

Flushing Medium

Product No.:

1084

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Explanation of Symbols (in random order)



Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure



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



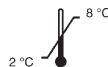
Indicates a medical device that needs protection from light sources



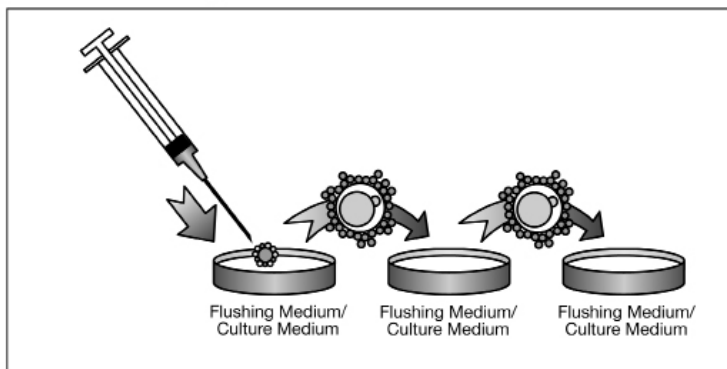
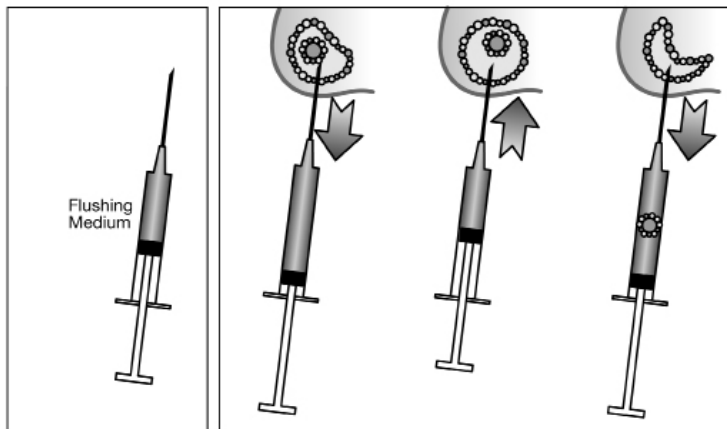
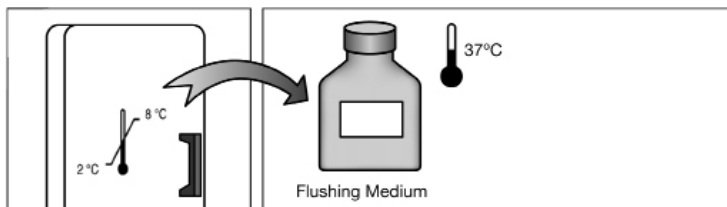
Indicates the need for the user to consult the instructions for use



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



Flushing Medium

Intended use

Flushing Medium is for retrieval, holding and washing of oocytes.

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®)*
(USA: ART supplement)

*Contains Recombinant Human Insulin

Human serum albumin (HSA)

Physiological salts

Glucose

Sodium pyruvate

Sodium bicarbonate

HEPES

Gentamicin sulphate 10µg/ml

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) $\geq 80\%$
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.

When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.

Do not freeze.

The product is provided in vials intended for single use.

Excess (unused) media should be discarded.

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. Pre-warm Flushing Medium to 37°C.
2. Keep Flushing Medium at 37°C in a heating block throughout the entire process of oocyte recovery and transport to the embryology laboratory.
3. Syringes used for flushing the follicle are filled with the Flushing Medium. Aspirate the follicular fluid and flush the follicle with a volume of medium equivalent to the amount of follicular fluid collected. Take care not to expand the follicle beyond its original size.
4. Wash oocytes with Flushing Medium or pre-equilibrated culture medium, taking care to remove any blood clots and granulosa cells.
5. Transfer oocytes to pre-equilibrated culture medium and store at 37°C in a 5-6% CO₂ environment.