femasys®

FemaSeed®
Intratubal Insemination with FemSperm®

Reference Guide

hcp.femaseed.com
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Summary Infertility Patient Journey

Female and Male Pathways

STEP 1: DIAGNOSTIC EVALUATION

Female

Requirement: Presence of at least one patent fallopian tube as determined by FemVue®.

FemVue is a saline–air contrast ultrasound procedure used to evaluate fallopian tube patency by visualizing the flow of contrast through the tubes in real time.

Clinical Staff

- Schedule patient during the follicular phase of her cycle.
- Perform FemVue procedure using transvaginal ultrasound in approximately 10-15 minutes.
- Results are available immediately and may be reviewed during the same visit or at next visit.

Male (not applicable for donor sperm)

Requirement: Presence of sperm as determined by FemSperm® at-home test.

FemSperm at-home test is a smartphone-based screening test that provides qualitative and quantitative information on key sperm parameters, including sperm presence.

Clinical Staff

- Provide FemSperm at-home test kit and answer any questions.

Couple can schedule an in-office visit together to review FemVue and FemSperm results and align on next steps, or review by phone and schedule next step.

STEP 2: PRE-PROCEDURE MONITORING & PREPARATION

Female

Ultrasound monitoring is performed to assess follicular development.

Clinical Staff

Based on the selected protocol (unstimulated or stimulated cycle), schedule ultrasound monitoring accordingly.

Male (not applicable for donor sperm)

FemSperm Collection Cup Kit is provided for semen collection.

Clinical Staff

- Provide FemSperm Collection Cup during visit or arrange for patient pick up.
- Review guidelines to optimize sperm quality during visit or by phone.

STEP 3: FEMASEED® IN-OFFICE FERTILITY TREATMENT

Female

Patient arrives ideally within one hour of sperm specimen collection.

Clinical Staff

- Prepare (wash) the sperm within one hour of collection of if donor sperm, following supplier's instruction for thawing specimen.
- Bring patient to GYN exam room with ultrasound upon arrival or approximately 30 minutes into sperm preparation.
- Perform FemaSeed procedure in few minutes using transvaginal or transabdominal ultrasound for placement assistance.

STEP 4: POST-PROCEDURE FOLLOW-UP

Female

Clinical Staff

- Schedule an in-office visit 2–3 weeks post-procedure for serum pregnancy test if patient suspects pregnancy. If pregnancy not confirmed, schedule a follow-up visit to discuss a subsequent FemaSeed treatment cycle or other options.

Detailed Diagnosis & Treatment Pathway

STEP 1: FEMALE DIAGNOSTIC EVALUATION

Requirement: Presence of at least one patent fallopian tube prior to FemaSeed procedure.
Scheduling: After completion of mentrual cycle and before the onset of ovulation.

Pre-Procedure

1. Prepare FemVue Saline-Air Device per Instructions for Use.
2. Pain management protocols should be implemented per practice guidelines.

FemVue Procedure Checklist

Sterile Supplies

Required

- ☐ FemVue Saline-Air Device
- ☐ Bowl (supplied with FemVue)
- ☐ Intrauterine balloon catheter (5Fr)
- ☐ Sterile saline
- ☐ Speculum (side-open recommended)
- ☐ Antiseptic solution
- ☐ Cotton swabs

Optional

- ☐ 20-30 cc sterile syringe for SIS
- ☐ Sponge forceps
- ☐ Os finder
- ☐ Tenaculum
- ☐ Paracervical block

FemVue Procedure Overview (Refer to Instructions for Use)

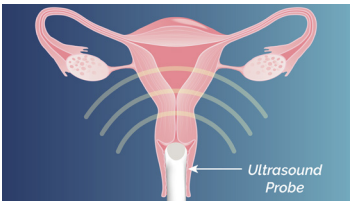
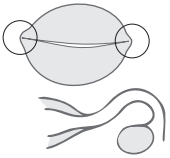


Figure 1

Step 1: Ultrasound Pre-Scan *(Figure 1)*

With transvaginal ultrasound, locate the following areas:

- Endometrial stripe and cornua
- Left and right adnexa
- Tubal course



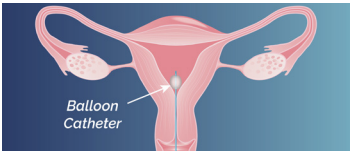


Figure 2

Step 2: Catheter Placement *(Figure 2)*

Prepare and insert balloon catheter per its Instructions for Use. Inflate balloon and position above internal cervical OS.

