



Heavy Oil for Embryo Culture

Catalog No. 90189

100 mL, 500 mL

Glossary of Symbols*:



Catalog Number



Consult instructions for use



Do not resterilize



Do not use if package is damaged



Keep away from sunlight



Lot Number



Manufacturer



Sterilized using aseptic processing techniques (filtration)



Storage Temperature
2-8°C



U.S. Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.



Use-by date:
Year - Month - Day

*Symbol Reference - EN ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labeling and 21 CFR 801.109.

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INTENDED PURPOSE/ USE

Heavy Oil for Embryo Culture is intended for use as an overlay during human assisted reproductive technology (ART) procedures.

INDICATION FOR USE

Heavy Oil for Embryo Culture is indicated for use in helping to minimize evaporation and to protect the media from changes in temperature, osmolality and pH.

The target population consists of individuals who are undergoing assisted reproduction technology procedures.

This device is to be used by staff trained in ART procedures in a clinical laboratory setting such as, but not limited to, fertility clinics or hospitals.

Although not provided, the product will require separate accessories/tools, such as pipettes and culture dishes, during use.

DEVICE DESCRIPTION

Sterile white mineral oil.

COMPOSITION

White mineral oil

QUALITY ASSURANCE

Heavy Oil for Embryo Culture is sterilized by membrane filtration and aseptically processed according to validated manufacturing procedures.

Each lot of Heavy Oil for Embryo Culture is tested for:

Endotoxin by LAL methodology ≤ 0.25 EU/mL

One-cell MEA tested and passed with 80% or greater reaching at least the blastocyst stage.

Human Sperm Survival Assay $\geq 70\%$ sperm survival after 24 hours

Sterility by the current USP Sterility Test <71>

Peroxide Value (POV) ≤ 0.10 mEq/kg

All results are reported on a lot specific Certificate of Analysis which is available upon request.

DIRECTIONS FOR USE

The use of an oil overlay is recommended when using reduced volumes of media to prevent evaporation and to insulate the media from changes to temperature, osmolality and pH.

Oil should be equilibrated in a CO₂ incubator and/or warmed to 37°C for several hours (or overnight) before use.

Washing of Heavy Oil for Embryo Culture is not required.

For additional details on the use of Heavy Oil for Embryo Culture, each laboratory should consult its own laboratory procedures and protocols which have been specifically developed to the laboratory's individual program.

STORAGE INSTRUCTIONS AND STABILITY

Store the unopened bottles away from light at 2°C to 8°C.

Do not freeze or expose to temperatures above 39°C.

When stored as directed, product is stable until the expiration date shown on the bottle.

Duration Following Bottle Opening:

The product, once opened, has an eight week shelf life when stored under the recommended conditions of 2° to 8°C.

PRECAUTIONS

The user facility of this device is responsible for maintaining traceability of the product and must comply with national regulations regarding traceability, where applicable.

Do not use any bottle of oil that shows evidence of particulate matter or microbial contamination.

Do not use any bottle in which the sterile packaging has been compromised.

To avoid problems with contamination, practice aseptic techniques.

WARNINGS

Do not use if packaging is damaged as the sterility or functionality may be compromised.

CONTRAINDICATION

Not for use as an injectable product.

DISPOSAL

Contain and dispose of in accordance with local state/provincial and national regulations/requirements.

ENVIRONMENTAL PRECAUTION

Do not allow product to enter drains.