

REF GISKIT B.V.: the GIS-Kit with GISK M969 or GISK N970



STERILE unless package has been opened or damaged.
FOR SINGLE USE ONLY. DO NOT REUSE.



The GIS-Kit is intended for use by medical professionals skilled in sonohysterography.

Description: Gel Instillation Sonohysterography (GIS). The GIS-Kit allows for quick and simple filling of the uterine cavity with ExEm[®] gel in order to subsequently obtain high quality (3D) ultrasound images. The GIS-Kit contains a syringe with ExEm[®] gel and a GIS catheter with cervical canule M969 or a GIS catheter with cervical canule N970. The M969 has a bit softer cervical applicator and is meant to be used for women who have already given birth to one or more children (M stands for multipara). The N970 has a somewhat stiffer cervical applicator and is meant for women that have not yet given birth (N stands for Nullipara). The difference between M969 and N970 does however not necessarily mean that the N970 cannot be used for Multipara and the M969 cannot be used for Nullipara.

Indications and usage: All indications for sonohysterography.



Contraindications:

The GIS-Kit should not be used in the presence of active pelvic infection, sexually transmitted disease, profuse bleeding or pregnancy. Nor in case of allergy to any of the constituents of ExEm[®] gel (hydroxyethylcellulose, glycerol and purified water).



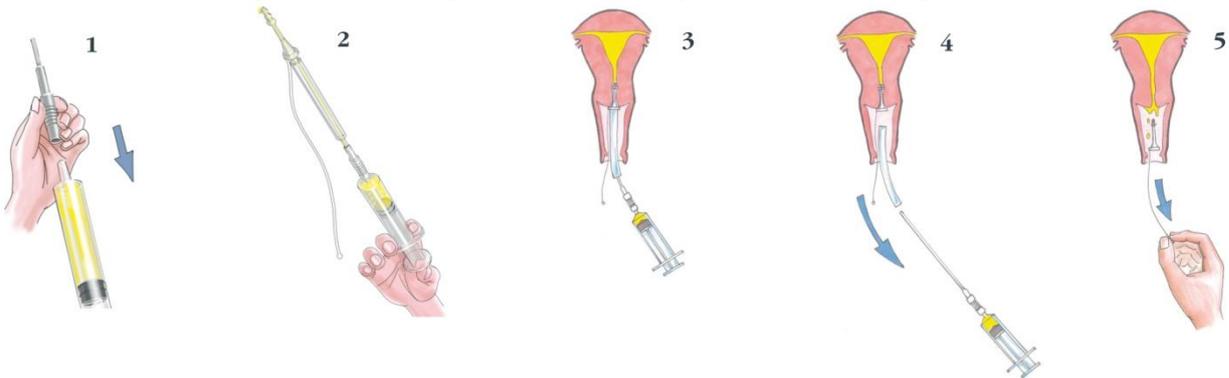
Precautions and warnings:

- The GIS-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. 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 GIS-Kit after the expiry date of the ExEm[®] gel, and/or the expiry date of the tubes/catheters and/or the expiry date of the cervical applicator.
- The ExEm[®] gel is not to be used for injections.



INSTRUCTIONS FOR USE:

1. Connect the with ExEm[®] gel pre-filled syringe to the purple luer cone of the inner tubing/catheter (Fig. 1).
2. Fill the cervical applicator with gel until the tubing and applicator are free of air bubbles (Fig. 2).
3. Insert the cervical applicator into the cervical canal of the uterus until a certain resistance is felt and instill the gel into the uterus until the patient experiences a certain feeling of pain. (Fig. 3).
4. Disconnect the syringe and leave the cervical applicator in place by pulling the syringe (and connected inner tubing/catheter) and holding the outer tubing of the cervical applicator (some drops of gel may leak) (Fig. 4).
5. Complete the ultrasound procedure.
6. Remove the cervical applicator by pulling the cord (ultrasonographer or patient) (Fig. 5).



Storage conditions: products containing ExEm[®] gel shall be stored in a room suitable for storage and at a temperature not exceeding +25°C. **Transport conditions:** during transport of products containing ExEm[®] gel a temperature in the tolerance range between -10°C and +40°C must be maintained. However, the products may temporarily (no longer than one week) be exposed to temperatures between -20°C and +40°C.

Patents granted or pending: WO2007/030002; WO2006/006861; EP1922107; EP1793860; US2009/062770; US 8992887



Sterile: The GIS-Kit contains the following sterile products with CE marking:

1. syringe with ExEm[®] gel (Farco-Pharma)
2. GIS catheter with cervical canule (Gynetics)

 Gynetics Medical Products n.v., Rembert Dodoensstraat 51, 3920 Lommel; Belgium

 Farco-Pharma GmbH, Gereonsmühlengasse 1-11, 50670 Köln; Germany

Assembled and distributed by: GISKIT B.V., Delftechpark 26, 2628 XH Delft; The Netherlands
Tel: +31 15 2600 955 • Fax: +31 15 8901777 • sales@iq-medicalventures.com • www.iq-medicalventures.com