

Frydman® Memory

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 embryo transfer																														
2.2	Trade name : Frydman® Memory																														
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 : Catheter including: <ul style="list-style-type: none">▪ a distal opening,▪ three insertion depth markings 5.5 cm, 6.5 cm and 7.5 cm from the extremity.▪ a formable stylet integrated within the catheter wall and which does not come in contact with the transfer lumen. The memory of shape allows the catheter to adapt to uterine flexion or a cryptic cervix. 2 models: <table><tr><th>Product name</th><th>Frydman Memory Standard model</th><th>Frydman Memory Extra-fine model</th></tr><tr><td>Reference</td><td>130MF45</td><td>1326301</td></tr><tr><td>Color code</td><td>White base</td><td>Blue base</td></tr><tr><td>Working length</td><td>18 cm</td><td>19 cm</td></tr><tr><td>Inner diameter</td><td>0.70 mm</td><td>0.70 mm</td></tr><tr><td>Outer diameter</td><td>2.10 mm</td><td>1.60 mm</td></tr><tr><td>Length of tapered distal tip</td><td colspan="2">4.5 cm</td></tr><tr><td>Insertion guide-marks</td><td colspan="2">5.5 / 6.5 / 7.5 cm</td></tr><tr><td>Components</td><td colspan="2">USP class VI Polyethylene</td></tr><tr><td>Functional features</td><td colspan="2">One piece catheter Integrated metallic stylet</td></tr></table>	Product name	Frydman Memory Standard model	Frydman Memory Extra-fine model	Reference	130MF45	1326301	Color code	White base	Blue base	Working length	18 cm	19 cm	Inner diameter	0.70 mm	0.70 mm	Outer diameter	2.10 mm	1.60 mm	Length of tapered distal tip	4.5 cm		Insertion guide-marks	5.5 / 6.5 / 7.5 cm		Components	USP class VI Polyethylene		Functional features	One piece catheter Integrated metallic stylet	
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2.5	Catalogue reference : Assisted Reproduction Techniques PRODUCT CODE : 130MF45 Frydman® Memory – Standard model 1326301 Frydman® Memory – Extra-fine model Packaging : Unit packaging Ordering unit : Unit Minimum order : box of 10 units Labelling :
2.6	Components and accessories : Polyethylene 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 : 5 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 : <ul style="list-style-type: none"> Before loading the embryos, bend the catheter inside its sterile packaging to fit it to the shape of the cervix determined during the mock procedure. Connect the catheter to an IVF syringe and flush it with the appropriate biological medium. Load the embryos in the catheter. Introduce the catheter without touching the uterine fundus (maximum 1 cm from the uterine fundus) using the insertion guide-marks. A slight rotation of the catheter may help clear cervical obstacles. Deposit the embryos gently by pressing on the syringe plunger. Remove the catheter gently using a rotating motion.
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>Before shaping the tip</p>  <p>Curvature after shaping the tip</p> 
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