



## 玻璃化解冻液

### 型号规格:

C007-4 W1:5ml×2 W2:5ml×1  
W3:5ml×1 W4:5ml×1

### 标识解释

	过滤灭菌
	生产批号
	生产日期
	有效期
	储存温度
	避光

### 注意事项和警告

1. 在使用该产品前,使用者应阅读和理解使用方法、注意事项,并掌握正确的使用程序。
2. 本产品不能用于注射。
3. 本产品为过滤灭菌产品,不适于再次灭菌。
4. 如果出现下列情况,请勿使用本产品:
  - 产品包装出现损坏,或封印已经损毁。
  - 产品已经超过保质期。
  - 产品已经变色、浑浊,或出现颗粒状物质。
5. 本产品含硫酸庆大霉素。应当采取适当预防措施,确保患者对该抗生素无过敏反应。
6. 本产品含有源自人类血液的人血白蛋白。该产品中的人血白蛋白经检测其HIV-Ab、TP、Anti-HCV均呈阴性,HBsAg、HBsAb、HBeAg、HBeAb、HbCAb均符合规定。所有的血液制品均应视为具有潜在传染性。
7. 本产品适用于一次性使用。开瓶后,将剩余未用的产品丢弃。
8. 为避免污染,使用时请注意采用无菌技术。
9. 本产品可与日本Kitazato产品进行配合使用,体外鼠胚试验:囊胚形成率≥80%,检测结果如下:

品牌	玻璃化解冻液批号	复苏率	囊胚形成率
Kitazato	Y20060901	100%	96.3%

其他厂家产品未进行试验。

10. 该产品在规定的储存条件及有效期内保持稳定有效。

### 适用范围

该产品适用于玻璃化冷冻的各胚胎期胚胎的解冻复温。

### 组成成分

L-谷氨酸	L-天门冬氨酸	氯化钠
L-脯氨酸	L-天门冬酰胺	氯化钾
L-亮氨酸	L-苯基丙氨酸	硫酸镁
L-苏氨酸	L-赖氨酸单盐酸盐	葡萄糖
L-缬氨酸	L-胱氨酸二盐酸盐	甘氨酸
L-色氨酸	L-精氨酸单盐酸盐	氯化钙
L-丝氨酸	磷酸二氢钾	乳酸钠
L-异亮氨酸	L-组氨酸盐酸盐水合物	牛磺酸
L-甲硫氨酸	4-羟乙基哌嗪乙磺酸	碳酸氢钠
人血白蛋白(10mg/mL)		氢氧化钠
L-酪氨酸二钠盐二水合物	3-(N-吗啉基)丙磺酸	丙磺酸钠
N(2)-L-丙氨酸-L-谷氨酰胺		

解冻液1:W1:

基础成分 海藻糖 硫酸庆大霉素(7.1μg/mL)

解冻液2:W2:

基础成分 海藻糖 硫酸庆大霉素(8.1μg/mL)

解冻液3:W3:

基础成分 海藻糖 硫酸庆大霉素(8.7μg/mL)

解冻液4:W4:

基础成分 硫酸庆大霉素(9.2μg/mL)

### 储存运输条件及有效期

1. 2°C~8°C密闭避光可保存6个月。
2. 运输应在2°C~8°C密闭避光条件下进行。

### 产品性能指标

1. pH值:W1~W4各组分pH值范围(37°C)均在7.2~7.6内。
2. 渗透压:  
W1渗透压在109mOsmol/kg~169mOsmol/kg内(稀释10倍);  
W2渗透压在63mOsmol/kg~94mOsmol/kg内(稀释10倍);  
W3渗透压在521mOsmol/kg~621mOsmol/kg内;  
W4渗透压在255mOsmol/kg~280mOsmol/kg内。
3. 细菌内毒素检测:W1~W4各组分细菌内毒素含量均<0.2EU/mL。
4. 产品无菌性:W1~W4各组分无菌检验均符合无菌规定。
5. 体外鼠胚试验:囊胚形成率≥80%。

### 禁忌症

对人血白蛋白过敏者禁用。

### 使用方法

1. 使用前把解冻液1(W1)放置在37°C下平衡,至少40分钟,解冻液2(W2)、解冻液3(W3)、解冻液4(W4)放置在室温(22~28°C)下平衡,至少30分钟。
2. 在培养皿中注入1.0ml解冻液1(W1),在37°C热板上操作。
3. 在培养皿中分别加入500ul解冻液2(W2)、解冻液3(W3)、解冻液4(W4),做成3个液滴,放置于室温。
4. 将载有胚胎的冷冻载体取出,迅速浸入到解冻液1(W1)中,观察胚胎脱离情况,胚胎脱离到解冻液中后取出冷冻载体,吸管收集并吹打胚胎,继续保持于解冻液1(W1)中浸泡(胚胎接触到解冻液1(W1)起,至胚胎转到解冻液2(W2)中止,整个过程中

间维持在50-60秒内完成)后转入到解冻液2(W2)中。(此操作需要在37°C下完成)

5. 将胚胎从解冻液1(W1)中转移到解冻液2(W2)中,保持3分钟。(此操作需要在室温下完成)
6. 将胚胎从解冻液2(W2)中转移到解冻液3(W3)中,保持5分钟。(此操作需要在室温下完成)
7. 将胚胎从解冻液3(W3)中转移到解冻液4(W4)中,保持1分钟后转移到培养液中,如果有辅助孵化等操作可以在解冻液4(W4)中完成。(此操作需要在室温下完成)

注:

