

SynVibro® Flush

Product No.:

1584

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a CooperSurgical Company

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



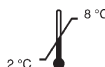
Indicates a medical device that needs protection from light sources



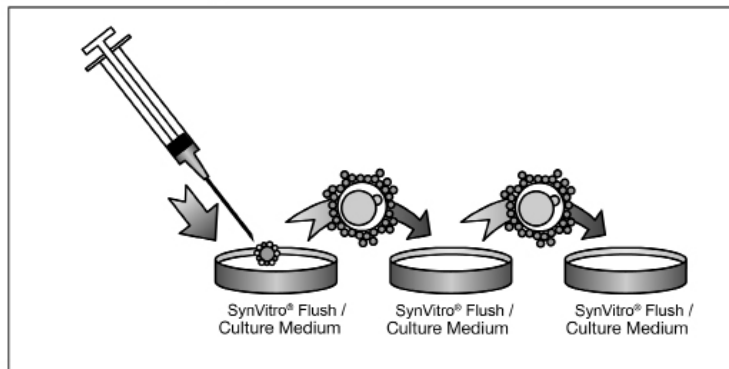
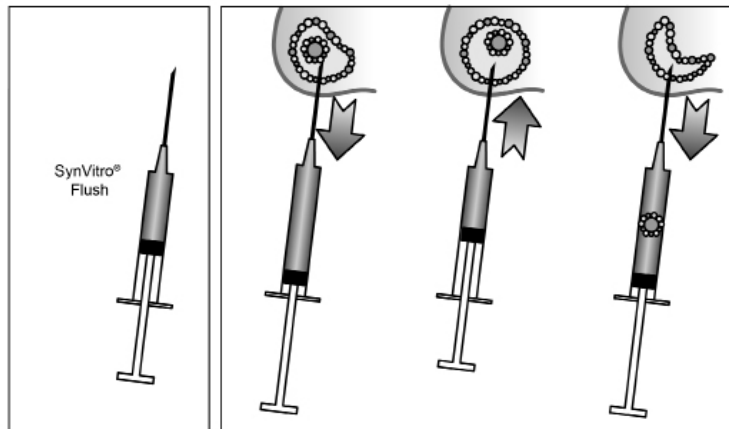
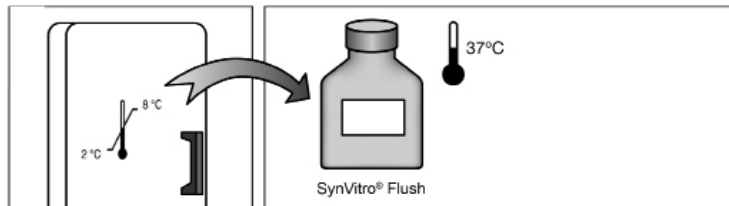
Indicates the need for the user to consult the instructions for use



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



SynVitro® Flush

Intended use

SynVitro® Flush 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

Physiological salts

Glucose

Sodium pyruvate

Sodium bicarbonate

HEPES

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

Do not freeze.

The product does not contain any anti microbial agents and 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.

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 SynVitro® Flush to 37°C
2. Keep SynVitro® Flush 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 SynVitro® Flush. 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 SynVitro® Flush 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.