



# Hypure™ Oil Light



## Intended use

Hypure™ Oil is intended to be used as an overlay for culture of embryos, oocytes and sperm in ART and micromanipulation procedures.

## Composition

Pharmaceutical grade quality paraffin oil.

## General information

Hypure™ Oil is pre-washed, ready to use mineral oil for use in IVF, ICSI and related artificial reproductive techniques.

The oil allows small volumes of medium to be used as it prevents the evaporation of media and maintain stable osmolality and pH in the culture medium.

## Instructions for use

**CAUTION:** The detailed usage of Hypure™ Oil is determined based on each laboratory's procedure and protocols that are optimised for individual medical purposes.

### Preparation :

- For culture, pre-equilibrate Hypure™ Oil as necessary, and the culture medium at 37 °C in a CO<sub>2</sub> incubator for several hours (or overnight),
- For ICSI, warm Hypure™ Oil and HEPES buffered medium at 37 °C.

### Instructions for use :

1. Put culture medium on a dish or place micro drop of culture medium on a dish.
2. Gently pipette equilibrated Hypure™ Oil over the medium until they are completely covered.

**Note:** Washing of oil for embryo culture is not required.

## Quality control specifications

The following tests were performed for each lot of this product:

- Sterility: SAL 10<sup>-3</sup>
- Endotoxin: < 0.1 EU/ml
- Mouse embryo assay: ≥ 80% blastocysts after 120 hours in culture
- Density: 0.83-0.86 g/ml
- Viscosity: < 30 cP at 30 °C
- Peroxide Value (POV): <0.1mEq/kg

## Storage instructions and stability

- Store between 15-25 °C.
- Keep away from sunlight.
- Once opened, store the product in the original packaging.
- Once opened, the product is stable for at least 28 days under aseptic conditions and at room temperature. After this period, please discard the remaining media.
- The product is stable after transport (max 5 days) at elevated temperatures (< 37 °C).
- This product is stable until the expiration date labelled on the bottle if the packaging is un-opened or undamaged.

## Contraindications

- Do not re-sterilize.
- Do not freeze the product.
- Do not use the product after expiration date.
- Do not use if packaging is damaged or broken.
- Do not use if product becomes discoloured, cloudy or shows any evidence of microbial contamination.

Ki158/V2

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### Warnings

**Note:** “Lifetime of the device is determined by the applied AR technique and is maximum to the period of embryo culture.”

- Always works under strict hygienic conditions (e.g. LAF-bench ISO Class 5) to avoid contamination. Aseptic technique should be used.
- In case of eye or skin contact with Hypure™ Oil, immediately flush eye/skin with water.
- Observe all federal, state and local environmental regulations when discarding the product.
- In case of infection, dispose of the product appropriately in a prescribed manner.
- The user shall be responsible for any problems caused by non-conformity to the present IFU.
- The oil may appear cloudy if removed from the incubator and allowed to stand at room temperature for extended periods of time. Such cloudiness usually disappears if the oil is re-equilibrated by replacing it in the incubator for several hours; if it does not disappear, discard the product.
- This product is intended to be used by medical specialist trained in fertility treatment.

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