

Intra uterine Cannula

Standard model & small model Genitor®

| 1. Compa | ny 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 |

| 2.1 | Common designation : Intra-uter | rine insemination catheter | |
|-----|--|---|--|
| 2.2 | Trade name : | | |
| | Intra uterine cannula – standard | model | |
| | Intra uterine cannula – small mod | del Genitor [®] | |
| 2.3 | Medical device classification : Classification | ass l | |
| | Relevant EU Directive : 93/42/CE | EE | |
| | Certified Body identification num | nber : CE 0459 | |
| | Manufacturer : Laboratoire CCD | | |
| 2.4 | Product features : | | |
| | | | |
| | Catheter with a flexible tip in trar | nsnarent nolvethvlene | |
| | Catheter with a flexible tip in tran | | uterine cavity without tra |
| | The catheter and its flexible tip a | are designed to provide access to the | - |
| | The catheter and its flexible tip a The sperm preparation is release | are designed to provide access to the ed near the tubal ostia through the ty | - |
| | The catheter and its flexible tip a | are designed to provide access to the ed near the tubal ostia through the ty | - |
| | The catheter and its flexible tip a The sperm preparation is release | are designed to provide access to the ed near the tubal ostia through the tw ip allows connection to a syringe. | wo distal openings on the |
| | The catheter and its flexible tip a The sperm preparation is release | are designed to provide access to the ed near the tubal ostia through the tw ip allows connection to a syringe. Insemination Cannula | - |
| | The catheter and its flexible tip a The sperm preparation is release Luer connector at the proximal ti | are designed to provide access to the ed near the tubal ostia through the tw ip allows connection to a syringe. Insemination Cannula Standard Model | wo distal openings on the Insemination Cannula |
| | The catheter and its flexible tip a The sperm preparation is release Luer connector at the proximal ti Total length | are designed to provide access to the ed near the tubal ostia through the tw ip allows connection to a syringe. Insemination Cannula Standard Model | wo distal openings on the Insemination Cannula Small Model Genitor® |
| | The catheter and its flexible tip a The sperm preparation is release Luer connector at the proximal ti | are designed to provide access to the ed near the tubal ostia through the tw ip allows connection to a syringe. Insemination Cannula Standard Model | No distal openings on the Insemination Cannula Small Model Genitor® 7 cm |
| | The catheter and its flexible tip a The sperm preparation is release Luer connector at the proximal ti Total length Length of flexible tip | are designed to provide access to the ed near the tubal ostia through the tw ip allows connection to a syringe. Insemination Cannula Standard Model 1 4 | wo distal openings on the Insemination Cannula Small Model Genitor® 7 cm 5 cm |
| | The catheter and its flexible tip a The sperm preparation is release Luer connector at the proximal ti Total length Length of flexible tip Internal volume | are designed to provide access to the ed near the tubal ostia through the tw ip allows connection to a syringe. Insemination Cannula Standard Model 1 4 0.40 mL | wo distal openings on the Insemination Cannula Small Model Genitor® 7 cm .5 cm 0.10 mL |
| | The catheter and its flexible tip a The sperm preparation is release Luer connector at the proximal ti Total length Length of flexible tip Internal volume Inner diameter | Are designed to provide access to the ed near the tubal ostia through the two ip allows connection to a syringe. Insemination Cannula Standard Model 1 0.40 mL 1.70 mm 2.10 mm | wo distal openings on the Insemination Cannula Small Model Genitor® 7 cm .5 cm 0.10 mL 0.65 mm |
| | The catheter and its flexible tip a The sperm preparation is release Luer connector at the proximal ti Total length Length of flexible tip Internal volume Inner diameter Outer diameter Insertion guide-marks Components | Are designed to provide access to the ed near the tubal ostia through the two ip allows connection to a syringe. Insemination Cannula Standard Model 1 1 0.40 mL 1.70 mm 2.10 mm 5.5 polye | wo distal openings on the Insemination Cannula Small Model Genitor® 7 cm 5 cm 0.10 mL 0.65 mm 1.60 mm / 6.5 cm ethylene |
| | The catheter and its flexible tip a The sperm preparation is release Luer connector at the proximal ti Total length Length of flexible tip Internal volume Inner diameter Outer diameter Insertion guide-marks | Are designed to provide access to the ed near the tubal ostia through the two ip allows connection to a syringe. Insemination Cannula Standard Model 1 0.40 mL 1.70 mm 2.10 mm 5.5 / Polye One pie | No distal openings on the Insemination Cannula Small Model Genitor® 7 cm .5 cm 0.10 mL 0.65 mm 1.60 mm / 6.5 cm |



