



Everything you need to know about the Foam procedure

Supporting your fertility journey:

A patient-friendly alternative for tubal patency testing for subfertile women or women with known or suspected infertility.

exem[®]
women's health



Are you trying to conceive?

Trying to conceive can be hard, both physically and emotionally. If you have been trying to conceive for over a year without success (or sooner if you are over 35 years old), you should talk to your gynecologist or fertility specialist and start a fertility check-up.

At an early stage of your fertility check-up, your gynecologist will examine the patency of your fallopian tubes. In other words, your gynecologist will examine if your fallopian tubes are open or blocked. Blocked or damaged fallopian tubes may be one of the reasons you have difficulty to conceive. This condition is what we refer to as fallopian tubal disorder or tubal disorder.

There are two main techniques to assess fallopian tube patency. Laparoscopy (surgery) and hysterosalpingography (also known as HSG). Both are experienced as uncomfortable and painful to many women. The Foam procedure is the latest innovation in tubal patency assessment and has already challenged the two established methods of tubal patency tests offering a reliable patient-friendly ultrasound-based procedure.

This booklet compiles everything you need to know about the Foam procedure and how it can quickly and safely determine the patency of your fallopian tubes.

What is the Foam procedure?

The Foam procedure, also referred to as Hysterosalpingo Foam Sonography or HyFoSy in scientific terms, is a simple ultrasound test aimed to determine whether your fallopian tubes are open or blocked.

The medium used during the Foam procedure is called ExEm® Foam. ExEm® Foam is made of ExEm® Gel – hydroxyethyl cellulose & glycerol and ExEm® Water – purified water.

The Foam procedure can be performed in an environment that you are familiar with: your gynecologist's office.

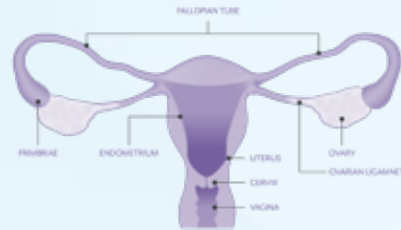
Did you know?

Performing a tubal patency test in a 'familiar' environment can help reduce patient's anxiety. In fact, a study suggests the importance to implement measures to reduce anxiety in tubal assessment tests such as counselling intervention and calm environment. The same study highlights that fear and anxiety increase discomfort during the procedure and are likely to influence perceived pain. ^[1]

I. Engels V, Medina M, Antolin E, Ros C, Amaro A, De-Guirior, et al. Feasibility, tolerability, and safety of hysterosalpingofoam sonography (HyFoSy). Multi- center, prospective Spanish study. J Gynecol Obstet Hum Reprod 2020;102004 23 nov.

Why is it important to check the fallopian tubes?

Fallopian tubes are an essential part of a woman's reproductive system. They are the tubal structures that connect the ovaries to the uterus. Open fallopian tubes are important to become pregnant and are the place where sperm and eggs initially meet before an embryo later travels to attach to the uterus. If both of your fallopian tubes are blocked, the sperm and the egg cannot meet and natural conception will not be possible. At least one patent tube is needed for natural conception.



Fallopian tubes are usually blocked by scar tissue or pelvic adhesions. These can be caused by many factors, including for example:

- Pelvic inflammatory disease
- Endometriosis
- Certain sexually transmitted infections (STIs)
- Past ectopic tubal pregnancy
- Fibroids
- Past abdominal surgery

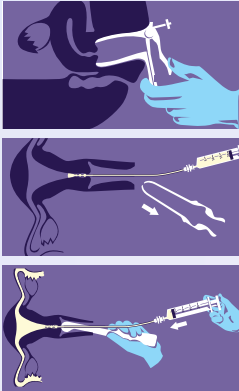
Safety and simplicity.

Before the procedure

- The Foam procedure should take place in the pre-ovulatory phase of your menstrual cycle (cycle days 6 through 11). This is after bleeding has stopped, but before ovulation occurs.
- It's important to have a negative pregnancy test within 24 hours before the procedure takes place.
- You should eat and drink as normal on the day of the procedure.
- Prior to the procedure, you will be asked to empty your bladder to ensure optimal visualization.

Step by Step procedure

- You will be asked to lie on your back on the examination table with your feet in stirrups. A routine transvaginal (internal) scan is carried out first.
- A speculum (instrument) is then placed in the vagina (when like having a smear).
- A catheter (a tube) is inserted into the cervix.
- The speculum is removed and the ultrasound probe is inserted into the vagina.
- ExEm® Foam is then gently infused through the catheter into the uterus and the fallopian tubes. The flow of the foam can be seen on the ultrasound.
- Patency of the fallopian tubes will be assessed and determined using small movements of the ultrasound probe.
- When completed, the ultrasound probe and catheter are removed.



4.

About the procedure.

 10 minutes



No radiation. No iodine.

The diagnosis is made by transvaginal ultrasound.



Less painful than HSG.

