femasys®

FemBloc®

Permanent Birth Control and Confirmation Test

Procedure Guide

Dear Healthcare Provider:

Congratulations! You have joined a growing number of providers who have chosen to offer FemBloc, a non-surgical permanent birth control option, to their patients.

The FemBloc Procedure Guide is a comprehensive guide that provides clinical instruction and information on the following:

I. Product and Procedure Overview: FemBloc
II. Product and Procedure Overview: Confirmation Test
III. Patient Selection and Counseling

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 FemBloc Representative.

INDICATIONS FOR USE

FemBloc Permanent Birth Control is indicated for non-surgical permanent birth control by occlusion of the fallopian tubes.

INTENDED PURPOSE

Blended Polymer

The FemBloc blended polymer is intended to stimulate wound healing response, gradually degrade and exit the body, resulting in complete tissue in-growth in a small section of the fallopian tubes.

Delivery System

FemBloc delivery system is intended to deliver FemBloc blended polymer into each uterine cavity cornu and both fallopian tubes.

IMPORTANT SAFETY INFORMATION

Who should not use FemBloc (Contraindications)

- Patients uncertain about their desire to end fertility.
- Known or suspected pregnancy; or at risk for pregnancy from unprotected intercourse earlier in current cycle.
- Known endometrial or myometrial conditions (e.g. submucous leiomyoma), uterine anomaly (e.g. unicornuate, bicornuate, arcuate, septate, or didelphic), or uterine position (e.g. retroflexion or anteflexion) that would interfere with insertion tube midline fundal placement, access to uterine cornual region, or lateral deployment of the catheters.
- Any condition which may prohibit proper visualization of the cervix or not allow the uterus to be appropriately instrumented.
- Active upper or lower genital tract infection.
- Any condition or medical treatment (e.g. systemic corticosteroids or chemotherapy) that compromises immune system.
- Less than 6 weeks post partum/post pregnancy termination at time of FemBloc procedure.
- Known hypersensitivity to cyanoacrylate or formaldehyde.

Pregnancy Considerations

- The FemBloc procedure should be considered irreversible. Patients should not rely on FemBloc for contraception until a Confirmation Test (modified sono hysterosalpingogram [M-Sono HSG]) confirms bilateral occlusion.
- Effectiveness rates for the FemBloc procedure are based on patients who had successful bilateral delivery of the blended polymer and Confirmation Test result of bilateral occlusion.
- Pregnancies (no ectopic pregnancies) have been reported among women who underwent the FemBloc procedure. All reported pregnancies were due to patient non-compliance or incorrect interpretation of the Confirmation Test (M-Sono HSG).

Clinical Trial Experience

Safety and effectiveness of FemBloc is not established in patients under 21 and over 50 years old. Women undergoing sterilization at a younger age are at greater risk of regretting their decision.

- There were no serious adverse events reported through five years of follow-up.
- The most common (≥5%) adverse events resulting from the FemBloc procedure were:
  - Bleeding/spotting
  - Pelvic or abdominal pain/uterine cramps
- The common adverse events were mostly classified as mild and the majority (61%) resolved on the day of the procedure and over 86% by day 3 post the FemBloc procedure.

I. Product and Procedure Overview: FemBloc

FEMBLOC COMPONENTS

FemBloc Delivery System

The delivery system has two flexible balloon catheters with each containing two lumens, one for inflation of the balloon and one for delivery of the blended polymer. The catheters are pre-loaded into the 15F insertion tube (5 mm diameter). The insertion tube has a series of 1 cm graduated markings at the distal end and an adjustable flange to aid placement at the uterine fundus. The device has built-in syringes for balloon inflation and lock to switch access to the blended polymer cartridge for delivery; all actuated in a step wise function by the plunger. Additional features include a slider to advance the catheters in and out of the insertion tube and a level to ensure proper device orientation. Safety interlocks are incorporated into the delivery system to ensure the correct order of steps are followed for the FemBloc procedure.

How Supplied
Sterile for single use only.
Sterilized by eythlene oxide.

Storage
Store in a cool, dry place.

