# *HyFoSy procedure using ExEm® Foam*

## Foam is the future.

Hysterosalpingo Foam Sonography (HyFoSy) is a new and attractive alternative for tubal patency assessment and diagnosis in subfertile women or women with known or suspected infertility. [1,2]

exem®
women's health

Tubal disease is among the most common causes of infertility and is the primary diagnosis in approximately up to 25 % of female infertility cases.[3] An inaccurate fallopian tube evaluation can lead to unnecessary procedures — such as tubal reconstructive surgery or in vitro fertilization — when other methods of conception are possible.

Laparoscopy is considered as the gold standard for diagnostic evaluation of tubal patency. However, this procedure is invasive and costly.[4] Other less costly and less invasive alternatives emerged: Hysterosalpingography (HSG) and Hysterosalpingo Contrast Sonography (HyCoSy).
Although HSG is less invasive than laparoscopy, it is often experienced as painful and uncomfortable for many women.[7] Moreover, HSG results in exposure to ionising radiation and ionated contrast medium.
HyCoSy, an ultrasound and patient-friendly procedure introduced in 1993, has been proposed as an alternative for HSG as a first line office tubal patency test. The accuracy of HyCoSy is comparable to that of HSG. [5,6] However, the commonly used echogenic medium for HyCoSy, Echovist® (Schering AG, Berlin, Germany) was taken out of market and replaced by saline and air. Saline and air which accuracy is not comparable to HSG, is now the mostly used alternative.[6]

In this context, Hysterosalpingo Foam Sonography (HyFoSy) was introduced in 2011 as a new minimally invasive procedure for tubal patency testing and as an alternative for HyCoSy.[7]

HyFoSy is a reliable and patient-friendly ultrasound-based procedure whose usefulness in **first-line tubal patency testing** has been demonstrated by several studies, including a large prospective cohort study [8] and a large randomized control study.[9]

# *Innovative. Simple. Safe.*

Foam is the future of tubal patency assessment.

**What is HyFoSy?**

The HyFoSy procedure allows to inspect the fallopian tubes and its relation to other pelvic organs/structures. It also provides extra details for the assessment of the patient's subfertile situation.
It is performed by a qualified sonographer and is technically an ultrasound examination that quickly helps to localize fallopian tubes and visualize tube abnormalities.

**What is the medium used during the HyFoSy procedure?**

ExEm® Foam is a medium made of ExEm® Gel – hydroxyethyl cellulose & glycerol and ExEm® Water – Purified water. When vigorously mixed, a highly echogenic foam containing 127 000 micro-air bubbles per ml is formed and can easily be seen by a qualified sonographer using 2D or 3D transvaginal ultrasound techniques.

**HyFoSy versus HSG?**

The HyFoSy procedure is less painful than HSG [7] and offers in-office real time results. It does not involve X-ray, iodine or placing a cervical tenaculum and traction on the cervix. Because of its combined efficacy and improved patient comfort, HyFoSy is an attractive option for the evaluation of tubal patency in subfertile women.


Over 1 million
fallopian tubes
assessed
worldwide

# *HyFoSy:*

making the uncomfortable more comfortable

**Efficacy & Effectiveness:**

There is consistent evidence that supports HyFoSy in-office procedure reliability. It has shown a high detection rate of tubal obstruction and good reproducibility [10, 11, 12] with concordances up to 100 % with HSG, and up to 97 % [13] with laparoscopy.

**Less invasive & patient-friendly:**

The HyFoSy procedure using ExEm® Foam enables an accurate diagnostic procedure without iodine, X-ray or Laparoscopy. It is also less painful than HSG: VAS* pain score 50+ % less compared to HSG.[7]

*VAS stands for Visual Analogue Scale

**Pregnancy:**

The HyFoSy procedure using ExEm® Foam provides similar pregnancy outcomes compared to HSG.[14]

**Convenient & less anxiety:**

HyFoSy is a convenient in-office procedure that can be performed in the gynecologist's office. 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.[8]

# *Improved level of detail and accuracy*

ExEm® Foam is a highly echogenic product and offers an exceptional visualization of the fallopian tubes. Moreover, studies confirm that, using the right imaging technique, the accuracy of a HyFoSy procedure using ExEm® Foam does not significantly differ from what you achieve through laparoscopy. The same studies demonstrate that HyFoSy has the ability to achieve significantly higher accuracy than 2D saline and air.[1]

**Fig. 1.** (see page 7.)
(a) axial section R1-L1. (b) triple band. (c)thin tube (L1 L2). (d)normal straight tube (R1 R2). (e) sinuous or tortuous tube. (f) tube near the probe. (g) tube far from the probe. (h) occlusion of the ostium (L1), spasm. (i) occlusion of the ostium (L1), salpingectomy. (j)occlusion of the ostium (L1), and vascular passage. (k)dotted passage in segment 2. (l) blockage of contrast medium in the infundibulum.