| 2.5 | PRODUCT CODE : | |
|-----|--|--|
| | 120400S : insemination Cannula – Standard Mode | I |
| | 120400M : insemination Cannula – Small Model G | enitor® |
| | Packaging : Unit packaging | |
| | Ordering unit : Unit | |
| | Minimum order : box of 25 units | |
| | Labelling : | |
| | 25 REF.120400S | 25 REF.120400M |
| | Sonde intra - utérine standard Insemination cannula standard For Insemination C € 0459 STERILE R MEA | () S |
| | Insemination cannula standard For Insemination C € 0459 STERILE R MEA S LOT 11111111 1 1111111 A USA caution : Only for sale by or on the order of a physician | Sonde intra - utérine petit modèle génitor Insemination cannula small genitor For Insemination C €0459 STERILE R MEA USA caution : Only for sale by or on the order of a physician |
| | For Insemination 일월 다 부 | Insemination cannula small genitor For Insemination C € 0459 STERILE R MEA |
| | C € 0459 STERILE R MEA Stead Stress Image: Stead Stress Stead Stress Image: Stead Stead Stress Stead Stead Stress Image: Stead | |
| | | |
| | | |
| | USA caution : Only for sale by or on the order of a physician 🛛 🥰 💆 | A USA caution : Only for sale by or on the order of a physician |
| 2.6 | Components and accessories : | |
| | Polyethylene | |
| | Active substances : | |
| | Latex free | |
| | Phtalates free | |
| | Contains no component of biological or animal ori | gin |
| 2.7 | Indications : | |
| | Intrauterine artificial insemination with prepared | sperm |

| 3. Sterili | zation method |
|------------|------------------------------------|
| | Sterile medical device : Yes |
| | Sterilization method : Irradiation |

| or | age 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. Opera | tional safety |
|----------|--|
| 5.1 | Technical safety : |
| | Single use medical device. Do not re-sterilize. Do not re-use. |
| 5.2 | Biological safety : |
| | N/A |



| 6. Instru | ctions for use |
|-----------|---|
| 6.1 | Operating instructions : |
| | 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 : |
| | 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 : |
| | None |

| 7. Addit | ional information on the product |
|----------|----------------------------------|
| | N/A |

| 8. Apper | ndices |
|----------|--------|
| | N/A |

| ctures | | | |
|--------|-----|------------------------|---|
| - | | INTER-OFENINE CONTENES | - |
| | S | tandard model | |
| | | | |
| | • • | GENITOR | |
| | | Genitor model | |
| | | | |



Intra-uterine insemination cannula with memory

| 1. Compa | ny profile | Update : November 2016 Issue date : August 2015 |
|----------|------------------------------------|--|
| 1.1 | Name : Laboratoire CCD | |
| 1.2 | Address : | Tel : + 33 (0)1 44 95 14 95 |
| | 48, rue des Petites Ecuries | E-mail : contact@ccdlab.com |
| | 75010 Paris | Site internet : www.ccd-lab.com |
| | FRANCE | |
| 1.3 | Medical Device Vigilance contact : | Tel : +33 (0)3 44 26 89 56 |
| | Emilie FEZELOT, Q/A manager | E-mail : efezelot@ccdlab.com |