Figure 1

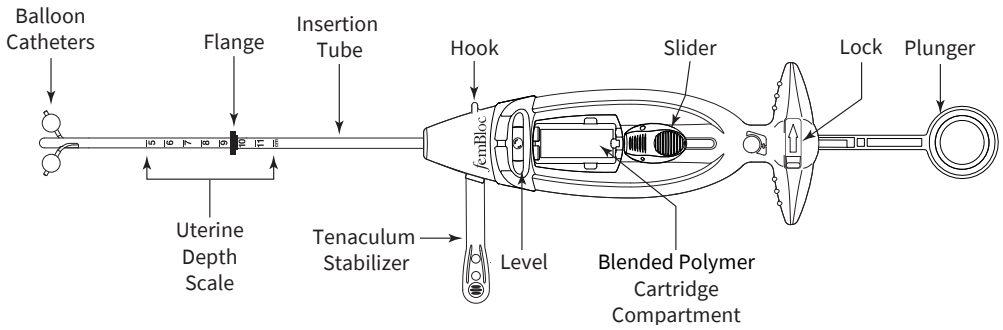


Figure 1 *shows the delivery system as it is provided with two catheters advanced from insertion tube.*

FemBloc Blended Polymer

The blended polymer is provided in a cartridge that is inserted into the delivery system as shown in figure 1. Once the blended polymer cartridge is inserted into the delivery system, it cannot be removed.

How Supplied
Sterile for single use only.
Sterilized by e-beam.

Storage
Store in a cool, dry place.

Figure 2

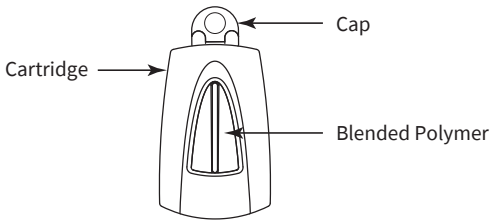


Figure 2 *shows the blended polymer as it is provided within the cartridge with a cap.*

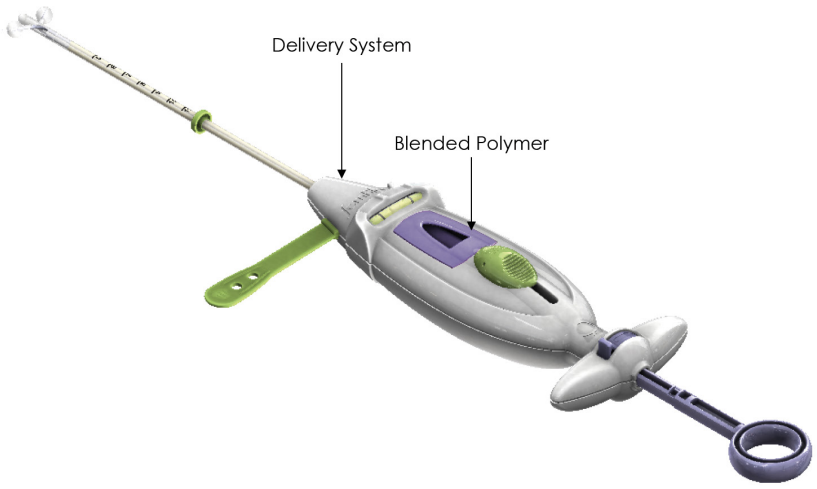
I. Product and Procedure Overview: FemBloc (continued)

FEMBLOC PRODUCT PREPARATION

Prior to the FemBloc procedure, the blended polymer cartridge is inserted into the delivery system, for single one-time use. Availability of a second delivery system and blended polymer is recommended for back-up.

Figure 3 *shows the blended polymer cartridge inserted into the delivery system.*

Figure 3



Required Additional Supplies

- Uterine sound
- Dilator (≤ 5mm)
- Antiseptic solution
- Cotton swabs
- Speculum
- Tenaculum (straight)

PRE-PROCEDURE CONSIDERATIONS

- Perform the FemBloc procedure during:
  - follicular phase of the menstrual cycle (not to exceed day 11 from first day of menses) after bleeding has stopped, or
  - any time she is not bleeding and protected from pregnancy if on hormonal contraceptive.
- Do NOT perform FemBloc if there is active uterine bleeding, fluid in uterine cavity, or blood in vagina as bleeding/fluid may affect balloon placement and/or blended polymer delivery.
- A uterine pregnancy test should be administered within 24 hours prior to the FemBloc procedure. The following criteria can be used to confirm a patient with no signs or symptoms of pregnancy is not pregnant:
  - It is ≤7 days after the start of patient's normal menses
  - Patient has not had sexual intercourse since the start of last normal menses
  - Patient has been correctly and consistently using a reliable form of contraception

Patient Comfort

Patient comfort is an important part of a successful procedure.