**Source Fig. 1.**
HyFoSy for Fallopian tube test, the how: Sonographic signs and standardization with a simple classification Jean-Marc Levaillant et al. 2022.

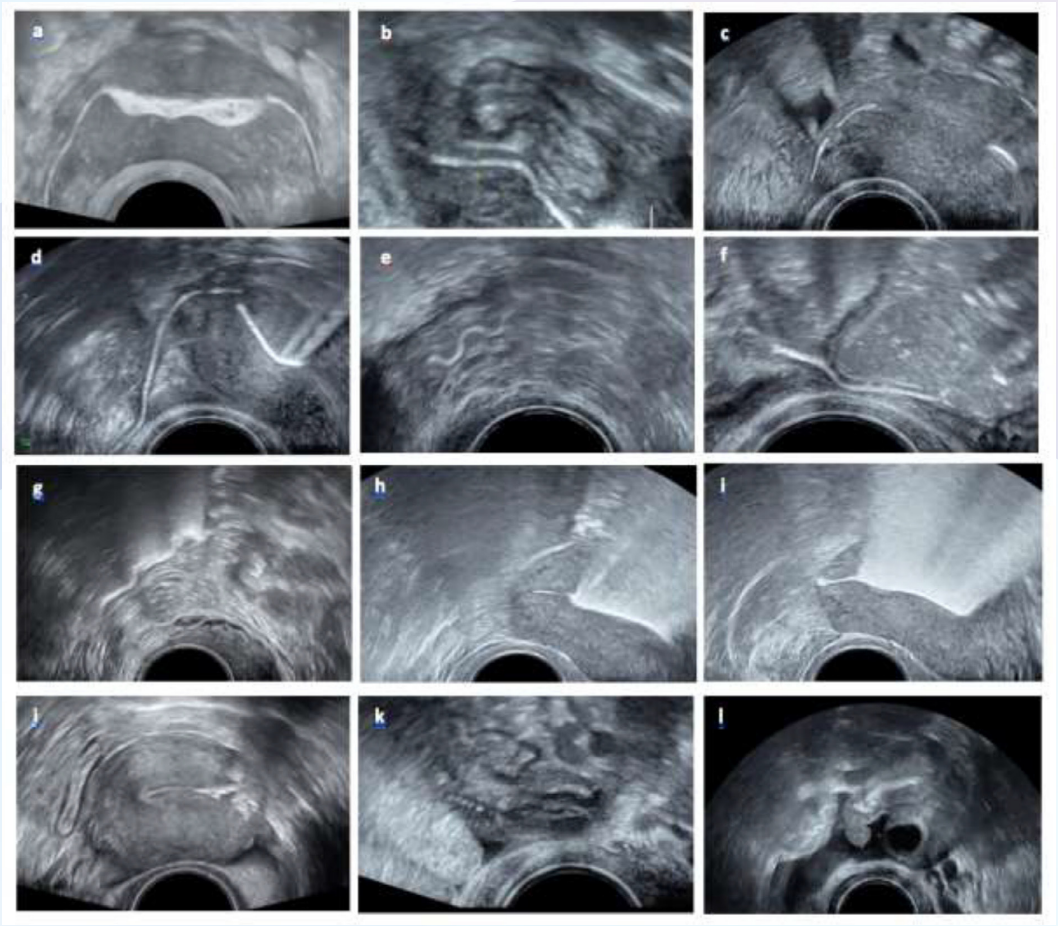


Fig. 1.

# *Simplicity and safety.*

Every step of the way.

**How is the HyFoSy procedure performed?**

Any 2D ultrasound machine, operated by a qualified sonographer, can be used for the HyFoSy procedure using ExEm® Foam. 3D or 2D/3D-High Definition Flow (HDF) Doppler ultrasound may offer enhanced accuracy and faster recognition of tubal patency in subfertile women. Any transcervical catheter with luer connection, designed for intrauterine application (at least 5Fr), can be used.

