

Full 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

Full Echo[®] provides maximum control over transfer conditions: Echogenicity is afforded by two transparent areas alternating with two white areas of different density throughout the length of the catheter. This patented technology leaves the transfer lumen visible during loading or microscope control, and provides excellent echogenicity during the transfer procedure.

Full Echo[®] devices include:

- an ultrasoft transfer catheter, echogenic on its whole length. The catheter includes a metal stiffener integrated in its structure to stiffen the proximal segment and improve handling without touching the catheter tip.
- an FEP (fluoroethylene propylene) outer sheath with 6 circular guide-marks, visible irrespective of the direction of the outer sheath when in use,
- a removable malleable stylet to shape the outer sheath prior to its insertion and help clear a difficult cervix more easily.

When placed in the outer sheath, the reimplantation catheter overhangs by 5 cm. Guide-marks close to the base are used to evaluate the length inserted in the uterine cavity.

Superior design and friction-free components ensure easy sliding motion of the inner catheter through the outer sheath.

Reference	Product name	Characteristics	
		Outer sheath	Inner catheter
FulEchETS-18	FULL ECHO® 18 cm	USP class VI FEP White catheter Outer diameter 2.3 mm 6 circular guide-marks Fitted with removable malleable stylet	2 echogenic white lines integrated in the catheter wall Ultrasoft on distal segment Integrated metal stiffener in the proximal segment to improve handling Outer diameter 1.5 mm Inner diameter 0.5 mm 50 mm overhang out of outer sheath 5 insertion guide-marks close to the base USP class VI PU
FulEchETS-23	FULL ECHO® 23 cm		

Class I medical device complying with Directives 93/42/EEC and 2007/47/EC.
 CE 0120 Marking.
 Single use: Discard after single use.
 Latex free.
 Individually sterile package.
 Sterilized by irradiation. Do not resterilize.

U.S. Federal law restricts this device for sale by or on the order of a physician.

Indications

- For In Vitro Fertilization (IVF): echo-guided embryo transfer when cervical access is easy (without guide) or difficult (with guide).

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 catheterisation with a mock catheter may be performed beforehand:

- either during the cycle preceding the embryo transfer,
- or immediately before the transfer.

Data collected during an echo-guided trial catheterisation 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.

Catheter preparation:

- Rinse the inner catheter with appropriate medium.
- Move the catheter to visualize under microscope the transparent areas and expose fully the catheter lumen.
- Load the catheter.

Echo-guided transfer when cervical access is easy:

- Insert the outer sheath and protected transfer catheter assembly up to the internal orifice of the cervix, rotating it slightly to clear any obstacle identified during the trial catheterization.
- Once the outer sheath is correctly positioned in the endocervix, at the distance determined during the trial catheterization, gently push the inner catheter through the outer sheath.
- When the first proximal guide-mark on the transfer catheter is level with the base of the outer sheath, their two distal extremities coincide in the uterine cavity.
- Push the inner catheter further inside the uterine cavity under ultrasound guidance to obtain the desired exposure.
- Deposit the embryos in the chosen site.
- Gently remove the outer sheath and transfer catheter together while maintaining pressure on the syringe's plunger to avoid any aspiration effect.

Echo-guided transfer when cervical access is difficult:

Using the outer sheath fitted with its stylet:

- Pre-shape the outer sheath and stylet in the packaging according to the cervical profile.
- Position the outer sheath and stylet assembly in the cervix, rotating it slightly to clear any obstacle.
- Record the length introduced in the cervix.
- Remove the stylet.
- Place the loaded transfer catheter in the outer sheath.
- Proceed with the transfer as described above.