- Analgesia is strongly recommended to be taken by patient prior to device placement. Examples include non-steroidal anti-inflammatory drugs (NSAIDs) such as, ketorolac or oral naproxen sodium.
- If NSAID use is contraindicated or not tolerated, oral acetaminophen may be taken.
- An anxiolytic agent may be prescribed or administered prior to device placement.

Pain management protocols should be implemented per practice guidelines.

I. Product and Procedure Overview: FemBloc (continued)

HOW FEMBLOC WORKS

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

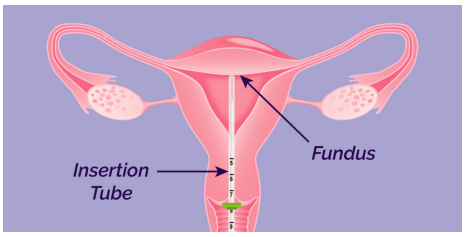


Figure 4

Step 1 *(Figure 4)*

The delivery system is placed by advancing the insertion tube through the patient's cervix and into the uterine cavity until the flange (previously set to sound measurement) contacts the external cervical os. This indicates that the distal end of the insertion tube is placed at the fundus of the uterine cavity as intended.

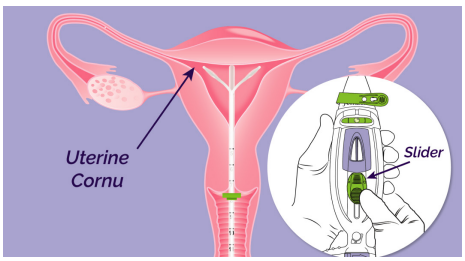


Figure 5

Step 2 *(Figure 5)*

By pushing the green slider forward, the two (2) balloon catheters are simultaneously advanced from the insertion tube a pre-set distance into the uterine cavity cornual region.

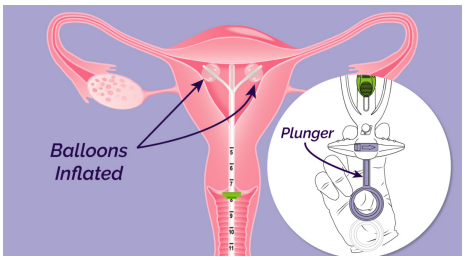


Figure 6

Step 3 *(Figure 6)*

The balloons are simultaneously inflated in each uterine cornu with air from syringes within the delivery system by depressing the plunger.

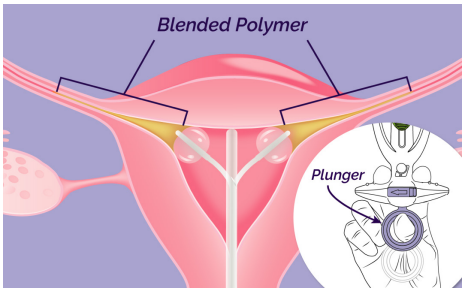


Figure 7

Step 4 *(Figure 7)*

The blended polymer is simultaneously delivered through the catheters into each cornu directed towards the tubal os and into each fallopian tube (~0.6 mL delivered to each side) by depressing the plunger.

Note: the majority of blended polymer will be in contact with the endometrium of the uterine cavity and a small amount is intended to enter the fallopian tubes.

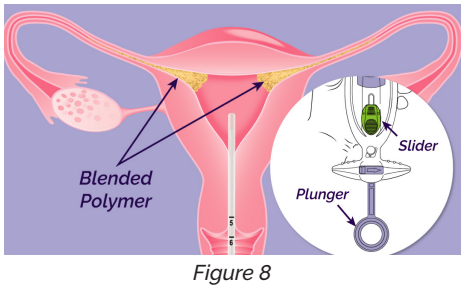


Figure 8

Step 5 *(Figure 8)*

The balloons are deflated by pulling back on the plunger and the catheters are retracted into the insertion tube by pulling back on the slider. The delivery system is then removed from the patient and disposed. The blended polymer is expected to exit the patient within 3 months.

Note: solidified blended polymer may appear on the insertion tube and/or balloons.

Step 6

Schedule confirmation test 3 months after the FemBloc procedure.

