

## Vit Kit - Warm NX (Vitrification Kit for Warming)













with Gentamicin and DSS

**Catalog No. 90183 Includes:**

- Thawing NX - TS (yellow cap)
- Dilution NX - DS (orange cap)
- Washing NX – WS (red cap)

For assisted reproductive procedures.

**Glossary of Symbols\*:**

	Catalog Number
	Lot Number
	Sterilized using aseptic processing techniques (aseptically filtered)
	Expiration: Year - Month - Day
	Caution, consult accompanying documents
	Consult instructions for use
	Storage Temperature 2-8°C
	Do not re-use
	Do Not Re-Sterilize
	Do Not Use If Package Is Damaged
	Phthalate, DBP, DEHP 1mL and 2mL container
	Manufacturer
<b>RX Only</b>	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

**FUJIFILM Irvine Scientific, Inc.**

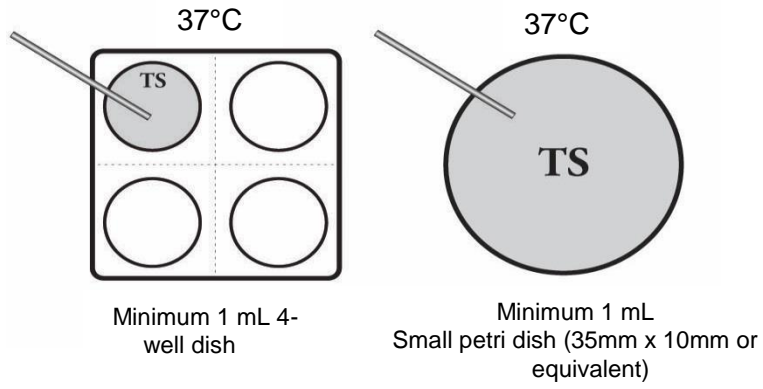
2511 Daimler Street, Santa Ana, California 92705 USA

• Telephone: 1 949 261 7800 • 1 800 437 5706 • Fax: 1 949 261 6522 • [www.irvinesci.com](http://www.irvinesci.com)

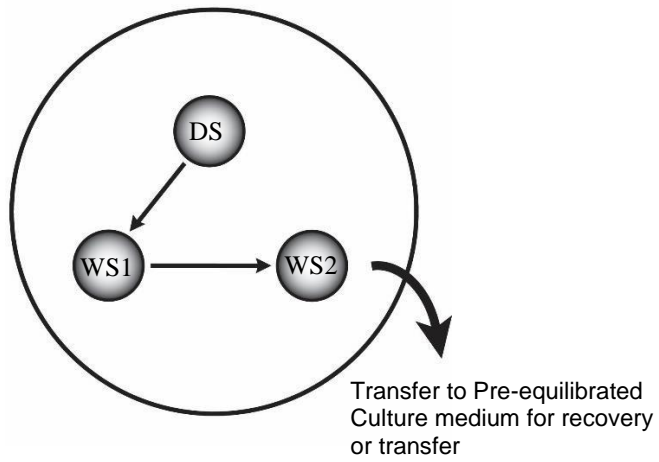
© 2019 FUJIFILM Irvine Scientific Inc. All rights reserved. The FUJIFILM Irvine Scientific logo, Vit Kit and Continuous Single Culture are trademarks of FUJIFILM Irvine Scientific, Inc. in various jurisdictions.

PN 41102-EN Rev.0

**Figure 1:**



**Figure 2:**



TS= Thawing Solution  
DS= Dilution Solution  
WS= Washing Solution

## ENGLISH

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

### INTENDED USE

Vit Kit - Warm NX is intended for use in assisted reproductive procedures for the thawing of vitrified human oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

### DEVICE DESCRIPTION

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

**Dilution NX-DS** (DS) is a dual buffered solution (HEPES and MOPS) of CSCM containing gentamicin sulfate, 20% DSS, and 0.5M trehalose.

**Washing NX-WS** (WS) is a dual buffered solution (HEPES and MOPS) of CSCM containing gentamicin sulfate and 20% DSS.

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 Vit Kit – Warm NX for a final concentration of 10 mg/mL HSA and 4 mg/mL Dextran.

These three solutions are to be used in sequence according to the step-wise microdrop thawing protocol.

