



0212-02

# BlastFreeze™

## Cat. No.:

10532010 2 x 10 ml (Vial 1, Vial 2)

## Symbols:

Catalogue Number



Batch Code



Sterilized using aseptic processing techniques (filtration)



Storage temperature limitation from 2°C to 8°C



Use by



Consult instructions for use, i.e. the package insert



## Technical Services:

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# MediCult

Innovation with Care

# BlastFreeze™

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## Intended use

BlastFreeze™ is for freezing blastocysts.

## Background

Cryopreservation of surplus embryos serves to augment the success of assisted conception treatments for infertile couples.

BlastFreeze™ is supplied as ready-to-use solutions prepared with glycerol and sucrose designed to freeze blastocysts. The protocol is a modification of the published recommendations: (Ménézo, 1996) and (Veiga & Ménézo, 1997).

The protocol has been proven in daily clinical practice at the University Medical Centre, Ljubljana, Slovenia since 1995.

## Composition

### Vial 1:

Earle's Balanced Salts Solution (EBSS)  
Synthetic Serum Replacement (SSR®)  
(USA: ART Supplement)  
Human serum albumin (HSA)  
Sodium pyruvate  
Sodium bicarbonate  
Streptomycin 50 mg/litre  
Penicillin 50.000 IU/litre  
Phenol Red  
Glycerol

### Vial 2:

Earle's Balanced Salts Solution (EBSS)  
Synthetic Serum Replacement (SSR®)  
(USA: ART Supplement)  
Human serum albumin (HSA)  
Sodium pyruvate  
Sodium bicarbonate  
Streptomycin 50 mg/litre  
Penicillin 50.000 IU/litre  
Phenol Red  
Glycerol  
Sucrose

## Quality control testing

Sterility tested  
pH tested  
Endotoxin tested  $\leq 0.1$  EU/ml (USP, Ph.Eur.)  
Mouse Embryo Assay (MEA) tested

**Note:** The results of each batch are stated on a Certificate of Analysis, which is available upon request.

## Storage instructions and stability

Store at 2-8°C and protected from light.  
The product has a minimum shelf life of 8 weeks from the date of shipment if stored according to the manufacturer's suggested guidelines.  
We recommend that the product should be used within 7 days of opening.  
Do not freeze prior to use.  
Whenever the product has been warmed to 37°C, it

should not be refrigerated again.

## Precautions and warnings

Do not use the product if:

- Product packaging appears damaged or if the seal is broken
- Expiry date has been exceeded.

The product contains small amounts of potentially hazardous human serum albumin, which has been obtained from an U.S. licensed source. It originates from larger pools of screened healthy donors, tested negative for HBsAg, Anti-HCV, anti-HIV1/-HIV2. Levels of ALT (GPT) in the plasma are determined and donations are rejected if the values found are above the upper limit of the specifications. Donors of the source material have been screened for CJD.

Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

## Handling

Equilibrate for a minimum of 2 hours in 5% CO<sub>2</sub> at 37°C prior to use.

## Instructions for use

1. Place the embryos in a 5% CO<sub>2</sub> incubator at 37°C in medium from Vial 1 for 10 minutes, and then in medium from Vial 2 for 10 minutes, also in a 5% CO<sub>2</sub> incubator.
2. Transfer the embryos into straws (a maximum of 2 embryos per straw) and begin the cooling program-

me as described below:

3. Cool from room temperature to -6°C in steps of 2°C per minute.
4. Seed manually at -6°C.
5. Cool from -6°C to -40°C in steps of 0.3°C per minute.
6. Cool from -40°C to -150°C in steps of 35°C per minute.
7. Transfer the straws into liquid nitrogen and store at -196°C.

## Reference

Ménézo, Y. (1996) in: Proceedings of ASRM, Boston, USA, p. 006

Veiga, A. & Ménézo, Y. (1997) in Proceedings of the 10<sup>th</sup> World Congress of in Vitro Fertilization and Assisted Reproduction, Vancouver, Canada, pp. 49-53.