

Frydman® Soft with Guide

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® Soft with Guide																																										
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>The device includes:</p> <ul style="list-style-type: none">▪ An outer sheath in polypropylene with 6 guide-marks every centimeter.▪ A transfer catheter in flexible polyethylene in its distal section and rigidified in its proximal section by an inner sheath, to help its handling.▪ A removable malleable metal guide wire coated in polyethylene. <table><tr><th>Frydman® Soft with Guide</th><th>Outer sheath</th><th>Guide wire</th><th>Transfer catheter</th></tr><tr><td>Functional features</td><td></td><td>Malleable</td><td>Supported on proximal segment to facilitate handling</td></tr><tr><td>Usable length</td><td>18 cm</td><td>17.5 cm</td><td>21.5 cm</td></tr><tr><td>Length of flexible tip</td><td>N/A</td><td>N/A</td><td>4.5 cm</td></tr><tr><td>Inner volume</td><td>N/A</td><td>N/A</td><td>0.20 ml</td></tr><tr><td>Inner diameter</td><td>N/A</td><td>N/A</td><td>1.15 mm</td></tr><tr><td>Outer diameter</td><td>2.20 mm</td><td>1.55 mm</td><td>1.60 mm</td></tr><tr><td>Components</td><td>Polypropylene</td><td>Polyethylene coated steel</td><td>Polyethylene</td></tr><tr><td>Markings</td><td>6 insertion guide-marks on distal segment</td><td>N/A</td><td>4 insertion guide-marks near the base</td></tr><tr><td>Color code</td><td>White base</td><td>Green base</td><td>White base</td></tr></table>			Frydman® Soft with Guide	Outer sheath	Guide wire	Transfer catheter	Functional features		Malleable	Supported on proximal segment to facilitate handling	Usable length	18 cm	17.5 cm	21.5 cm	Length of flexible tip	N/A	N/A	4.5 cm	Inner volume	N/A	N/A	0.20 ml	Inner diameter	N/A	N/A	1.15 mm	Outer diameter	2.20 mm	1.55 mm	1.60 mm	Components	Polypropylene	Polyethylene coated steel	Polyethylene	Markings	6 insertion guide-marks on distal segment	N/A	4 insertion guide-marks near the base	Color code	White base	Green base	White base
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2.5	Catalogue reference : Assisted Reproduction Techniques PRODUCT CODE : 1307000 Frydman® Soft with guide 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, shape the outer sheath and its stylet in their sterile packaging, to fit the profile of the cervical canal. Position the outer sheath in the cervix, while recording the length introduced in the cervical canal. Remove the metal stylet. Rinse first the transfer catheter with the appropriate biological medium and load the catheter with the embryos. Place the loaded transfer catheter in the outer sheath positioned in the cervix. When the first 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 to obtain the desired exposure while controlling the centimeter guide-marks close to the base. Expel the embryos gently by pushing the syringe's plunger. Remove the outer sheath and catheter together to avoid any aspiration effect.
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	
	<div> <div> <p>Clearing the cervical os :</p>  <p>Outer sheath fitted with guide wire</p> </div> <div> <p>Depositing the embryo :</p>  <p>Transfer catheter in outer sheath</p> </div> </div>