- ① 如果需要复温解冻更多的胚胎,重复上述2~3步骤,需使用新的器皿以及新鲜的解冻液。
- ② 操作所有培养液时尽量避免气泡产生。
- ③ 每次转移胚胎的时候应尽量减少携带上一种培养液。
- ④ 解冻液1(W1)在37°C下操作;解冻液2(W2)-解冻液4(W4)在室温下操作。

### 成都艾伟孚生物科技有限公司

Chengdu AIVFO Biotechnology Co.,LTD

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生产许可证编号:

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## DMSO Warming Kit

C007-4 W1:5ml×2 W2:5ml×1  
W3:5ml×1 W4:5ml×1

### Explanation of Symbols

	Sterilized using aseptic processing techniques
	Batch code
	Date of manufacture
	Use-by date
	Temperature limitation
	Keep away from sunlight

### Precautions and Warnings

1. Before using this product, users should read and understand the operation and precautions.
2. This product cannot be used for injection.
3. This product is sterilized by filtration and is not suitable for re-sterilization.
4. Do not use this product if:
  - Product packaging is damaged, or the seal has been destroyed.
  - The product exceeds the shelf life.
  - The product has become discolored, cloudy, or granular.
5. This product contains gentamicin sulfate. Appropriate precautions should be taken to ensure that the patients are not allergic to the antibiotic.
6. This product contains human serum albumin derived from human blood. The human serum albumin in the product has been tested to be negative for HIV-AB, TP and anti-HCV, and HBsAg, HBsAb, HBeAg, HBeAb and HBcAb all meet the requirements. All blood products should be considered potentially infectious.
7. This product is suitable for single use. After opening the bottle, discard the remaining unused product.

8. In order to avoid contamination, please use aseptic technique.

9. This product can be used with Kitazato products of mainstream companies in the market, mouse embryo assay(MEA)-1-Cell MEA $\geq$ 80%, the test results are as follows:

Brand	Vitrification thawing lot number	Recovery rate	Blastocyst formation rate
Kitazato	Y20060901	100%	96.3%

Other manufacturers' products have not been tested.

10. The product remain stable and effective within the specified storage conditions and the shelf life.

### Intended use

This product is suitable for thawing and rewarming of vitrified embryos.

### Composition

L - valine  
L - serine  
L - proline  
L - leucine  
L - threonine  
L - isoleucine  
L - asparagine  
L - tryptophan  
L - methionine  
L - aspartic acid  
L - glutamic acid  
L - phenylalanine  
Pyruvic acid sodium  
L - cystine dihydrochloride  
N(2) - L-alanyl -L-glutamine  
L - lysine monohydrochloride  
L - arginine monohydrochloride  
3 - (N-morpholine) propionic acid  
Potassium dihydrogen phosphate  
L - histidine hydrochloride hydrate  
Human Ssrum Albumin(10mg/mL)  
L - tyrosine disodium salt dihydrate  
4-hydroxyethyl piperazine ethyl sulfonic acid

W1:

Base ingredients: Trehalose, Gentamicin sulfate (7.1 $\mu$ g/mL).

W2:

Base ingredients: Trehalose, Gentamicin sulfate (8.1 $\mu$ g/mL).

W3:

Base ingredients: Trehalose, Gentamicin sulfate (8.7 $\mu$ g/mL).

W4:

Base ingredients: Gentamicin sulfate (9.2 $\mu$ g/mL).

### Storage and Transportation

1. Store dark at 2°C~8°C for 6 months.
2. Store dark at 2°C~8°C during transportation.

### Product performance index

1.pH (37°C) : 7.2~7.6 .

2.Osmolality :

W1: 109 mOsmol/kg~169 mOsmol/kg (diluted 10 times);

W2 : 63 mOsmol/kg to 94 mOsmol/kg (diluted 10 times);

W3 : 521mOsmol/kg~621mOsmol/kg ;

W4 : 255mOsmol/kg~280mOsmol/kg .

3. Endotoxin : < 0.2EU /mL.

4. Sterility testing : Pass.

5. 1-Cell Mouse embryo assay :  $\geq$ 80%.

### Contraindications

Those who are allergic to human serum albumin are prohibited.

### Operation

1. Bring the quantity to be used of W1 and equilibrate for at least 40 minutes at 37°C, W2, W3 and W4 to room temperature (22-28°C) for at least 30minutes prior to warming vitrified specimens.

2. Dispense a minimum volume of 1mL of W1 and put it on 37°C heated stage.

3. Prepare a dish with 500 $\mu$ L droplets of W2, W3, W4 and place the dish at room temperature.

4. Remove the frozen carrier which with the embryo facing up, and immediately plunge it into W1. Under microscopic observation, gently move the carrier until the embryos are released, and gently pipette the embryos, if floating, and place at the bottom. Leave the embryos for a total of 50-60s in the W1.(This operation needs to be carried out at 37°C)

5. Transfer the embryos into W2 and remain for 3 minutes (This operation needs to be carried out at room temperature).

6. Transfer the embryos into W3 and remain for 5 minutes (This operation needs to be carried out at room temperature).

7. Transfer the embryos into W4 and remain for 1 minute, then transfer it to culture medium.

Operation such as assisted incubation can be completed in W4. (This operation needs to be carried out at room temperature)

Note:

① If more embryos need to be rewarmed and thawing, repeat the above steps 2 to 7, using new utensils and fresh thawing solution.

② When operating all culture medium, avoid bubbles as far as possible.

③ Every time you transfer an embryo, you should try to reduce the amount of culture fluid.

④ W1 is operated at 37°C; W2 to are operated at room temperature.