



0239-01

EmbryoAssist™

Product No.

1212

Symbols:

Catalogue Number

REF

Batch Code

LOT

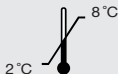
Sterilized using aseptic processing techniques (filtration)



Keep away from sunlight



Temperature limitation
from 2°C to 8°C



Use by



Consult operating instructions



Technical Services:

E-mail: customer.service@medicult.com

Internet: 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

EmbryoAssist™

Intended use

EmbryoAssist™ is for culture of embryos up to the 4-8 cell stage (Day 2 or 3 after insemination). Can also be used for fertilisation of oocytes.

Composition

Synthetic Serum Replacement (SSR®) (USA: ART

Supplement)

Human serum albumin (HSA)

Glucose

Pyruvate

Lactate

Physiological salts

Amino acids

L-glutamine (stable form)

Taurine

Vitamins

EDTA

Sodium bicarbonate

HEPES

Penicillin 50.000 IU/l

Streptomycin 50 mg/l

Phenol Red

Quality control testing

Sterility tested

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

Do not freeze.

Whenever the product has been warmed, it should not be refrigerated again.

In order to maintain the product in optimal condition we recommend that it should be used within 7 days of opening.

Minimum shelf life is 8 weeks from the day of shipment out of Denmark.

The product should be stored with a minimal headspace as per the original packaging, in order to avoid a reduction in the level of sodium bicarbonate in the medium.

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.

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 (Rx only).

Instructions for use

1. Carry out fertilisation (Day 0) in pre-equilibrated EmbryoAssist™ or Universal IVF Medium (Product No. 1030/1031). Where ICSI is required, the oocytes are transferred to the preferred fertilisation medium immediately after injection.
2. At 16-20 hours (Day 1), check for formation of pronuclei and transfer the pre-zygotes to a pre-equilibrated culture dish containing 50 µl microdrops or 0.5 ml wells/dishes of EmbryoAssist™ medium for further culture. The embryos should be cultured singly or in multiples to a maximum of 4 per well.
3. The embryos are prepared and transferred to the uterus in 20-30 µl of a transfer medium (eg. UTM™ (Product No. 1052/1152) at Day 2 or Day 3 when they have reached the 4-8 cell stage.
4. The embryos can be kept in the same medium from Day 1 until Day 3, and therefore no extra media changes are needed compared to Day 2 transfer.

