femasys®

FemaSeed®

Intratubal Insemination and FemSperm®

Reference Guide

Dear Healthcare Provider:

Congratulations! You have joined a growing number of providers who have chosen to offer FemaSeed Intratubal Insemination to their patients.

This reference guide provides clinical instruction and information on the following:

I. FemaSeed Product and Procedure Overview
II. FemSperm Product Kits and Instruction Overview
III. Patient Selection and Counseling
IV. FemaSeed Patient Benefits & Procedure Highlights

To prepare for your first procedures, enroll in Femasys' online training at femasys.learnupon.com.

If you have any questions that cannot be answered by this guide or the Instructions for Use, please do not hesitate to contact your FemaSeed Representative.

I. FemaSeed Product and Procedure Overview

INDICATIONS FOR USE

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

DEVICE DESCRIPTION

FemaSeed consists of curved transfer catheter, guide catheter and separate syringe (StopLock®).

IMPORTANT SAFETY INFORMATION

Who should not use FemaSeed (Contraindications)

- 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

Warning

If injecting sperm, always wash spermatozoa before use. The introduction of unwashed spermatozoa into the uterine cavity may result in severe adverse reaction. (Go to section II for instruction on preparing sperm with FemSperm®)

FEMASEED INTRATUBAL INSEMINATION

Key Components

1. Flexible guide catheter (11F or 3.8mm)
   - Pre-loaded with single curved transfer catheter
   - 1 cm graduated markings at distal end and adjustable flange to aid in placement at uterine fundus
2. Curved transfer catheter
   - Balloon at distal end to secure in cornu
   - Two lumens, one for balloon inflation and one for washed sperm delivery
3. Handle
   - Built-in syringe and plunger allow for aspiration of the specimen (up to 1.0 cc) into transfer catheter and delivery of entire sample into patient
   - Safety interlock to ensure transfer catheter is advanced prior to balloon inflation
   - Slider (green) to advance the transfer catheter in and out of the guide catheter
   - Marker to indicate specimen volume if delivering to both tubes
4. StopLock syringe
   - Attaches to luer on handle to inflate and deflate balloon with air to fixed volume

How Supplied

Sterile for single use only.
Sterilized by ethylene oxide.

Storage

Store in a cool, dry place.

Required Equipment

- Ultrasound and probe(s) (transabdominal and/or transvaginal)

Required Additional Supplies

- Speculum (side-open if using transvaginal ultrasound)
- Uterine sound (optional)

Figure 1

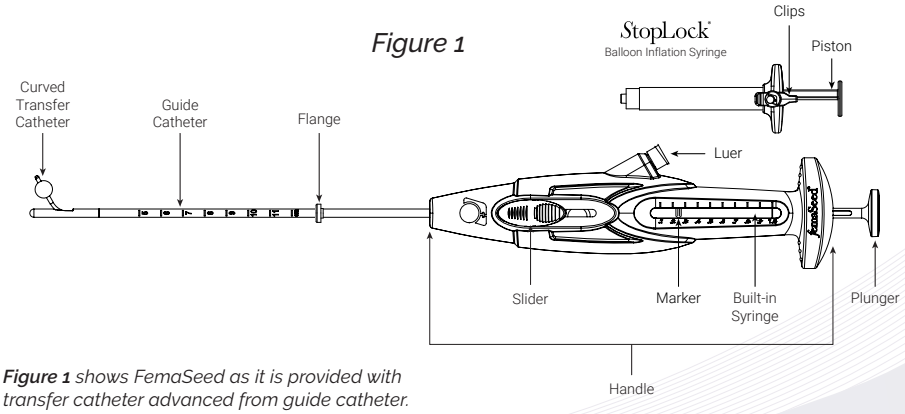

Figure 1 *shows FemaSeed as it is provided with transfer catheter advanced from guide catheter. StopLock® balloon inflation syringe is provided.*

I. FemaSeed Product and Procedure Overview (continued)

FemaSeed's Instructions for Use contains additional details.

PRE-PROCEDURE

- Sperm must be washed (go to section II for FemSperm overview).
- Assess patient for pregnancy prior to procedure.
- Determine specimen volume (max 1.0 mL) and if delivery to one or both sides. Place specimen in well of FemaSeed tray packaging.
- Fill FemaSeed by placing tip of the transfer catheter into well and aspirating into catheter.
- Pain management protocols should be implemented per practice guidelines.

HOW FEMASEED WORKS

The following steps comprise the principles of operation during the FemaSeed procedure.

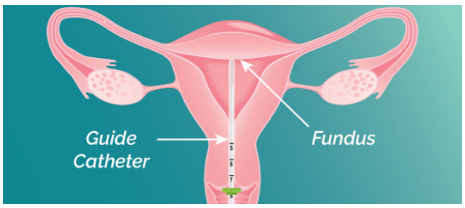

Figure 2

Step 1 *(Figure 2)*

The guide catheter is advanced through the patient's cervix and into the uterine cavity to the fundus, where it remains for the entire procedure. Ultrasound may be used to confirm fundal placement.

