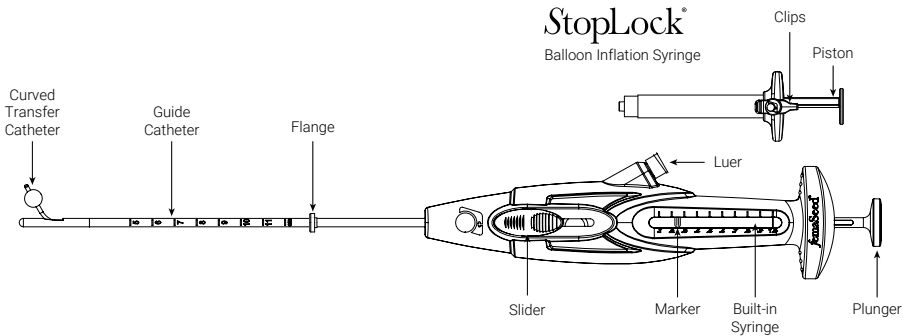


**CAUTION** – Federal (USA) law restricts this device to sale by or on the order of a physician.

## Instructions for Use



### DEVICE DESCRIPTION

FemaSeed consists of polymer curved transfer catheter, polymer guide catheter and separate syringe.

### INDICATIONS FOR USE

FemaSeed is intended to introduce washed sperm or in vitro fertilized (IVF) embryos into the uterine ostium via ultrasound guidance.

### CONTRAINDICATIONS

Should not be used in:

- Active vaginal or intrauterine infection
- Sexually transmitted disease
- Recent uterine perforation
- Recent or current pregnancy
- Presence of intrauterine device
- Pregnant patients or in patients suspected of being pregnant

### WARNINGS

- Sterile device. Do not use if sterile barrier is damaged.
- For single use only. Do not reuse, reprocess or resterilize.
- If injecting sperm, always wash spermatozoa before use. The introduction of unwashed spermatozoa into the uterine cavity may result in severe adverse reaction (refer to published medical literature for the methods of washed spermatozoa).
- If injecting embryos, accessories used during the procedure should be constructed of embryo-compatible materials.
- Dispose of in accordance with all local, state, and national Medical/Hazardous Waste practices.

### PRECAUTIONS

- Read instructions before using device.
- This product is intended for use by physicians trained and experienced in assisted reproduction techniques. Standard techniques should be employed.

### BATCH CERTIFICATION

Each production lot of FemaSeed is confirmed to meet the following requirements:

- Human Sperm Survival Assay (HSSA),  $\geq 80\%$  of control motility at 24 hours following 30-minute exposure.
- Endotoxin - (LAL) test per AAMI/ANSI ST72 and USP <85>, <20 EU/device.
- 2-Cell MEA:  $\geq 80\%$  embryos developed to expanded blastocyst at 72 hours.

# FDI-200 • FemaSeed®

Intratubal Insemination

## INSTRUCTIONS FOR USE

**NOTE:** It is important to determine the exact catheter volume prior to use. To determine catheter volume, aspirate transfer media or other appropriate liquid into catheter, using built-in syringe.

### I. DEVICE PREPARATION

1. Expel air from balloon by attaching syringe, pulling back piston, and moving slider back until curved transfer catheter is within guide catheter. Remove syringe, pull piston fully back, and re-attach. Leave syringe attached for remainder of procedure.

**NOTE:** Air must be expelled from balloon to avoid damage.

Check balloon by moving slider forward until it clicks and inflating balloon for 10 seconds. Deflate balloon by pinching clips of syringe.

2. Fill FemaSeed with specimen by a) placing tip of curved transfer catheter into specimen container and b) retracting plunger to aspirate specimen.

**NOTE:** Tray package includes optional built-in well for specimen. Optional marker allows for volume level.

**NOTE:** When loading washed sperm, do not exceed 1 mL (the maximum volume of FemaSeed).

**NOTE:** When loading embryos, prepare (cleavage or blastocyst stage) for transfer and load in an appropriate volume (e.g., 50-100 uL) of transfer medium.

### II. DEVICE PLACEMENT

**NOTE:** Side open speculum recommended.

1. Prior to insertion, move slider back until curved transfer catheter is fully retracted and contained within guide catheter.
2. Under ultrasound guidance, pass the preassembled curved transfer catheter and guide catheter transvaginally through cervix to the fundus.

**NOTE:** Optional sounding can be performed prior to ultrasound and flange can be set on guide catheter for aid in fundal positioning.

**NOTE:** If any difficulty when inserting is encountered, gentle traction of the cervix with a tenaculum or dilation may be helpful.

**WARNING:** To reduce risk of uterine perforation, do not use force to overcome resistance if encountered during insertion.

3. Advance curved transfer catheter approximately 2 cm into the uterine ostium by moving slider forward until it clicks.

**NOTE:** StopLock syringe is located on the same side the curved transfer catheter will exit the guide catheter.

4. Once in position, slowly inflate balloon in the uterine ostium by depressing piston until it locks.

**NOTE:** Balloon will not inflate until curved transfer catheter is fully advanced.

5. Using ultrasound, confirm balloon location in the uterine ostium.
6. Slowly instill desired specimen into the uterine ostium of the fallopian tube.
7. Deflate balloon by pinching clips of syringe.
8. Retract curved transfer catheter by moving slider back.

**NOTE:** If delivery of sperm to uterine ostium of contralateral fallopian tube is desired, rotate handle 180 degrees and repeat steps 3-8.

### III. PATIENT POST-CARE

1. Remove device and discard.

**NOTE:** Upon device removal, confirm presence of flange on guide catheter.

CE 0123



Emergo Europe  
Westervoortsejdijk 60  
6827 AT Arnhem  
The Netherlands  
Tel: (31) (0) 70 345-8570

#### VIGILANCE REPORTING

Serious incidents occurring in the European Union in relation to FemaSeed should be reported to the Authorized Representative and/or the Manufacturer as indicated below:

**Authorized Representative:** Emergo – EmergoVigilance@ul.com

**Manufacturer:** Femasys Inc. – Vigilance@femasys.com



Manufacturer

**Femasys Inc.**

3950 Johns Creek Court, Suite 100

Suwanee, GA 30024 USA

Tel: (877) 336-2562

Fax: (404) 581-5903

www.femasys.com

Patent Listing: www.femasys.com/patents



www.femaseed.com

A symbol glossary can be found at:

<https://femasys.com/resources/download>

