

Stylet for Frydman[®] Soft/Ultrason Catheter

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	F-Stylet
Designation	Stylet for Frydman[®] Soft/Ultrason catheter
Units per box	Box of 10 units
Usable length	17.5 cm
External diameter	1.55 mm
Components	Polyethylene coated steel

Malleable metal guidewire coated in polyethylene, 17.5 cm long, and 1.55 mm in diameter.

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): the Stylet for Frydman® Soft/Ultrasoft Catheter is used with the transfer catheters Frydman® Ultrasoft 4.5 or Frydman® Ultrasoft 4.5 Echo, when access through the cervix is difficult. It is used to rigidify and shape the outer sheath to a desired profile.

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

Use of the Stylet for Frydman® Soft/Ultrasoft during a transfer with Frydman® Ultrasoft 4.5 or Frydman® Ultrasoft 4.5 Echo in case of difficult cervical access:

- Separate the transfer catheter from the outer sheath so that biologist can load the embryos, taking care to leave the outer sheath in its sterile packaging.
- Place the malleable stylet in the outer sheath which has remained in its sterile packaging.
- Without taking it out of the packaging, pre-shape the stylet with outer sheath, based on the data collected during the trial catheterization.
- Gently insert the outer sheath and stylet up to the internal orifice of the cervix, rotating it slightly if insertion is difficult.
- Once the stylet with outer sheath is positioned correctly in the endocervix at the distance recorded during the trial catheterization, remove the stylet from the outer sheath.
- Proceed with the embryo transfer using one of the following transfer catheters previously loaded:
 - Frydman® Ultrasoft 4.5
 - Frydman® Ultrasoft 4.5 Echo