Studies found that the Foam procedure is 50% less painful than HSG.^[2]



Convenient.

The ultrasound based procedure can be performed by your gynecologist in his or her office. You will not be asked to visit a radiologist after your appointment with your gynecologist.



Less appointments.

Immediate results and diagnosis.

2. Dreyer K, Out R, Hompes PGA, Mijatovic V. Hysterosalpingo-foam sonography, a less painful procedure for tubal patency testing during fertility workup compared with (serial) hysterosalpingography: a randomized controlled trial. *FertilSteril* 2014;102(3):821-5 sept.

Every step of the way.

After the procedure

Following the procedure, you may notice a small amount of foam discharge and/or spotting. This is normal and a sanitary pad will be provided if needed. Your doctor will discuss the results and recommended steps with you. If you have any questions or concerns prior to or following the procedure, please contact your healthcare provider. For additional information about the Foam procedure, feel free to visit:

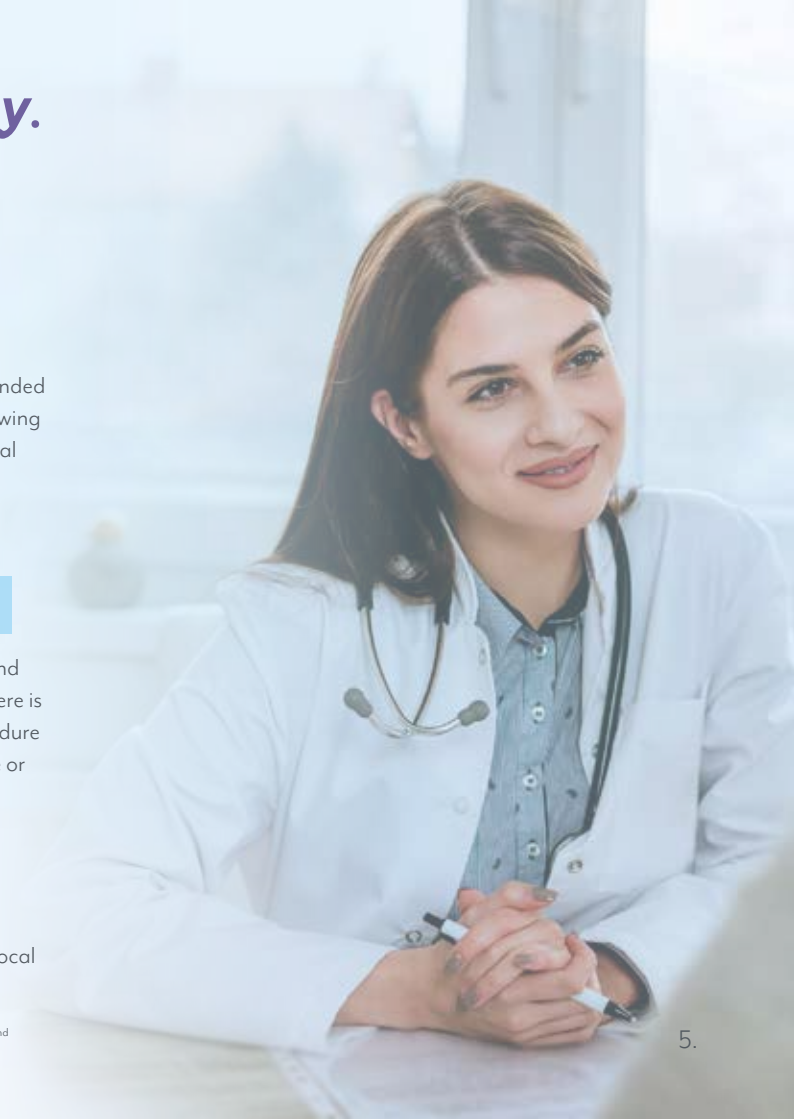
europe.exemfoam.com/patient

Contraindications and precautions

The Foam procedure can only be used when you are not pregnant and when there is no bleeding. The Foam procedure cannot be used if there is an active pelvic infection or sexually transmitted diseases. The procedure will not be performed if the routine transvaginal scan shows that one or both fallopian tubes are swollen (hydrosalpinx).

Note: Some patients may experience painful uterine contractions, vasovagal reaction, abdominal pain, fluid loss or spotting. These symptoms are well known and related to all intra-uterine and tubal patency testing procedures. Pain treatment should be according to local protocol.

ExEm® Foam is a procedure pack consisting of CE marked components (medical devices ExEm® Gel (class Is), ExEm® Water (class Is) and Combifix® Adapter (class IIa)). With ExEm® Foam, a foam can be created for Hysterosalpingo Foam Sonography (HyFoSy).





Moving women's health forward.

exem[®]
women's health

Giskit MD B.V.
Veerkade 5 F
3016 DE Rotterdam
The Netherlands
Office +31 102619100

europe.exemfoam.com/patient

ExEm[®] is a registered trademark of GISKIT MD B.V.