PRODIMED

Echogyn® Embryoview®

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	Designation	Units per box	Common characteristics		Specific characteristics of inner catheter
			Outer sheath	Inner catheter	
EchET 18	**Echogyn® Embryoview® 18 cm**	Box of 10 units	FEP White catheter White base External diameter 2.3 mm - 7 French 6 circular guide-marks every centimeter	PU Overhang out of outer sheath 50 mm External diameter 1.5 mm - 4.5 French Internal diameter 0.45 mm Echogenic marker in the catheter wall Yellow base 5 depth markings near the base	Ultrasoft on whole length
EchET 23	**Echogyn® Embryoview® 23 cm**	Box of 10 units			
EchETS 18	**Echogyn® Embryoview® M 18 cm**	Box of 10 units			Supported model : Ultrasoft on distal segment Metal stiffener integrated into the wall of the proximal segment to improve handling
EchETS 23	**Echogyn® Embryoview® M 23 cm**	Box of 10 units			

Echogyn® Embryoview® and Echogyn® Embryoview® M devices include:

- an FEP (fluoroethylene propylene) outer sheath with 6 circular guide-marks every centimeter, visible irrespective of the direction of the outer sheath when in use
- a embryo transfer catheter in ultrasoft polyurethane with an echogenic metal marker integrated in the catheter wall

When placed in the outer sheath, the transfer catheter overhangs by 5 cm. Centimeter guide-marks close to the base are used to read the length inserted in the uterine cavity.

In the Echogyn® Embryoview® version, the inner transfer catheter does not have an integrated metal stiffener and is therefore ultrasoft on its whole length.

In the Echogyn® Embryoview® M version (supported model), the inner transfer catheter has a metal stiffener integrated in its structure to stiffen the proximal segment and improve handling without touching the catheter tip.

Both above-mentioned versions are available in two usable lengths: 18 and 23 centimeters.

With its unique and novel concept, no metal part (echogenic marker or stiffener) comes in contact with the embryo, the medium or the uterine mucosa. The echogenic marker does not conceal the transfer lumen during loading or during post-transfer microscope control. The extreme flexibility of the transfer catheter preserves the integrity of the mucosa.

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): echo-guided embryo transfer in the uterine cavity.

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 an echo-guided 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.

Catheter preparation:
- The outer sheath can be slightly pre-shaped in its packaging, taking care to bend only the tip (do not bend the inner catheter's metal stiffener if using the supported model Echogyn® Embryoview® M).
- Rinse the inner catheter with appropriate medium.
- Leave the transfer catheter in the outer sheath while loading the embryos.
- Once the catheter has been loaded, pull back the transfer catheter slightly inside the outer sheath to protect its extremity.

Echo-guided transfer in case of easy cervical access:
- Insert the outer sheath and protected transfer catheter set up to the internal orifice of the cervix, rotating it slightly to clear any obstacle in the cervix recorded during the trial catheterization.
- Once the outer sheath is correctly positioned in the endocervix, at the distance recorded 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 inner catheter together while maintaining pressure on the syringe's plunger to avoid any aspiration effect.

Echo-guided transfer in case of difficult cervical access:
Using the outer sheath with a stylet (available separately):
- Pre-shape the outer sheath with the stylet in the packaging according to the cervical profile.
- Position the outer sheath and stylet set 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.