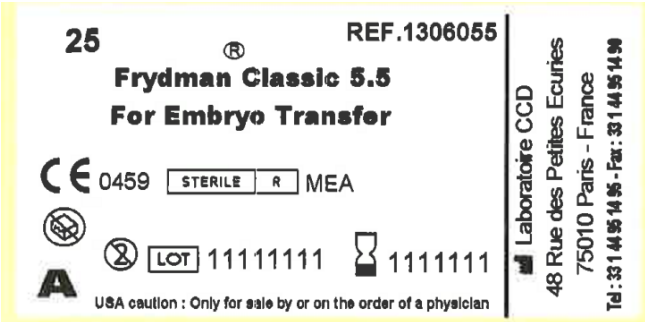


Frydman® Classic

1. Company profile		Update : November 2015 Issue date : August 2015
1.1	Name : Laboratoire CCD	
1.2	Address : 48, rue des Petites Ecuries 75010 Paris	Tel : + 33 (0)1 44 95 14 95 E-mail : contact@ccdlab.com Site internet : www.ccd-lab.com
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 embryo transfer																												
2.2	Trade name : Frydman® Classic																												
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 : One piece catheters in polyethylene with: <ul style="list-style-type: none"> ▪ A flexible extremity, ▪ An atraumatic distal opening. 2 models: <table border="1"> <thead> <tr> <th></th><th>Frydman® Classic 4.5</th><th>Frydman® Classic 5.5</th></tr> </thead> <tbody> <tr> <td>Functional features</td><td>One piece catheter</td><td>One piece catheter</td></tr> <tr> <td>Usable length</td><td>18 cm</td><td>19 cm</td></tr> <tr> <td>Length of the flexible tip</td><td>4.5 cm</td><td>5.5 cm</td></tr> <tr> <td>Inner diameter</td><td>1.1 mm</td><td>1.1 mm</td></tr> <tr> <td>Outer diameter</td><td>1.6 mm</td><td>1.6 mm</td></tr> <tr> <td>Insertion guide-marks</td><td>5.5 cm, 6.5 cm, 7.5 cm</td><td>6.5 cm, 7.5 cm, 8.5 cm</td></tr> <tr> <td>Components</td><td>Polyethylene</td><td>Polyethylene</td></tr> <tr> <td>Color code</td><td>White base</td><td>White base</td></tr> </tbody> </table> <p>The trial transfer catheter presents similar features to the real transfer catheter Frydman® Classic 4.5, but its extremity is closed and its base is green.</p>			Frydman® Classic 4.5	Frydman® Classic 5.5	Functional features	One piece catheter	One piece catheter	Usable length	18 cm	19 cm	Length of the flexible tip	4.5 cm	5.5 cm	Inner diameter	1.1 mm	1.1 mm	Outer diameter	1.6 mm	1.6 mm	Insertion guide-marks	5.5 cm, 6.5 cm, 7.5 cm	6.5 cm, 7.5 cm, 8.5 cm	Components	Polyethylene	Polyethylene	Color code	White base	White base
	Frydman® Classic 4.5	Frydman® Classic 5.5																											
Functional features	One piece catheter	One piece catheter																											
Usable length	18 cm	19 cm																											
Length of the flexible tip	4.5 cm	5.5 cm																											
Inner diameter	1.1 mm	1.1 mm																											
Outer diameter	1.6 mm	1.6 mm																											
Insertion guide-marks	5.5 cm, 6.5 cm, 7.5 cm	6.5 cm, 7.5 cm, 8.5 cm																											
Components	Polyethylene	Polyethylene																											
Color code	White base	White base																											

2.5	<p>Catalogue reference : Assisted Reproduction Techniques</p> <p>PRODUCT CODE :</p> <p><u>Transfer catheters :</u></p> <p>1306045 Frydman® Classic 4.5</p> <p>1306055 Frydman® Classic 5.5</p> <p><u>Trial transfer catheter :</u></p> <p>1322901 Mock Catheter</p> <p>Packaging : Unit packaging</p> <p>Ordering unit : Unit</p> <p>Minimum order : box of 25 units</p> <p>Labelling :</p> 
2.6	<p>Components and accessories :</p> <p>Polyethylene</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

	<p>Sterile medical device : Yes</p> <p>Sterilization method : Irradiation</p>
--	---

4. Storage and shelf life

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

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 : To proceed with the embryo transfer: <ul style="list-style-type: none"> ▪ Connect the catheter to an IVF syringe, ▪ Rinse with the appropriate biological medium. ▪ Load the embryos in the catheter. ▪ Introduce the catheter in the cavity without touching the uterine fundus using the insertion depth markings. ▪ Expel the embryos slowly. ▪ Remove the catheter gently.
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

	
--	--