

Echogyn® Embryoview®

1. Company's profile		Update : November 2016 Issue date : August 2015
Name : Laboratoire CCD		
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2. Product information	
2.1	Common designation : Catheter for ultrasound-guided embryo transfer
2.2	Trade name : Echogyn® Embryoview®
2.3	Medical device classification : Class I Relevant EU Directive : 93/42/CEE Certified Body identification number : CE 0459 Manufacturer : Laboratoire CCD
2.4	<p>Product features :</p> <p>Echogyn® Embryoview® devices include:</p> <ul style="list-style-type: none"> ▪ an FEP (fluoroethylene propylene) outer sheath with 6 circular guide-marks, visible irrespective of the direction of the outer sheath when in use, ▪ an ultrasoft transfer catheter with an echogenic metal marker integrated in the catheter wall. <p>When placed in the outer sheath, the transfer catheter overhangs by 5 cm. Guide-marks close to the base are used to read the length inserted in the uterine cavity.</p> <p>In the Echogyn® Embryoview® version, the inner transfer catheter does not have an integrated metal stiffener and is therefore ultrasoft on its whole length.</p> <p>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.</p> <p>With its specific 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 viewing. During transfer, it provides selective visibility of the catheter tip. The extreme flexibility of the transfer catheter preserves the integrity of the mucosa. The product design and choice of components ensure friction-free sliding motion of the inner catheter through the outer sheath.</p>

PRODUCT INFORMATION RECORD

	Outer sheath	Transfer catheter
Functional features	Supplied without stylet The stylet is available separately	Echogenic metal marker integrated in the catheter wall distal tip
Usable length	18 or 23 cm depending on the model	23 or 28 cm depending on the model
Outer diameter	2.3 mm	1.5 mm
Inner diameter	N/A	0.6 mm
Distal tip	Tapered tip	Round-shaped tip Ultra soft on distal (intra-uterine) segment) or on its whole length, depending on the model : the « M » models feature a metal stiffener integrated the proximal segment to improve handling Overhang out of outer sheath 50 mm
Components	USP class VI FEP	USP class VI PU
Markings	6 circular insertion depth guide-marks	5 depth markings near the base
Color code	White catheter White base	Transparent catheter Yellow base

2.5

Catalogue reference : Assisted Reproduction Techniques

PRODUCT CODE :

Transfer catheters

Non supported :

1325501 Echogyn® Embryoview® - 18 cm

1325301 Echogyn® Embryoview® - 23 cm

Supported on proximal segment :

1325901 Echogyn® Embryoview® M - 18 cm

1325701 Echogyn® Embryoview® M - 23 cm

Trial transfer catheters

Non supported :

1325601 Echogyn® Mock - 18 cm

1325401 Echogyn® Mock - 23 cm

Supported on proximal segment :

1326001 Echogyn® M Mock - 18 cm

1325801 Echogyn® M Mock - 23 cm

Stylets :

1326101 Stylet with FEP Outer Sheath – 18 cm

1322701 Stylet with FEP Outer Sheath – 23 cm

Packaging : Unit packaging

Ordering unit : Unit

Minimum order : box of 10 units

Labelling :

2.6	Components and accessories : Polyurethane Active substances : Latex free Phtalates free Contains no component of biological or animal origin
2.7	Indications : Embryo transfer

3. Sterilization method

	Sterile medical device : Yes Sterilization method : Irradiation
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4. Storage and shelf life

	Current conservation and storage conditions : Store in a dry place, away from light Specific precautions : Do not use if unit packing is damaged Product shelf life : 3 years
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5. Operational safety

5.1	Technical safety : Single use medical device. Do not re-sterilize. Do not re-use.
5.2	Biological safety : N/A

6. Instructions for use

6.1	Operating instructions : Catheter preparation: <ul style="list-style-type: none"> ▪ 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: <ul style="list-style-type: none"> ▪ 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.
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	<ul style="list-style-type: none"> ▪ Deposit the embryos in the chosen site. ▪ Gently remove the outer sheath and transfer catheter together while maintaining pressure on the syringe's plunger to avoid any aspiration effect. <p>Echo-guided transfer in case of difficult cervical access: Using the Stylet with FEP Outer Sheath (available separately):</p> <ul style="list-style-type: none"> ▪ 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.
6.2	Indications : Embryo transfer
6.3	Precautions for use : <ul style="list-style-type: none"> • Check that the packaging is not damaged • Before use, check the integrity of the medical device • Prior to embryo loading, rinse the transfer catheter with appropriate medium according to state of the art practices
6.4	Contra-indications : <ul style="list-style-type: none"> • None

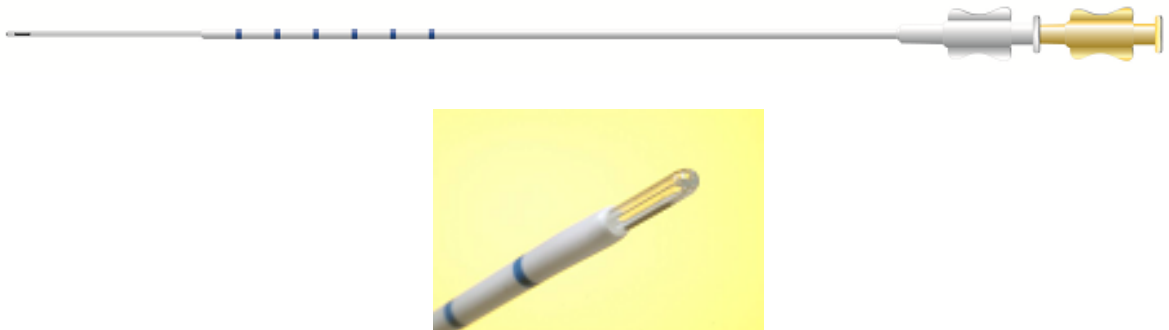
7. Additional information on the product

	N/A
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8. Appendices

	N/A
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9. Pictures

	 <p>Echogenic metal marker embedded in the distal tip</p>
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