SINGLE USE ONLY

Instructions For Use

Intended use: Slow-release insemination, delivering approximately 1ml sperm into the uterus over a 3-4 hour period.

ONLY TO BE ADMINISTERED BY A QUALIFIED MEDICAL PRACTITIONER (EU & USA) IN A MEDICAL FACILITY (USA ONLY). IN A CLINICAL TRIAL COMPARING SLOW RELEASE WITH BOLUS IUI, SLOW RELEASE STUDY SUBJECTS WERE FREE TO AMBULATE AND BLADDER EMPTYING WAS NOT RESTRICTED. INSTRUCTIONS FOR BLADDER EMPTYING AND PATIENT POSITION ARE AT THE DISCRETION OF THE PRESCRIBING PRACTITIONER.

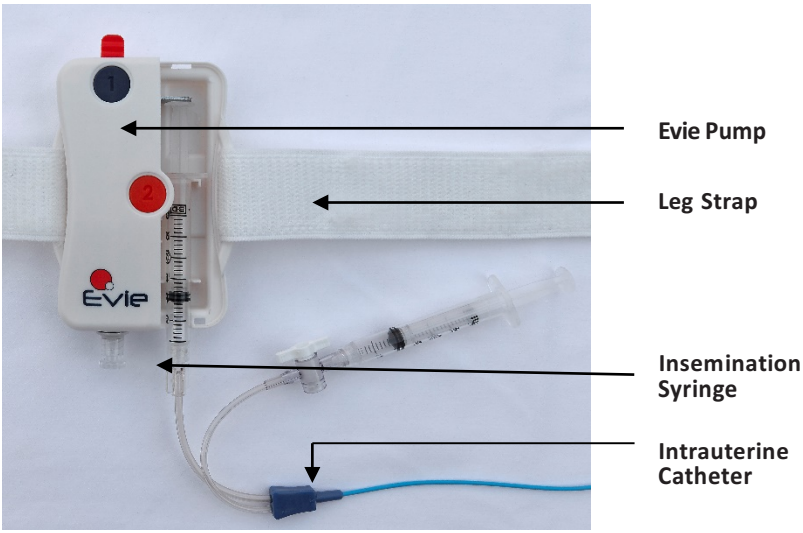
Each Evie kit comprises:

1x Evie Pump (Disposable, single use), devised for slow-release insemination of sperm

1x Intrauterine Sterile Catheter (Disposable, single use) (Length 28cm, Diameter (OD)): 5 Fr, maximum balloon inflation: 1ml, devised to deliver sperm to the uterus

1x Sterile Insemination syringe (Disposable, single use) (Volume: 3ml), to contain and deliver sperm to the catheter

1x Leg strap (non-sterile)



(Figure 1: Representation of contents)

Warranty Statement: If this EVIE unit has been damaged in transit because of obvious physical damage to any of the sealed packs or kit contents, please do not use it. Either contact your supplier or Reproductive Sciences directly (using the details below) for an exchange, quoting the batch and lot details of the damaged product.

Support support@reproductivesciences.co.uk

Ordering sales@reproductivesciences.co.uk

Web www.reproductivesciences.co.uk

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Distributed by: Reproductive Sciences Ltd., 147 Hoole Lane, Chester, Cheshire, CH2 3EQ, UK
Tel: +44 (0) 1925 202203

Storage Conditions: Store in a dry, cool place out of direct sunlight.

Lot Testing (catheter & insemination syringe) - Certificate of analysis available upon request.

- HSSA - Non toxic to human sperm - indicates that sperm has a forward progressive motility rate $\geq$ 60% of the control after 4 hours of contact with the product.

- Bacterial endotoxin - non pyrogenic indicates that the test products contained < 0.5 EU/ml.

Disclaimer: Fertiligent can make no guarantee that the use of EVIE as a device to facilitate pregnancy will be successful. Clinical advice given to each patient must take into account individual circumstances, particularly if the proposed treatment represents a final opportunity of pregnancy. Fertiligent can accept no liability for the decision to use Evie as part of fertility treatment in this respect.

Precautions

1. Check that there appears to have been no damage to the contents during transportation.
2. Check that the sterile packaging of the catheter and the syringe are intact.
3. Check that the expiration date has not passed.
4. Ensure that only the syringe and catheter that are supplied within the kit are used.
5. The catheter balloon should be filled gradually using sterile saline only. **Do not inflate with air!**
6. The catheter should be gently inserted into the uterus through the cervical canal, similar to a standard intrauterine insemination (IUI) or hysterosalpingogram (HS) procedure.
7. Advise the patient to wear appropriate clothing for the EVIE procedure and to wear clothing which is not too tight on the legs. A below-knee dress or skirt may be more suitable so that the EVIE device may be worn comfortably without being restricted by clothing.