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

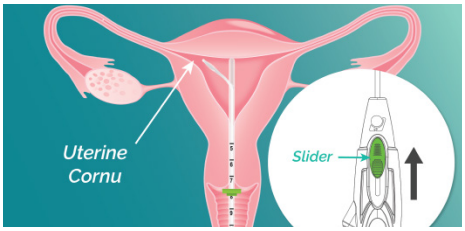

Figure 3

Step 2 *(Figure 3)*

The transfer catheter is advanced from guide catheter by moving green slider forward.

Note: The syringe is located on the same side the transfer catheter will exit (i.e., syringe on right, transfer catheter exits right, located on patient's left side).

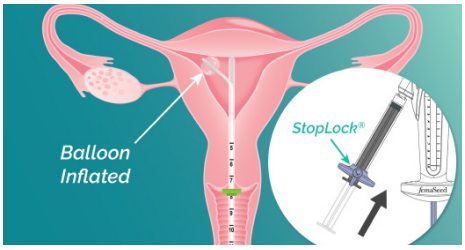

Figure 4

Step 3 *(Figure 4)*

The balloon is inflated in the uterine cornu by depressing plunger of the StopLock syringe.

Note: Balloon will not inflate until transfer catheter is fully advanced.

Confirm balloon is located in the uterine cornu with ultrasound prior to specimen delivery into the selected fallopian tube.

Note: Side-open speculum is removed if transvaginal ultrasound probe is used.

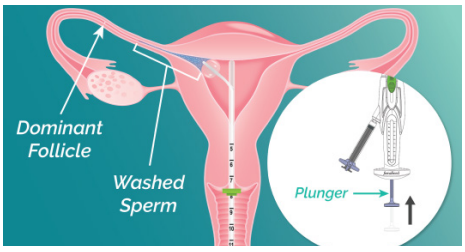

Figure 5

Step 4 *(Figure 5)*

The washed sperm is delivered through the transfer catheter into the cornu and fallopian tube by depressing plunger of handle.

Note: Slow delivery ensures forward flow of specimen.

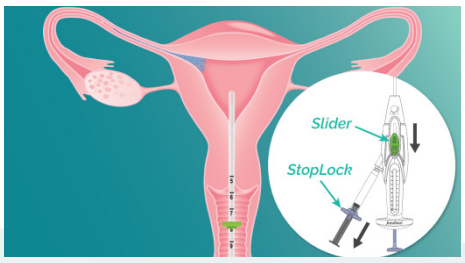

Figure 6

Step 5 *(Figure 6)*

The balloon is deflated by pulling back on plunger of StopLock and transfer catheter is retracted into guide catheter by moving green slider back.

Note: If delivery of washed sperm is desired to the contralateral fallopian tube, handle is rotated 180° and steps 2-5 are repeated.

FemaSeed is then removed from the patient and disposed.

II. FemSperm Product Kits and Instruction Overview

DISPOSABLE COMPONENTS
(Supplies for 5 patients)

- Specimen collection cup within custom packaging with built-in test tube rack *(Figure 7)*
- Sample Preparation (5 components) *(Figure 8)*
- Pipettes (sterile)
- Delicate Task Wipes

How Supplied
For single use.

Storage
No special requirements except Sample Preparation must be refrigerated.

Figure 7

REUSABLE COMPONENTS
(Each sold separately)

- Centrifuge *(Figure 9)*
- OPTIONAL Refrigerator

How Supplied
For multiple uses.

Storage
No special requirements.

Figure 8

OPTIONAL SPERM ANALYSIS COMPONENTS (not shown)
(Sold in box containing one of each component or can be purchased separately)

- Sperm Quality Analyzer (SQA) with computer
- Sperm Analysis disposables
- SQA Clean/QC kit
- Scale
- Manual Pipettor and holder

How Supplied
For multiple uses.

Storage
No special requirements.

Figure 9

II. FemSperm Product Kits and Instruction Overview (continued)

According to WHO, sperm processing should begin within one hour after sample collection.
Sample should be kept at room temperature.

PRE-SPERM PREPARATION

1. Confirm only one patient's specimen (collection cup in custom package) and documentation are present in the work area.
2. Confirm patient identifiers have been completed on collection cup and built-in test tube rack labels.
3. Retrieve one FemSperm Sample Preparation box *(Figure 8)* from Refrigerator.
4. Ensure a minimum of 8 Pipettes are available to perform the sperm preparation.

FemSperm Sample Preparation Instructions for Use contains additional details.

