

FUJIFILM



Irvine**Scientific**

**Serum Substitute Supplement
(SSS)**

Catalog No. 99193

100 mL, 12 x 12 mL Kits

For assisted reproductive procedures.

INDICATION FOR USE

SSS is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of SSS as a supplement for culture medium. Not for use as an injectable product.

DEVICE DESCRIPTION

SSS consists of 84% human serum albumin from therapeutic-grade source material (50 mg/mL, 5% w/v) and 16% human serum globulins (10 mg/mL, 1% w/v) in a saline solution.

COMPOSITION

<u>Proteins, Hormones, and Growth Factors</u>	<u>Other</u>
Human Serum Globulin	WFI Quality Water
Human Serum Albumin	

QUALITY ASSURANCE

SSS is a protein supplement which is membrane filtered and aseptically processed according to manufacturing procedures which have been validated to meet a sterility assurance level (SAL) of 10^{-3} .

Each lot of SSS 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 (such as CSCM, etc.) 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 are:

Procedure	SSS
Oocyte Retrieval	10% v/v
Sperm Washing	10% v/v
ICSI	10% v/v
Post Cryopreserved	20% v/v
Embryo Transfer	10-50% v/v

Warm the protein supplemented media to 37°C and equilibrate to desired pH in a CO₂ 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 is stable until the expiration date shown on the bottle and vial label when stored unopened as directed.

As human source material is present in the product it may develop some protein precipitate during storage or in culture over time. This protein precipitate 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 that include the indicated application for which the device is intended

Do not use any bottle of medium which shows evidence of particulate matter, extreme cloudiness or is not pale yellow in color.

To avoid problems with contamination, handle using aseptic techniques and discard any excess medium that remains in the bottle after the procedure is completed.

*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 for Hepatitis B surface antigen (HBsAg), 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 precautions. Donors of the source material have also been screened for CJD.

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

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



Storage Temperature
2-8°C



Do not re-use



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.



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

© 2019 FUJIFILM Irvine Scientific, Inc. All rights reserved. SSS, FUJIFILM Irvine Scientific, and the FUJIFILM Irvine Scientific logo are trademarks of FUJIFILM Irvine Scientific, Inc. in various jurisdictions.

PN 40609 REV.10