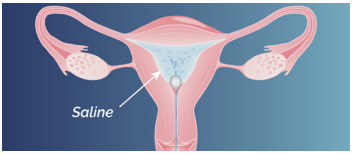


Figure 3

Step 3: Uterine Cavity Assessment (optional) *(Figure 3)*

Perform an SIS per your practice guidelines.

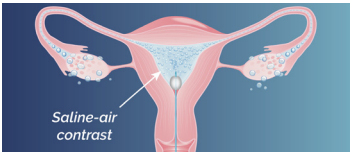


Figure 4

Step 4: Fallopian Tube Assessment *(Figure 4)*

Attach FemVue to balloon catheter, slowly depress plunger, and observe bubbles exiting catheter. Bubbles may flow through cornua, over tubal course, and exit adnexa/ovaries.

STEP 2: PREPARE FOR OPTIMAL FEMASEED PROCEDURE

Female

Natural (Unstimulated) Cycles:

- Follicular monitoring via ultrasound is generally started around day 9–10 of the cycle to track follicle growth and approach ovulation.
- May advise patient to use ovulation predictor kit at home to identify LH surge.

Note: advise patient to begin testing a few days before expected ovulation based on cycle length.

Stimulated Cycles (e.g., with ovulation induction medications):

- Example medications include: clomiphene citrate (Clomid or Serophene), letrozole. Follow medication instructions for use.
- Follicular monitoring begins early in cycle (2-3 days) to obtain baseline and continues at regular intervals until ovulation.

Ovulation Trigger:

- Example medications include: human chorionic gonadotropin (hCG), GnRH agonists (Lupron). Follow medication instructions for use.
- Trigger may be used to induce final oocyte maturation to time FemaSeed procedure.

Male

Instructions to Optimize Sperm Specimen Collection:

- Abstain from ejaculation for 2–5 days before collecting sample.
- Collect the sample by masturbation only.
- Bring specimen sample to office ideally within 1 hour of collection or obtain sample on-site.

STEP 3: FEMASEED PROCEDURE

Prepare Sperm with FemSperm Sperm Wash (Refer to Instructions for Use)

1. Prepare workspace (see checklist below).
2. Confirm patient information on all labels (not applicable for donor sperm).
   - Document in "Office Use Only" section of label on foam insert of sample collection cup kit *(Figure 11)*: a) date and time of receipt of sample and b) start date and time of preparation.
3. Check if sperm specimen is liquefied by:
   - Placing sterile pipette in sample collection cup and drawing up specimen (approximately 0.3-0.5 mL). Avoid touching sides or bottom of cup.
   - Gently squeezing bulb to release specimen back into cup and if it falls smoothly without stretching it is liquefied. If not, proceed with gentle mechanical liquefaction (#4 below).

4. ***Optional:*** If specimen is not liquefied, perform mechanical steps:
   a. Fully submerge the tip of sterile pipette into specimen cup.
   b. Slowly press and release pipette bulb to draw specimen into pipette.
   c. Slowly press and release pipette bulb to dispense and then draw specimen into pipette.
   d. Perform 3-5 cycles at a slow pace.
   e. Recheck specimen to ensure liquefied before proceeding (#3 above).

FemSperm Specimen Preparation Checklist

Supplies

Required

- ☐ Disposable sterile transfer pipettes
- ☐ One (1) FemSperm Sperm Wash kit *(Figure 5)*
  - Two (2) centrifuge tubes with BLACK CAPS (SpermCare 90%, 1 mL)
  - Two (2) GREEN CAP vials (sperm wash medium 2 mL)
  - One (1) BLUE CAP vial (sperm wash medium 0.75 mL)
- ☐ One (1) Centrifuge (pre-programmed FemSperm recommended)

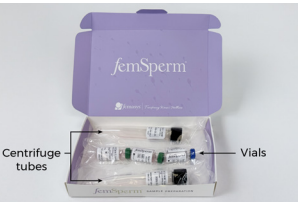


Figure 5
Note: Sperm Wash kit must be kept in refrigerator until use.

