

SynVibro® Hyadase

Product No.:

1511

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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



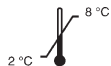
Indicates a medical device that needs protection from light sources



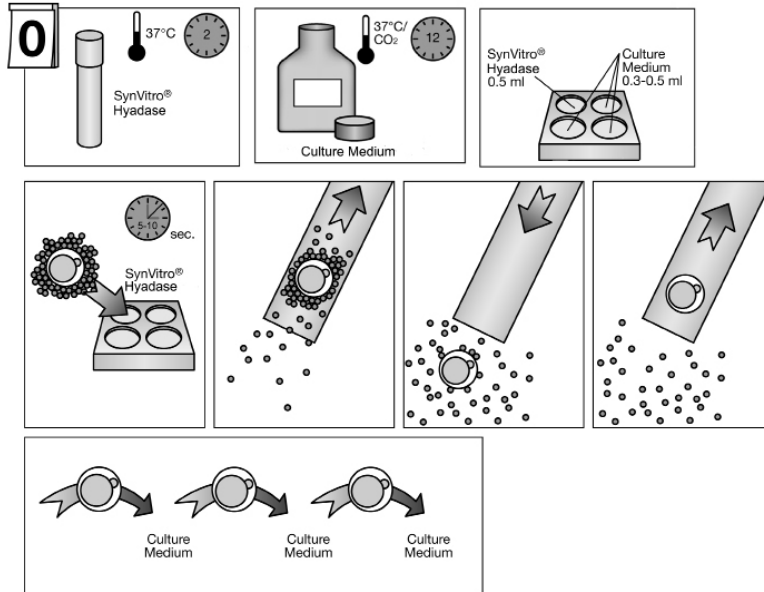
Indicates the need for the user to consult the instructions for use



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



SynVibro® Hyadase

Intended use

SynVibro® Hyadase is for the removal of the cumulus complex and corona radiata surrounding the oocyte in preparation for ICSI.

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

Pharmaceutical grade hyaluronidase
80 IU/ml

(non-bovine source)

Glucose

Sodium pyruvate

Calcium chloride

Magnesium sulphate

Sodium chloride

Sodium bicarbonate

HEPES

Quality control testing

Sterility tested (Ph.Eur., USP)

Osmolality tested (Ph.Eur., USP)

pH tested (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.

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 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.

After retrieval of the oocytes, it is recommended that the oocyte rest in pre-equalibrated culture medium for a minimum of 2 hours before denudation.

Instructions for use

1. Prepare a four-well dish with one well of SynVibro® Hyadase (3-500 µl) and the other three wells with pre-equilibrated culture medium (3-500 µl).
2. Place one or several oocyte-cumulus complex(es) in the well with SynVibro® Hyadase. After approximately 10 seconds, remove the cumulus complex by gently drawing the oocyte up and down in a denudation pipette.
3. Transfer the oocyte(s) to a well with culture medium using a denudation pipette, and remove the remaining corona cells in the same way.
4. Wash the oocyte(s) thoroughly by transferring them between several wells of culture medium.
It is recommended to leave the oocyte(s) in culture medium in a CO₂ environment at 37°C for a short period of time before proceeding with ICSI.