PRODIMED

Echogyn® Embryoview® Mock
Echogyn® Embryoview® M Mock

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	
EchTT-18	**Echogyn® Embryoview® Mock 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 Echogenic marker in the catheter wall Green base 5 depth markings near the base	Ultrasoft on whole length
EchTT-23	**Echogyn® Embryoview® Mock 23 cm**	Box of 10 units			
EchTTS-18	**Echogyn® Embryoview® M Mock 18 cm**	Box of 10 units			Supported model : Ultrasoft on distal segment Metal stiffener integrated in the wall of the proximal segment to improve handling
EchTTS-23	**Echogyn® Embryoview® M Mock 23 cm**	Box of 10 units			

The Echogyn® Embryoview® Mock 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
- an inner trial transfer catheter in ultrasoft polyurethane with an echogenic metal marker integrated in the polyurethane

When placed in the outer sheath, the inner 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® Mock version, the inner catheter does not have an integrated metal stiffener and is therefore ultrasoft on its whole length.

In the Echogyn® Embryoview® M Mock version (supported model), the inner 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 uterine 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 an In vitro fertilization (IVF) procedure, a trial catheterization with a trial transfer catheter may be performed previously:

- either during a cycle prior to the embryo transfer
- or immediately 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.

The echogenic marker optimizes trial transfer conditions as the cervical canal and transfer site can be visualized precisely.

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

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 Mock).

Proceed as if for a real embryo transfer:

- 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.
- Remove the outer sheath and trial catheter together.