

Continuous Single Culture®–NX Complete (CSCM–NXC)

Catalog # 90168

2 X 20 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 Use If Package Is Damaged
	Do not resterilize
	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, J.D. and Racowsky, C. *The development of fertilized human ova to the blastocyst stage in KSOM^{AA} medium: is a two-step protocol necessary?* RBMOnline, 5:133-140, 2002.

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

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

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

Biggers, J.D. and McGinnis, L.K. *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



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ENGLISH

INDICATIONS FOR USE

Continuous Single Culture®-NX Complete (CSCM-NXC) is intended for use as a culture medium for human gametes and embryos from fertilization through day 5/6 of development in vitro. This device can be used for transfer of embryos to the uterus.

QUALITY ASSURANCE

CSCM-NXC 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-NXC is tested for:

- Endotoxin (LAL): ≤ 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.

BUFFER SYSTEM

CSCM-NXC uses sodium bicarbonate as a buffering system. This is specifically designed for use in a CO₂ incubator.

DIRECTIONS FOR USE

CSCM-NXC is a complete, ready-to-use medium containing Human Serum Albumin (HSA). It is not necessary to add any protein before use.

COMPOSITION:

Salts & Ions

Sodium Chloride
Potassium Chloride
Potassium Phosphate
Calcium Chloride
Magnesium Sulfate

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

Protein

Human serum albumin

EQUILIBRATION

CSCM-NXC should be pre-warmed to 37°C and equilibrated to the desired pH overnight in a 5-6% CO₂ incubator prior to use. A sufficient volume of medium is required so that oocyte recovery, insemination, embryo culture and embryo transfer dishes can be prepared.

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

Fertilization:

On the day before oocyte retrieval, prepare insemination dishes with CSCM-NXC overlaid with oil and pre-equilibrate overnight to 37°C in a CO₂ incubator. Immediately upon oocyte collection and identification, place oocytes into the 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:

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 CSCM-NXC overlaid with oil and pre-equilibrate overnight to 37°C in a 5-6% CO₂ 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-NXC 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).

Embryo Transfer:

On the day prior to embryo transfer CSCM-NXC should be pre-warmed to 37°C and equilibrated to the desired pH overnight in a 5-6% CO₂ incubator prior to use. A sufficient volume of medium is required for the embryo transfer. On the day of transfer, remove the cultured embryo that has been selected for transfer to the equilibrated volume of CSCM-NXC. Using a syringe and embryo transfer catheter aseptically draw-up 5-8 µl of the equilibrated CSCM-NXC followed by the selected embryo and lastly another 5-8 µl of more equilibrated CSCM-NXC for a total of 15-20 µl. After the embryo is loaded into the catheter it is ready for immediate transfer to the 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 bottles refrigerated at 2° to 8°C.

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

Duration Following Bottle Opening:

Product 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.

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

US: CSCM-NXC 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.