

# SAGE 1-Step™

## Product No.:

6701

## Customer Service:

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### ORIGIO a/s

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# origio

a CooperSurgical Company

## Explanation of Symbols (in random order)



Use within 7 days of opening



Do not use if package is damaged



Discard excess (unused) media following warming



Indicates the medical device manufacturer



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



Indicates the manufacturer's catalogue number so that the medical device can be identified



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



Indicates the temperature limits to which the medical device can be safely exposed

# SAGE 1-Step™

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This product is intended for the in vitro fertilisation and culture of human gametes and embryos from fertilisation until Day 5/6 of development. The medium 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

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)

EDTA

Sodium hyaluronate

Sodium bicarbonate

Phenol red

## 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](http://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 for a minimum of 2 hours in 5-6% CO<sub>2</sub> at 37°C prior to use. It is recommended that the pH of the medium is measured under laboratory working conditions and the level of CO<sub>2</sub> adjusted to attain the desired pH range for optimal embryo development. The desired pH range for SAGE 1-Step™ is 7.3 ± 0.1.
2. After fertilisation, transfer zygotes to fresh pre-equilibrated SAGE 1-Step™ and return the dish to the incubator.
3. The SAGE 1-Step™ has been designed for uninterrupted culture, without media change, until the desired developmental stage of the embryo has been reached.

## Embryo transfer

1. The embryos are prepared and transferred to the uterus in fresh pre-equilibrated SAGE 1-Step™.
2. Flush the transfer catheter with SAGE 1-Step™ prior to use.