### COMPOSITION

#### **Salts and Ions**

Potassium Phosphate  
Sodium Chloride  
Potassium Chloride  
Magnesium Sulfate  
Calcium Chloride  
Sodium Phosphate  
Sodium Citrate

#### **Buffers**

Sodium Bicarbonate  
HEPES  
MOPS

#### **Amino Acids**

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

#### **Antioxidant**

Sodium Citrate  
EDTA

#### **Antibiotic**

Gentamicin Sulfate

#### **Energy Substrates**

Glucose  
Pyruvic Acid  
Sodium Lactate

#### **Protein Source**

Human Serum Albumin

#### **Cryoprotectant**

Dextran  
Trehalose  
Ethylene Glycol  
Dimethylsulfoxide

## QUALITY ASSURANCE

The solutions in Vit Kit-Warm NX are membrane filtered and aseptically processed according to manufacturing procedures which have been validated.

Each lot of Vit Kit - Warm NX receives the following tests:

Solutions:

- Endotoxin by Limulus Amebocyte Lysate (LAL) methodology ( $\leq 0.6$  EU/ml)
- Mouse Embryo Assay (one-cell) ( $\geq 80\%$  expanded Blastocyst)
- Sterility by the current USP Sterility Test <71> (Pass)

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

## FOR WARMING:

### MATERIALS REQUIRED BUT NOT INCLUDED

- Sterile 4-well dish or sterile small petri dishes (35 X 10 mm or equivalent)
- Disposable gloves
- Transfer pipettes
- Stopwatch or timer
- Liquid nitrogen reservoir
- Liquid nitrogen
- Culture medium with protein, pre-equilibrated to 37°C in CO<sub>2</sub> incubator prior to thawing procedure
- 37°C incubator without CO<sub>2</sub> or heating stage
- Additional items required by IFU of vitrification device of choice

## DIRECTIONS FOR USE

Vit Kit – Warm NX components (per application)

- 1 mL of Thawing NX – TS (TS)
- 50  $\mu$ L of Dilution NX – DS (DS)
- 2 x 50  $\mu$ L of Washing NX – WS (WS)

## WARMING PROTOCOL

**NOTE: The warming steps include plunging the device into the 37°C TS and subsequent diluting and washing in DS and WS at room temperature**

1. Set up thawing dish (as shown in **Figure 1**):  
**At 37°C:** Aseptically dispense a minimum volume of 1 mL of TS and warm to 37°C in an incubator without CO<sub>2</sub> 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<sub>2</sub> storage to an LN<sub>2</sub> filled holding reservoir in preparation for warming procedure.
3. Place LN<sub>2</sub> 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 TS.
4. Remove TS dish from 37°C incubator or heating stage and place it under focus on top of the microscope stage.
5. Prepare the device for warming by referring to corresponding device IFU and internal laboratory procedure(s).  
**NOTE: Laboratory should consult their own procedures and protocols.**
6. After specimen(s) are in TS following the device specific protocol, leave the specimen(s) for a total of 1 minute.
  - Thirty (30) seconds following exposure into TS, gently pipette the specimen(s) if floating, and place at the bottom of the TS.**Steps 7-10 must be performed at room temperature (22-27°C).**
  - At room temperature: Aseptically dispense one (1) 50  $\mu$ L drop of DS on a sterile petri dish (see **Figure 2**)
7. Transfer specimen(s) to DS for 4 minutes. Gently pipette specimens once to ensure complete rinse in DS.  
**NOTE: The specimen will remain shrunken during exposure to DS.**
8. During the 4 minute exposure in DS, aseptically dispense two (2) 50  $\mu$ L drops of WS (WS1, WS2) as shown in diagram. (see **Figure 2**)
9. Transfer specimen(s) to WS1 then WS2 for 4 minutes each, undisturbed.  
**NOTE: The specimen(s) should re-expand to the original size within 2-3 minutes in WS.**
10. Process the specimen(s) as indicated below:
  - a) OOCYTE(S) should be transferred to pre-equilibrated culture medium in accordance with laboratory protocol for recovery (2-3 hours to allow time for spindle re-formation) prior to subsequent manipulations.
  - b) There are two options for warmed EMBRYO(S):
    - i) For immediate transfer to patient: transfer EMBRYO(S) to pre-equilibrated 'transfer' medium.
    - ii) For further culture: transfer EMBRYO(S) to pre-equilibrated culture medium for a 4 hour recovery period. After recovery period, transfer EMBRYO(S) to culture medium with 10% (v/v) protein and incubate accordingly until desired developmental stage has been reached for transfer to patient.

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

## STORAGE INSTRUCTIONS AND STABILITY

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

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 AND WARNINGS**

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.

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

To avoid problems with contamination, handle using aseptic techniques.

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

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

**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 to the antibodies to Hepatitis C (HCV), and antibodies to 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 pre-cautions. Donors of the source material have also been screened for CJD.

#### **CONTRAINDICATION**

Product contains Gentamicin Sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.