

UTM™

Product No.:

1152

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origio

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Explanation of Symbols (in random order)



Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure



Do not use if package is damaged



Discard excess (unused) media following warming



Indicates the medical device manufacturer



Indicates the manufacturer's batch code so that the batch or lot can be identified



Indicates the date after which the medical device is not to be used



Indicates the manufacturer's catalogue number so that the medical device can be identified



Indicates a medical device that has been manufactured using accepted aseptic techniques



Indicates a medical device that needs protection from light sources



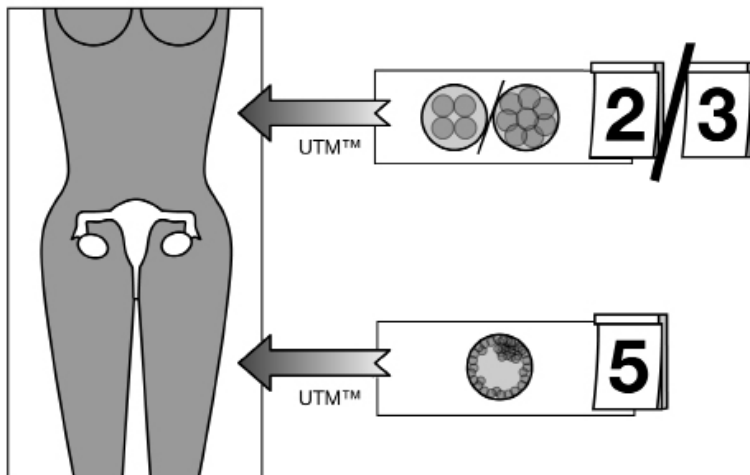
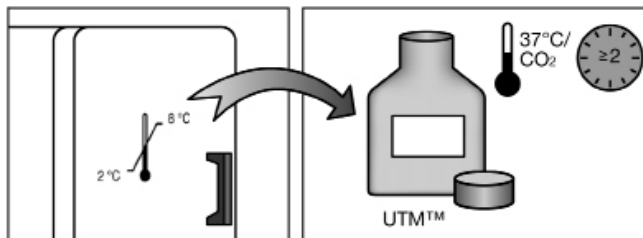
Indicates the need for the user to consult the instructions for use



Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions



Indicates the temperature limits to which the medical device can be safely exposed



Intended use

UTM™ is for transfer of embryos and blastocyst.

This product is for ART treatment, whether the cause of infertility is male or female. The product should only be used by professionals trained in ART treatment.

Composition

Human serum albumin (HSA)
Sodium hyaluronate
Glucose
Pyruvate
Physiological salts
Amino acids
Nucleotides
Vitamins
Insulin, recombinant
Cholesterol
Sodium bicarbonate
Gentamicin sulphate 10 µg/ml

Quality control testing

Sterility tested (Ph.Eur., USP)
Osmolality tested (Ph.Eur., USP)
pH tested (Ph.Eur., USP)
Endotoxin tested ≤ 0.1 EU/ml (Ph.Eur., USP)
1 cell Mouse Embryo Assay (MEA) $\geq 80\%$
Blastocysts by 96h

Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.fertility.coopersurgical.com.

Storage instructions and stability

The products are aseptically processed and supplied sterile.

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

When stored directed by the manufacturer the product is stable until the expiry date shown on the vial label.

Do not freeze.

The product is provided in vials intended for single use.

Excess (unused) media should be discarded.

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.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HCV, and non-reactive for HBsAg, HCV RNA and HIV-1 RNA. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

The potential risk of reproductive or developmental toxicity due to the use of ART media has not been determined and is still unknown.

Note: Dispose of the device in accordance with local regulations for disposal of medical devices.

Instructions for use

1. Equilibrate for a minimum of 2 hours in 5-6% CO₂ at 37°C prior to use.
2. The embryos are prepared and transferred to the uterus in 20 to 30 µl of pre-equilibrated UTM™.
3. Flush the transfer catheter with UTM™ prior to use.