

# Frydman<sup>®</sup> Soft 4.5 with guide

## Warning

Read the complete directions before use.

- Failure to properly follow the instructions, warnings and cautions may lead to serious surgical consequences or injury to the patient.
- These procedures should only be performed by persons having adequate training and familiarity with these techniques.
- Consult medical literature regarding techniques, complications and hazards prior to performance of these procedures.
- To be used by or under the direction of qualified persons in line with local guidelines governing Assisted Reproductive Techniques, if applicable.

STERILE: Contents sterile unless package has been opened or damaged. Discard if product or packaging is damaged.

## Description

Order code	<b>FET-G</b>		
Designation	<b>Frydman<sup>®</sup> Soft 4.5 with guide</b>		
Units per box	Box of 10 units		
Features	<b>Inner catheter</b>	<b>Outer sheath</b>	<b>Stylet</b>
Usable length	21.5 cm	18 cm	17.5 cm
Length of flexible tip overhanging the outer sheath	4.5 cm	-	-
Internal volume	0.20 ml	-	-
External diameter	1.60 mm	2.20 mm	1.55 mm
Components	Polyethylene	Polypropylene	Polyethylene coated steel
Specific feature	Supported by an internal steel micro tube 0.5 mm in diameter	-	-

The device includes:

- An outer sheath in polypropylene with 6 guide-marks every centimeter
- An embryo transfer catheter in flexible polyethylene in its distal section and rigidified in its proximal section by an inner metal sheath, to help its handling
- A malleable metal stylet coated in polyethylene

Class I medical device, complying with Directive 2007/47/CE.

CE 0120 Marking.

U.S. Federal law restricts this device for sale by or on the order of a physician.

Single use: Discard after single use.  
Latex free.  
Individually sterile package.  
Sterilized by irradiation. Do not resterilize.

### Indications

In vitro fertilization (IVF): embryo transfer in the uterine cavity when cervical access is difficult.

### Contraindications

The catheter should not be used:

- in the presence of chronic cervical infection
- in the presence of or after recent pelvic inflammatory disease
- for intra-fallopian procedures

### Caution

- Prior to use, all devices coming in contact with gametes should be checked for integrity and rinsed with appropriate biological media.
- The catheter should never be forced against digitally felt resistance while inside the uterine cavity, as this may result in damage to the endometrial tissue and bleeding.
- The outer sheath and stylet should not be advanced further than the internal os, and should certainly never enter the uterine cavity, as this may result in damage to the endometrial tissue and bleeding.
- The inner catheter is only to be used with the outer sheath as provided.

### Instructions for use

A trial catheterization can be performed beforehand

- either during a cycle prior to the embryo transfer
- or just before the transfer

Data collected during a trial catheterization is recorded in the patient's file (uterus size, shape of cervical canal, selection of most suitable device) to help anticipate any difficulty during the real transfer and to help choose the best suited catheter.

To proceed with the embryo transfer with the Frydman® Soft 4.5 with guide:

- Before loading the embryos, shape the outer sheath and its stylet in their sterile packaging, to fit the profile of the cervical canal.
- Position the outer sheath in the cervix, while recording the length introduced in the cervical canal.
- Remove the stylet.
- Rinse first the transfer catheter with the appropriate biological medium and load the catheter with the embryos.

- Place the loaded transfer catheter in the outer sheath positioned in the cervix.
- When the first guide-mark on the inner catheter is level with the base of the outer sheath, their two distal extremities coincide in the uterine cavity.
- Gently push the inner catheter gently further inside the uterine cavity to obtain the desired exposure while controlling the centimeter guide-marks close to the base.
- Expel the embryos gently by pushing the syringe's plunger.
- Remove the outer sheath and transfer catheter together to avoid any aspiration effect.