Recommended

- ☐ FemSperm Delicate Task Wipes

Sperm Wash Procedure Overview (Refer to Instructions for Use)

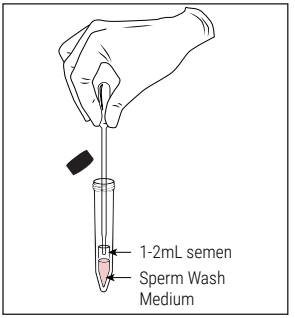


Figure 6

Step 1: Add Semen Specimen *(Figure 6)*

Using a pipette, gently layer up to 1 mL of sperm specimen from collection cup into centrifuge tube (black cap). If specimen remains, layer up to 1 mL in second tube.

Note: Do not exceed 2 mL per tube.

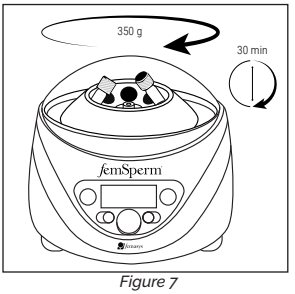


Figure 7

Step 2: First Spin *(Figure 7)*

After placing both tubes opposite each other in centrifuge, press P1 to spin for 30 minutes.

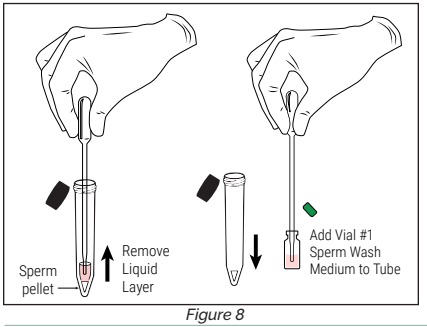


Figure 8

Step 3: First Wash *(Figure 8)*

Using new pipette, remove liquid layer from each tube and using a new pipette draw up contents of sperm wash medium (green vial) and add to each tube with sperm pellet. Gently agitate each tube.

Note: If only specimen in one tube, discard extra sperm wash medium (green vial).

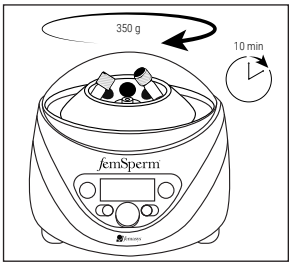


Figure 9

Step 4: Second Spin *(Figure 9)*

After placing both tubes opposite each other in centrifuge, press P2 to spin for 10 minutes.

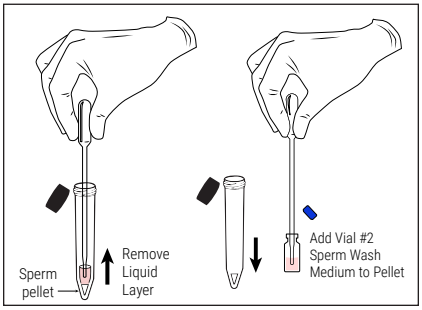


Figure 10

Step 5: Final Wash *(Figure 10)*

Using new pipette, remove liquid layer from each tube and using a new pipette draw up contents of sperm wash medium (blue vial) and add to one tube with sperm pellet. Gently agitate.

Note: If second tube with pellet, using the same pipette draw up the contents of the first tube and add to second tube. Gently agitate.

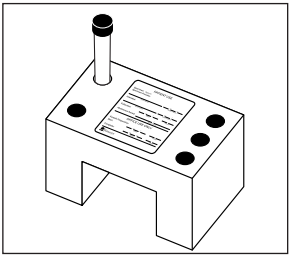


Figure 11

Step 6: Final Step *(Figure 11)*

Document the Sample Prepartion End Date/ Time on collection box insert.

