

Spirette® and Mucat® catheters

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 : Cervical mucus aspiration catheter
2.2	Trade name : Spirette® Mucat®
2.3	Medical device classification : Class I Relevant EU Directive : 93/42/CEE Certified Body identification number : CE 0459 Manufacturer : Laboratoire CCD
2.4	Product features : These catheters are 23.5 cm long, 3.10 mm in external diameter, 2.60 mm in internal diameter, with an opening at the distal tip. They include two parts: <ul style="list-style-type: none"> ▪ a flexible sheath with 4 guide-marks at 4, 7, 8 and 10 cm from the distal tip, ▪ an internal polyethylene plunger. The flexible sheath is made of polypropylene. The Mucat® is the simplified version of the Spirette® with no handling knob at the plunger's base.
2.5	PRODUCT CODE : 1106000 Spirette® - sterile 110600S Mucat® - sterile 11060NS Mucat® - non sterile Packaging : Unit packaging for the sterile presentations Pack of 25 units for the non-sterile presentation Ordering unit : Unit Minimum order : box of 25 units Labelling : <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="border: 1px solid black; padding: 5px; width: 45%;"> <p>25 REF.1106000</p> <p style="text-align: center;">Spirette®</p> <p style="text-align: center;">For Mucus Sampling</p> <p>CE 0459 STERILE R</p> <p>LOT 11111111 11111111</p> <p>A USA caution : Only for sale by or on the order of a physician</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Laboratoire CCD 48 Rue des Petites Ecuries 75010 Paris - France Tel : 33 1 44 95 14 95 - Fax : 33 1 44 95 14 99</p> </div> <div style="border: 1px solid black; padding: 5px; width: 45%;"> <p>25 REF.110600S</p> <p style="text-align: center;">Mucat Stérile</p> <p style="text-align: center;">For Mucus Sampling</p> <p>CE 0459 STERILE R</p> <p>LOT 11111111 11111111</p> <p>A USA caution : Only for sale by or on the order of a physician</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">Laboratoire CCD 48 Rue des Petites Ecuries 75010 Paris - France Tel : 33 1 44 95 14 95 - Fax : 33 1 44 95 14 99</p> </div> </div>

2.6	Components and accessories : Polyethylene Active substances : Latex free Phtalates free Contains no component of biological or animal origin
2.7	Indications : <ul style="list-style-type: none"> ▪ Direct exocervical or endocervical aspiration ▪ Hühner test

3. Sterilization method

	Sterile medical device : Yes for the presentations concerned 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

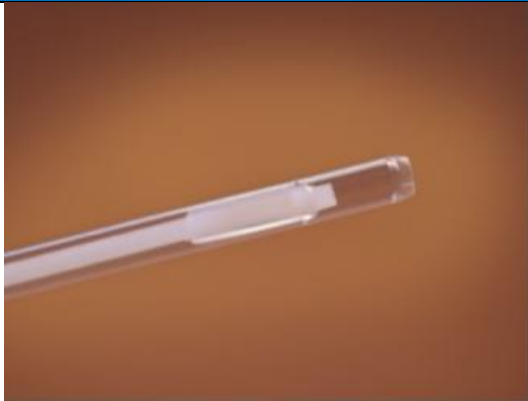

6. Instructions for use

6.1	Operating instructions : The Spirette® and Mucat® are used without a syringe. The aspiration is performed with the integrated plunger. <ul style="list-style-type: none"> ▪ Insert the extremity of the device in the sampling zone: exocervix or endocervix. ▪ Pull the plunger to perform aspiration. ▪ Remove the device. ▪ Push on the plunger to expel the specimen for examination.
6.2	Indications : <ul style="list-style-type: none"> ▪ Direct exocervical or endocervical aspiration ▪ Hühner test

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
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 style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>Spirette®</p> </div> <div style="text-align: center;">  <p>Mucat®</p> </div> </div>