

Full Echo®

1. Company profile		Update : November 2015 Issue date : August 2015
1.1	Name : Laboratoire CCD	
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1.3	Medical Device Vigilance contact : Emilie FEZELOT, Q/A manager	Tel : +33 (0)3 44 26 89 56 E-mail : efezelot@ccdlab.com

2. Product information	
2.1	Common designation : Catheter for ultrasound-guided embryo transfer
2.2	Trade name : Full Echo®
2.3	Medical device classification : Class I Relevant EU Directive : 93/42/CEE Certified Body identification number : CE 0459 Manufacturer : Laboratoire CCD
2.4	Product features : <p>Full Echo® provides maximum control over transfer conditions, due to its echogenicity. Echogenicity is afforded by two transparent areas alternating with two white areas of different density throughout the length of the catheter. This patented technology leaves the transfer lumen visible during loading or microscope control, and provides excellent echogenicity during the transfer procedure.</p> <p>Full Echo® devices include:</p> <ul style="list-style-type: none"> ▪ an ultrasoft transfer catheter, echogenic on its whole length. The catheter includes a metal stiffener integrated in its structure to stiffen the proximal segment and improve handling without touching the catheter tip. ▪ an FEP (fluoroethylene propylene) outer sheath with 6 circular guide-marks, visible irrespective of the direction of the outer sheath when in use, ▪ a removable malleable stylet to shape the outer sheath prior to its insertion and help clear a difficult cervix more easily. <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> <p>Superior design and friction-free components ensure easy sliding motion of the inner catheter through the outer sheath.</p>

	<table><tr><th>Full Echo®</th><th>Outer sheath</th><th>Transfer catheter</th></tr><tr><td>Functional features</td><td>Supplied without stylet A malleable stylet is available separately</td><td>2 echogenic while lines integrated in the catheter wall <u>Patented Technology</u> Integrated metal stiffener in proximal segment to improve handling</td></tr><tr><td>Usable length</td><td>18 or 23 cm depending on reference</td><td>23 or 28 cm depending on reference</td></tr><tr><td>Outer diameter</td><td>2,3 mm</td><td>1,5 mm</td></tr><tr><td>Inner diameter</td><td>N/A</td><td>0,5 mm</td></tr><tr><td>Distal tip</td><td>Tapered tip</td><td>Round shaped tip Ultra soft on distal segment 50 mm overhang out of outer sheath</td></tr><tr><td>Components</td><td>USP class VI FEP</td><td>USP class VI PU</td></tr><tr><td>Markings</td><td>6 circular insertion guide marks</td><td>5 insertion guide marks near the base</td></tr><tr><td>Color code</td><td>White catheter White base</td><td>Transparent catheter with 2 while lines White base</td></tr></table>	Full Echo®	Outer sheath	Transfer catheter	Functional features	Supplied without stylet A malleable stylet is available separately	2 echogenic while lines integrated in the catheter wall <u>Patented Technology</u> Integrated metal stiffener in proximal segment to improve handling	Usable length	18 or 23 cm depending on reference	23 or 28 cm depending on reference	Outer diameter	2,3 mm	1,5 mm	Inner diameter	N/A	0,5 mm	Distal tip	Tapered tip	Round shaped tip Ultra soft on distal segment 50 mm overhang out of outer sheath	Components	USP class VI FEP	USP class VI PU	Markings	6 circular insertion guide marks	5 insertion guide marks near the base	Color code	White catheter White base	Transparent catheter with 2 while lines White base
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2.5	<p>Catalogue reference : Assisted Reproduction Techniques</p> <p>PRODUCT CODE :</p> <p><u>Transfer catheters :</u></p> <p>1326401 Full Echo® 18 cm Reference.</p> <p>1326501 Full Echo 23 cm Reference.</p> <p><u>Stylets :</u></p> <p>1326101 Stylet with FEP Outer Sheath – 18 cm</p> <p>1322701 Stylet with FEP Outer Sheath – 23 cm</p> <p>Packaging : Unit packaging</p> <p>Ordering unit : Unit</p> <p>Minimum order : box of units</p> <p>Labelling :</p>																											
2.6	<p>Components and accessories :</p> <p>Polyurethane</p> <p>Active substances :</p> <p>Latex free</p> <p>Phtalates free</p> <p>Contains no component of biological or animal origin</p>																											
2.7	<p>Indications :</p> <p>Embryo transfer</p>																											

3. Sterilization method

Sterile medical device : Yes
Sterilization method : Irradiation

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

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:

- Rinse the inner catheter with appropriate medium.
- Move the catheter to visualize under microscope the transparent areas and expose fully the catheter lumen.
- Load the catheter.

Echo-guided transfer when cervical access is easy:

- Insert the outer sheath and protected transfer catheter assembly up to the internal orifice of the cervix, rotating it slightly to clear any obstacle identified during the trial catheterization.
- Once the outer sheath is correctly positioned in the endocervix, at the distance determined 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.
- 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.

Echo-guided transfer when cervical access is difficult:

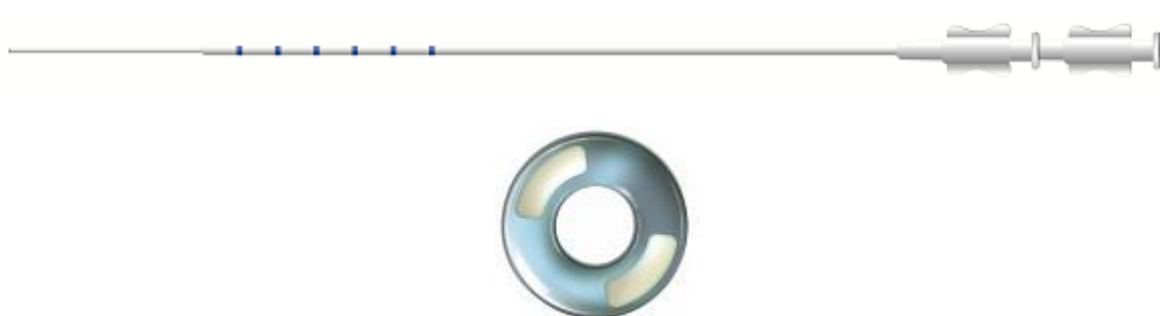
Using the outer sheath fitted with its stylet:

- Pre-shape the outer sheath and stylet in the packaging according to the cervical profile.
- Position the outer sheath and stylet assembly in the cervix, rotating it slightly to clear any obstacle.
- Record the length introduced in the cervix.
- Remove the stylet.

	<ul style="list-style-type: none"> 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

8. Appendices	
	N/A

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