

Ultrasoft Mock Echo

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	FTT-E	
Designation	Ultrasoft Mock Echo	
Units per box	Box of 10 units	
Technique	Echoguided Trial Transfer	
	Outer sheath	Inner catheter
Usable length	14.5 cm	21.5 cm
Length of flexible tip overhanging the outer sheath	-	4.5 cm
External diameter	2.20 mm	1.55 mm
Hysterometry guide marks	6	-
Components	Polypropylene	Polyurethane
Echo marker	-	Stainless steel echo marker integrated in the catheter tip
Specific feature	-	Closed extremity

The Ultrasoft Mock Echo catheter includes:

- a polypropylene outer sheath with 6 hysteroscopy guide-marks
- an ultra-flexible inner catheter with an echogenic internal marker made of stainless steel. The catheter's extremity is closed
- When in the outer sheath, the ultra-flexible inner catheter sticks out 4.5 cm from the distal extremity of the outer sheath. The length introduced inside the uterus can be determined with 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

Ultrasound-guided trial catheterization before an embryo transfer.

A trial catheterization can be performed

- 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.

The Ultrasoft Mock Echo Catheter is used to reproduce the exact conditions of a real transfer with a Frydman[®] Ultrasoft 4.5 or a Frydman[®] Ultrasoft 4.5 Echo catheter.

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 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

- Proceed as if for a real embryo transfer:
- For the first attempt at a trial catheterization, introduce the set (outer sheath and ultra-flexible catheter sticking out by 4.5 cm) in the cervical orifice under ultrasound guidance.

If access through the cervix is easy:

- The ultrasoft catheter tip clears the cervix without difficulties.
- Ultrasound images show the configuration of the cervix as well as the progression of the ultra-soft catheter up to the chosen transfer site.

If the ultra-flexible catheter meets a cervical obstacle:

- Slide the outer sheath over the ultra-soft catheter to protect its tip during the introduction.
- Under ultrasound guidance, insert the outer sheath and protected trial catheter set up to the internal orifice of the cervix, rotating it slightly to clear any obstacle in the cervix.
- Once the outer sheath is correctly positioned in the endocervix, record the length introduced in the cervical canal.
- Under ultrasound guidance, gently push the inner catheter through the outer sheath.
- When the first proximal guide-mark of the inner trial catheter is level with the base of the outer sheath, their two distal extremities coincide in the uterine cavity.
- Gently push the trial catheter further into the uterine cavity to obtain the desired exposure.
- Record the total length not to be exceeded, the size of the uterus, the shape of the cervical canal, and any obstacle met.
- Gently remove the outer sheath and trial catheter together.