

Hysterosalpingo Foam Sonography (HyFoSy) Ultrasound Tubal Patency Testing

The HyFoSy Procedure

Proven Track Record 1 mil+

fallopian tubes assessed

50+ countries performing HyFoSy

> 40+ clinical publications with positive outcomes

10+ years of experience in clinics globally



Foam is the future











Proximal portion of left tube at isthmus



Transverse uterus, Bilateral tubes



Right fallopian tube



Patent tube right



Foam around ovary





Bilateral proximal patent fallopian tubes

Images below were scanned in a European clinical setting. Individual scanning techniques may vary.



Patent fallopian tube



Patent tube with spillage around ovary

Patent fallopian tube



Spillage around ovary



Additional images and video samples available upon request.

Images below were scanned in a European clinical setting. Individual

scanning techniques may vary. (Source: Ludwin I., et al. 2017)



ExEm® Foam images of the uterus with the fallopian tubes in two women with known or suspected infertility. The left column shows patency in both fallopian tubes and the right column shows occlusion in left tube.

Technology used (top to bottom):

- 2D-HyFoSy (A+B)
- Offline HD-live rendered
- 3D-HyFoSy (C+D)
- 2D-HDF-HyFoSy (E+F)
- Offline color-rendered
- 3D-HDF-HyFoSy (G+H)

Patent tube right, Proximal block left tube



When constituted, ExEm® Foam produces approximately 127,000 micro air bubbles, making the image bright and white, providing a clear view of where the foam is.

When the foam is injected into the uterus and tubes, patent fallopian tubes will appear as a thin, echogenic (bright white) line, when visualized with ultrasound. If the white line does not appear, the tubes might be occluded.

The HyFoSy Procedure The only option comparable to the Gold Standard.



Ultrasound tubal patency testing with foam (HyFoSy): Doppler techniques objectively confirm the contrast flow and generate easy to interpret pictorial documentation of exam. (A) 2D-HyFoSy in gray scale (left) and tissue Doppler imaging (center and right). (B) 3D-HyFoSy in gray scale (left), HDlive render mode (center and right). (C) 3D-HyFoSy and power Doppler. Power Doppler generates a highly useful sign called flaming tube sign and makes diagnosis very easy to interpret for low and medium experienced users (53).

(Source: Devine. Modern pre-ART uterine and tubal assessment. Fertil Steril 2022)

"The addition of Doppler with high-definition flow imaging improved the accuracy of HyFoSy to the level of laparoscopy."

ExEm[®] Foam benefits

ExEm® Foam is an FDA-approved ultrasound contrast agent that allows for convenient in-office ultrasound tubal patency testing for woman with known or suspected infertility. Studies suggest that the accuracy of ExEm® Foam used with 2D/3D-HDF-HyFoSy does not significantly differ from the gold standard laparoscopy with dye procedure².

The HyFoSy procedure using ExEm[®] Foam is less painful than X-ray HSG³ and offers real-time results. It does not involve X-ray, iodine or placing a cervical tenaculum and traction on the cervix. These features provide patients with a more comfortable and less painful procedure (than X-ray HSG), as well as a quick and conventient option for the evaluation of tubal patency.

The HyFoSy procedure

Any 2D ultrasound machine, operated by a skilled sonographer, can be used to perform 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 women with known or suspected infertility⁴. Any transcervical catheter with luer connection, designed for intrauterine application (5 Fr. or larger), can be used.

ExEm® Foam Kit



Side opening speculum



Sterile disposables for aseptic reconstitution of the foam



Gynecological catheter 5-Fr or larger

Exam table with stirrups



□ 2D US machine with vaginal probe







Transvaginal probe with cover



The procedure is straightforward

- 1. Prepare ExEm[®] Foam as indicated in the prescribing Information.
- 2. Place side-opening speculum.
- 3. Insert a small amount of foam into the catheter to expel air. Place the catheter in the cervix.
- 4. Remove the speculum and place TVUS transducer under the catheter.
- 5. Confirm proper placement of catheter; infuse 1 ml. Foam into the uterine cavity (foam will be visible).
- 6. Once confirmed, infuse 2-3 ml to fill the fallopian tubes.
- 7. Start longitudinally, spot fundus and rotate to transverse plane. This will visualize the flow of the foam through the tubes.
- 8. Spot intramural of right tube and continue to distal.
- 9. Tubal patency is determined by the ability of the foam to fill, or flowing through, the tubes and/or spilling of foam intra-abdominally.
- 10. Repeat at left side (be prepared for a winding tube).



