

Liquid Paraffin

Product No.:

1010



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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



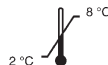
Indicates a medical device that needs protection from light sources



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



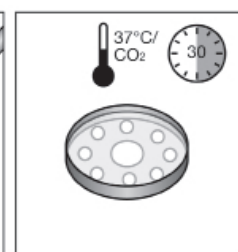
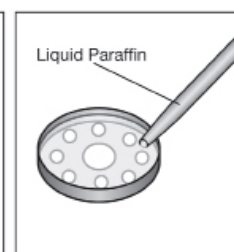
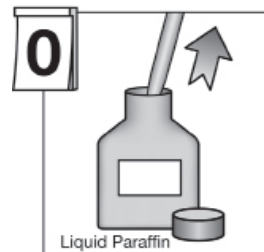
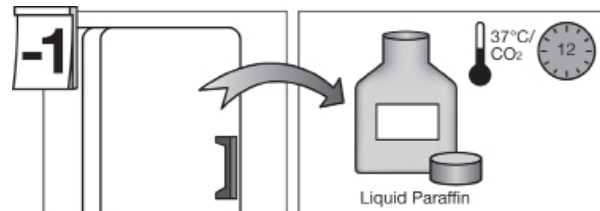
Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions



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



Product conforms to the Medical Device Directive 93/42/EEC



Liquid Paraffin

Intended use

Liquid Paraffin is used as an oil overlay for culture media during IVF and ICSI procedures.

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:

Light Liquid Paraffin, Ph.Eur., which has been pre-washed with Universal IVF Medium.

Quality control testing

Sterility tested (Ph.Eur., USP)

Endotoxin tested $\leq 0.1\text{EU/ml}$ (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 as directed by the manufacturer the product is stable until the expiry date shown on the vial label.

Do not freeze.

The product does not contain any antimicrobial agents and 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.

During the manufacturing process the product is washed with medium containing small amounts of human serum albumin (HSA), which has been obtained from a U.S. licensed source. 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. Place the Liquid Paraffin in an incubator with a 5-6% CO₂ environment at 37°C for at least 12 hours prior to use.
2. Pipette the intended volume of medium to be used for the micro drop on the bottom of a Petri dish.
3. Gently pipette the equilibrated Liquid Paraffin into the Petri dish until the micro drops are sufficiently covered with oil.