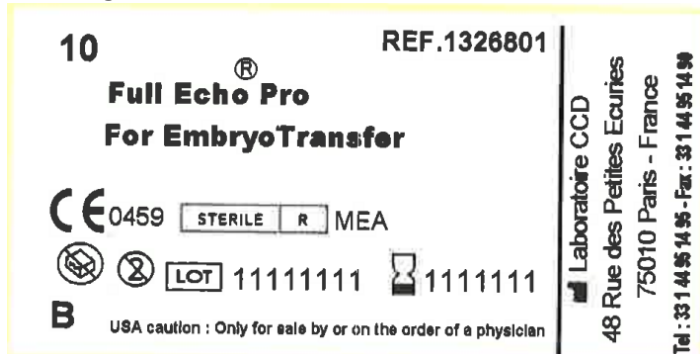


## Full Echo® Pro

1. Company's profile		Update : November 2016 Issue date : August 2015
1.1	<b>Name :</b> Laboratoire CCD	
1.2	<b>Address :</b> 48, rue des Petites Ecuries 75010 Paris	<b>Tel :</b> + 33 (0)1 44 95 14 95 <b>E-mail :</b> contact@ccdlab.com <b>Site internet :</b> www.ccd-lab.com
1.3	<b>Medical Device Vigilance contact :</b> Emilie FEZELOT, Q/A manager	<b>Tel :</b> +33 (0)3 44 26 89 56 <b>E-mail :</b> efezelot@ccdlab.com

2. Product information	
2.1	<b>Common designation :</b> Catheter for ultrasound-guided embryo transfer
2.2	<b>Trade name :</b> Full Echo® Pro
2.3	<b>Medical device classification :</b> Class I <b>Relevant EU Directive :</b> 93/42/CEE <b>Certified Body identification number :</b> CE 0459 <b>Manufacturer :</b> Laboratoire CCD
2.4	<p><b>Product features :</b></p> <p>Full Echo® Pro features 2 patented technologies providing maximum control over transfer conditions.</p> <ul style="list-style-type: none"> <li>▪ The outer sheath with <b>memory of shape</b> results from a specific <b>patented technology</b>, so that it can be shaped to fit the cervical profile.</li> <li>▪ <b>Echogenicity</b> is afforded by two white areas alternating with two transparent areas of different density throughout the length of the transfer catheter. This <b>patented technology</b> leaves the transfer lumen visible during loading or microscope control, and provides excellent echogenicity during the transfer procedure.</li> </ul> <p>The Full Echo® Pro device includes 3 pieces:</p> <ul style="list-style-type: none"> <li>▪ An ultrasoft transfer catheter, echogenic on its whole length. The catheter includes a metal stiffener integrated in its structure to support the proximal segment and improve handling without touching the catheter tip.</li> <li>▪ An outer sheath in a medium density polyethylene (PE) compound, bearing 6 numbered insertion guide-marks.</li> <li>▪ A removable malleable obturator, in transparent copolymer, with a smooth rounded tip, to prevent obstruction while clearing the cervix.</li> </ul> <p>When placed in the outer sheath, the transfer catheter overhangs by 5 cm. Guide-marks close to the base are used to evaluate the length inserted in the uterine cavity.</p>

## PRODUCT INFORMATION RECORD

	Full Echo® Pro	Outer sheath	Stylet	Transfer catheter
	<b>Functional features</b>	Malleable tube with memory of shape <u>Patented technology</u>	Removable Malleable	2 echogenic while lines integrated in the catheter wall - <u>Patented technology</u> Ultrasoft on distal segment Integrated metal stiffener in the proximal segment to improve handling 50 mm overhang out of outer sheath
	<b>Usable length</b>	16 cm		21 cm
	<b>Outer diameter</b>	2.7 mm		1.5 mm
	<b>Inner diameter</b>	1.9 mm		0.5 mm
	<b>Distal tip</b>	Tapered tip	Rounded tip	Tapered tip
	<b>Components</b>	PE based formulation	Co-polymers	USP Class VI PU
	<b>Markings</b>	6 numbered insertion guide-marks	N/A	5 insertion guide-marks close to the base
	<b>Color code</b>	Blue tube White base	Transparent rod White base	Transparent tube with 2 while lines White base
<b>2.5</b>	<b>Catalogue reference :</b> Assisted Reproduction Techniques <b>PRODUCT CODE :</b> 1326801                      Full Echo® Pro <b>Packaging :</b> Unit packaging <b>Ordering unit :</b> Unit <b>Minimum order :</b> box of 10 units <b>Labelling :</b> <div data-bbox="255 1135 957 1487" data-label="Image">  </div>			
<b>2.6</b>	<b>Components and accessories :</b> Polyurethane <b>Active substances :</b> Latex free Phtalates free Contains no component of biological or animal origin			
<b>2.7</b>	<b>Indications :</b> Embryo transfer			

**3. Sterilization method**

	<b>Sterile medical device</b> : Yes <b>Sterilization method</b> : Irradiation
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**4. Storage and shelf life**

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

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

**6. Instructions for use**

<b>6.1</b>	<b>Operating instructions</b> : <b>Catheter preparation:</b> <ul style="list-style-type: none"> <li>▪ Rinse the inner catheter with appropriate medium.</li> <li>▪ Move the catheter to visualize under microscope the transparent area and expose fully the catheter lumen.</li> <li>▪ Load the catheter.</li> </ul> <b>Echo-guided transfer:</b> <ul style="list-style-type: none"> <li>▪ Pre-shape the outer sheath and obturator according to the cervical profile.</li> <li>▪ Position the outer sheath and obturator assembly in the cervix, rotating it slightly to clear any obstacle.</li> <li>▪ Record the length introduced in the cervix.</li> <li>▪ Remove the obturator.</li> <li>▪ Insert the loaded transfer catheter into the outer-sheath.</li> <li>▪ 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.</li> <li>▪ Push the inner catheter further inside the uterine cavity under ultrasound guidance to obtain the desired exposure.</li> <li>▪ Deposit the embryos in the chosen site.</li> <li>▪ Gently remove the outer sheath and transfer catheter together while maintaining pressure on the syringe's plunger to avoid any aspiration effect.</li> </ul>
<b>6.2</b>	<b>Indications</b> : Embryo transfer

<b>6.3</b>	<b>Precautions for use :</b> <ul style="list-style-type: none"> <li>• Check that the packaging is not damaged</li> <li>• Before use, check the integrity of the medical device</li> <li>• Prior to embryo loading, rinse the transfer catheter with appropriate medium according to state of the art practices</li> </ul>
<b>6.4</b>	<b>Contra-indications :</b> <ul style="list-style-type: none"> <li>• None</li> </ul>


## 7. Additional information on the product

	N/A
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## 8. Appendices

	N/A
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## 9. Pictures

	 <p>Cross section view of the transfer catheter : Transparent wall and 2 integrated echogenic white lines</p>
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