**Requirements:**

1 ExEm® Foam
2 Side opening speculum
3 Sterile disposables for aseptic preparation of the foam
4 Gynecological chair with stirrups
5 2D/3D ultrasound machine with transvaginal probe
6 Transvaginal catheter of at least 5Fr (a balloon catheter is not necessary)

**Please read the Instructions For Use carefully before using ExEm® Foam. Reference is also made to the Important Safety Information and Contraindications as set out on page 20 of this brochure.**

**Step 1:** Connect the ExEm® Water and the ExEm® Gel syringes to the coupling device. The coupling device is included in ExEm® Foam procedural kit.

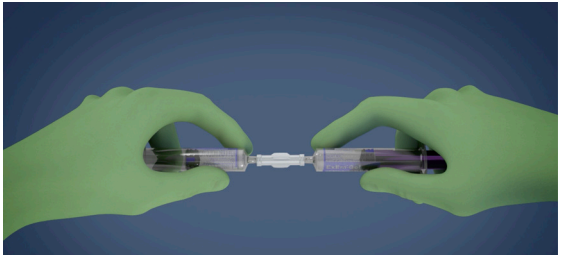

Figure 1.

**Step 2.** Vigorously mix the ExEm® Water with ExEm® Gel by injecting the fluids (fig.2) from one syringe through the coupling device into the other syringe for at least 10 times. This creates a milky white foam .

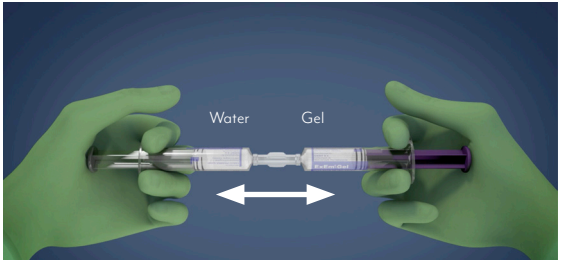


Figure 2.

**Step 3:** Leave the foam in either one of the syringes and disconnect the other syringe and coupling device.

**Step 4:** Connect the syringe containing the foam to the catheter.

**Step 5:** Introduce side-opening speculum. (fig. 3.)

**Step 6:** By gently filling the catheter with foam, allow the air to escape before introduction in the ostium. (fig. 4.) Gently introduce the catheter into the cervix.

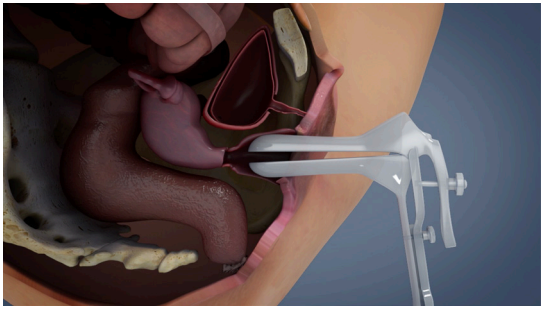

Figure 3.

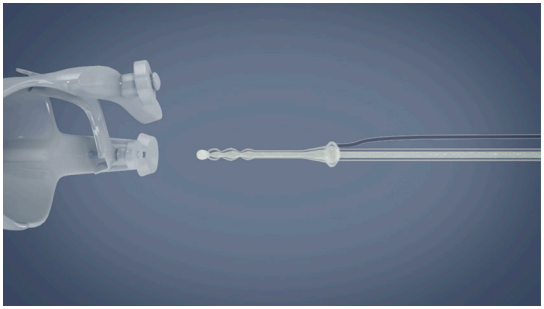

Figure 4.

**Step 7:** Remove speculum. (fig. 5.)

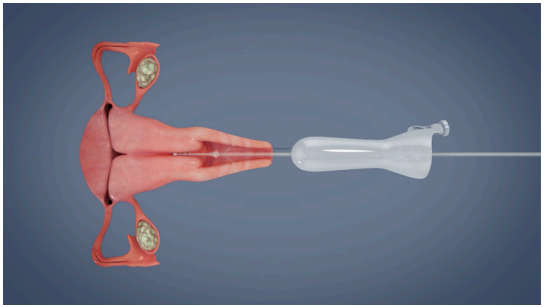

Figure 5.

**Step 8:** Position the ultrasound transducer and slowly infuse 2-3 ml of foam. The foam will be visible in uterine cavity and continues to flow through the tubes.
Rotation of the ultrasound transducer (from longitudinal plane to transversal plane) enables visualization of the movement of the foam through fallopian tubes. The foam is stable for 5 minutes. (fig. 6.)

