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SAGE™ Vitrification Warming Kit

Product No.

ART-8031
ART-8034

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Indication for use
SAGE Vitrification Warming Kit is intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

Product Description
1.0 M Sucrose Warming Solution (ART-8031-A) is a MOPS buffered solution of modified HTF containing non-essential and essential amino acids, gentamicin sulfate (10 µg/mL), 1.0 M sucrose and 12 mg/mL human albumin.
0.5 M Sucrose Warming Solution (ART-8031-B) is a MOPS buffered solution of modified HTF containing non-essential and essential amino acids, gentamicin sulfate (10 µg/mL), 0.5 M sucrose and 12 mg/mL human albumin.
MOPS Solution (ART-8031-C) is a MOPS buffered solution of modified HTF containing non-essential and essential amino acids, gentamicin sulfate (10 µg/mL) and 12 mg/mL human albumin.

Package
ART-8031-A: 1.0 M Sucrose Warming Solution (1M WS)
ART-8031-B: 0.5 M Sucrose Warming Solution (0.5M WS)
ART-8031-C: MOPS Solution (MS)

Pack size
ART-8031: 6 x 2 mL:
ART-8031-A: 2 x 2 mL vial
ART-8031-B: 2 x 2 mL vial
ART-8031-C: 2 x 2 mL vial

ART-8034: 12 x 2 mL:
ART-8031-A: 8 x 2 mL vial
ART-8031-B: 2 x 2 mL vial
ART-8031-C: 2 x 2 mL vial

Composition
Physiological salts
EDTA
Gentamicin sulphate 10 µg/mL
Amino acids
Calcium lactate
Glucose
Sodium pyruvate
Sodium bicarbonate
Sucrose (only ART-8031-A and ART-8031-B)
Human Serum Albumin 12 mg/mL
MOPS, biological buffer
Phenol red

Quality Assurance
Sterility tested (Ph.Eur., USP<71>)
Osmolality tested (Ph.Eur., USP<785>)
pH tested (pH.Eur., USP<791>)
Endotoxin tested <0.5 EU/mL (Ph.Eur., USP<85>)
1-cell MEA ≥80% blastocyst at 96h
HSA analysis (Ph.Eur., USP).
Note: The results of each batch are stated on a Certificate of Analysis, which is available at www.fertility.coopersurgical.com.

STORAGE INSTRUCTIONS AND STABILITY
The product is aseptically processed and supplied sterile.
Store in original container at 2°C - 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
Warning: The long-term safety of vitrification on children born from this procedure is unknown.
Warning: This media product includes the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.
Caution: Federal law restricts this device to sale by or on the order of a physician or trained in its use (Rx Only).
Caution: This product contains albumin, a derivative of human blood.
Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was tested and found non-reactive for HBsAg and negative for Anti-HIV-1/-2, HIV-1, HBV, and HCV. Furthermore, source material has been tested for parvovirus B19 and found to be non-elevated. No known test methods offer assurances that products derived from human blood will not transmit infectious agents.
Caution: Do not use if the product becomes discolored, cloudy, turbid, or shows any evidence of microbial contamination.
Caution: Do not use the product if packaging appears damaged or the expiry date has been exceeded.
Caution: The user should read and understand the Instruction for Use, Warnings and Precautions, and be trained in the correct procedure before using the Vitrification and Vitrification Warming Kits for vitrification procedures.

WARMING AND DILUTION PROTOCOL
The warming and dilution procedure is to be performed at 35-37°C. Use a heated microscope stage for the procedures below.
Minimize exposure of specimens to light during incubation in the Warming Solutions.
Bring the solutions to 35-37°C before use.
Refer to the Directions For Use accompanying the carrier device.

PROCEDURE – Oocytes, zygotes, embryos and blastocysts
Maximum of 1 straw processed per dispensed media.

1. Fill a suitable reservoir with enough liquid nitrogen to completely submerge the carrier to be warmed.

2. Quickly transfer the carrier to the reservoir while keeping it submerged under liquid nitrogen. Place reservoir close to the work station.

3. Once the media and dish(es) have reached 37°C, and just before use, mix vial contents and aseptically dispense 0.5–4 mL 1M WS dependent on carrier and warming process, 0.5 mL 0.5M WS and 2 x 0.25 mL MS into the dish(es) (see Figure 1).
(Note: for oocytes use minimum 1 mL).

4. Prepare the preferred carrier as recommended by the manufacturer and quickly (within 2 seconds) transfer the specimen(s) to be warmed from the liquid nitrogen into 1M WS. The specimen(s) will float from the device into the 1M WS. Leave them in this solution for one minute. They will remain shrunken and float to the top of the drop.
Note: After each transfer of specimen(s), blow out any remaining fluid in the transfer pipette and draw up some solution from the next drop prior to the next manipulation. Avoid creating air bubbles during transfers.

5. Draw up some 0.5M WS into the transfer pipette and transfer the specimen(s) from the drop of 1M WS with minimal volume to 0.5M WS for 3 minutes.
Note: The specimen(s) will remain shrunken during exposure to 0.5M WS.

6. Transfer the specimen(s) to the bottom of the first drop of MS (MS1) in minimal volume.

7. Leave specimen(s) in MS1 for 5 minutes before moving specimen(s) to the second MS drop (MS2) for another 5 minutes.

8. After the 2 MS steps, transfer specimen(s) to the preferred media equilibrated according to the manufacturer's recommendations.
We recommend that you allow recovery in a CO_2 incubator for 1-2 hours before further manipulation and 2 hours before transfer.

Figure 1