

Frydman[®] Memory Catheter 4.5

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	FET-M
Designation	Frydman [®] Memory Catheter 4.5
Units per box	Box of 10 units
Total length	18 cm
Internal diameter	1.10 mm
External diameter	2.10 mm
Hysterometry guide-marks	5.5 / 6.5 / 7.5 cm
Components	Polyethylene
Specific features	One piece catheter Integrated metal guidewire

One piece catheter in polyethylene including:

- A distal opening,
- Three hysterometry guide-marks from the extremity.
- A formable guidewire integrated within the catheter wall and which does not come in contact with the transfer lumen.



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 when access through the cervical canal 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.

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 chose the best suited catheter.

To proceed with the embryo transfer with the Frydman[®] Memory Catheter 4.5:

- Before loading the embryos, pre-shape the catheter in its sterile envelope to fit the configuration of the cervix as defined during the trial catheterization.
- Connect the catheter to an IVF syringe and rinse it with the appropriate biological medium.
- Load the embryos in the catheter.
- Gently introduce the catheter without touching the uterine fundus using the hysterometry guidemarks. A slight rotation of the catheter helps overcome certain cervical obstacles.
- Expel the embryos gently by pushing the plunger of the syringe.
- Remove the catheter gently while rotating it.