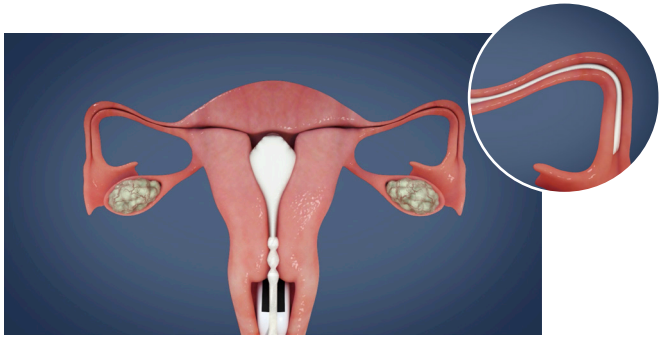

Figure 6.

**Step 9:** Determine tubal patency.

**Result**

During the ultrasound procedure the foam will appear as an echogenic line along the length of the tube on the image confirming that the fallopian tubes are patent. If not, one or both of the fallopian tubes might be blocked.
The foam is absorbed within 48 hours.

# *GIS* catheter*
# Performance. All in one.

**GIS catheter is:**

- **Specially designed** for sonohysterosalpingography and HyFoSy
- **100% Compatible** with ExEm® Foam
- **Patient-friendly** by design with a **flexible cervical tip**


## *Available as a bundle*

ExEm® Foam + GIS catheter



*GIS catheter is a CE marked medical device (Class Is).

# *Designed by gynecologists*

for an improved patient and doctor experience

ExEm® Foam used during the HyFoSy procedure was developed by Dutch gynecologists Dr. Niek Exalto and Prof. Dr. Mark Hans Emanuel. The root name 'ExEm' is derived by combining the two first letters of the last names of the product inventors of , ExEm® Foam, Drs. Exalto and Emanuel.

Both Dr. Exalto and Prof.Dr Emanuel envisioned an easier, less-invasive tubal patency procedure with better visualization capabilities, without the burdens which come with HSG (e.g. use of X-ray and iodine, and the need for an additional appointment).

First launched in Europe in 2011, ExEm® Foam has been used in over 1 million fallopian tubes worldwide, providing a safe, successful alternative to HSG, laparoscopy or saline and air.

**"To overcome the usual drawbacks of available HSG, there was a need for an easier, less invasive procedure, with a better visualization of fallopian tubes"**

# *Tubal patency assessment procedures timeline*

**1910** **Laparoscopy:** Jacobaeus (1910), Palmer (1947).

**1914** **First HSG** is performed (Carey).

**1966** Emergence of ultrasound based techniques with **saline infusion sonography** (SIS) (Corfman and Taylor).

**1993** Introduction of **Hysterosalpingo Contrast Sonography** (HyCoSy) (Deichert), a patient friendly ultrasound technique. However, the common contrast medium Echovist® (Schering AG, Berlin, Germany) was taken out of market and replaced by saline and air. Saline and air which accuracy is not comparable to HSG, is now the mostly used alternative.[6]

**2011** Introduction of **Hysterosalpingo Foam Sonography** (HyFoSy) (Exalto and Emanuel), an in-office procedure for tubal patency testing in women with known or suspected infertility or subfertility. ExEm® Foam is the medium used in HyFoSy.

**2017** **HyFoSy proven accuracy and minimum invasiveness.** Studies confirmed that, with proper imaging technique, HyFoSy with ExEm® Foam does not significantly differ from laparoscopy with dye, and has the ability to achieve significantly higher accuracy than 2D saline and air.

**2022** **HyFoSy, the future of tubal patency assessment** The foam study, a large randomized control study confirms that HyFoSy leads to similar pregnancy outcomes, compared with HSG as first-choice patency test. HyFoSy is experienced as significantly less painful than HSG.[14]

*Moving women's health forward*

# References:

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4.Laparoscopy and dye is seen as essential under certain conditions. For instance, in the UK, the NICE (national Institute for Health and Care Excellence) guidance states that "Women who are thought to have comorbidities (such as pelvic inflammatory disease, previous ectopic pregnancy or endometriosis) should be offered laparoscopy and dye so that tubal and other pelvic pathology can be assessed at the same time."

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**Important safety information:**
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).
ExEm® Foam is intended for use by medical professionals skilled in ultrasound tubal patency testing. ExEm® Foam is intended for single use only.

**Contraindications:**
- Do not use the foam during pregnancy.
- Do not use the foam if the patient may be pregnant.
- Do not use the foam between ovulation and menstruation.
- Do not use the foam in the presence of active pelvic infection, sexually transmitted diseases and profuse bleeding.
- Do not use the foam in case of allergy to any of the constituents of ExEm® Gel (hydroxyethyl cellulose, glycerol and purified water).

***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.***

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women's health

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