| 2.1 | Common designation : Intra-uter | rine insemination cannula with shape memory |
|-----|--|--|
| 2.2 | Trade name : Intra-uterine insem | nination cannula with shape memory |
| 2.3 | Medical device classification : Cl | ass l |
| | Relevant EU Directive : 93/42/CE | E |
| | Certified Body identification nur | nber : CE 0459 |
| | Manufacturer : Laboratoire CCD | |
| 2.4 | Product features : | |
| | Catheter with a blunt-end tip and | d two lateral distal openings. |
| | The catheter is fitted with a def | ormable steel guidewire imbedded in its structure, which does no |
| | | nination 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. |
| | | |
| | The intrauterine catheter with sh | hape memory is particularly adapted to a stenotic cervix. |
| | The intrauterine catheter with sh | |
| | The intrauterine catheter with sh | |
| | The intrauterine catheter with sh | hape memory is particularly adapted to a stenotic cervix. |
| | | Insemination Cannula with shape memory |
| | Total length | Insemination Cannula with shape memory 17 cm |
| | Total length Usable length | Insemination Cannula with shape memory Insemination Cannula with shape memory Inseminati |
| | Total length Usable length Length of tapered tip | Insemination Cannula with shape memory Insemination Cannula with shape memory I7 cm I8 cm 4.5 cm |
| | Total length Usable length Length of tapered tip Internal volume | Insemination Cannula with shape memory Insemination Cannula with shape memory I7 cm I8 cm I.5 cm O.27 mL |
| | Total length Usable length Length of tapered tip Internal volume Inner diameter | Insemination Cannula with shape memory Insemination Cannula with shape memory 17 cm 18 cm 4.5 cm 0.27 mL 1.10 mm |
| | Total length Usable length Length of tapered tip Internal volume Inner diameter Outer diameter | Insemination Cannula with shape memory Insemination Cannula with shape memory 17 cm 18 cm 4.5 cm 0.27 mL 1.10 mm 2.10 mm |
| | Total lengthUsable lengthLength of tapered tipInternal volumeInner diameterOuter diameterInsertion guide-marks | Insemination Cannula with shape memory Insemination Cannula with shape memory 17 cm 18 cm 4.5 cm 0.27 mL 1.10 mm 2.10 mm 5.5 / 6.5 cm |
| | Total lengthUsable lengthLength of tapered tipInternal volumeInner diameterOuter diameterInsertion guide-marks | Insemination Cannula with shape memory Insemination Cannula with shape memory 17 cm 18 cm 4.5 cm 0.27 mL 1.10 mm 2.10 mm 5.5 / 6.5 cm Polyethylene |



| 2.5 | PRODUCT CODE : 12040MF Packaging : Unit packaging Ordering unit : unit Minimum order : box of 25 units Labelling : | | |
|-----|--|------------|--|
| | 25 REF.12040MF Sonde intra - utérine à mémoire Insemination cannula with memory For Insemination C€0459 STERILE R MEA S LOT 1111111 I 111111 A USA caution : Only for sele by or on the order of a physician | | |
| 2.6 | Components and accessories : | | |
| | Polyethylene Active substances : | | |
| | Latex free | | |
| | Phtalates free | | |
| | Contains no component of biological or anim | al origin | |
| 2.7 | Indications : | | |
| | Intrauterine artificial insemination with prep | ared sperm | |

| 3. Sterilization method | | | |
|-------------------------|------------------------------------|--|--|
| | Sterile medical device : Yes | | |
| | Sterilization method : Irradiation | | |

| rage | e 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. | |
| 5.2 | Biological safety : | |
| | N/A | |



| 6. Instructions for use | | |
|-------------------------|--|--|
| 6.1 | Operating instructions : | |
| | 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 : | |
| | 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 : | |
| | None | |

| 7. Additional information on the product | | |
|--|-----|--|
| | N/A | |

| 8. Appen | dices | | | |
|----------|-------|--|--|--|
| | N/A | | | |

| 9. Pictu | res |
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