II. Product and Procedure Overview: Confirmation Test

CONFIRMATION TEST COMPONENTS

The FemBloc Confirmation Test requires the use of two components:

- FemChec Controlled Saline-Air Device *(Figure 9)*
- Intrauterine HSG catheter

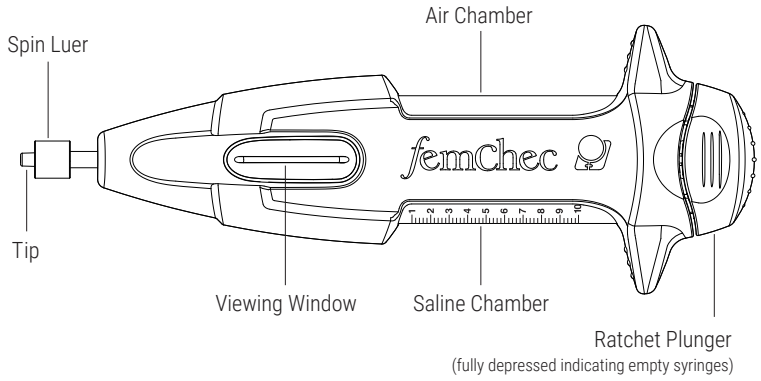
Both components are provided separately, sterile and are not reusable.

How Supplied
Sterile for single use only.
Sterilized by eythlene oxide.

Storage
Store in a cool, dry place.

Figure 9 *shows the FemChec device. It is provided with a bowl.*

Figure 9



Required Additional Supplies

- Antiseptic solution
- Cotton swabs
- Speculum (side-open)
- Sterile saline

CONSIDERATIONS

Pre-Procedure

- Confirmation Test is containdicated for:
  - known or suspected pregnancy
  - active upper or lower genital tract infection
- Perform the Confirmation Test during:
  - follicular phase of the menstrual cycle (not to exceed day 11 from first day of menses) after bleeding has stopped, or
  - any time she is not bleeding and protected from pregnancy if on hormonal contraceptive.

Patient Comfort

Patient comfort is an important part of a successful procedure.

- Analgesia is strongly recommended to be taken by patient prior to device placement. Examples include non-steroidal anti-inflammatory drugs (NSAIDs) such as, ketorolac or oral naproxen sodium.
- If NSAID use is contraindicated or not tolerated, oral acetaminophen may be taken.

Pain management protocols should be implemented per practice guidelines.

Procedure

- Two operators are recommended for device and ultrasound handling.
- Confirmation test requires the delivery of sufficient contrast media to achieve and maintain adequate distension of each uterine cornu.
- Improper interpretation of the Confirmation test may result in pregnancy.
- Follow Instructions for Use for the FemChec® controlled saline-air device and intrauterine catheter.

II. Product and Procedure Overview: Confirmation Test (continued)

HOW CONFIRMATION TEST WORKS

The following steps comprise the principles of operation during the FemBloc Confirmation Test.

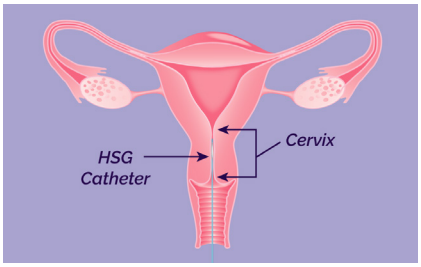


Figure 10

Step 1 *(Figure 10)*

The intrauterine HSG catheter is placed through the patient's cervix.

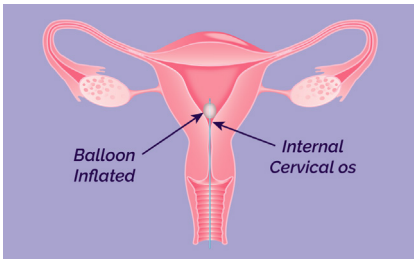


Figure 11

Step 2 *(Figure 11)*

The balloon is inflated with separate syringe and positioned at the internal cervical os.

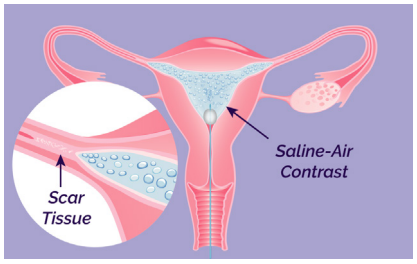


Figure 12

Step 3 *(Figure 12)*

Under ultrasound, saline-air contrast is delivered from the FemChec device connected to the intrauterine HSG catheter to evaluate the fallopian tubes for occlusion.

