Fast Warm - NX

Catalog No. 90196 **6 x 2mL, 2 x 20mL**

For assisted reproductive procedures.

Glossary of Symbols*:

REF	Catalog Number
LOT	Lot Number
STERILE A	Sterilized using aseptic processing techniques (filtration)
MD	Medical Device
UDI	Unique Device Identification
8°C 2°C	Storage Temperature 2-8°C
nexpringhealth.com	Consult instructions for use
	Do not use if package is damaged
STERILIZE	Do not re-sterilize
	Contains Human Blood or plasma derivatives.
	Expiration: Year - Month - Day
	Manufacturer
	Date of Manufacture: Year - Month
Rx Only	U.S. Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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

Irvine Scientific, LLC
1830 E. Warner Ave., Santa Ana, California 92705 USA
Telephone: 1 949 261 7800 • 1 800 437 5706 • Fax: 1 949 261 6522 • www.nexpringhealth.com

P/N 021086, Rev.7
Effective Date:

U.S. CAUTION

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

INTENDED USE

Fast Warm – NX is intended for use in assisted reproductive procedures for the thawing of vitrified human blastocyst stage embryos.

INDICATION FOR USE

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DEVICE DESCRIPTION

Fast Warm – NX is a dual buffered solution (HEPES & MOPS) of Continuous Single Culture Medium (CSCM) containing gentamicin sulfate, 20% (v/v) Dextran Serum Supplement (DSS), and 1.0M trehalose.

DSS is a protein supplement consisting of 50 mg/mL therapeutic grade Human Serum Albumin (HSA) and 20 mg/mL Dextran. DSS is used at 20% (v/v) in Fast Warm – NX for a final concentration of 10 mg/mL HSA and 4 mg/mL Dextran.

COMPOSITION:

Amino Acids
L-Arginine
Glycine
L-Histidine
L-Lysine
L-Proline
L-Tyrosine
L-Alanine
L-Aspartic Acid
L-Asparagine
L-Glutamic Acid
L-Isoleucine
L-Leucine
L-Methionine
L-Phenylalanine
L-Serine
L-Threonine
L-Tryptophan
L-Valine
L-Cystine
L-Alanyl-L-Glutamine

Salts and Ions
Sodium Chloride
Potassium Chloride
Magnesium Sulfate
Calcium Chloride
Potassium Phosphate

Antioxidants
Sodium Citrate
EDTA

Antibiotic
Gentamicin Sulfate

Energy Substrates
Dextrose
Sodium Pyruvate
Sodium Lactate

Protein Source
Human Serum Albumin

Buffers
Sodium Bicarbonate
HEPES
MOPS

Cryoprotectants
Trehalose
Dextran

QUALITY ASSURANCE

Fast Warm – NX is membrane filtered and aseptically processed according to manufacturing procedures which have been validated.

Each lot of Fast Warm – NX is tested for:
Endotoxin USP <85> by Limulus Amebocyte Lysate (LAL) methodology (≤ 0.6 EU/mL)
One-cell MEA system: ≥80% embryos developed to expanded blastocyst at 96 hours after one minute of exposure
Sterility by the current USP Sterility Test <71> (No microbial growth)
Osmolality USP <785>: 1550-1900 mOsm/kg, 1:1 dilution, results are multiplied by a dilution factor of 2
pH USP <791>: 7.05-7.45

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

MATERIALS REQUIRED BUT NOT INCLUDED

- Sterile 4-well dish or sterile small petri dishes (35 x 10mm or equivalent)
- Disposable gloves
- Transfer Pipettes
- Stopwatch or Timer
- Liquid nitrogen reservoir
- Liquid nitrogen (LN_2)
- Culture medium with protein, pre-equilibrated to 37°C in CO_2 incubator prior to thawing procedure
- 37°C incubator without CO_2 or heating stage
- Additional items required by IFU of vitrification device of choice

