

Stylet with outer sheath

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	Stylet
CStylet-18	Stylet with outer sheath - 18 cm	Box of 10 units	FEP White catheter White base	No inner catheter
CStylet-23	Stylet with outer sheath - 23 cm	Box of 10 units	External diameter 2.3 mm 7 French 6 circular guide-marks every centimeter	Removable malleable stylet the same length as the outer sheath

The Stylet with outer sheath includes:

- an FEP (fluoroethylene propylene) outer sheath with 6 circular guide-marks every centimeter, visible regardless the direction of the outer sheath when in use
- a removable malleable inner stylet

The Stylets with outer sheath are available in two usable lengths to fit the following transfer devices:

- Echogyn[®] Embryoview[®] - 18 and 23 cm
- Echogyn[®] Embryoview[®] M - 18 and 23 cm
- Classic Ultrasoft - 18 and 23 cm

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) procedures:

To be used for transfers expected to be difficult based on a trial transfer or a previous attempt in combination with the following devices:

- Echogyn[®] Embryoview[®] - 18 and 23 cm
- Echogyn[®] Embryoview[®] M - 18 and 23 cm
- Classic Ultrasoft - 18 and 23 cm

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 stylet and its 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.

Instructions for use

- Without taking it out of the packaging, pre-shape the Stylet with outer sheath, based on the data collected during the trial catheterization.
- Insert the Stylet with outer sheath up to the internal orifice of the cervix, rotating it slightly if insertion is difficult.
- Once the Stylet with outer sheath is positioned correctly in the endocervix at the distance recorded during the trial catheterization, remove the stylet from the outer sheath.
- Proceed with the embryo transfer using one of the following transfer catheters previously loaded:
 - Echogyn[®] Embryoview[®] - 18 and 23 cm
 - Echogyn[®] Embryoview[®] M - 18 and 23 cm
 - Classic Ultrasoft - 18 and 23 cm