0639-03

ORIGIO®
Sequential Blast™

Product No.:

8305

8306

Customer Service:
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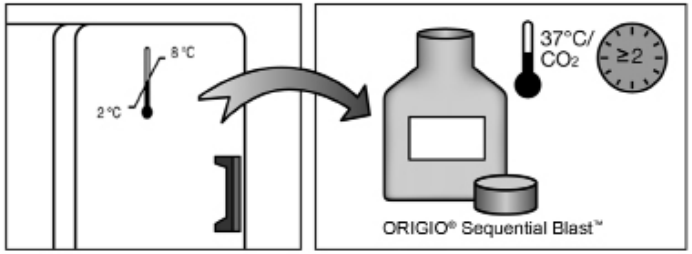
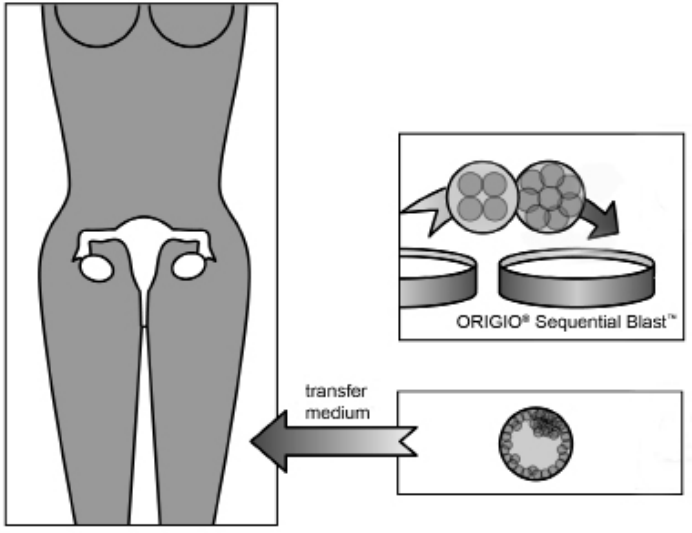
a CooperSurgical Company

Explanation of Symbols (in random order)

7 Days	Use within 7 days of opening
	Do not use if package is damaged
37°C	Discard excess (unused) media following warming
	Indicates the medical device manufacturer
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Indicates the date after which the medical device is not to be used
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified
STERILE A	Indicates a medical device that has been manufactured using accepted aseptic techniques
	Indicates a medical device that needs protection from light sources
	Indicates the need for the user to consult the instructions for use
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions
8 °C 2 °C	Indicates the temperature limits to which the medical device can be safely exposed





ORIGIO® Sequential Blast™

For culture from the 4-8 cell stage through to the blastocyst stage. Can also be used for embryo transfer.

This product is for ART treatment, whether the cause of infertility is male or female. The product should only be used by professionals trained in ART treatment.

Composition
Synthetic Serum Replacement (SSR®)
Recombinant Human Insulin 0.5 µg/ml
Human serum albumin (HSA) 5 mg/ml
Gentamicin sulphate 10 µg/ml
Glucose
Sodium pyruvate
Calcium lactate
Physiological salts
Amino acids
L-glutamine (stable form)
Vitamins
EDTA
Sodium hyaluronate
Sodium bicarbonate
Phenol red (only product no.8306).

Quality control testing
Sterility tested (Ph.Eur., USP)
Osmolality tested (Ph.Eur., USP)
pH tested (Ph.Eur., USP)
Endotoxin tested ≤ 0.1 EU/ml (Ph.Eur., USP)
1 cell Mouse Embryo Assay (MEA) ≥ 80% Blastocysts by 96h
Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.fertility.coopersurgical.com.

Storage instructions and stability
The products are aseptically processed and supplied sterile.
Store in original container at 2-8°C, protected from light.
Do not freeze.
Discard excess (unused) media following warming.
The product is to be used within 7 days after opening.
When stored as directed by the manufacturer the product is stable until the expiry date shown on the label.

Precautions and warnings
Do not use the product if:
1. Product packaging appears damaged or if the seal is broken.
2. Expiry date has been exceeded.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HCV, and non-reactive for HBsAg, HCV RNA and HIV-1 RNA. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

The potential risk of reproductive or developmental toxicity due to the use of ART media has not been determined and is still unknown.

Note: Dispose of the device in accordance with local regulations for disposal of medical devices.

Instructions for use
1. Equilibrate ORIGIO® Sequential Blast™ for a minimum of 2 hours in 5-6% CO_2 at 37°C prior to use. The time required to achieve full equilibration depends on volume of medium and oil overlay.
2. At the 4-8 cell stage the embryos are carefully washed in pre-equilibrated ORIGIO® Sequential Blast™ and transferred to fresh drops or wells of ORIGIO® Sequential Blast™.
3. The embryos should be moved to fresh drops/wells of ORIGIO® Sequential Blast™ every other day until blastocyst formation at Day 5/ Day 6.

Embryo transfer
1. The embryos are prepared and transferred to the uterus in 20 to 30 µl of pre-equilibrated fresh ORIGIO® Sequential Blast™ or preferred transfer medium.
2. Flush the transfer catheter with the chosen transfer medium prior to use.

Each laboratory should make its own determination of which medium to use for each particular procedure.