




# Pearl Tip®

1. Company profile		Update : November 2015 Issue date : August 2015
1.1	<b>Name :</b> Laboratoire CCD	
1.2	<b>Address :</b> 48, rue des Petites Ecuries 75010 Paris	<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> Catheter for embryo transfer																											
2.2	<b>Trade name :</b> Pearl Tip																											
2.3	<b>Medical device classification :</b> Class I <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> Pearl Tip® devices include:</p> <ul style="list-style-type: none"> <li>▪ A curved outer sheath with an atraumatic spherical tip, a sliding stopper and 6 circular insertion guide-marks, visible irrespective of the direction of the outer sheath when in use. An arrow on the base indicates the direction of the distal curvature.</li> <li>▪ A flexible or firm transfer catheter (depending on the model) fitted with an inner metal stylet in the proximal segment to improve handling.</li> </ul> <p>When placed in the outer sheath, the transfer catheter overhangs by 50 mm. Guide-marks close to the base are used to evaluate the length inserted in the uterine cavity.</p> <table border="1"> <thead> <tr> <th>Pearl Tip®</th> <th>Outer sheath</th> <th>Transfer catheter</th> </tr> </thead> <tbody> <tr> <td><b>Functional features</b></td> <td>Spherical tip Distal curvature Sliding cervical stopper</td> <td>Integrated metal stiffener in the proximal segment to improve handling</td> </tr> <tr> <td><b>Working length</b></td> <td>200 mm</td> <td>250 mm</td> </tr> <tr> <td><b>Outer diameter</b></td> <td>2.20 mm</td> <td>1 mm</td> </tr> <tr> <td><b>Inner diameter</b></td> <td>N/A</td> <td>0.6 mm</td> </tr> <tr> <td><b>Distal tip</b></td> <td>Spherical tip</td> <td>Flexible or semi-flexible depending on the model 50 mm overhang out of outer sheath</td> </tr> <tr> <td><b>Components</b></td> <td>USP class VI polymer</td> <td>USP class VI PVA</td> </tr> <tr> <td><b>Markings</b></td> <td>Arrow on the base for the direction of the curvature 6 circular insertion guide-marks on distal segment</td> <td>5 insertion guide-marks near the base</td> </tr> <tr> <td><b>Color code</b></td> <td>Grey colored catheter</td> <td>Soft model : White base Classic model : Yellow base</td> </tr> </tbody> </table>	Pearl Tip®	Outer sheath	Transfer catheter	<b>Functional features</b>	Spherical tip Distal curvature Sliding cervical stopper	Integrated metal stiffener in the proximal segment to improve handling	<b>Working length</b>	200 mm	250 mm	<b>Outer diameter</b>	2.20 mm	1 mm	<b>Inner diameter</b>	N/A	0.6 mm	<b>Distal tip</b>	Spherical tip	Flexible or semi-flexible depending on the model 50 mm overhang out of outer sheath	<b>Components</b>	USP class VI polymer	USP class VI PVA	<b>Markings</b>	Arrow on the base for the direction of the curvature 6 circular insertion guide-marks on distal segment	5 insertion guide-marks near the base	<b>Color code</b>	Grey colored catheter	Soft model : White base Classic model : Yellow base
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<b>2.5</b>	<p><b>Catalogue reference :</b> Assisted Reproduction Techniques</p> <p><b>PRODUCT CODE :</b>  1323961 Pearl Tip® Soft  1323951 Pearl Tip® Classic</p> <p><b>Packaging :</b> Unit packaging  <b>Ordering unit :</b> Unit  <b>Minimum order :</b> box of 10 units  <b>Labelling :</b></p> <div data-bbox="252 562 927 898" style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">10 <span style="float: right;">REF.1323961</span></p> <p style="text-align: center;"><b>Pearl Tip Soft</b>  <b>For Embryo Transfer</b></p> <p>CE 0459 <span style="border: 1px solid black; padding: 2px;">STERILE</span> <span style="border: 1px solid black; padding: 2px;">R</span> MEA</p> <p>   <span style="border: 1px solid black; padding: 2px;">LOT</span> 11111111  11111111 </p> <p><b>B</b> USA caution : Only for sale by or on the order of a physician</p> <div style="font-size: small; text-align: right;"> Laboratoire CCD  48 Rue des Petites Ecuries  75010 Paris - France  Tel : 33 1 44 95 14 95 - Fax : 33 1 44 95 14 99 </div> </div>
<b>2.6</b>	<p><b>Components and accessories :</b>  Polyurethane</p> <p><b>Active substances :</b>  Latex free  Phtalates free  Contains no component of biological or animal origin</p>
<b>2.7</b>	<p><b>Indications :</b>  Embryo transfer</p>

### 3. Sterilization method

	<p><b>Sterile medical device :</b> Yes  <b>Sterilization method :</b> Irradiation</p>
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### 4. Storage and shelf life

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

<b>5.1</b>	<p><b>Technical safety :</b>  Single use medical device. Do not re-sterilize. Do not re-use.</p>
<b>5.2</b>	<p><b>Biological safety :</b>  N/A</p>

### 6. Instructions for use

<b>6.1</b>	<b>Operating instructions :</b> <b>Catheter loading:</b> <ul style="list-style-type: none"> <li>▪ Leave the transfer catheter inside the outer sheath during embryo loading. Once the catheter is loaded, pull back the transfer catheter slightly inside the outer sheath to protect its tip.</li> </ul> <b>Embryo transfer:</b> <ul style="list-style-type: none"> <li>▪ Slide the outer sheath stopper up to the desired length to be inserted inside the cervical canal.</li> <li>▪ Insert the outer sheath with the protected transfer catheter up to the internal orifice of the cervix using a slight rotation to clear any obstacle identified during the trial catheterization. The Pearl Tip® atraumatic spherical tip is designed to facilitate passage through the cervix. The sliding stopper is used as a guide-mark to stop the outer sheath's progression through the cervix.</li> <li>▪ Once the outer sheath is correctly placed inside the endocervix, based on the distance recorded during the trial catheterization, gently push the inner catheter through the outer sheath.</li> <li>▪ When the first proximal guide-mark on the transfer catheter is level with the base of the outer sheath, their distal extremities are level inside the uterine cavity.</li> <li>▪ Continue to push the transfer catheter inside the uterine cavity to the desired distance.</li> <li>▪ Deposit the embryos in the chosen site.</li> <li>▪ Gently remove the outer sheath and catheter together, maintaining pressure on the syringe plunger to avoid any aspiration.</li> </ul>
<b>6.2</b>	<b>Indications :</b> Embryo transfer
<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 embryo loading, rinse the transfer catheter with appropriate medium according to state of the art practices</li> <li>•</li> </ul>
<b>6.4</b>	<b>Contra-indications :</b> <ul style="list-style-type: none"> <li>• None</li> <li>•</li> </ul>

**7. Additional information on the product**

N/A

**8. Appendices**

N/A

**9. Pictures**

Transfer catheter in its outer sheath