ExEm[®] Foam should not be used on patients who are pregnant, have known or suspected lower genital tract inflammation or infection, have had a gynecologic procedure with in the last 30 days, have vaginal bleeding, or have known or suspected reproductive tract neoplasia.

Common side effects include pelvic and abdominal pain, vasovagal reactions (and associated symptoms nausea such as and faintness), and post-procedure spotting. See full prescribing information (available at www.exemfoam.com/resources) for further details or scan QR code below with your smart device.

Prepare your patients

We strongly encourage you to read the full prescribing information and educate your patients about the HyFoSy Procedure using ExEm® Foam in advance of their appointment.

Ideal Patient Profile:

- Negative pregnancy test within the 24 hours before ExEm® Foam administration
- Pre-ovulatory phase of her menstrual cycle (cycle days 6 through 11)
- No known or suspected lower genital tract inflammation or infection
- No gynecologic procedure within the last 30 days
- No vaginal bleeding
- No known or suspected reproductive tract neoplasia
- Empty bladder 5 10 minutes prior to appointment

Patient Friendly

- Gentle, Less Painful, Less Anxiety
- Safe (no radiation, no iodine)
- **More Convenient**

Helpful tips

For optimal imaging results, we highly recommend viewing the ExEm® Foam procedural video and the following checklist:

Check your catheter	
	You will need a 5fr or larger, IUI, or balloon catheter. If using a balloon catheter, it is not necessary to fully inflate the balloon.
	As a reminder, verify the catheter is in proper position.
Check your ultrasound settings	
	Scan under your Gyn settings on the ultrasound machine.
	Set your imaging depth at a level to include the entire uterus, as well as the adnexa and posterior to the uterus.
	If you are having difficulty visualizing the fallopian tube, decrease the gain settings on the ultrasound machine. This will allow for more contrast and easier visualization of the fallopian tube.
	While you can certainly do 3D images with this technique it is not necessary, a standard 2D image is all that is needed to perform this exam.
	When performing a 3D sweep, make sure your sector angle is completely open for maximum visualization of the fallopian tubes.
Check your patient	
	For optimal visualization, it is beneficial for your patient to have an empty bladder; this will also reduce discomfort. If you find it helpful for catheter placement, ask your patient to leave a small amount in her bladder.
	It is recommended to perform a quick ultrasound prior to the procedure to ensure a hydrosalpinx is not visualized. This will also allow you to get familiar with your patient's anatomy.
	If you are having difficulty visualizing the tube or ovary during the HyFoSy procedure, you may try gently pressing on your patient's abdoment on help push any gas and bowel away that may be effecting visualization.
	If you are having difficulty following the tube from the intramural portion of the tube, you can start at the ovary and work your way back to the uterus.
	Once you see a portion of the tube, make small movements to elongate the entire tube.
	As the foam travels through the cavity of the uterus, it will take time to make it's way into the fallopian tubes and spill out. It may take more than 30 seconds until visualization of the foam traveling through the tubes may be seen.
Check the foam	
	If you are having trouble visualizing the foam when injecting into the cavity, check the foam to make sure the consistency is a milky white concentrate. If it's not, reconstitute the foam then inject again.

er going through the above items you still experience image quality issues, please contact your assigned ExEm® Foam Clinical lications Specialist or Sales Executive.



1.888.963.EXEM (3936)



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www.exemfoam.com

References

- 1. Devine, K, et al. Modern assessment of the uterine cavity and fallopian tubes in the era of high-efficacy assisted reproductive technology. Fertil Steril. 2022 [ul;118(1):19-28. doi: 10.1016/j.fertnstert.2022.05.020. PMID: 35725118; PMCID: PMC9348809.
- 2. Ludwin I., Ludwin, A. et al. Accuracy of hysterosalpingo-foam sonography in comparison to hysterosalpingo-contrast sonography with air/saline and to laparoscopy with dye. Human Reproduction 2017, 32(4):758–769
- 3. Dreyer, K., Out, R. et al. Hysterosalpingo-foam sonography, a less painful procedure for tubal patency testing during fertility workup compared with (serial) hysterosalpingography: A randomized controlled trial. Fertility and Sterility 2014, 102(3):821-25
- 4. Riganelli L., Casorelli A. et al. Ultrasonography reappraisal of tubal patency in assisted reproduction technology patients: comparison between 2D and 3D-sonohysterosalpingography. A pilot study. Minerva Ginecologica 2018, 70(2):123-8

Important Safety Information

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