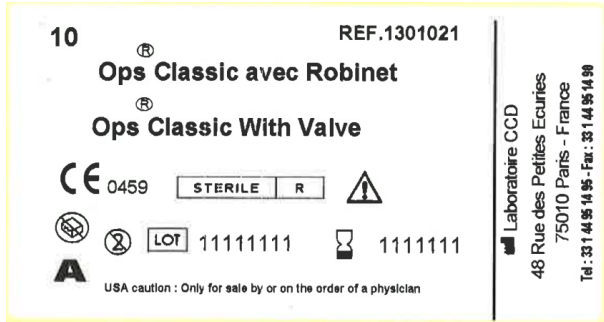


# OPS® Classic

1. Company 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 FRANCE	<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> Oocyte collection device																														
2.2	<b>Trade name :</b> OPS® Classic																														
2.3	<b>Medical device classification :</b> Class IIa <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>The OPS® Classic includes:</p> <ul style="list-style-type: none"> <li>▪ An echogenic triple bevel, single lumen needle.</li> <li>▪ A thin aspiration tube connecting the needle to a bung. The latter fits on a collector tube, such as the Falcon® sterilized by irradiation.</li> <li>▪ A suction tube connecting the bung to the vacuum source.</li> <li>▪ A triple channel valve (for the model concerned) between the collection needle and the bung is used to either aspirate or rinse the follicles.</li> </ul> <p>2 models:</p> <table border="1" style="margin-left: 40px;"> <thead> <tr> <th>Designation</th> <th>OPS® Classic With Valve</th> <th>OPS® Classic Without Valve</th> </tr> </thead> <tbody> <tr> <td>Order code</td> <td>1301021</td> <td>1301020</td> </tr> <tr> <td>Flushing valve</td> <td>Yes</td> <td>No</td> </tr> <tr> <td colspan="3"><b>NEEDLE</b></td> </tr> <tr> <td>Type</td> <td colspan="2">Triple bevel – Simple flux</td> </tr> <tr> <td>Usable length</td> <td colspan="2">30 cm</td> </tr> <tr> <td>External diameter</td> <td colspan="2">1.5 mm – G 17</td> </tr> <tr> <td>Internal diameter</td> <td colspan="2">1,2 mm</td> </tr> <tr> <td>Echogenic zone</td> <td colspan="2">Ground surface on 2 cm and 5 mm</td> </tr> <tr> <td colspan="3"><b>COLLECTION TUBE</b></td> </tr> </tbody> </table>	Designation	OPS® Classic With Valve	OPS® Classic Without Valve	Order code	1301021	1301020	Flushing valve	Yes	No	<b>NEEDLE</b>			Type	Triple bevel – Simple flux		Usable length	30 cm		External diameter	1.5 mm – G 17		Internal diameter	1,2 mm		Echogenic zone	Ground surface on 2 cm and 5 mm		<b>COLLECTION TUBE</b>		
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2.5	<p><b>Catalogue reference :</b></p> <p><b>PRODUCT CODE :</b></p> <p><u>Collection set :</u></p> <p>1301021                      OPS® Classic for oocyte collection – With valve</p> <p>1301020                      OPS® Classic for oocyte collection – Without valve</p> <p><u>Vial :</u></p> <p>1313000                      Tube 15 mL</p> <p><b>Packaging :</b> Unit packaging</p> <p><b>Ordering unit :</b> Unit</p> <p><b>Minimum order :</b></p> <p>Collection set : box of 10 units</p> <p>Vial : box of 100 units</p> <p><b>Labelling :</b></p> 																										
2.6	<p><b>Components and accessories :</b></p> <p>Steel, Polyurethane</p> <p><b>Active substances :</b></p> <p>Latex free</p> <p>Phtalates free</p> <p>Contains no component of biological or animal origin</p>																										
2.7	<p><b>Indications :</b></p> <p>Oocyte collection</p>																										

**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. Read carefully the instructions before use.
<b>5.2</b>	<b>Biological safety</b> : N/A

**6. Instructions for use**

<b>6.1</b>	<b>Operating instructions</b> : <ul style="list-style-type: none"> <li>▪ Check the integrity of the device (bevel sharpness, connection parts, tubing).</li> <li>▪ Rinse the system with a biological medium adapted to the collection.</li> <li>▪ Check the bung is tightly connected to the collector tube.</li> <li>▪ Collect the oocytes under controlled negative pressure to limit the risks of zona pellucida rupture.</li> <li>▪ The three-channel valve (in the model concerned), which can be connected to a 10 ml syringe, is used to rinse the follicles under low pressure.</li> <li>▪ Once the collecting tube is full, it can be easily replaced by the next one.</li> <li>▪ At the end of the procedure, rinse the device to ensure there is no oocyte left inside the catheter or the needle.</li> </ul>
<b>6.2</b>	<b>Indications</b> : Oocyte collection
<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 use, rinse the device 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**

Bung



Classic needle