ExEm® Foam-kit FK10, FK10-LM969 or FK10-LN970

[FK250 = 25 FK10; FK250-LM969 = 25 FK10-LM969; FK250-LN970 = 25 FK10-LN970]

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 gel foam is created which causes a fast and simple distension of the walls of the fallopian tubes. Subsequently high quality ultrasound images can be obtained.

The ExEm® Foam-kit FK10 is a procedure pack that contains a 10 ml syringe with ExEm® gel, a 10 ml syringe with purified water, an empty 20 ml syringe, a coupling device.

The ExEm® Foam-kit FK10-LM969 or FK10-LN970 contains also an ExEm® HSG 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 the package of one of the products 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 purified water, the 20 ml syringe, the coupling device and/or the catheter.
- 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.

Patents pending: NL 2003660; PCT/NL2010/050679.
INSTRUCTIONS FOR USE:

1. Connect the empty 20 ml syringe and the coupling device. (Fig. 1.)
2. Connect the 10 ml syringe with purified water to the coupling device and the 20 ml syringe.
3. Inject the complete contents of purified water into the 20 ml syringe. (Fig. 2.)
4. 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.
5. Connect the 10 ml syringe with ExEm® gel to the coupling device which is left on the 20 ml syringe.
6. Dilute the ExEm® gel with the purified 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. 3.)
7. Leave the gel foam in the 20 ml syringe and disconnect the empty ExEm® gel syringe and coupling device.
8. Connect the 20 ml syringe containing the gel foam to the (ExEm® HSG) Catheter and infuse the foam within approximately 5 minutes.

10. By gently filling the catheter with gel foam, allow the air to escape the catheter before introduction. Introduce the catheter into the cervix.

11. Remove speculum.
12. Position the ultrasound transducer and slowly infuse the foam to avoid discomfort.

Storage conditions: the ExEm® Foam-kit shall be stored in a suitable room and at a temperature between +5°C and +25°C.
Transport conditions: During transport of the ExEm® Foam-kit a temperature in the tolerance range between +5°C and +25°C must be maintained.
Sterile: The ExEm® Foam-kit FK10, FK10-LM969 or FK10-LN970 is a non-sterile procedure pack that contains the following sterile products:

- 10 ml syringe with ExEm® gel (Farco-Pharma)
- 10 ml syringe with purified water (Farco-Pharma)
- 20 ml syringe (Terumo)
- coupling device (Infumed)
- only FK10-LM969 or FK10-LN970: ExEm® HSG Catheter (Origio/Artworks)

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