

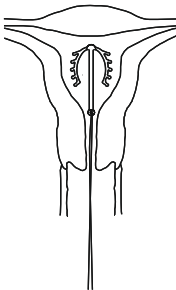
**Figure 4: EMILY in the Fundal Position**

**Step 5**

**Release EMILY and withdraw the inserter TUBE**

Pull the Inserter tube all the way down to release EMILY from the insertion tube (**Figure 5**). The threads will release automatically.

Check that the threads are hanging freely.  
Be careful not to pull on the threads as this will displace EMILY.

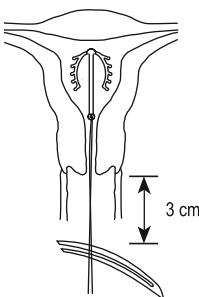


**Figure 5:  
Releasing EMILY from the Insertion Tube**

**Step 6 Cut the threads**

Cut the threads perpendicular to the thread length, for example, with sterile curved scissors, leaving about 3 cm length outside the cervix (**Figure 6**).

**NOTE:** Cutting threads at an angle may leave sharp ends.



**Figure 6: Cutting the Threads**

**EMILY insertion is now completed.**

In case difficulties arise during insertion, the patient complains of pain, or if there is any doubt that the system is not in the correct position, verify with ultrasound or X-ray. Remove the system if it is not positioned properly in the intrauterine cavity and insert a new one. A removed system must never be reinserted.

*Manufactured and Marketed by:*



**HLL Lifecare Limited**

(A Government of India Enterprise)

Akkulam, Sreekariyam P.O,  
Thiruvananthapuram-695 017,  
Kerala, India.  
Ph: +91-471-2441384, 2442641/42,  
Fax: +91-471-2441383  
E-mail : enquiry@lifecarehll.com

**CORPORATE OFFICE**

HLL Bhavan, Poojappura,  
Thiruvananthapuram- 695 012,  
Tel: 0091-471-2354949  
Fax:0091-471-2355125

**WOMEN'S HEALTH CARE DIVISION**

No. 12, 1st Floor,  
Velachery Taramani 100 feet Road,  
Velachery, Chennai- 600 042  
Tel: 0091-44-32215603  
Fax:0091-44-32215604

**INTERNATIONAL EXPORTS DIVISION**

HLL Lifecare Ltd,  
Plot No. 16A/1,  
Cochin Special Economic Zone  
Kakkanad, Cochin- 682 037  
Tel: 0091-484-2413378

R<sub>x</sub>

**Levonorgestrel**

Releasing Intrauterine System



**Brief Prescription Information  
Booklet**

**For Intrauterine use**



## EMILY

### (Levonorgestrel releasing intrauterine system) BRIEF PRESCRIBING INFORMATION

Approval date (India): 2011

#### INDICATIONS AND USAGE

Emily contains 52 mg of levonorgestrel. The release rate is approximately 20µg levonorgestrel per day. Emily is a sterile, levonorgestrel releasing intrauterine system indicated for:

- Intrauterine contraception for up to 5 years, in women who have at least one child.
- Treatment for women who suffer from heavy menstrual bleeding and who are willing to accept LNG IUD as an alternative to hysterectomy or oral medications.

#### DOSAGE AND ADMINISTRATION

- Release rate of levonorgestrel is approximately 20 mcg per day; Emily should be replaced after 5 years.
- To be inserted by a trained healthcare provider using strict aseptic technique. Healthcare providers are advised to become thoroughly familiar with the insertion instructions before attempting insertion.
- Patient should be re-examined and evaluated 4 to 12 weeks after insertion; then, yearly or more often if indicated

#### DOSAGE FORMS AND STRENGTHS

One sterile intrauterine system consisting of an M-shaped polyethylene frame with a steroid reservoir containing 52 mg levonorgestrel held within an inserter tube.

#### CONTRAINDICATIONS

- Known or suspected pregnancy
- Current or recurrent pelvic inflammatory disease
- Lower genital tract infection
- Postpartum endometritis
- Undiagnosed abnormal uterine bleeding
- Uterine anomalies including fibroids if they distort the uterine cavity
- Uterine or cervical malignancy
- Known or suspected progestin-dependent neoplasia, including breast cancer
- Cervicitis
- Cervical dysplasia
- Active liver disease or dysfunction
- Actual benign or malignant liver tumors
- Septic abortion within the previous three months
- Hypersensitivity to levonorgestrel or any of the other ingredients in the formulation or component of the container components of EMILY.
- Bacterial endocarditis
- Established immunodeficiency
- Acute malignancies affecting blood or leukemias
- Recent trophoblastic disease with elevated hCG levels

#### WARNINGS AND PRECAUTIONS

- If pregnancy should occur with Emily in place, remove Emily.
- There is increased risk of ectopic pregnancy
- Group A streptococcal infection has been reported; strict aseptic technique is essential during insertion.
- Before using Emily, consider the risks of PID.
- Bleeding patterns become altered, may remain irregular and amenorrhea may ensue.
- Perforation may occur during insertion. Risk is increased in women with fixed retroverted uteri, during lactation, and postpartum.

