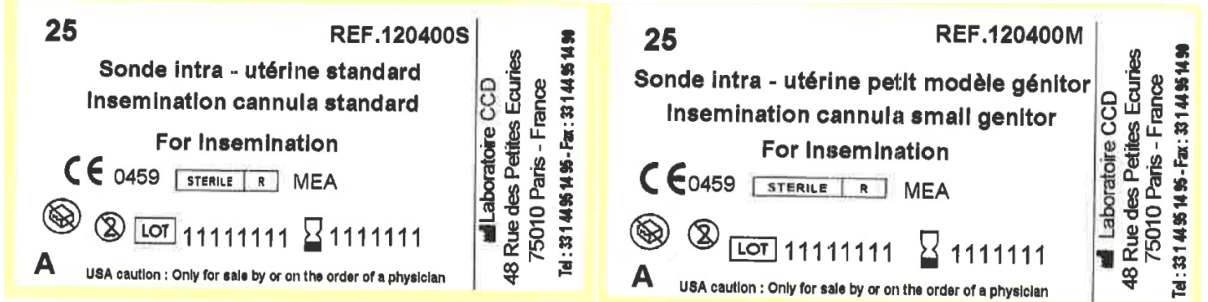


Intra uterine Cannula

Standard model & small model Genitor®

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 : Intra-uterine insemination catheter																												
2.2	Trade name : Intra uterine cannula – standard model Intra uterine cannula – small model Genitor®																												
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>Catheter with a flexible tip in transparent polyethylene. The catheter and its flexible tip are designed to provide access to the uterine cavity without trauma. The sperm preparation is released near the tubal ostia through the two distal openings on the tip. A Luer connector at the proximal tip allows connection to a syringe.</p> <table><tr><th></th><th>Insemination Cannula Standard Model</th><th>Insemination Cannula Small Model Genitor®</th></tr><tr><td>Total length</td><td colspan="2">17 cm</td></tr><tr><td>Length of flexible tip</td><td colspan="2">4.5 cm</td></tr><tr><td>Internal volume</td><td>0.40 mL</td><td>0.10 mL</td></tr><tr><td>Inner diameter</td><td>1.70 mm</td><td>0.65 mm</td></tr><tr><td>Outer diameter</td><td>2.10 mm</td><td>1.60 mm</td></tr><tr><td>Insertion guide-marks</td><td colspan="2">5.5 / 6.5 cm</td></tr><tr><td>Components</td><td colspan="2">Polyethylene</td></tr><tr><td>Specific features</td><td colspan="2">One piece catheter 2 distal openings</td></tr></table>			Insemination Cannula Standard Model	Insemination Cannula Small Model Genitor®	Total length	17 cm		Length of flexible tip	4.5 cm		Internal volume	0.40 mL	0.10 mL	Inner diameter	1.70 mm	0.65 mm	Outer diameter	2.10 mm	1.60 mm	Insertion guide-marks	5.5 / 6.5 cm		Components	Polyethylene		Specific features	One piece catheter 2 distal openings	
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2.5	<p>PRODUCT CODE : 120400S : insemination Cannula – Standard Model 120400M : insemination Cannula – Small Model Genitor®</p> <p>Packaging : Unit packaging Ordering unit : Unit Minimum order : box of 25 units Labelling :</p> <div data-bbox="252 533 1465 833">  </div>
2.6	<p>Components and accessories : Polyethylene Active substances : Latex free Phtalates free Contains no component of biological or animal origin</p>
2.7	<p>Indications : Intrauterine artificial insemination with prepared sperm</p>

3. Sterilization method

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

	<p>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</p>
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5. Operational safety

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

6. Instructions for use

6.1	Operating instructions : <ul style="list-style-type: none"> ▪ Connect the syringe with the sperm preparation and purge the catheter. ▪ Insert a speculum and wipe the cervix thoroughly. ▪ If necessary, place the cervix in the uterine axis using Pozzi forceps to help the catheter introduction. ▪ Pass the catheter through the cervix, up to the uterus. ▪ Inject the sperm very slowly, 1 cm from the tubal ostia. ▪ Remove the catheter.
6.2	Indications : Intrauterine artificial insemination with prepared sperm
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 use, rinse the device 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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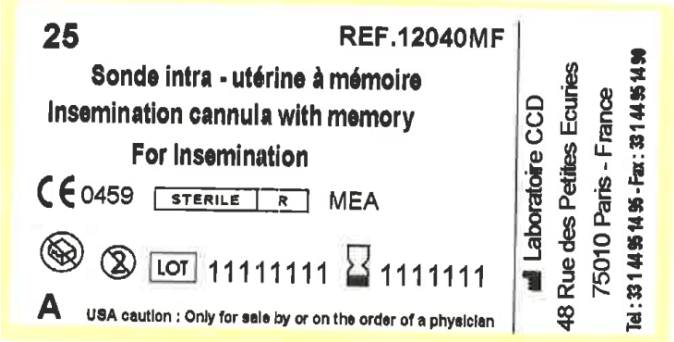
9. Pictures

	 <p>Standard model</p>
	 <p>Genitor model</p>

Intra-uterine insemination cannula with memory

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 : Intra-uterine insemination cannula with shape memory																				
2.2	Trade name : Intra-uterine insemination cannula with shape 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	<p>Product features :</p> <p>Catheter with a blunt-end tip and two lateral distal openings.</p> <p>The catheter is fitted with a deformable steel guidewire imbedded in its structure, which does not come in contact with the insemination lumen. The guidewire helps give the desired curve to the catheter before its insertion. The proximal tip is a Luer connector to connect a syringe.</p> <p>The intrauterine catheter with shape memory is particularly adapted to a stenotic cervix.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th><th>Insemination Cannula with shape memory</th></tr> </thead> <tbody> <tr> <td>Total length</td><td>17 cm</td></tr> <tr> <td>Usable length</td><td>18 cm</td></tr> <tr> <td>Length of tapered tip</td><td>4.5 cm</td></tr> <tr> <td>Internal volume</td><td>0.27 mL</td></tr> <tr> <td>Inner diameter</td><td>1.10 mm</td></tr> <tr> <td>Outer diameter</td><td>2.10 mm</td></tr> <tr> <td>Insertion guide-marks</td><td>5.5 / 6.5 cm</td></tr> <tr> <td>Components</td><td>Polyethylene</td></tr> <tr> <td>Specific features</td><td>One piece catheter 2 distal openings Integrated malleable steel guide wire</td></tr> </tbody> </table>		Insemination Cannula with shape memory	Total length	17 cm	Usable length	18 cm	Length of tapered tip	4.5 cm	Internal volume	0.27 mL	Inner diameter	1.10 mm	Outer diameter	2.10 mm	Insertion guide-marks	5.5 / 6.5 cm	Components	Polyethylene	Specific features	One piece catheter 2 distal openings Integrated malleable steel guide wire
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2.5	PRODUCT CODE : 12040MF Packaging : Unit packaging Ordering unit : unit Minimum order : box of 25 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 : Intrauterine artificial insemination with prepared sperm

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"> Leave the catheter in the packaging and give it the desired shape, to fit the patient's cervical profile. Connect the syringe with the sperm preparation and purge the catheter. Insert a speculum and wipe the cervix thoroughly. If necessary, place the cervix in the uterine axis using Pozzi forceps to help the catheter introduction. Pass the catheter through the cervix, up to the uterus. Inject the sperm very slowly, 1 cm from the tubal ostia. Remove the catheter.
6.2	Indications : Intrauterine artificial insemination with prepared sperm
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 use, rinse the device 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	
	