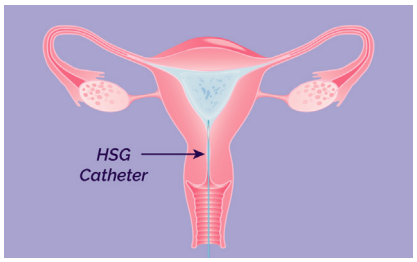


Figure 13

Step 4 *(Figure 13)*

The balloon is deflated and the catheter removed from the patient and disposed.

PROCEDURE TIPS

- A baseline transvaginal ultrasound scan is helpful to identify the following areas of interest:
  1. Endometrial stripe and cornua *(Figure 14)*
  2. Left and right adnexa/ovary
  3. Tubal course by scanning from each adnexa/ovary to each cornu *(Figure 15)*
  4. Cul-de-sac for presence of fluid
  5. Position of uterus

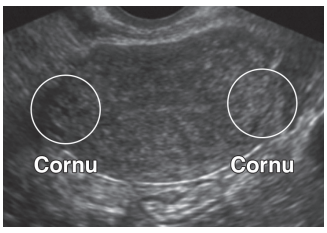


Figure 14

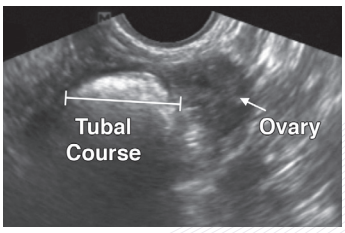


Figure 15

II. Product and Procedure Overview: Confirmation Test (continued)

KEY INSTRUCTIONS

1. Insert catheter per Instructions for Use.
2. Connect FemChec to catheter per device's Instructions for Use.

I. Fallopian Tube Assessment Preparation

1. It is critical to obtain uterine cornu distension to ensure proper fallopian tube evaluation.
2. Contrast should be delivered slowly to minimize air intravasation and backflow around the balloon that may prevent tubal assessment.

II. Tubal Evaluation for Occlusion

Once uterine cavity cornu distension is achieved, the fallopian tubes can be evaluated individually by holding the probe STEADY for the recommended times for each area:

1. Distended uterine cornu and proximal tube for minimum of **30 seconds**
2. Fallopian tube to ovary/adnexa by slow scan
3. Ovary/adnexa for minimum of **30 seconds**
4. Cul-de-sac for minimum of **10 seconds**
5. Steps 1-4 for contralateral fallopian tube
6. Repeat evaluation of any areas of interest

III. Tubal Occlusion Determination

1. Bilateral tubal occlusion achieved only with confirmation of ALL four criteria:
   a. No bubbles (contrast) visualized flowing beyond cornua and into either fallopian tube
   b. No bubbles (contrast) visualized in either fallopian tube
   c. No bubbles (contrast) visualized around adnexa/ovaries
   d. No bubbles (contrast) visualized in cul-de-sac

If satisfactory bilateral tubal occlusion is confirmed, the patient should be told to rely on FemBloc for contraception.

2. Bilateral tubal occlusion NOT achieved with observation of 1 or more criteria:
   a. Bubbles (contrast) visualized flowing beyond cornua and into either fallopian tube
   b. Bubbles (contrast) visualized in either fallopian tube
   c. Bubbles (contrast) visualized around either adnexa/ovary
   d. Bubbles (contrast) visualized in cul-de-sac

If bilateral tubal occlusion is NOT confirmed, the patient should remain on alternative contraception, while contraceptive options are discussed.

3. Inconclusive findings includes all other findings and/or procedure with suboptimal view(s), such as limited or no uterine cornua distension, limited or no bubbles (contrast) swirling in uterine cornua (insufficient contrast), shadowing (air intravasation) precluding evaluation of areas such as cornu and adnexa/ovary, retroflexed/anteflexed uterus, improper balloon positioning with considerable backflow, bowel position preventing proper visualization of bubbles (contrast), and inadequate hold times of area (each cornu, each tube, each adnexa/ovary, cul-de-sac). Patient should remain on alternative contraception, and a repeat Confirmation Test should be performed in at least one month but no later than three months.

III. Patient Selection and Counseling

FEMBLOC IS AN APPROPRIATE OPTION FOR WOMEN WHO DESIRE PERMANENT BIRTH CONTROL:

- The patient must be certain that her family is complete, and understand that the procedure should be considered irreversible.
- The patient must be willing to use alternative contraception until the Confirmation Test confirms that her tubes are occluded.

Sideline patients

Many of these women sideline themselves due to various reasons such as fear of surgical risks, inconvenience, or economic constraints.

FemBloc allows you to provide your patients with the next advancement of permanent contraception.

