

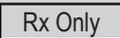
# Continuous Single Culture®-NX (CSCM-NX)

Catalog # 90167

20 mL and 60 mL

For assisted reproductive procedures.

## Glossary of Symbols\*:

	Catalog Number
	Lot Number
	Sterilized using aseptic processing techniques (filtration)
	Expiration: Year - Month - Day
	Caution, consult accompanying documents
	Storage Temperature
	Manufacturer: Irvine Scientific®
	Do not resterilize
	Do not use if package is damaged
	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.

Biggers, JD. and Racowsky, C. *The development of fertilized human ova to the blastocyst stage in KSOM<sup>AA</sup> medium: is a two-step protocol necessary?* RBMOnline, 5:133-140, 2002.

Pool, TB. *Recent advances in the production of viable human embryos in vitro.* RBMOnline, 4:294-302, 2002.

Biggers, JD. *Thoughts on embryo culture conditions.* RBMOnline, 4 (suppl.1):30-38, 2001.

Lane, M., Hooper, K., and Gardner, DK. *Effect of essential amino acids on mouse embryo viability and ammonium production.* J. Asst. Reprod. Genet. 18: 519-525, 2001

Biggers, JD. and McGinnis, LK. *Evidence that glucose is not always an inhibitor of mouse preimplantation development in vitro.* Hum. Reprod 16:153-163, 2001.

Devreker, F., Van den Bergh, M., Biramane, J., Winston, RML, Englert, Y., and Hardy, K. *Effects of taurine on human embryo development in vitro.* Hum. Reprod. 14: 2350-2356, 1999.



# IrvineScientific®

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

PN 41069 Rev.1

## ENGLISH

### INDICATIONS FOR USE

Continuous Single Culture®-NX (CSCM-NX) is intended for use as a culture medium for human gametes and embryos from fertilization through day 5/6 of development in vitro.

### QUALITY ASSURANCE

CSCM-NX 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 CSCM-NX is tested for:

Endotoxin (LAL):  $\leq 0.25$  EU/mL

One-Cell MEA  $\geq 80\%$  expanded blastocyst at 96 hours

Sterility by the current USP Sterility Test  $<71>$

Human Sperm Survival Assay  $\geq 70\%$  of original motility at 24 hours

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

### COMPOSITION:

#### Salts & Ions

Calcium Chloride

Magnesium Sulfate

Potassium Chloride

Potassium Phosphate

Sodium Chloride

#### Buffer

Sodium Bicarbonate

#### Energy Substrates

Dextrose

Sodium Lactate

Sodium Pyruvate

#### Antioxidant

EDTA

Sodium Citrate

#### Dipeptide

Alanyl-glutamine

#### Antibiotic

Gentamicin (10µg/mL)

#### Amino Acids

Alanine

Arginine

Asparagine

Aspartic Acid

Cystine

Glutamic Acid

Glycine

Histidine

Isoleucine

Leucine

Lysine

Methionine

Phenylalanine

Proline

Serine

Threonine

Tryptophan

Tyrosine

Valine

### BUFFER SYSTEM

CSCM-NX uses sodium bicarbonate as a buffering system. This is specifically designed for use in a CO<sub>2</sub> incubator.

### DIRECTIONS FOR USE

#### PROTEIN SUPPLEMENTATION

CSCM-NX does not contain protein components. General laboratory practice includes protein supplementation when using this medium. The amount of protein supplementation may vary among laboratories and is dependent on the phase of processing/growing the gametes and embryos. Consult your individual laboratory protocols.

The following are recommendations for protein supplementation based upon the indications for use of the CSCM-NX:

#### For Fertilization and Embryo Culture:

When using Irvine Scientific Human Serum Albumin (HSA), a 100 mg/mL solution, use at 5 mg/mL. For 10 mL of medium, add 0.5 mL of HSA solution to 9.5 mL of the medium.

When using Irvine Scientific Serum Substitute Supplement (SSS), a 60 mg/mL protein solution, use at 10% (v/v). For 10 mL of medium, add 1.0 mL SSS to 9.0 mL of medium.

#### EQUILIBRATION

CSCM-NX (supplemented with protein) should be pre-warmed to 37°C and equilibrated to the desired pH overnight in a 5-6% CO<sub>2</sub> incubator prior to use. A sufficient volume of protein supplemented medium is required so that oocyte recovery, insemination and embryo culture dishes can be prepared.

The following are general procedures for the indications for use of CSCM-NX:

#### Fertilization:

On the day before oocyte retrieval, prepare oocyte collection and insemination dishes with pre-supplemented CSCM-NX overlaid with oil and pre-equilibrate overnight to 37°C in a CO<sub>2</sub> incubator. Immediately upon oocyte collection and identification, place oocytes into the oocyte collection dish with pre-equilibrated medium and return to the incubator for the desired period (1-4 hours) prior to insemination by conventional IVF or ICSI.

#### Conventional IVF (use insemination dishes):

1. It is recommended to aseptically dispense 50,000-100,000/mL motile sperm per microdroplet containing 1-3 oocytes.
2. Return the insemination dish to the incubator and check for normal fertilization 16-20 hours post insemination.

#### Intracytoplasmic Sperm Injection (ICSI):

1. Following at least 1 hour post oocyte denuding (and no more than 4 hours following oocyte retrieval), remove denuded oocytes from incubator and inseminate with sperm per standard ICSI protocol for your individual laboratory.
2. Immediately following insemination, place 1-3 inseminated oocytes into a fresh drop of the pre-equilibrated insemination dish, return dish to the incubator and check for normal fertilization 16-20 hours post insemination.

#### Embryo Culture:

On the day of fertilization (one day prior to fertilization assessment), prepare embryo culture dishes with pre-supplemented CSCM-NX overlaid with oil and pre-equilibrate overnight to 37°C in a 5-6% CO<sub>2</sub> incubator.

Following fertilization assessments with the identification of the presence of normal fertilization (two pronuclei and two polar bodies), transfer 2PN zygotes into the pre-equilibrated CSCM-NX culture dish previously prepared. It is recommended to allow the embryos to grow in a continuous, uninterrupted culture system without changing medium, until the desired developmental stage is reached (up to day 5/6 of development).

If medium change is desired for embryo culture beyond day 3, after 48 hours of embryo culture (of the fertilized embryos), the embryos should be transferred into a new dish of fresh pre-equilibrated CSCM-NX (pre-supplemented with protein).

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.

#### Duration Following Bottle Opening:

The product without protein supplement should be used within four (4) weeks from opening.

#### 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 bottle of medium which shows evidence of particulate matter, or cloudiness.

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

Not for injection use.

#### CONTRAINDICATION

**CSCM-NX contains the antibiotic Gentamicin Sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.**