

Frydman[®] Ultrasoft 4.5 Echo

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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 Ultra	FET Ultra-E	F-Stylet
Designation	Frydman [®] Ultrasoft 4.5	Frydman [®] Ultrasoft 4.5 Echo	Stylet for Frydman [®] Ultrasoft
Units per box	Box of 10 units		Box of 10 units
Technique	Classic Embryo Transfer	Echoguided Embryo Transfer (echogenic metal ring around the catheter tip)	Clearing difficult cervixes

Features	Frydman [®] Ultrasoft 4.5		Stylet for Frydman [®] Ultrasoft
	Frydman [®] Ultrasoft 4.5 Echo		
	Outer sheath	Inner catheter	
Usable length	14.5 cm	21.5 cm	17.5 cm
Length of flexible tip	-	4.5 cm	-
Internal volume	-	0.18 ml	-
Internal diameter	-	0.7 mm	-
External diameter	2.20 mm	1.55 mm	1.55 mm
Components	Polypropylene	Polyurethane	Polyethylene coated steel

FRYDMAN_ULTRASOFT_4_5_ FRYDMAN_ULTRASOFT_4.5_ECHO_US_IR_Version V5_March_2010

The devices include:

- an outer sheath in polypropylene with 6 guide-marks every centimeter
- a transfer catheter in ultrasoft polyurethane in its distal section and rigidified in its proximal section by an internal sheath for better handling

The echogenic model of this catheter has a beveled ring at its tip in brushed stainless steel visible on ultrasound images.

When placed in the outer sheath, the transfer catheter sticks out by 4.5 cm from the distal extremity of the outer sheath. The length of the catheter inside the uterus can be calculated from the centimeter guide-marks near the base.

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 when cervical access is easy (without stylet) or difficult (with stylet).
- The ultrasoft transfer catheter limits trauma caused when going through a narrow or angled cervix.
- The stylet (available separately) is used to shape the outer sheath prior to its insertion and clear a difficult cervix more easily.
- The echogenic model optimizes the transfer conditions as the cervical canal and transfer site can be visualized.

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.

Use without stylet (easy cervical access):

- Leave the transfer catheter in the outer sheath while the biologist loads the embryos.
- When the catheter is loaded, pull back the transfer catheter slightly inside the outer sheath to protect its extremity.
- Gently introduce the set (outer sheath and protected transfer catheter) up to the internal orifice of the cervix. When the first guide-mark on the transfer catheter is level with the base of the outer sheath, their two distal extremities coincide in the uterine cavity.
- Gently push the inner catheter inside the outer sheath to obtain the desired exposure and deposit the embryos.
- Remove the outer sheath and catheter together, to avoid any aspiration effect.

Use with the Stylet for Frydman® Soft/Ultrasoft catheter (difficult cervical access):

- Separate the transfer catheter from the outer sheath so that the biologist can load the embryos, taking care to leave the outer sheath in its sterile packaging.
- Place the malleable metal stylet in the outer sheath which has remained in its sterile packaging.
- Pre-shape the outer sheath with its stylet while still in the packaging to suit the shape of the cervical canal.
- Position the outer sheath and its stylet in the cervix and record the length introduced inside the cervix.
- Remove the stylet.
- Place the loaded transfer catheter in the outer sheath. When the first guide-mark on the transfer catheter is level with the base of the outer sheath, their two distal extremities coincide in the uterine cavity.
- Gently push the inner catheter inside the outer sheath to obtain the desired exposure and deposit the embryos.
- Remove the outer sheath and catheter together, to avoid any aspiration effect.

Use with ultrasound guidance:

The two procedures above can be used when performing a transfer with ultrasound guidance, which is made easier with the Frydman® Ultrasoft 4.5 Echo.