



0213-02

BlastThaw™

Cat. No.:

10542010 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



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MediCult

Innovation with Care

Intended use

BlastThaw™ is for thawing blastocysts frozen using BlastFreeze™ (Cat. No. 10532010)

Background

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

BlastThaw™ is supplied as ready-to-use solutions prepared with sucrose designed to thaw blastocysts frozen using BlastFreeze™ (Cat. No. 10532010). The protocol is a modification of the published recommendations: (Ménézo, 1996), (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
Sucrose

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
Sucrose

Quality control testing

Sterility tested

pH tested

Endotoxin tested ≤ 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

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% CO₂ at 37°C prior to use.

Instructions for use

Warm straws at room temperature by leaving them on the table for 10-15 seconds.

Step 1 of the thawing procedure is intended to be performed under a stream of 5% CO₂ in air and the intensity of the stream is regulated according to the colour of the media to maintain pH stability.

1. Place the embryos in medium from Vial 1 for 10 minutes at room temperature and then in medium from Vial 2 for 10 minutes at room temperature.
2. After thawing, place the blastocysts in equilibrated

Universal IVF Medium (Cat.No. 1030 or 1031) and aspirate the embryos up and down in the pipette 5 times to insure thorough washing (this should take only a few seconds).

3. Transfer to equilibrated fresh Universal IVF Medium and allow blastocysts to recover for a minimum of 30-60 minutes in a 5% CO₂ in air incubator before embryo transfer.

Reference

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

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