



English

GISKIT B.V.: ExEm® Foam Kit FK05, FK05-LM969 or FK05-LN970

STERILE unless package has been opened or damaged.

FOR SINGLE USE ONLY. DO NOT REUSE.

The ExEm® Foam Kit is intended for use by medical professionals skilled in ultrasound tubal patency testing.

Description

With the ExEm® Foam Kit, a foam can be created for Hysterosalpingo Sonography.

By diluting the ExEm® Gel with ExEm® Water (= purified water), a gel foam is created which enables a fast and simple distension of the walls of the fallopian tubes. Subsequently high quality ultrasound images can be obtained. The ExEm® Foam Kit **FK05** contains a 10 ml syringe with 5 ml ExEm® Gel, a 10 ml syringe with 5 ml ExEm® Water and a coupling device. The ExEm® Foam Kit **FK05-LM969** or **FK05-LN970** contains also a GIS Catheter with cervical canule LM969 or LN970.

Indications and usage All indications for creating foam for Hysterosalpingo Sonography.

Contraindications

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

Precautions and 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.
- This device is intended for single use only. Any foam not used in one examination session must be discarded.
- Do not reuse, re-sterilize or autoclave. Reuse of single use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilization may compromise essential material and design characteristics leading to device failure. The manufacturer will not be responsible for any direct, incidental or consequential damages resulting from re-sterilization or reuse.
- Do not use the ExEm® Foam Kit after the expiry date of the ExEm® Gel, the ExEm® Water, the coupling device and/or the GIS catheter.
- Do not use the ExEm® Gel and the ExEm® Water separately for Hysterosalpingo Sonography.
- The ExEm® Gel and the ExEm® Water are not to be used for injections.

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.

INSTRUCTIONS FOR USE

1. Dilute the 5 ml ExEm® Gel with the 5 ml ExEm® Water by mixing the fluids from one syringe through the coupling device into the other syringe (at least 10 times). This creates a gel foam (fig. 1).
2. Leave the gel foam in one syringe and disconnect the other syringe and coupling device.
3. Connect the syringe containing the gel foam to a suitable (GIS) catheter and infuse the gel foam within approximately 5 minutes.
4. Introduce side-opening speculum (fig. 2).
5. By gently filling the catheter with gel foam, allow the air to escape the catheter before introduction. Introduce the catheter into the cervix (fig. 3).
6. Remove speculum (fig. 4).
7. Position the ultrasound transducer and slowly infuse small amounts of gel foam, 2-3 ml, to avoid discomfort (fig. 5).
8. Determine tubal patency (fig. 6).

Storage conditions The ExEm® Foam Kit shall be stored in a suitable room and at a temperature between +4 °C and +25 °C. **Transport conditions** During transport of the ExEm® Foam Kit a temperature in the tolerance range between -10 °C and +40 °C must be maintained. However, the products may temporarily, that is no longer than 72 hours, be exposed to temperatures between -20 °C and +60 °C.

Sterile The ExEm® Foam Kit FK05 contains the following sterile products with CE marking:

1. 10 ml syringe with 5 ml ExEm® Gel (FARCO-PHARMA GmbH)
2. 10 ml syringe with 5 ml ExEm® Water (FARCO-PHARMA GmbH)
3. coupling device (B. Braun Melsungen AG)
4. only FK05-LM969 or FK05-LN970: GIS Catheter (Gynetics Medical Products N.V.)