ThermoBlast™ Kit

Intended Use

For warming of human blastocysts vitrified with VitriBlast™.

Caution

- Federal Law restricts this device to sale by or on the order of a physician or practitioner trained in its use.
- The user should read and understand the Directions for Use, Warnings and Precautions, and be trained in the correct procedure before using the Nidacon Kits for vitrification of human blastocysts.
- 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
- Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

  There are no reports of proven virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes.

  It is strongly recommended that every time ThermoBlast™ is used for a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

Warnings

- The long term safety of blastocyst vitrification on children born following this method of embryo cryopreservation is unknown
- The long term safety of blastocyst collapse on children born following this procedure has not been established

Precautions

- Use aseptic procedures at all times
- Do not use any vial or solution that shows evidence of particulate matter or cloudiness
- Do not use contents if tamper-evident seal is broken or if scew cap accidentically comes in contact with unsterile surfaces
- Please check for regulatory compliance governing the use of ART products in your country
- Do not re-use. Reuse may result in biological contamination and/or property changes in the product.

Components

Sodium chloride	Sodium pyruvate
Potassium chloride,	EDTA
Magnesium sulphate	HEPES
Potassium dihydrogen phosphate	Sucrose
hSA Human serum albumin	Purified Water
Sodium bicarbonate	
Calcium lactate	
Glucose	

Performance Characteristics

pH	7.20-7.50
Endotoxin levels	<0.5 EU/mL
MEA Reexpanded blastocysts after exposure	>80%
Sterile filtered	SAL 10^{-3}

Product Description

All VitriBlast™ Kit and ThermoBlast™ Kit solutions contain a modified HEPES buffered HTF medium. VitriBlast, solution 2, will after inclusion of additives also contain DMSO 7.5% and Ethyleneglycol 7.5%. VitriBlast™, solution 3, in addition includes Ficoll 0.14 mM, Sucrose 0.67 M and will after inclusion of additives also contain DMSO 15% and Ethyleneglycol 15% (DMSO and Ethyleneglycol are included as additives solely in the VitriBlast™ Kit). ThermoBlast™, solution 4, in addition contains Sucrose 0.5 M and solution 5 contains Sucrose 0.25 M

Protein Supplement

ThermoBlast™ Kit contains the component human serum albumin (hSA)

Storage and Stability

Before opening, store at 2 to 30ºC and avoid temperatures above or below these values. Under these conditions ThermoBlast™ Kit has a shelf-life of 12 months. The expiry date is shown on both bottles and cartons

No claims are made regarding the shelf-life of ThermoBlast™ Kit in opened vials

No antibiotics, unstable additives or preservatives have been added by the manufacturer to ThermoBlast™ Kit

Ordering Information

Volume	**Article No.**
4x10 mL	TBK-010

www.nidacon.com

For further technical information or assistance, please contact your distributor or the manufacturer

Manufacturer:
Nidacon, Flöjelbergsgatan 16 B, SE-431 37 Mölndal, Sweden
Tel: +46-31-703 06 30, Fax: +46-31-40 54 15
E-mail: contact@nidacon.com, www.nidacon.com

Nidacon

INS-TBK-EC16

Reagents and Equipment

- ThermoBlast™ kit
- Sterile pipettes
- Culture dishes (NUNC 4-well)
- CO_2 Incubator
- Stopwatch or timer
- Heated stage
- Inverted microscope

Directions for Use

Warming Vitrified blastocysts with ThermoBlast™

1. Label a 4 well culture dish with the patient ID and each well with each solution number

2. Prepare the culture dish by adding 1 ml of ThermoBlast™4 into the first well, 1 ml ThermoBlast™5 to the second well and 1mL of ThermoBlast™6 to the third well

3. Incubate at 37ºC in 5-6% CO_2 for **30 minutes**

4. Immerse the part of the device, containing the blastocyst in the surface of solution 4. Allow the blastocyst to fall off. Identify its presence in the well and incubate for **2 minu tes** on the heated stage. Note that 2 minutes is for the total incubation time.

5. Transfer the blastocyst to ThermoBlast™ 5. Incubate for **3 minutes** on the heated stage

6. Transfer the blastocyst to ThermoBlast™ 6. Incubate for **5 minutes** on the heated stage

7. Transfer to culture medium

8. For a correct evaluation, wait 1-4 hrs before transfer, in order to allow the blastocyst to reexpand

Temperature limit

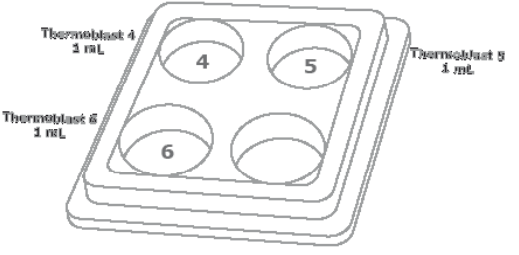
Use by - see label

STERILE A Sterilized Using Aseptic Processing Techniques

LOT Batch code

Consult instructions for use

Manufacturer



References

Lane M et al. (1999) Vitrification of mouse and human blastocysts using a novel cryoloop container-less technique. Fertility and Sterility. Vol 72, No 6, pp1073-1078, **Mukaida T, Takahashi K, Kasai M.** (2003) Blastocyst cryopreservation: ultrarapid Vitrification using cryoloop technique. Reproductive BioMedicine Online., Vol. 6, No. 2, pp221-225, **Mukaida T et al.** (2003) Vitrification of human blastocysts using cryoloops: clinical outcome of 223 cycles. Hum Reprod., Vol. 18, No. 2, pp384-391, **Hardarson T et al.** (2006) Vitrification and warming human blastocysts by use of a laser to artificially induce blastocyst collapse prior to vitrification. Acta Obstet Gynecol Scand., 86 p. 119-120, **Kartberg A-J et al**, (2008), Vitrification with DMSO protects embryo membrane intergrity better than solution without DMSO, Reproductivie Medicine Online, Volume 17, 3 September 2008. ***For more references please visit nidacon.com***