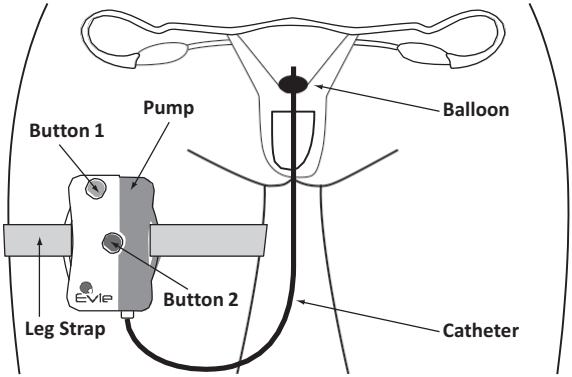
Warning

Only for use for patients designated for intrauterine insemination.
Increasing the dwell time of an IUI catheter may increase the risk of ascending infection. The use of good aseptic technique and sterile drapes may help reduce infection risk. Prophylactic antibiotics may be considered as per institutional guidelines if there is a valid clinical indication for use.

In the event of any unforeseen circumstances which causes the user any concern, please contact the medical practitioner immediately for their advice.

Potential Adverse Events - **(same as in standard IUI procedure)**

Ascending infection, bleeding, abdominal pain or cramping, slight skin irritation by strap and device. Advise the patient to contact the appropriate clinician should any of these occur.



(Figure 2: Diagrammatic representation of EVIE in situ)

Instructions for use

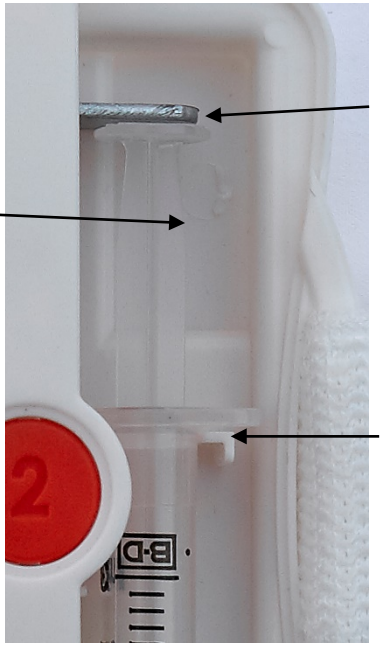
1. Before starting the procedure, the patient must be in the lithotomy position with a speculum inserted. The vagina and cervix must be cleaned using normal saline solution.
2. Sound uterus to determine uterine depth.
3. Attach leg strap to pump and pump to patient's **right leg**.
4. Orient pump with Button 1 toward patient's head (Figure 2).
5. Fill supplied **insemination syringe** with **1.5 ml** of prepared sperm.
6. Remove catheter with attached **balloon inflation syringe** from sterile package and discard yellow tip protector.
7. Connect **insemination syringe** to catheter injection line.
8. Flush catheter by advancing **insemination syringe** to **1.0 ml** setting. Do not disconnect **insemination syringe**.
9. Disconnect **balloon inflation syringe** from balloon inflation line of catheter and fill syringe with no more than 1 ml sterile saline.
10. Re-connect **balloon inflation syringe** to open stopcock. Insert catheter into the uterus to sounded depth using depth marks as a guide (Figure 3).
11. Gradually inflate balloon with 1.0 ml saline. Close stopcock to maintain balloon inflation.

12. Pull back gently on catheter shaft to seat balloon against and seal internal cervical os.

13. Remove pump cover by pressing release tab at top of pump next to Button 1.

14. Insert **insemination syringe** into cradle of pump as shown in Figure 4.

(Figure 4)



(Figure 5)

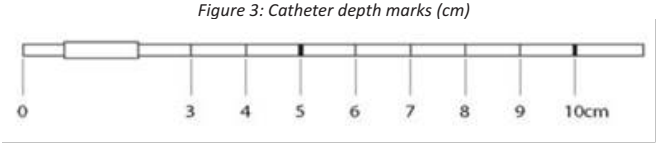
15. **Syringe wings and plunger end must lie between tabs and syringe lever arm to ensure proper operation of syringe (Figure 5).**

16. With syringe in place, re-install cover on pump by first inserting tab at bottom of pump before finally locking tab at top of pump (as shown in Figure 6).

17. Disconnect and discard the **balloon inflation syringe**.

18. Activate the pump by pulling out red safety tab and firmly pressing **Button 1** (Figure 6). Record Start Time.

Figure 3: Catheter depth marks (cm)



(Figure 6)

Instructions for Removal

NOTE: If the patient is to remove the device, the clinician must first explain the removal instructions to the patient. Record the start time and end time (start + 4 hours) below. Cut this section off and give to the patient as a reference.

1. After 4 hours push the **Button 2** firmly until it moves inward. Make sure that the button remains depressed a few seconds, or depress several times to ensure that all sperm has been delivered. Wait for one minute before the next step.
2. **Important** - open stopcock on catheter to deflate balloon, as withdrawing the catheter with an inflated balloon may cause pain. A small quantity of saline may be expelled after balloon is deflated.
3. **Gently** withdraw the catheter. Release the leg strap.
4. Place entire device in the disposal bag supplied and discard of appropriately.

Start Time: _____

End Time: _____(Start + 4 hours)

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