- Embedment in the myometrium and partial or complete expulsion may occur.
- Persistent enlarged ovarian follicles should be evaluated.

#### ADVERSE REACTIONS

The most common adverse reactions reported in clinical trials with a similar device (> 10%users) are uterine/vaginal bleeding alterations (51.9%), amenorrhea (23.9%), intermenstrual bleeding and spotting (23.4%), abdominal/pelvic pain (12.8%) and ovarian cysts (12%).

#### DRUG INTERACTIONS

- Drugs or herbal products that induce certain enzymes, such as CYP3A4 may decrease the serum concentration of progestins.

#### USE IN SPECIFIC POPULATIONS

- Small amounts of progestins pass into breast milk resulting in detectable Steroid levels in infant serum.
- Use of this product before menarche is not indicated.
- Use in women over 65 has not been studied and is not approved.

#### INSERTION INSTRUCTIONS FOR EMILY

- In women of fertile age, EMILY should be inserted within seven days of the onset of menstruation.
- The system can also be inserted after first trimester Medical Termination of Pregnancy
- EMILY is not suitable for use as a postcoital contraceptive.
- Before insertion, the patient must be informed of the efficacy, risks and side effects of EMILY.
- A physical examination including pelvic examination, examination of the breasts and cervical smear should be performed.
- Pregnancy and sexually transmitted diseases should be excluded and any genital infections must be successfully treated.
- The position of the uterus and the size of the uterine cavity should be determined.
- Fundal positioning of EMILY is particularly important in order to ensure uniform exposure of the endometrium to the progestogen, prevent expulsion and maximize efficacy.
- Visualize the cervix with the aid of a speculum and thoroughly cleanse the cervix and vagina with a suitable antiseptic solution.
- Grasp the upper lip of the cervix with a suitable holding forceps. Gentle traction on the holding forceps has been shown to align the cervical canal with the uterine cavity. The holding forceps should remain in position throughout the insertion procedure to maintain gentle traction on the cervix to facilitate insertion.
- Gently move a uterine sound into the uterine cavity to the fundus to determine the direction of the cervical canal and the utero-cervical length (sound measure), and to exclude a uterine septum, synechiae or sub mucosal fibroids. It is important not to force the insertion. Should the cervical canal be too narrow, consider the need for dilatation and the use of analgesics or paracervical block.

#### INSERTION PROCEDURES

##### Step 1

##### Opening of the sterile package

Wear sterile gloves on your hands.  
Open the sterile package completely.  
Pick up the thread hanging end of inserter tube.

##### Step 2

##### Setting the flange

Set the upper edge of the flange to the depth measured during the uterine sounding.  
(Figure 1)

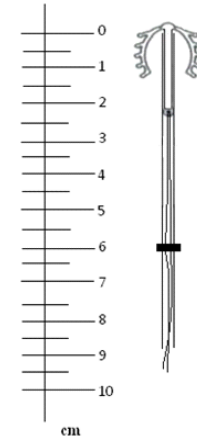


Figure 1: Setting the Flange to the Uterine Depth

##### Step 3

##### EMILY is now ready to be inserted

Grasp the holding forceps with your one hand and apply gentle traction to align the cervical canal with the uterine cavity.

While maintaining traction on the cervix, gently advance the insertion tube through the cervical canal and into the uterine cavity **until the flange is 1.5 to 2 cm from the external cervical os.**

**CAUTION: do not advance flange to the cervix at this step.**

Maintaining the flange 1.5 to 2 cm from the cervical os allows sufficient space for the arms to retain its original shape within the uterine cavity (Figures 2 and 3).

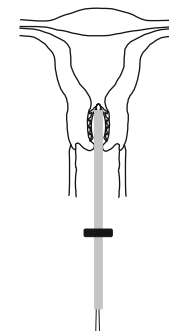


Figure 2: Insertion of EMILY

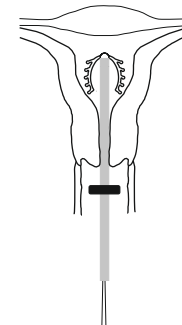


Figure 3: Advancing Insertion Tube until Flange is 1.5 to 2 cm from Cervical OS

##### Step 4 Advance to fundal position

Gently advance the inserter tube into the uterine cavity until the flange meets the cervix and you feel fundal resistance. EMILY should now be in the desired fundal position (Figure 4).