Keep the prepared specimen at room temperature with cap securely fastened until ready for use in the FemaSeed procedure.

FemaSeed Preparation (Refer to Instructions for Use)

1. Determine specimen volume (max 1.0 mL) and if delivery to one or both fallopian tubes.
2. Place specimen in well of FemaSeed tray packaging.
3. Fill FemaSeed by placing tip of the transfer catheter into well and aspirating into catheter.
4. Pain management protocols should be implemented per practice guidelines.

FemaSeed Procedure Checklist

Sterile Supplies

Required

- ☐ FemaSeed
- ☐ Ultrasound and probes (transabdominal and/or transvaginal)
- ☐ Speculum (side-open if using transvaginal ultrasound)

Optional

- ☐ Uterine sound
- ☐ Dilator
- ☐ Tenaculum

FemaSeed Procedure Overview (Refer to Instructions for Use)

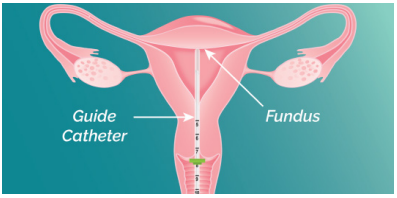


Figure 12

Step 1: Transcervical Placement *(Figure 12)*

After speculum placement, uterine sounding may be performed; if so, adjust the flange to measured depth. Insert guide catheter to fundus for entire procedure. Use ultrasound guidance to confirm placement. Full bladder may aid in placement and visualization.

Note: Avoid tapping at fundus to minimize potential for tubal spasm.

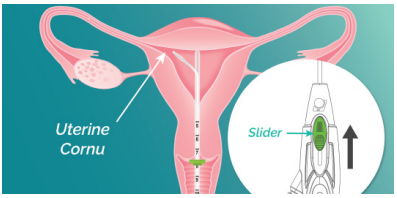


Figure 13

Step 2: Catheter Positioning *(Figure 13)*

Advance transfer catheter by moving green slider forward.

Note: 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).

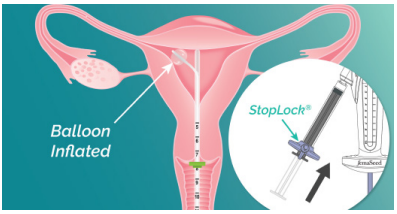


Figure 14

Step 3: Balloon Placement *(Figure 14)*

Inflate balloon in uterine cornu by depressing plunger of the StopLock syringe.

Use transabdominal or transvaginal (remove speculum) ultrasound to confirm proper placement before sperm delivery.

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

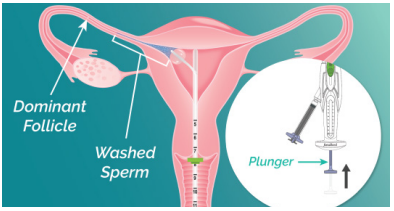


Figure 15

Step 4: Sperm Delivery *(Figure 15)*

Deliver sperm SLOWLY to ensure forward flow into the fallopian tube by depressing the plunger handle. Ultrasound may be used to visualize delivery.

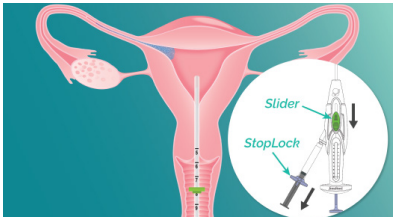


Figure 16

Step 5: Device Removal *(Figure 16)*

Deflate balloon by pulling back on plunger of StopLock and retract transfer catheter 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.

Patient should rest approximately 10 minutes.

Quick Reference Checklist

Prior to FemaSeed

- ☐ At least one patent fallopian tube (FemVue)
- ☐ Presence of sperm confirmed (FemSperm at home test)
- ☐ Ovulation timing confirmed (via ultrasound, ovulation predictor kit, or hCG trigger)

Day of FemaSeed

- ☐ Sperm sample collected and delivered within 1 hour (FemSperm collection cup)
- ☐ Required products on-site: FemaSeed, FemSperm Sperm Wash and centrifuge

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