



0208-02

# BlastAssist<sup>®</sup> System

## Cat. No.:

10392010 2 x 10 ml

10402010 2 x 10 ml

## Symbols:

Catalogue Number

REF

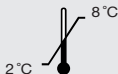
Batch Code

LOT

Sterilized using aseptic processing techniques (filtration)

STERILE A

Storage temperature limitation from 2°C to 8°C



Use by



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



## Technical Services:

E-mail: [customer.service@medicult.com](mailto:customer.service@medicult.com)

Internet: [www.medicult.com](http://www.medicult.com)

Customer Service:

Tel: +45 46 79 02 02, Fax: +45 46 79 03 02

MediCult a/s

Møllehaven 12, DK-4040 Jyllinge • Denmark

Tel: +45 46 79 02 00 • Fax: +45 46 79 03 00



# MediCult

Innovation with Care

# BlastAssist® System

---

## Intended use

The BlastAssist® System is designed for use with or without Universal IVF (Cat.No. 1030/1031) from fertilisation through to blastocyst development.

## Background

The sequential culture of human embryos in this synthetic media system from fertilisation to the blastocyst stage has been shown to facilitate the selection of embryos with higher implantation rates.

## Composition

### Medium 1

Synthetic Serum Replacement (SSR®)

(USA = Art Supplement)

Human serum albumin (HSA)

Glucose

Sodium pyrovalate

Lactate

Potassium sulphate

Magnesium sulphate

Sodium chloride

Sodium hydrogen phosphate

Non-essential Amino Acids

L-glutamine

Taurine

Sodium bicarbonate

HEPES

Streptomycin 50 mg/litre

Penicillin 50.000 IU/litre

Phenol Red (Except product 1040)

### Medium 2

Synthetic Serum Replacement (SSR®)

(USA = Art Supplement)

Human serum albumin (HSA)

Glucose

Sodium pyrovalate

Lactic Acid

Potassium sulphate

Magnesium sulphate

Sodium chloride

Sodium hydrogen phosphate

Essential Amino Acids

Non-essential Amino Acids

L-glutamine

Sodium bicarbonate

Streptomycin 50 mg/litre

Penicillin 50.0000 IU/litre

Phenol Red (Except product 1040)

## Quality control testing

Sterility tested

Osmolality 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 cool at 2-8°C and protected from light.

The product has a minimum shelf life of 26 days from the date of shipping if stored according to the manufacturer's suggested guidelines.

We recommend that the products 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.

The product contains L-glutamine in its bio-available form to give maximum delivery of the component within the culture environment. However, L-glutamine is relatively unstable and as a consequence the shelf life of the formulation is reduced. Decomposition of L-glutamine is highly temperature dependent. The rate of decomposition at 37°C is more than 10 times higher than at 4°C.

**The exposure of the product to 37°C prior to use should therefore be kept to a minimum.**

## Precautions and warnings

Do not use product if:

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

The product contains small amounts of potentially hazardous human serum albumin, which has been obtained from a 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: US federal law restricts this device to sale by or on the order of a physician.

## Instructions for use

Two protocols are recommended for use with this product and the user should select the most appropriate method to integrate blastocyst culture into routine laboratory practices.

Where microdrop culture is chosen as the preferred method, it is important to use MediCult Liquid Paraffin (Cat. No. 1010) that has been quality assured for this procedure. Other lesser grade oils may remove important lipids from the media as well as introducing non-qualified elements to the culture system that could detrimentally affect the development of the embryos.

## Protocol 1:

### Day 5 Embryo Transfer

1. Recover oocytes as normal and prepare sperm according to preferred procedure. Carry out fertilisation in Medium I and where ICSI is required, transfer to Medium I immediately after injection.
2. At 16-20 hours, check for pronuclei, then carefully wash and transfer zygotes to fresh microdrops or open dishes of Medium I. Culture volumes of 50µl

for microdrops and 0.5mls for wells/dishes should be used and embryos may be cultured singly or in multiples to a maximum of 4 embryos.

3. At the 4-8 cell stage, the embryos should be carefully washed in Medium 2 and transferred to fresh microdrops or open dishes of the same medium. Culture volumes of 50µl for microdrops or 0.5mls for wells/dishes should be used and the embryos should be cultured singly or in multiples to a maximum of 4 in this second stage medium.
4. The embryos should be moved to fresh drops of Medium 2 every other day until blastocyst formation at approximately Day 5.
5. Embryos should be prepared and transferred to the uterus in Medium 2.

## **Protocol 2:**

### **Flexible procedure for Day 2 or Day 5 embryo transfer**

If enough oocytes or zygotes are available, the embryologist may elect to split the oocytes or zygotes between both media types where the couples' blastocyst formation potential is unknown, in order to increase the chances of having an embryo transfer. Zygotes can either be divided between Universal IVF (Cat.No. 1030/1031) for Day 2 transfer or freezing at the pronuclear/cleavage stage and 'Medium 1 and 2' for development only to blastocyst. It is not recommended to transfer embryos cultured in the latter formulations on Day 2.

1. Recover oocytes as normal and prepare sperm according to preferred procedure. Carry out fertilisation in Universal IVF and where ICSI is required, transfer to Universal IVF immediately after injection.
2. When checking for pronuclei between 16-20 hours, zygotes intended to be cultured to Day 2 for replacement/cryopreservation, should be transferred to Universal IVF and cultured in this medium until replacement/cryopreservation. Those embryos cultured in Universal IVF can be frozen using Embryo Freezing media products (Cat. No. 1026/1079).
3. Zygotes intended to be cultured to the blastocyst stage, should be washed carefully in Medium 1 and then transferred to fresh microdrops or dishes/wells of the same medium. Culture volumes of 50ul for microdrops and 0.5mls for open dishes should be used and embryos may be cultured singly or in multiples to a maximum of 4 embryos.
4. At the 4-8 cell stage, embryos in Medium 1 should be carefully washed in Medium 2 and then transferred to fresh microdrops or open dishes of the same medium. Culture volumes of 50ul for microdrops and 0.5mls for wells/dishes should be used and embryos can be cultured singly or in multiples to a maximum of 4 in this second stage medium.
5. The embryos should be moved to fresh drops of Medium 2 every other day until blastocyst formation occurs at approximately Day 5.
6. Embryos should be prepared and transferred to the uterus in Medium 2.