

Classic Ultrasoft 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	Outer sheath	Inner catheter
CTT-18	Classic Ultrasoft Mock 18 cm	Box of 10 units	FEP White catheter White base	PU Overhang out of outer sheath 50 mm External diameter 1.5 mm - 4.5 French
CTT-23	Classic Ultrasoft Mock 23 cm	Box of 10 units	External diameter 2.3 mm - 7 French 6 circular guide-marks every centimeter	Ultrasoft on whole length Green base 5 depth markings near the base

Classic Ultrasoft 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 internal trial transfer catheter in ultrasoft polyurethane on all its length

When positioned inside 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.

Classic Ultrasoft Mock devices are available in two usable lengths: 18 and 23 centimeters.

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):

A trial catheterization with a mock catheter may be performed previously:

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

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

- Before opening the packaging, the outer sheath may be slightly pre-shaped.
- Proceed as if for a real transfer:
- Insert the outer sheath and protected trial catheter set up to the internal orifice of the cervix, rotating it slightly if insertion is difficult.
- Once the outer sheath is positioned correctly in the endocervix, record the length inserted.
- Gently push the trial transfer catheter through the outer sheath.
- When the first proximal guide-mark of the mock catheter is level with the base of the outer sheath, their two distal extremities coincide in the uterine cavity.

- Gently push the inner trial transfer 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.
- Remove the outer sheath and inner catheter together.