







Ovo[®] Needle ART of CCD[®]

1. Company profile		Update : November 2016 Issue date : August 2015
1.1	Name : Laboratoire CCD	
1.2	Address : 48, rue des Petites Ecuries 75010 Paris FRANCE	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 : Oocyte collection needle																
2.2	Trade name : Ovo [®] Needle ART of CCD [®]																
2.3	Medical device classification : Class IIa Relevant EU Directive : 93/42/CEE Certified Body identification number : CE 0459 Manufacturer : Laboratoire CCD																
2.4	<p>Product features : Simple flow, triple bevel needle, with a 5 mm grooved echogenic zone before the beveled tip. The needle is fitted with a Luer cone to connect a syringe.</p> <table border="1" data-bbox="331 1211 1359 1487"> <thead> <tr> <th>Designation</th> <th>Ovo[®] Needle- ART of CCD[®]</th> </tr> </thead> <tbody> <tr> <td>Order code</td> <td>1313701</td> </tr> <tr> <td>Type of needle</td> <td>Triple bevel – Simple flux</td> </tr> <tr> <td>Usable length</td> <td>30 cm</td> </tr> <tr> <td>External diameter</td> <td>1.4 mm – G 17</td> </tr> <tr> <td>Inner diameter</td> <td>1 mm</td> </tr> <tr> <td>Echogenic zone</td> <td>Grooves near the bevel</td> </tr> <tr> <td>Connection</td> <td>Luer-lock</td> </tr> </tbody> </table>	Designation	Ovo [®] Needle- ART of CCD [®]	Order code	1313701	Type of needle	Triple bevel – Simple flux	Usable length	30 cm	External diameter	1.4 mm – G 17	Inner diameter	1 mm	Echogenic zone	Grooves near the bevel	Connection	Luer-lock
Designation	Ovo [®] Needle- ART of CCD [®]																
Order code	1313701																
Type of needle	Triple bevel – Simple flux																
Usable length	30 cm																
External diameter	1.4 mm – G 17																
Inner diameter	1 mm																
Echogenic zone	Grooves near the bevel																
Connection	Luer-lock																
2.5	<p>Catalogue reference : PRODUCT CODE : 1313701 Ovo[®] Needle ART of CCD[®] for oocyte collection</p> <p>Packaging : Unit packaging Ordering unit : Unit Minimum order : box of 10 units</p> <p>Labelling :</p>																

	<p>10 REF.1313701 Alguille Ovo ART OF CCD 30cm / G17 Needle Ovo ART OF CCD 30cm / 1.50mm Oocyte Collection Needle</p> <p>CE 0459      LOT 11111111  11111111</p> <p>USA caution : Only for sale by or on the order of a physician</p> <p>Laboratoire CCD 48 Rue des Petites Ecuries 75010 Paris - France Tel : 33 1 44 55 14 95 - Fax : 33 1 44 55 14 90</p>
2.6	Components and accessories : Steel Active substances : Latex free Phtalates free Contains no component of biological or animal origin
2.7	Indications : <ul style="list-style-type: none"> ▪ Oocyte collection ▪ Ovarian cyst aspiration

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 : 5 years
--	---

5. Operational safety

5.1	Technical safety : Single use medical device. Do not re-sterilize. Do not re-use. Read carefully the instructions before use.
5.2	Biological safety : N/A

6. Instructions for use

<p>6.1</p>	<p>Operating instructions :</p> <ul style="list-style-type: none"> ▪ Check the integrity of the device (bevel sharpness, connection part). ▪ Rinse the needle and syringe set with a biological medium suited to fine needle aspiration. ▪ Depending on the approach chosen, perform the fine needle aspiration using ultrasound guidance or coeloscopy.
<p>6.2</p>	<p>Indications :</p> <ul style="list-style-type: none"> ▪ Oocyte collection ▪ Ovarian cyst aspiration
<p>6.3</p>	<p>Precautions for use :</p> <ul style="list-style-type: none"> • Check that the packaging is not damaged • Before use, check the integrity of the medical device • Prior to use, rinse the device with appropriate medium according to state of the art practices

<p>6.4</p>	<p>Contra-indications :</p> <ul style="list-style-type: none"> • None
-------------------	---


7. Additional information on the product

	<p>N/A</p>
--	------------

8. Appendices

	<p>N/A</p>
--	------------

9. Pictures

	<div style="text-align: center;">  <p>Echogenic grooves near the bevel</p> </div>
--	---