Women choosing no children

Women done having children but using non-permanent IUDs or implants

Women concerned with hormones

FEMBLOC BENEFITS

Safe

- Demonstrated safety from clinical trials were consistent with those typically observed for intrauterine transcervical procedures, with no on-going safety concerns through five years.[1]
- No reports of serious adverse events (n=0/229).[1]
- Most common non-serious adverse events reported were spotting/bleeding and/or pelvic pain/cramps that usually resolved shortly after the procedure.[1]

Effective

- 0% pregnancy rate with FemBloc[1], providing compelling evidence of effectiveness.
- Significantly lower than historic surgical sterilization (5.7% pregnancy rate for surgical (laparoscopic) sterilization).[2]
- Confirmation test after FemBloc confirms procedure success before patient relies on FemBloc for permanent contraception.

Convenient

- Time-saving option for permanent contraception since the procedure is performed quickly with no surgery.
- No recovery downtime, resume normal activities immediately.

Affordable

- FemBloc is a cost-effective option to offer patients no longer intending children.
- FemBloc allows for expanded practice services with a non-surgical, minimally invasive permanent contraceptive option.

1. Liu, J. H., Blumenthal, P. D., Castano, P. M., Chudnoff, S. C., Gawron, L. M., Johnstone, E. B., Lee-Sepsick, K. (2025). FemBloc Non-Surgical Permanent Contraception for Occlusion of the Fallopian Tubes. J Gynecol Reprod Med, 9(1), 01-12. doi: 10.33140/JGRM.09.01.05.
2. Gariepy AM, Lewis C, Zuckerman D, et al. Comparative Effectiveness of Hysteroscopic and Laparoscopic Sterilization for Women: A Retrospective Cohort Study. Fertility and Sterility, 2022, 117(6):1322-1331. doi:10.1016/j.fertnstert.2022.03.001.

III. Patient Selection and Counseling (continued)

PATIENTS MAY HAVE QUESTIONS AND CONCERNS ABOUT THE FEMBLOC PROCEDURE. IT IS IMPORTANT TO MANAGE THEIR EXPECTATIONS WITH THE FOLLOWING INFORMATION:

Procedure Highlights

- The FemBloc procedure should be considered irreversible.
- Counsel patients that FemBloc does not protect against human immunodeficiency virus (HIV) or other sexually transmitted infections (STIs).
- Explain what FemBloc is and how it works, and be sure to distribute the Patient Brochure to detail the benefits and risks of FemBloc.
- FemBloc is a permanent birth control procedure that works with the body to create natural tissue in-growth for blockage of the fallopian tubes to prevent pregnancy.
    - The procedure involves delivering a temporary blended polymer into each fallopian tube, solidifying upon contact with the tissue.
        - The blended polymer triggers a natural healing response and degrades, leaving the patient with her own tissue in a small section of each fallopian tube. The tissue in-growth creates a barrier that keeps sperm from reaching the eggs and prevents contraception.
- Three months after the FemBloc procedure, a Confirmation Test is performed to confirm the fallopian tubes are blocked before the patient is told to rely on FemBloc for permanent contraception.
    - Patients must continue to use alternative contraception (except an IUD) to prevent pregnancy, until Confirmation Test result is received.
    - Important: meet with patients to discuss the results of the FemBloc Confirmation Test.
- IMPORTANT: Not all women will achieve successful delivery of the blended polymer to both fallopian tubes. Discuss a management plan with the patient in the event bilateral occlusion is not achieved.
    - If the blended polymer is not successfully placed, or confirmed by the FemBloc Confirmation Test, women may choose:
        a. to undergo the FemBloc procedure again
        b. to undergo surgical sterilization
        c. another method of contraception

Clinical Data Highlights

- The FemBloc procedure is highly safe based on 5-year clinical study data (N=229). No serious adverse events were reported and the most common non-serious adverse events were spotting/bleeding (59%) and pain/cramps (55%) that resolved quickly (61% on the day of the procedure and 86% by day 3).
    - Most women return to normal activities immediately.
- No pregnancies were reported in women accurately told to rely on FemBloc (N=51).
    - However, no method of contraception is 100% effective. Like all birth control methods, there is a risk of pregnancy.

Summary Patient Benefits

- No surgical risks, including anesthesia and incisions.
- Effective alternative to surgical sterilization with benefit of confirmation test.
- Accessible, less invasive option.
- Convenient with immediate return to normal activities.
- Most natural solution with no hormones or implants.

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