

# Classic Ultrasoft

## 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 codes | Designation                        | Units per box   | Outer sheath  | Inner catheter  |
|-------------|------------------------------------|-----------------|---|---|
| CET-18      | <b>Classic Ultrasoft<br/>18 cm</b> | Box of 10 units | FEP<br>White catheter<br>White base<br>External diameter<br>2.3 mm - 7 French | PU<br>Overhang out of outer sheath<br>50 mm<br>External diameter<br>1.5 mm - 4.5 French<br>Internal diameter 0.7 mm<br>Ultrasoft on whole length<br>Yellow base<br>5 depth markings near the base |
| CET-23      | <b>Classic Ultrasoft<br/>23 cm</b> | Box of 10 units | 6 circular guide-marks every centimeter                                       |   |

Classic Ultrasoft Catheters 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 embryo transfer catheter in ultrasoft polyurethane on the whole length

When positioned inside 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.

Classic Ultrasoft Catheters 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): embryo transfer when cervical access is easy (without stylet) or difficult (using Stylet with outer sheath).
- The extreme flexibility of the transfer catheter preserves the integrity of the mucosa.
- The stylet (available separately) is used to shape the outer sheath prior to its insertion and clear a difficult cervix more easily.

### 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 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 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.

#### Easy cervical access:

- Before loading the embryos: the outer sheath can be slightly pre-shaped in its packaging.

- Catheter loading: 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.
- Transfer:
- 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.
- Gently push the inner catheter in the uterine cavity to obtain the desired exposure while controlling the centimeter guide-marks close to the base.
- Deposit the embryos in the chosen site.
- Gently remove the outer sheath and catheter together while maintaining pressure on the syringe's plunger to avoid any aspiration effect.

**Difficult cervical access:**

Using the Stylet with outer sheath (available separately).

- Before opening the packaging, pre-shape the outer sheath with the stylet according to the cervical profile.
- Position the outer sheath and its stylet in the cervix, rotating it slightly to clear obstacles.
- 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.