

CryoSperm™

Product No.:

1101

Customer Service:

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origio

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



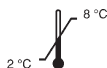
Indicates a medical device that needs protection from light sources



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

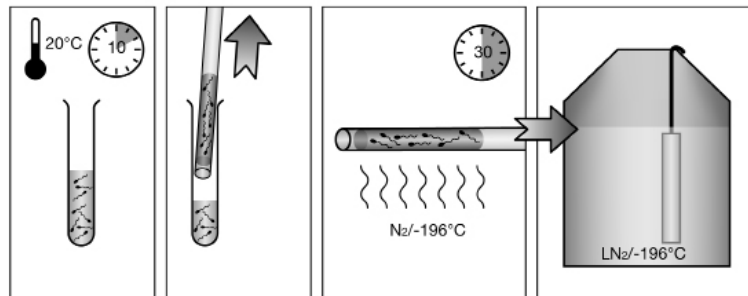
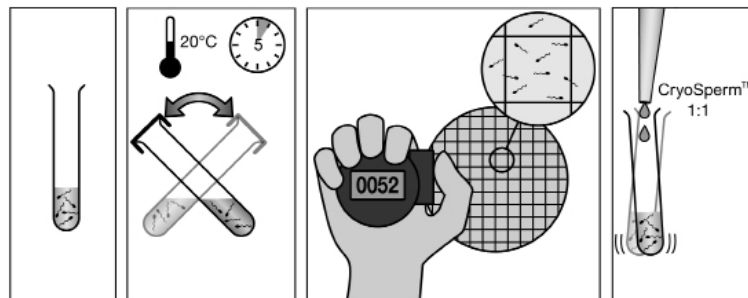
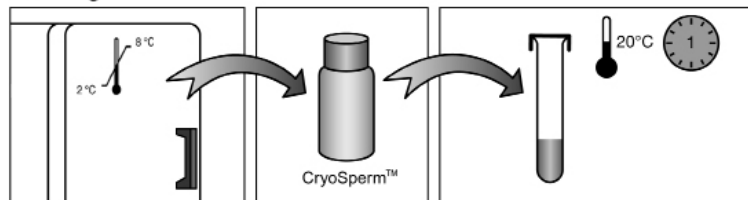


Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions



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

Freezing



CryoSperm™

Intended use

CryoSperm™ is for freezing of human spermatozoa.

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

Glycerol
Raffinose
Glucose
Sodium pyruvate
Sodium lactate
Physiological salts
Amino acids
Sodium bicarbonate
HEPES
Gentamicin sulphate 10µg/ml

Quality control testing

Sterility tested (Ph.Eur., USP)
pH tested (Ph. Eur.,USP)
Endotoxin tested ≤ 0.1 EU/ml (Ph.Eur., USP)

Sperm Survival Test $\geq 80\%$

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 prior to use.

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:

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.

Note:

Concentrating the sperm prior to freezing can enhance post-thaw recovery of semen samples with low sperm counts. A final concentration of minimum 10 million/ml is recommended.

To avoid cytotoxic effect from dead spermatozoa etc. it is recommended that

the semen sample is prepared soon after collection.

Instructions for use

Freezing:

1. After liquefaction, measure the total volume of the ejaculate and carry out semen analysis as required.
2. Ensure that both semen sample and CryoSperm™ are at room temperature and dilute the semen 1:1 (v/v) with CryoSperm™. The medium should be added drop by drop onto the semen and the solution carefully mixed after each addition.
3. The mixture is left at room temperature for a minimum of ten minutes.
4. Load the diluted semen into straws or cryo-tubes and seal according to the manufacturer's recommendations.
It is very important to leave some air space in the lower part of the straw for sealing as well as to allow expansion of the solution during freezing.
5. Suspend the straws horizontally for 30 minutes, just above the surface of the liquid nitrogen. Cryo-tubes should be attached to a cane and then suspended above the surface of the liquid nitrogen for the same period of time.
6. Finally, transfer the straws or cryo-tubes into the liquid nitrogen and store at -196°C.

Thawing:

1. Warm straws at room temperature for 5 minutes.
2. Open the straws or cryo-tubes according to the manufacturer's instructions and remove the thawed semen.
Immediately prepare sperm by the density gradient or the swim-up procedure.