

# EXEM<sup>®</sup> FOAM KIT

## FREQUENTLY ASKED QUESTIONS

### WHAT IS IT MADE OF?

ExEm Foam consists of:

1. ExEm gel – hydroxyethyl cellulose & glycerol.
2. Purified water.
3. When mixed together, a foam of micro-air bubbles is formed.


### WHAT DOES THE EXEM FOAM KIT CONSIST OF?

The new ExEm Foam Kit FK05 now contains a 10ml syringe with 5ml of ExEm<sup>®</sup> gel, a 10ml syringe with 5ml ExEm purified water and a coupling device.

### IS IT A DRUG?

No. It is a Class I Medical device.

### IS IT A SINGLE USE DEVICE?

Yes. For single use only. Do not reuse. 

### IS IT LICENSED FOR UK?

Yes. CE marked for Europe specifically for intra-uterine investigations.

### HOW LONG HAS IT BEEN ON THE MARKET?

ExEm Gel has been available as a component of the GIS Kit (intra-uterine scanning) since 2007 and as part of the ExEm Foam Kit (tubal patency testing) since its launch in March 2010.

### IS IT SAFE? EVIDENCE?

Yes. Since its launch in 2010, over 16000 tubal patency tests (as @ Dec 2014) have been carried out in the UK and Ireland with no reported adverse or allergic reactions.

*‘The combination of glycerol, hydroxyethyl cellulose and purified water is considered to be safe for intrauterine application and tubal patency testing’*

Niek Exalto, Mario Stassen, Mark Hans Emanuel. Safety aspects and side effects of ExEm gel and foam for uterine cavity distension and tubal patency testing. *Reproductive Biomedicine Online* 2014; <http://dx.doi.org/10.1016/j.rbmo.2014.07.015>

Further evidence and safety data is available in the business case document.

### IS THE HYCOSY PROCEDURE UNCOMFORTABLE FOR THE PATIENT?

No. ‘HyCoSy was a well-tolerated examination with a very low rate of side effects and no late complications that required no atropine or anti-inflammatory drugs’

Luca Savelli, Paola Pollastri *et al.* Tolerability, side effects and complications of hysterosalpingocontrast Sonography (hycosy). *Fertility and sterility* 2009 October; Vol. 92, issue 4, pp. 1481-1486.

### WHAT IS THE DIFFERENCE BETWEEN HYCOSY AND HYFOSY?

In principle, none. HyFoSy is the HyCoSy procedure using the ExEm **Foam**.

## WHAT CATHETER SHOULD YOU USE?

Preferably GIS M969 catheter – de Smit Medical, balloon catheter – 7 french recommended. NB: 5 french may be used but care should be taken as the reduced lumen may require a slightly greater force when infusing.

## WHAT IS THE GIS CATHETER?

The GIS catheter (de Smit Medical) has a tapered soft tip that is inserted gently into the external OS adapting to each individual patient. By removing the need to insert a balloon catheter fully into the uterus (or inflating a balloon catheter in the cervical canal) some of the discomfort experienced by some patients may be reduced. How do you use the ExEm Foam Kit?

Dilute the 5 ml ExEm® gel with the 5 ml ExEm® 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. Leave the gel foam in one syringe and disconnect the other syringe and coupling device.

Connect the syringe containing the gel foam to a suitable catheter and infuse the gel foam within approximately 5 minutes.

## HOW MUCH DO YOU NEED PER EXAMINATION?

Typically, approximately 2-3 ml. On occasions, more may be required.

## ARE THERE ANY CONTRAINDICATIONS?

### **ExEm Foam Kit:**

Do not use the gel foam in case of allergy to any of the constituents of ExEm gel (hydroxyethyl cellulose, glycerol and purified water).

### **Tubal patency test:**

During pregnancy.

If the patient may be pregnant.

Between ovulation and menstruation.

If the patient has co-morbidities.

In the presence of active pelvic infection, sexually transmitted diseases, and profuse bleeding.

## CAN A PATIENT TRY FOR A NATURAL PREGNANCY OR HAVE AN IUI STRAIGHT AFTER THE HYCOSY?

ExEm is sperm friendly so pregnancy (or even an IUI) can be tried for in the same cycle.

## ULTRASOUND SCANNING OF THE UTERUS

### WHICH SHOULD I DO FIRST, THE TUBAL PATENCY TEST OR THE UTERINE SCAN?

When conducting a combined diagnostic session, the intrauterine scan should always be conducted prior to the tubal patency test. The Uterine scan may highlight conditions that negate the need for the patency test – Hydrosalpinx.

### CAN I USE THE EXEM GEL ON ITS OWN (WITHOUT MIXING WITH PURIFIED WATER) TO SCAN THE UTERUS?

Yes. The ExEm Gel on its own is an excellent dilator and will facilitate enhanced images due to its highly echogenic nature. **Caution:** due to the high viscosity of the ExEm Gel, a wait of at least 2 hours is recommended before then conducting a tubal patency test.

## HOW LONG SHOULD I WAIT BETWEEN THE UTERINE SCAN AND THE PATENCY TEST?

This will depend upon the contrast solution used for the uterine scan.

No contrast – immediately.

Saline – wait for a few minutes for the cavity to empty (remove the catheter).

ExEm Gel – min 2 hours.

## WHEN SHOULD I PERFORM THE PATENCY TEST?

‘Tests of tubal patency are usually performed during the follicular phase of the cycle after menstruation has ceased’

*The Fallopian Tube in Infertility and IVF Practice, chapter on Fallopian Tube Patency Testing – Stephen R. Killick: Cambridge Medicine*

## WHAT SHOULD I DO IN THE EVENT OF TUBAL SPASM?

Wait a few minutes for the spasm to stop and then continue scanning. It should not be necessary to infuse more foam unless echogenicity has been low.

## HOW LONG DO THE MICROBUBBLES STAY AS A FOAM?

At least 5 - 7 minutes (sealed syringe). The remaining solution may be remixed in the syringe to re-introduce the air bubbles.

## HOW LONG DO YOU HAVE VISUALISATION ONCE THE FOAM HAS BEEN INFUSED?

Once the required amount of the foam has been infused (2 – 3 ml) echogenicity should be maintained for approximately 7 minutes. If the test is prolonged, it may be necessary to infuse more of the Foam.

## HOW MUCH DOES IT COST?

Please contact de Smit Medical for all pricing information.

## HOW CAN I ORDER & PAY?

Only official orders will be accepted with payment being made against invoice issued.

## STORAGE REQUIREMENTS? TEMPERATURE? LIFE?

Store in suitable room and at a temperature between +5°C and +25°C.

**During transport of the ExEm Foam Kit, a temperature in the tolerance range between +5°C and +25°C must be maintained. However, the products may temporarily (no longer than one week) be exposed to temperatures up to +40°C.**

Typically, 2 years shelf life detailed on packaging, unopened.

## CAN THE EXEM FOAM KIT BE USED ON A PATIENT WHO HAS AN ALLERGY TO FISH?

There is no compound in the ExEm Foam Kit related to fish.