recyclable waste/ medical waste.

**Contraindications:**

1. Pregnancy known or suspected
2. Genital bleeding due to an unknown cause
3. Past history of ectopic pregnancy
4. Genital tract infections or PID
5. Sexually transmitted disease during the last 12 months
6. Abortion with infection during the last 3 months
7. Uterine malformation
8. Abnormal / Unresolved Pap Smear
9. Acute liver disease
10. Women or her partner having multiple sexual partners
11. Leukaemia, AIDS or any other condition likely to increase susceptibility to infections
12. Hypersensitivity to any component of this product
13. Known or suspected carcinoma of the breast

**Direction for ELOIRA Users**

1. Bleeding or spotting between periods may occur during the first weeks after insertion. If they continue or are severe, report to the clinic.

2. Cramping may occur following the insertion, usually for short time, but could last for several hours or even days. This can be relieved by taking mild analgesic tablets, using hot compresses on abdomen, and or exercising moderately.

3. 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.

4. If ELOIRA is expelled, return to the clinic. There is no continued protection after expulsion.

5. Return to the clinic for check-up or for replacement of ELOIRA (five years after insertion), as instructed by the physician.

6. If your period is delayed (with symptoms of pregnancy, such as nausea, tender breasts, etc.) report immediately to the clinic.

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

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Effective Date:31/03/2013



# eloira

Hormonal Intrauterine System

## Freedom for sure



## Instruction for Use

**Indications:** ELOIRA is indicated for contraception and is effective for up to 5 years.

**Mechanism of Action**

The vertical part of the Frame contains the hormone, Levonorgestrel. The system releases Levonorgestrel into the body at a constant rate, but in very small amounts (20 micrograms per 24hrs). ELOIRA prevents pregnancy by controlling the development of the lining of uterine walls so that the lining is not thick enough to support pregnancy, Eloira also thickens the mucus in the cervical canal such that the sperm cannot travel through the uterine cavity to fertilize the egg.

**Adverse Reaction**

Since ELOIRA is an Intrauterine Contraceptive System, the common possible adverse reaction for all the intrauterine method of contraception could be applicable to ELOIRA. These include, but are not limited to Ectopic pregnancy, PID, irregular bleeding, Amenorrhea, Embedment or Perforation, abdominal pain, back pain, etc.

In addition, few adverse reactions related to use of hormones like depression, hypertension, nausea, weight increase etc., may also occur in rare cases.

**Guidelines for Physicians**

The Physician should encourage the user to come for a follow-up visit in case of any problem or doubt regarding the usage of ELOIRA. During the follow up, the physicians should pay particular attention to the following points:

1. If pregnancy has occurred and the threads are still visible, ELOIRA should be removed.

2. Should pregnancy occur, it is more likely to be ectopic than in non-users of this method. Physicians should take note of this.

3. For users having increased risk of infections (such as through using pulmonary shunts), physicians should take appropriate steps prior to the insertion.

4. Removal of ELOIRA is advisable if user is exposed to conditions that substantially increase the risk of Pelvic Inflammatory Disease (PID).

**A) Preparing the User**

1. Before insertion of ELOIRA, it is recommended that the user be counselled about this method of contraception and is informed about the process of insertion.

2. Aseptic techniques should be used at all times including the use of sterile equipment and gloves.

3. Prior to insertion, the vagina and cervix should be cleansed with an antiseptic solution.

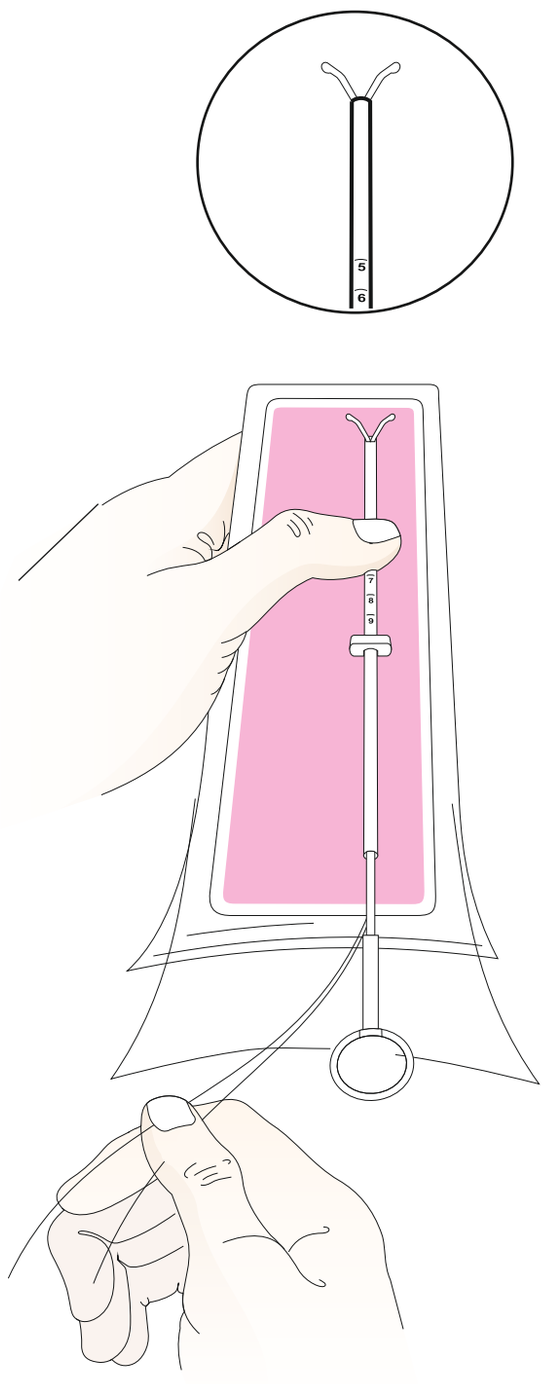
4. The cervix should be visualised by means of speculum and its anterior lip grasped with a tenaculum. Gentle traction on the tenaculum will tend to reduce the angle between the cervical canal and endometrial cavity and will greatly facilitate introduction of the uterine sound. The tenaculum should remain on the cervix, throughout the insertion of the ELOIRA so that gentle traction on the cervix can be maintained.

