

McGill Cryoleaf™

Product No.:

4077

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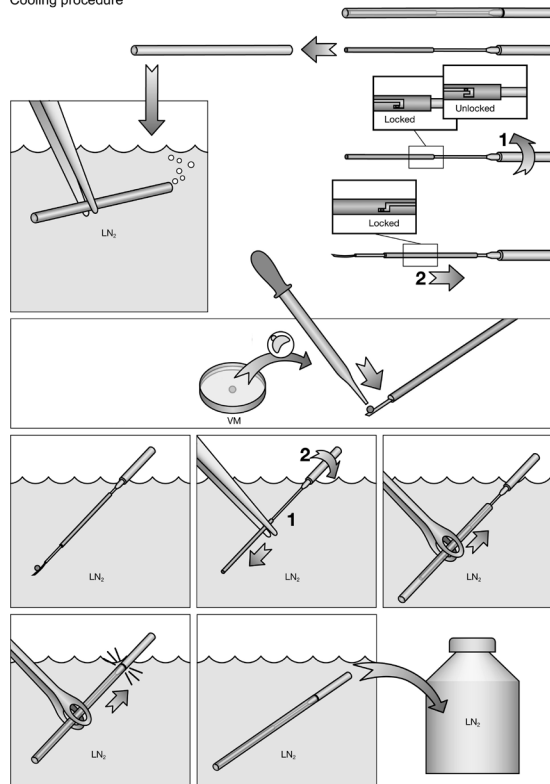
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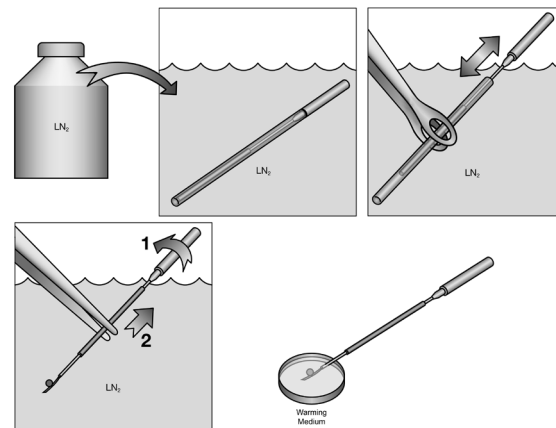
Distributor: ORIGIO AUSTRALASIA Pty Ltd

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Cooling procedure



Warming procedure



McGill Cryoleaf™

For storage of vitrified human oocytes.

This product is for IVF treatment of women, whether the cause of infertility is male or female. The product should only be used by professionals trained in IVF treatment.

Quality control testing

Mouse Embryo Assay (MEA) tested

Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.origio.com.

Storage instructions and stability

Store in original container at 2-25°C, protected from light.

When stored as directed by the manufacturer the product is stable until the expiry date shown on the label.

Precautions and warnings

Do not use the product if:

1. Product packaging appears damaged or if the seal is broken.

2. Expiry date has been exceeded.

Do not reuse.

The red dot on the pouch indicates that the product has been sterilized using the e-beam processing technique. Do not use the product if the dot is yellow

Note: The McGill Cryoleaf™ is an open system which means that the oocytes are in direct contact with liquid nitrogen (LN₂). ORIGIO recommends that you use a container that is suitable for the LN₂, and which can be sterilised. It is also recommended to change LN₂ between patients to avoid the risk of contamination and to use LN₂ which complies with pharmacopoeia specifications.

Note: The recommended maximum load of the McGill Cryoleaf™ is 2-3 oocytes.

Caution: The potential risk of reproductive or developmental toxicity due to the use of the McGill Cryoleaf™ has not been determined and is still unknown.

Instructions for use

Cooling

1. Prepare oocytes for vitrification according to laboratory protocol.
2. Plunge the outer cover of the McGill Cryoleaf™ into the LN₂ bath and let the air come out.
3. Quickly load the vitrified oocytes into the McGill Cryoleaf™ using a suitable pipette and as little medium as possible (<1 µl). The McGill Cryoleaf™ should stay dry during the process. Make sure to remove excess medium carefully and quickly using the pipette.
4. Quickly insert the McGill Cryoleaf™ with the oocytes directly into liquid nitrogen (LN₂).
5. Carefully slide the protective sleeve (green) over the tip with the oocytes and lock it into place by turning. Take care that the McGill Cryoleaf™ remains immersed in LN₂ at all times.
6. Insert the McGill Cryoleaf™ into the outer cover and press tightly. Take care that the McGill Cryoleaf™ remains immersed in LN₂ at all times.
7. Transfer to storage container while keeping the McGill Cryoleaf™ immersed in LN₂.

Warming

1. Prepare the warming media according to laboratory protocol.
2. Collect the McGill Cryoleaf™ from the storage container and place into bath of LN₂.
3. Using forceps, remove the outer cover from the McGill Cryoleaf™. Take care that all parts of the McGill Cryoleaf™ except the handle remain immersed in LN₂ at all times.
4. Unlock the inner part with the forceps tip and slide it upwards. Ensure that the McGill Cryoleaf™ still remains immersed in LN₂.
5. Take the McGill Cryoleaf™ out of the LN₂ and quickly transfer the oocytes into the first warming medium.
6. The oocytes will then loosen from the McGill Cryoleaf™ and be released into the warming medium, where they should stay for a maximum of 3 minutes (at this point, the oocytes are still shrunken).
7. Perform the thawing procedure according to laboratory protocol.