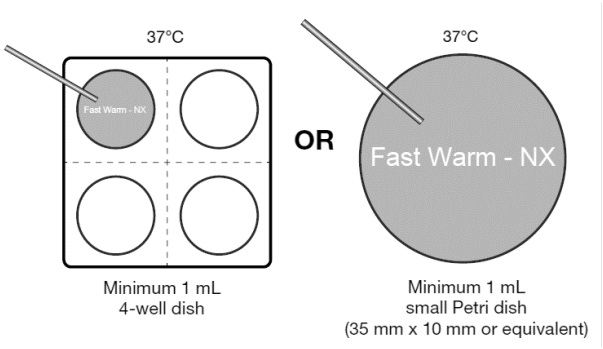
DIRECTIONS FOR USE

WARMING

1. Set up thawing dish (as shown in Figure 1):
   - At 37°C: Aseptically dispense a minimum volume of 1 mL of Fast Warm - NX and warm to 37°C in a humidified incubator without CO_2 or on a heating stage at least 30 minutes prior to starting warming procedure.
2. Identify the device sample(s) to be warmed and quickly transfer from LN_2 storage to an LN_2 filled holding reservoir in preparation for warming procedure.
3. Place LN_2 filled holding reservoir in close proximity to the working area and stage of the microscope in order to achieve subsequent rapid manipulation from reservoir to Fast Warm – NX.
4. Prepare the device for warming by referring to corresponding device IFU and internal laboratory procedure(s). Laboratory should consult their own procedures and protocols.
5. Remove Fast Warm - NX dish from 37°C incubator without CO_2 or heating stage and place it under focus on top of the microscope stage.
6. After specimen(s) is in Fast Warm - NX following the device-specific protocol, leave the specimen(s) for a total of 1 minute.
   - Thirty (30) seconds following exposure into Fast Warm - NX, gently pipette the specimen(s) if floating, and place at the bottom of the Fast Warm - NX.
7. Process the specimen(s) as indicated below:
   a) There are two options for warmed blastocyst stage embryos:
      i. For immediate transfer to patient: Transfer blastocyst stage embryos to pre-equilibrated transfer medium.
      ii. For further culture: Transfer blastocyst stage embryos to pre-equilibrated culture medium and incubate accordingly until desired developmental stage has been reached for transfer to patient.

For additional details on the use of this product, each laboratory should consult its own laboratory procedures and protocols which have been specifically developed and optimized for your individual medical program.

FIGURE 1.



STORAGE INSTRUCTIONS AND STABILITY

Store unopened vials refrigerated at 2°C to 8°C. When stored as directed, Fast Warm – NX are stable until the expiration date shown on the vial labels.

Do not use medium for more than fourteen (14) days once containers have been opened.

As human source material is present in the product, it may develop some particulate matter during storage. This type of particulate matter is not known to have an effect on product performance.

PRECAUTIONS

This device is intended to be used by staff trained in assisted reproductive procedures. These procedures include the intended application for which this device is intended.

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

WARNINGS

Do not use any vial of solution which shows evidence of damage, leakage, particulate matter, or cloudiness. Discard the product in accordance with applicable regulations.

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

Do not re-sterilize after opening.

To avoid problems with contamination, handle using aseptic techniques and discard any excess medium that shows any evidence of contamination after opening. (See DISPOSAL for discard instructions.)

Do not use after the expiration date.

The vitrification device used for warming should be cleared for use by the FDA for vitrification procedures.

Currently, research literature indicates the long-term effects of vitrification on embryos remains unknown.

This product contains Gentamicin Sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic before product use.

This product contains HSA. Patients should be advised by the end user or physician that the product contains HSA and the patient should be checked for sensitivity or allergic reactions to HSA, and its excipients, before product use.

US: This product contains Human Serum Albumin (HSA). Human source material used in the manufacture of this product has been tested by FDA-licensed kits and found to be non-reactive for Hepatitis B Surface Antigen (HBsAg) and the antibodies to Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV). However, no test method offers complete assurance that products derived from human sources are noninfectious. Handle all human source material as if it were capable of transmitting infection, using universal precautions.

CONTRAINDICATIONS

No known contraindications.

DISPOSAL

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

ENVIRONMENTAL PRECAUTION

Do not allow product to enter drains.