5. The uterine sound should then be introduced in the endocervical cavity until it reaches the fundus. As soon as the direction and the length of the cervical canal and endometrial cavity have been determined, the ELOIRA may be prepared for insertion.

**B) Loading ELOIRA**

ELOIRA can be prepared for insertion inside the sterile package as per the instructions given below:

**Fig. 1**



**Step 1**

Ensure vertical arm of Frame is fully inside the insertion tube.

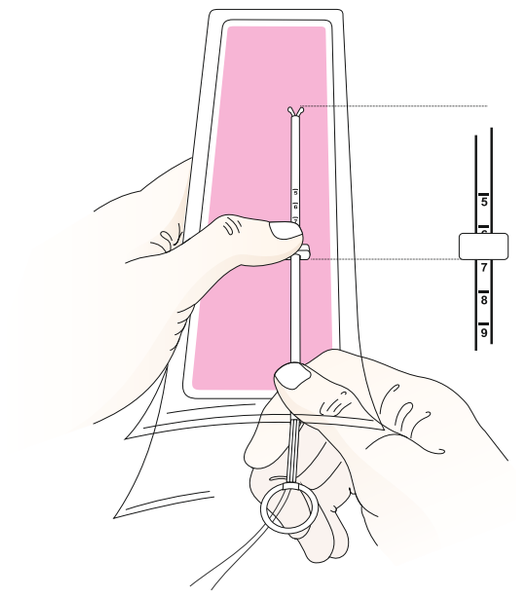
**Step 2**

Place the package on a clean, hard, flat surface. Partially open the plastic covering from the end marked as 'OPEN' approximately far enough to expose the lower end of the insertion tube. However, ELOIRA and insertion tube are not to be withdrawn. As shown in Fig. 1, while holding the tube firmly with one hand, pull the threads such that the arms get folded inside the insertion tube.

**Step 3**

Steadying the flange with one hand, move the insertion tube until the flange's lower rim indicates the previously sounded length on the scale as shown in Fig. 2.

**Fig. 2**



**Step 4**

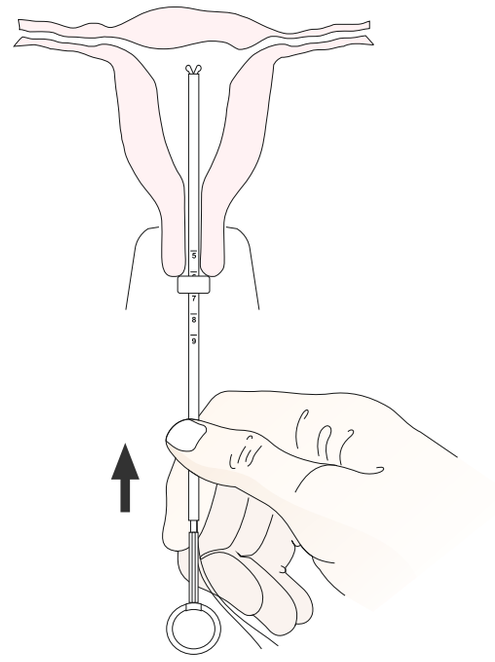
ELOIRA is now ready for insertion. Peel the remaining cover of the package and lift the loaded tube, keeping it horizontal so that the frame or white solid rod does not fall out. Be careful not to dislodge the Frame by pushing the white solid rod upward. Do not let insertion assembly touch any unsterile surface that may contaminate it.

**C) Inserting the Loaded ELOIRA**

**Step 1**

Gently introduce the loaded ELOIRA through the cervical canal and advance upward until flange comes into contact with cervix. Ensure that the flange is in the horizontal plane as shown in the Fig. 3.

**Fig. 3**



**Step2**

Holding the white solid rod stationery by one hand, withdraw the insertion tube by your free hand to touch the ribbed part of the solid rod. The arms of the Frame are now unfolded as shown in Fig 4.

**Fig. 4**

