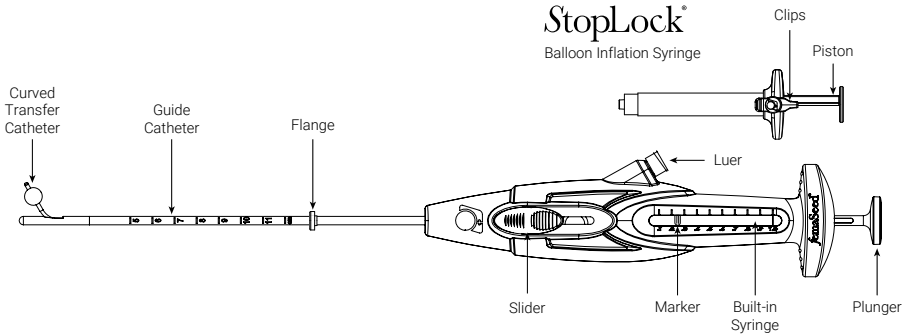


CAUTION – Federal (USA) law restricts this device to sale by or on the order of a physician.

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.

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. Squeeze air from balloon and attach syringe to FemaSeed luer for remainder of procedure.

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

Check balloon by inflating 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 into built-in syringe.

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 until it clicks.
- 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.

A symbol glossary can be found at:
<https://femasys.com/resources/downloads>



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