SPERM PREPARATION OVERVIEW

1. Remove custom insert (test tube rack) within box *(Figure 7)* to access collection cup with specimen.
2. Place vials and test tubes from Sperm Wash box *(Figure 8)* into test tube rack.
3. Allow sample to liquefy at room temperature for 20-30 minutes.
4. Perform a viscosity check as detailed in instructions for use.
5. Use pipette to transfer 1.0 cc of sperm specimen from collection cup to test tube. Using same Pipette, repeat for second test tube. If additional specimen remains, continue process one additional time to a maximum of 2.0 cc per each test tube.
6. Place both test tubes in Centrifuge *(Figure 9)* and press P1 (30 min pre-programmed time).
7. Remove top liquid layer from each test tube using new pipette, leaving sperm pellet.
8. Using a new pipette, add contents of one green vial to each test tube and gently agitate.
9. Place test tubes in Centrifuge and press P2 (10 min pre-programmed time).
10. Remove top liquid layer from each test tube using new pipette, leaving sperm pellet.
11. Add contents of blue vial to one test tube and gently agitate. Pour or use new pipette to transfer contents of first test tube into second test tube and gently agitate.
12. Place test tube with final washed sperm in test tube rack to safely secure until the FemaSeed procedure.
13. Discard used supplies and disinfect work area for next patient.

OPTIONAL Sperm Analysis Post-Wash

Follow instructions from Sperm Quality Analyser (SQA) summarized below:

1. Place a pipette tip on the Manual Pipettor and press operating button to first stop.
2. Place pipette tip into test tube containing final washed sperm and release operating button.
3. Dispense sperm sample on capillary by pressing operating button to second stop.
4. Insert capillary with sample into SQA for post-wash analysis.
5. Discard used supplies and disinfect work area for next patient.

III. Patient Selection and Counseling

FEMASEED IS AN APPROPRIATE OPTION FOR WOMEN WHO DESIRE ARTIFICIAL INSEMINATION FOR PREGNANCY.

- Millions of women and couples struggle with infertility[1]
- Only a fraction pursue treatment for various reasons, including economic barriers or emotional burden.
- Consider FemaSeed Intratubal Insemination as a First-Step Treatment Option for:

Couples who are infertile

Same sex couples

Patients that have no exposure to sperm

Sideline patients

Many of these women sideline themselves due to various reasons such as economic constraints or fear of the fertility journey.

FemaSeed allows you to provide your patients with the next generation of artificial insemination.

Non-IVF patient

- Lack of insurance coverage for IVF/financial burden
- High emotional and physical cost of IVF treatment
- Time burden
- Religion
- Does not want to go to referral center

Patients not yet engaged in care

- Discouraged with low success rate for IUI
- Overwhelmed with process
- Still evaluating practices/ options
- Lack of knowledge of new fertility methods
- Lack of access to REI clinics

Donor community

- LGBTQ+ Community
- Single women
- Low male sperm count

IV. FemaSeed Patient Benefits and Procedure Highlights

FEMASEED PATIENT BENEFITS

Safe

- Demonstrated safety from pivotal trial establishes risk profile is comparable to IUI.
- Achieve delivery into the fallopian tube without the potential risks associated with catheterization.
- No risks associated with IVF, including surgical egg extraction, hormone injections and embryo management.

Effective

Demonstrated effectiveness from pivotal trial establishes significant better pregnancy rate than IUI, specifically for low male sperm count (1-20 million)[2]:

- 26.3% per subject pregnancy rate with FemaSeed for low male sperm count (1-20 million)[2]
  - 17.5% FemaSeed per cycle pregnancy rate versus 6.7% IUI per cycle[3]
- Enhances natural fertilization by precise targeted delivery of a predetermined quantity of sperm to one or both fallopian tubes, where conception occurs.

Convenient

- Time-saving option for insemination since the procedure is performed quickly at gynecologist's office without referral to infertility center.
- No recovery downtime, resume normal activities immediately.

Affordable

- FemaSeed is cost-effective option to offer your patients at the beginning of their journey.
- FemaSeed allows for expanded practice services as a first-step option prior to assisted reproductive approaches.
- Fewer FemaSeed cycles may move the patient to IVF sooner.

PROCEDURE HIGHLIGHTS

- FemaSeed procedure offers a first-line infertility treatment option.
- Explain what FemaSeed is and how it works, and be sure to distribute the Patient Brochure to detail the benefits and risks of FemaSeed.

IMPORTANT: Not all women will achieve pregnancy.

I. Counsel patients that although sperm is placed in the fallopian tube where conception occurs, pregnancy may not occur for many reasons, such as:

- egg quality or availability
- sperm quality and function
- timing of ovulation
- other underlying health factors

II. Discuss a management plan with the patient in the event pregnancy is not achieved. Women may choose:

a. to undergo the FemaSeed procedure again
b. to go to an infertility referral center to explore in vitro fertilization (IVF)
c. to delay or stop further treatment

1. https://www.cdc.gov/nchs/nsfg/key_statistics/i-keystat.htm
2. Liu, J. H., Glassner, M., Gracia, C. R., Johnstone, E. B., Schnell, V. L., Thomas, M. A., Morrison, L., Lee-Sepsick, K. (2024). FemaSeed Directional Intratubal Artificial Insemination for Couples with Male-Factor or Unexplained Infertility Associated with Low Male Sperm Count. J Gynecol Reprod Med, 8(2), 01-12. doi: 10.33140/JGRM.8316
3. Duran et al. (2002) Intrauterine insemination: a systematic review on determinants of success. Human Reproduction, vol.8, no. 4, pp. 373-384.

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