

Ultra RapidWarm Blast™



Indication for use

Ultra RapidWarm™ Blast is indicated for warming of vitrified human blastocyst stage embryos.

Contraindications

No known contraindications.

Product Description

Ultra RapidWarm Blast contains one medium for the warming of vitrified human blastocyst stage embryos. The medium consists of a MOPS buffered solution containing gentamicin, human serum albumin and sucrose.

For use after warming to 37 °C in ambient atmosphere.

Storage instructions and stability

Store dark at 2 to 8 °C.

Ultra RapidWarm Blast is stable until the expiry date shown on the bottle labels and the LOT specific Certificate of Analysis.

Media bottles can be used for up to two weeks after first opening, use aseptic technique and minimize the time outside the refrigerator. Record opening date on the bottle. Discard excess media no later than two weeks after first opening.

Directions for use

The patient target group is an adult or reproductive-age population that undergoes IVF treatment.

Do not place Ultra RapidWarm Blast in a CO₂ environment.

The following is the general procedure for using Ultra RapidWarm Blast.

Warning:

Warming procedures are performed at 37 °C.

1. Place at least 0.5 mL of warming solution into a dish and warm to 37 °C for a minimum of 15 minutes on a heated stage/plate. The time may vary and must be validated by the laboratory.
2. Prepare the vitrification device containing the vitrified blastocysts according to its Instructions for Use.
3. Remove the vitrification device from the liquid nitrogen and immediately plunge the tip into the warming solution.

4. Leave the blastocyst(s) for 2 minutes.
5. Wash the blastocyst(s) several times with culture medium, then incubate until further use.

Warnings

Do not use after the expiration date.

Do not re-sterilize after opening.

Use within two weeks of opening.

Currently, research literature indicates the long-term effects of warming vitrified embryos remain unknown. Discard product if bottle integrity is compromised. Do not use Ultra RapidWarm Blast if it appears cloudy.

To avoid contamination Vitrolife strongly recommends that media should be opened and used only with aseptic technique.

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, HBc, HCV, and HTLV I/II and non-reactive for HbsAg, HCV RNA and HIV-1 RNA and syphilis. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

Ultra RapidWarm™ Blast contains gentamicin. The product is only in direct contact with embryos. Ensure appropriate precautions are taken to minimize the risk of contact with individuals with known hypersensitivity/allergy to gentamicin.

Specifications

Sterility, USP <71> No evidence of microbial growth

Mouse Embryo Assay one-cell system:
≥80% embryos developed to expanded blastocyst at 96 hours after 2 minutes of exposure.

Bacterial endotoxins (LAL assay),
USP <85>, [EU/mL] < 0.5

pH, USP <791>, tested

Osmolality, USP <785>, tested

LOT specific test results are available on the Certificate of Analysis provided with each delivery.

Precautions

Caution: Federal Law restricts this device to sale by or on the order of a physician or embryologist.

Ultra RapidWarm Blast contains human serum albumin and gentamicin.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

Discard the product according to standard clinical practice for medical hazardous waste when the procedure is finished.

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Symbols glossary

* Medical devices – Symbols to be used with information to be supplied by the manufacturer (ISO 15223-1:2021).

Symbol	Title	Reference and symbol ID
	Consult instructions for use	*Ref no: 5.4.3
	Manufacturer	*Ref no: 5.1.1
	Date of manufacture	*Ref no: 5.1.3
	Use-by date	*Ref no: 5.1.4
	Batch code	*Ref no: 5.1.5
	Catalogue number	*Ref no: 5.1.6
	Sterilized using aseptic processing techniques (filtration)	*Ref no: 5.2.2
	Single sterile barrier system	*Ref no: 5.2.11
	Temperature limit	*Ref no: 5.3.7
	Keep away from sunlight (light sources)	*Ref no: 5.3.2
	Contains human blood or plasma derivatives	*Ref no: 5.4.6
	Medical Device	*Ref no: 5.7.7

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