

Frydman[®] Classic Catheter 4.5

Frydman[®] Classic Catheter 5.5

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-C4.5 | FET-C5.5 |
|----------------------------|---|---|
| Designation | Frydman [®] Classic Catheter 4.5 | Frydman [®] Classic Catheter 5.5 |
| Units per box | Box of 25 units | Box of 25 units |
| Total length | 18 cm | 19 cm |
| Length of the flexible tip | 4.5 cm | 5.5 cm |
| Internal volume | 0.25 ml | 0.28 ml |
| Internal diameter | 1.1 mm | 1.1 mm |
| External diameter | 1.6 mm | 1.6 mm |
| Hysterometry guide-marks | 5.5 / 6.5 / 7.5 cm | 6.5 / 7.5 / 8.5 cm |
| Components | Polyethylene | Polyethylene |

One piece catheters in polyethylene with:

- An atraumatic distal opening
- A flexible extremity
- A strengthened proximal section for better handling

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 the permeability of the cervical canal is normal.

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 choose the best suited catheter.

To proceed with the embryo transfer with the Frydman[®] Classic Catheter 4.5 or 5.5:

- Connect the Frydman[®] Classic Catheter to an IVF syringe and rinse with the appropriate biological medium.
- Load the embryos in the catheter.
- Gently introduce the catheter in the cavity without touching the uterine fundus using the hysteroscopy guide-marks.
- Expel the embryos slowly by pushing the syringe's plunger.
- Remove the Frydman[®] Classic Catheter gently.