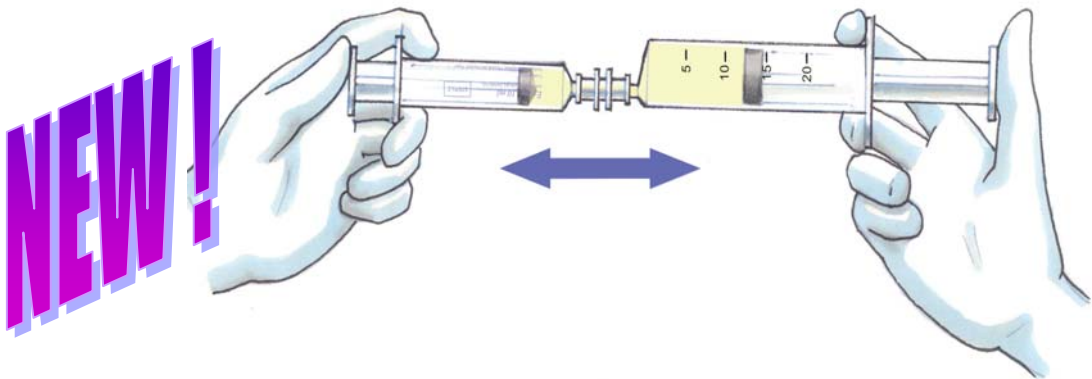
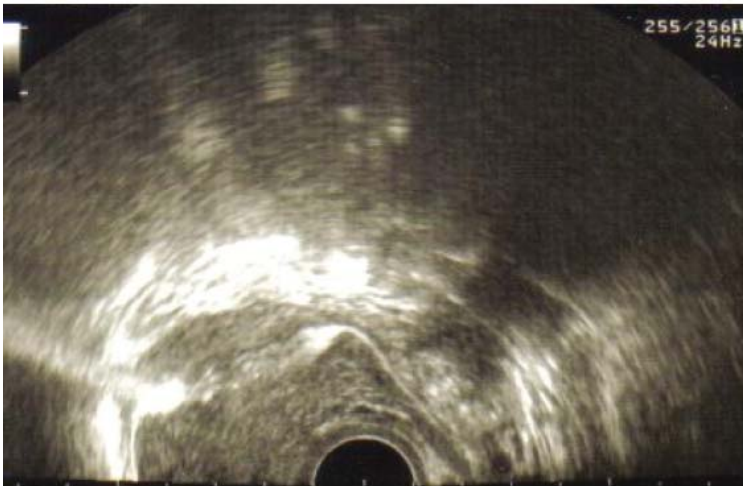


# ExEm® Foam Kit



The ExEm® Foam Kit enables easy recognition of tubal patency by using a new technique: Hysterosalpingo Foam Sonography (HyFoSy). The ExEm® Foam Kit has been developed for creating a foam. After infusing the foam through the uterine cavity into the fallopian tubes, practical ultrasound images can be obtained to check the patency of the fallopian tubes in infertility patients. This technique also enables verification of the correct placement of the micro implants after a sterilization procedure (Essure or Adiana).

## Benefits



- Clinic based solution
- A bright visualization of contour of fallopian tubes and uterine cavity contour
- Used in combination with ultrasound imaging
- Useful in case of infertility or after a sterilization procedure
- Less need for radiology or laparoscopy

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## GISKIT B.V.: ExEm® Foam-kit

**STERILE unless package has been opened or damaged.**

**FOR SINGLE USE ONLY. DO NOT REUSE.**

**Description:** With the ExEm® Foam-kit, a foam can be created for Hysterosalpingo Sonography. By diluting the ExEm® gel with purified water, a foam is created which causes a fast and simple extension of the walls of the fallopian tubes. Subsequently high quality ultrasound images can be obtained. The ExEm® Foam-kit contains a 10 ml syringe with ExEm® gel, a 10 ml syringe with purified water, an empty 20 ml syringe and a coupling device.

**Indications and usage:**

All indications for creating foam for Hysterosalpingo Sonography.

**Contraindications:**

Do not use the foam during pregnancy.

Do not use the foam if the patient is suspected to be pregnant/could 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 (hydroxyethylcellulose, glycerol and purified water).

**Warnings:**

The ExEm® Foam-kit should be considered as contaminated medical waste after use.

Do not use if package has been previously opened or damaged.

Do not re-sterilize.

Reuse of this product can result in danger to the patient.

Do not use the ExEm® Foam-kit after expiry date of ExEm® gel, the purified water, the 20 ml syringe and/or the coupling device.

Do not use the ExEm® gel and the purified water separately for Hysterosalpingo Sonography.

The ExEm® gel and the purified water are not to be used for injections.



**INSTRUCTIONS FOR USE:**

Connect the empty 20 ml syringe and the coupling device. (Fig. 1.)

Connect the 10 ml syringe with purified water to the coupling device as mounted on the 20 ml syringe.

Inject the complete contents of purified water into the 20 ml syringe. (Fig. 2.)

Disconnect the empty 10 ml syringe and leave the coupling device on the 20 ml syringe. The 20 ml syringe is now partly filled with purified water.

Connect the 10 ml syringe with ExEm® gel with the coupling device which is left on the 20 ml syringe.

Dilute the ExEm® gel with the purified water by injecting the fluids from one syringe through the coupling device into the other syringe (at least 10 times). This creates a foam. (Fig. 3.)

Leave the foam in the 20 ml syringe and disconnect the syringes.

Subsequently the Hysterosalpingo Sonography procedure can be executed. Attention: when executing the Hysterosalpingo Sonography procedure use at least a 7 French catheter.

**Storage conditions:** the ExEm® Foam-kit shall be stored in a suitable room and at a temperature not exceeding +25°C.

**Transport conditions:** During transport of the ExEm® Foam-kit a temperature in the tolerance range between +40°C and -10°C must be maintained. However, the Products may temporarily (no longer than one week) be exposed to temperatures up to +40°C and -20°C.

**Important notice:** Farco-Pharma GmbH, the manufacturer of the 10 ml syringe with purified water, has extended the intended use of the purified water with "dilution of gels".

**Patents pending:** NL 2003660.

**Sterile:**

The ExEm® Foam-kit contains the following sterile products with CE markings:

Farco-Pharma 10 ml syringe with ExEm® gel

Farco-Pharma 10 ml syringe with purified water

NIPRO 20 ml syringe

Infused coupling device

**FOR FURTHER INFORMATION VISIT [WWW.EXEMFOAMKIT.CO.UK](http://WWW.EXEMFOAMKIT.CO.UK)**