

0616-05

# Embryo Freezing Pack

Symbol:



Do not use if package is damaged



Discard excess (unused) media following warming.

Product No.:

1026

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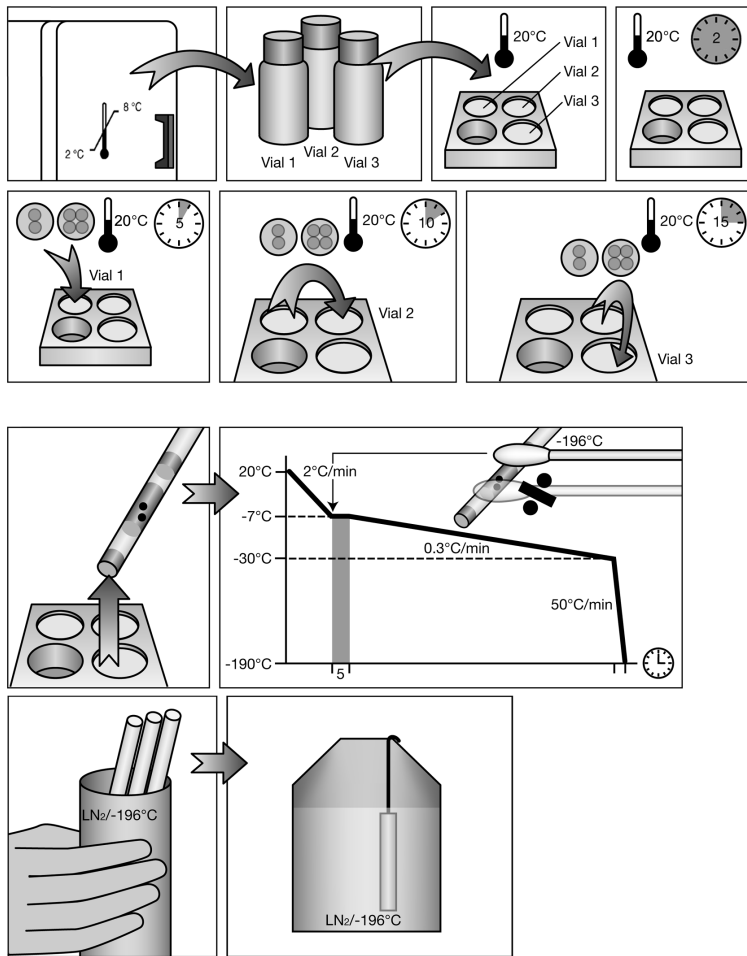
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Distributor: ORIGIO AUSTRALASIA Pty Ltd

# origio

a CooperSurgical Company



# Embryo Freezing Pack

## Intended use

Embryo Freezing Pack is for freezing of human zygotes and cleavage stage embryos.

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

## Composition

### Vial 1:

Synthetic Serum Replacement (SSR®)\*  
(USA: ART Supplement)  
\*Contains Recombinant Human Insulin  
Human serum albumin (HSA)  
Physiological salts

### Vial 2:

Synthetic Serum Replacement (SSR®)\*  
(USA: ART Supplement)  
\*Contains Recombinant Human Insulin  
Human serum albumin (HSA)  
1,2-propanediol  
Physiological salts

### Vial 3:

Synthetic Serum Replacement (SSR®)\*  
(USA: ART Supplement)  
\*Contains Recombinant Human Insulin  
Human serum albumin (HSA)  
1,2-propanediol  
Sucrose  
Physiological salts

## Quality control testing

Sterility tested (Ph.Eur., USP)  
pH tested (Ph.Eur., USP)

Endotoxin tested  $\leq 0.1$  EU/ml (Ph.Eur., USP)  
1 cell Mouse Embryo Assay (MEA)  $\geq 80\%$   
Blastocysts by 96h

**Note:** The results of each batch are stated on a Certificate of Analysis, which is available on [www.origio.com](http://www.origio.com).

## Storage instructions and stability

The products are aseptically processed and supplied sterile.

Store in original container at 2-8°C, protected from light.

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

Do not freeze prior to use.

The product does not contain any antimicrobial agents and is provided in vials intended for single use.

Excess (unused) media should be discarded.

## 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.

**Caution:** All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HCV, and non-reactive for HBsAg, HCV RNA and HIV-1 RNA. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

The potential risk of reproductive or developmental toxicity due to the use of ART media has not been determined and is still unknown.

**Note:** Dispose of the device in accordance with local regulations for disposal of medical devices.

## Instructions for use

1. Pre-warm for a minimum of 2 hours at room temperature.
2. Zygotes or embryos at the 2-4-cell development stage are placed in medium from Vial 1 for 5 minutes at room temperature.
3. Transfer zygotes or embryos to medium from Vial 2 for 10 minutes at room temperature.  
*Just before the zygotes or embryos are transferred to medium from Vial 3 the inside of the cryo straws are cleaned with the same solution but from another dish.*
4. Transfer the zygotes or embryos to medium from Vial 3 for 15 minutes, still at room temperature.

5. Medium from Vial 3 is used to load the zygotes or embryos in the straws. Freezing is carried out according to the cooling programme below.
6. Cool from room temperature to  $-7^{\circ}\text{C}$  at a rate of  $2^{\circ}\text{C}$  per minute.
7. Hold for 5 minutes. Manual seeding. Do not seed the straw close to the zygote/embryo and do not drop or shake it.  
*When the solution is white, seeding has been initiated.*
8. Cool from  $-7^{\circ}\text{C}$  to  $-30^{\circ}\text{C}$  at a rate of  $0.3^{\circ}\text{C}$  per minute.
9. Cool from  $-30^{\circ}\text{C}$  to  $-190^{\circ}\text{C}$  at a rate of  $50^{\circ}\text{C}$  per minute.
10. Transfer the straws into liquid nitrogen and store at  $-196^{\circ}\text{C}$ .