



0211-05

# ISMI™, ISM2™ and UTM™

## Cat. No.:

10500010	10 ml	11500010	10 ml
10500060	60 ml	11500060	60 ml
10510010	10 ml	11510010	10 ml
10510060	60 ml	11510060	60 ml
10520010	10 ml	11520010	10 ml

## Symbols:

Catalogue Number



Batch Code



Sterilized using aseptic processing techniques (filtration)



Protect from light



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

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# MediCult

Innovation with Care

# ISM1™, ISM2™ and UTM™

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## Intended use

ISM1™ can be used both for the IVF insemination procedure and for culture of embryos until Day 3.

ISM2™ is for culture of embryos from Day 3 and through to the blastocyst stage.

UTM™ is especially designed for transfer of embryos cultured in ISM1™ or ISM2™.

## Composition

### ISM1™ & ISM2™

Human serum albumin (HSA)

Glucose and derived metabolites

Physiological salts

Essential amino acids

Non-essential amino acids

Vitamins

Nucleotides

Sodium bicarbonate

Streptomycin 40 mg/litre

Penicillin 40.000 IU/litre

Phenol Red (Except product I150 and I151)

### UTM™

Sodium hyaluronate Ph.Eur.4Ed.

Human serum albumin (HSA)

Glucose and derived metabolites

Physiological salts

Essential amino acids

Non-essential amino acids

Vitamins

Nucleotides

Sodium bicarbonate

Streptomycin 40 mg/litre

Penicillin 40.000 IU/litre

Phenol Red (Except product I152)

## Quality control testing

Sterility tested

Osmolality tested

pH tested

Ph.Eur. endotoxin tested  $\leq 0.1$  EU/ml

Mouse Embryo Assay (MEA) tested  $\geq 80\%$

**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.

In order to maintain ISM1™, ISM2™ and UTM™ in optimal condition, 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 warning

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 HBbsAg, 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.

Not for injection.

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. Recover oocytes as normal and prepare sperm according to preferred procedure.  
Carry out insemination (Day 0) in pre-equilibrated ISM1™ or Universal IVF Medium (Cat. No. 1030/1031). Where ICSI is required the insemination is performed in pre-warmed SynVibro® ICSI Holding

Medium (Cat. No. 1585).

2. **a)** If Universal IVF Medium was chosen as the insemination medium for IVF, in order to get better embryo morphology an early rinse in ISM1™ is recommended at 4 hours, after which the oocytes are carefully transferred to a pre-equilibrated culture dish containing 50 µl microdrops or 0.5 ml wells/dishes of ISM1™ covered with Liquid Paraffin (Cat. No. 1010).  
**b)** In case of ICSI, immediately after injection the oocytes are transferred to the pre-equilibrated culture dish of ISM1™.  
The embryos should be cultured singly or in multiples to a maximum of 4 per well.
3. At 16-20 hours (Day 1), check for formation of pronuclei, then carefully wash and transfer zygotes to fresh 50 µl microdrops or 0.5 ml wells/dishes of ISM1™ covered with Liquid Paraffin. The embryos should be cultured singly or in multiples to a maximum of 4 per well and are kept in the same medium until Day 3.

## Embryo transfer Day 2 or Day 3:

The embryos are prepared and transferred to the uterus in 20 to 30 µl of pre-equilibrated UTM™. It is very important to flush the transfer catheter with UTM™ prior to use.

4. At Day 3, in case of blastocyst culture, the embryos are carefully washed in pre-equilibrated ISM2™ and transferred to fresh 50 µl microdrops or 0.5 ml

wells/dishes of the same medium. The embryos should be cultured singly or in multiples to a maximum of 4 per well in this second stage medium, until blastocyst formation at approximately Day 5.

**Blastocyst transfer:**

Blastocysts should be prepared and transferred to the uterus in 20 to 30  $\mu$ l of pre-equilibrated UTM™. It is very important to flush the transfer catheter with UTM™ prior to use.