

**FUJIFILM**



Irvine**Scientific**

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**SSS-NX**

**(Serum Substitute Supplement-NX)**

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**Catalog No. 90194**

**100 mL, 12x10 mL Kits**

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For assisted reproductive technology (ART) procedures.

## INTENDED USE

SSS-NX is intended for use in assisted reproductive technology (ART) procedures which include gamete and embryo manipulation and culture. These procedures include the use of SSS-NX as a supplement for ART media.

## DEVICE DESCRIPTION

SSS-NX consists of approximately 50 mg/mL protein in a saline solution. Of this,  $\geq 83\%$  is albumin,  $\leq 17\%$  is alpha and beta globulins, and  $\leq 1\%$  is gamma globulin.

## COMPOSITION

### Proteins

Human Serum Globulins

Human Serum Albumin

## QUALITY ASSURANCE

SSS-NX is a protein supplement which is membrane filtered and aseptically processed according to manufacturing procedures which have been validated.

Each lot of SSS-NX is tested for:

Endotoxin by LAL methodology

Biocompatibility by Mouse Embryo Assay

Sterility by the current USP Sterility Test <71>

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

## DIRECTIONS FOR USE

General laboratory practice includes protein supplementation when using various culture media for gamete and embryo procedures. The amount of protein supplementation can vary among laboratories and is dependent on the phase of processing/ growing the gametes and embryos.

General recommendations for SSS-NX are:

Procedure	SSS-NX
Embryo Culture	10% v/v
Oocyte Retrieval	10% v/v
Sperm Washing	10% v/v
Fertilization	10% v/v
Post Cryopreservation	20% v/v

Warm the protein supplemented media to 37°C and equilibrate to desired pH in a CO<sub>2</sub> incubator prior to use.

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 bottles refrigerated at 2° to 8°C.

Do not freeze or expose to temperatures greater than 39°C.

SSS-NX is stable until the expiration date shown on the bottle and vial label when stored unopened as directed.

### **PRECAUTIONS AND WARNINGS**

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

Do not use any bottle of medium which shows evidence of excessive particulate matter or cloudiness or is not amber in color.

To avoid problems with contamination, handle using aseptic techniques.

\*Human source material used in the manufacture of this product has been tested and found to be non-reactive using tests to determine Hepatitis B surface antigen (HBsAg), antibodies to Hepatitis C Virus (HCV), and antibodies to Human Immunodeficiency Virus 1 and 2 (HIV-1/ HIV-2). Furthermore, all plasma units have been analyzed by validated PCR technique for above mentioned and is tested by in-process NAT testing for Hepatitis A Virus (HAV). 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 and personal protective equipment (PPE). Donors of the source material have also been screened for Creutzfeldt Jakob Disease (CJD) and Syphilis.

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

### **CONTRAINDICATIONS**

Patient is allergic to Human Serum Albumin or Human Serum Globulins.

### **DISPOSAL**

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

## Glossary of Symbols\*:

**REF**

Catalog Number

**LOT**

Lot Number

**STERILE A**

Sterilized using aseptic processing techniques  
(filtration)



Expiration:  
Year - Month - Day



Caution, consult accompanying documents  
Consult instructions for use



Consult instructions for use or  
consult electronic instruction for use

irvinesci.com



Storage Temperature  
2-8°C



Do not re-use



Do not re-sterilize



Do not use if package is damaged and  
consult instruction for use

**UDI**

Unique device identifier

**MD**

Medical device



Contains human blood or plasma derivatives



Contains a medical substance



Date of manufacture



Manufacturer

**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.



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