PRODUCT INFORMATION SpermTec® Cryo

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Catalogue no.	•	
STC-5		5 ml
STC-10		10 ml
STC-20		20 ml

Application

SpermTec® Cryo is a four times concentrated ready-to-use HEPES buffered cryopreservation medium for freezing human semen at ultra low temperatures (-196°C) in liquid nitrogen.

Composition

SpermTec® Cryo is a HEPES buffered freezing medium for human sperm. It contains 26,7% glycerol in order to protect the sperm from damage due to the freezing process and it contains 0,4% HSA.

Material not included

- Sperm freezing straws (e.g. CBS high security sperm straws)
- · Freezing tank with liquid nitrogen
- LAF Bench (ISO Class 5)
- Sterile pipettes

Quality Control

- pH: 7,20 7,9 (Release criteria: 7,20 – 7,6
- Endotoxin: < 0,25 EU/m
- Sterility: Se ile, SAL I
- Sperm Survival Test
 (after 4h exposure of extreated sperm to illustest
 medium)
- Chamical composition
- Use of Ph Euror USP grade products if available
- Not MEA test
- Certificate of Analysis available upon request

Sterility

SpermTec® Cryo is sterilized by sterile filtration.

STERILE A

Precautions and warnings

Always work under hygienic conditions (LAF-bench, ISO Class 5) to avoid possible contamination.

Always wear protective clothing when working with specimens.

Handle specimens as if capable of transmitting HIV or hepatitis.

Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be completely excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of proven virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes.

The above media do not contain antibiotics

Pre-use checks

Do not use if the seal on the bottle is broken or open when the product is delivered.

Do not use if the product is used thy signs of microbial

contamination or becomes clouds.

Storage Conditions

Store rehaperated (2° - 8°C). Do not use a few appiry date. Do not freeze a consuse. See away from supply the.

the opening the contents, do pouse the product lost usen and 7 days. Step the product must be mainly used and product in the 6 stored at 2° - 8° C. Stable as the proport (up 6 5 days) at elevated emperature.

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Gynotec B.V.

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1	Distributor:



Instructions for use

Sperm Preparation

SpermTec[®] Cryo can be used in combination with SpermTec[®] ready-to-use gradients.

Before freezing

It is recommended to concentrate the sperm before freezing in case of very low sperm concentrations. This may increase the sperm quality after thawing and will reduce the number of straws to be frozen.

After thawing

In case needed, use sperm preparation techniques after thawing to eliminate dead sperm cells and debris. Dilute the concentrated sperm in a washing medium or any other medium to your use.

Method

Ensure that all media is well mixed before use.

Freezing

- Allow the semen to liquefy at room temperature for 30 minutes.
- Add 1 part SpermTec[®] Cryo to 3
- Add SpermTec[®] Cryo drop are while gents, swirling the sample.

Caution: To avoid cold spock make sure SpermTec® Cryo is at room comperature.

- Leave the sample for 10 minutes at room temperature for equilibration.
- Suck the mixture into the Negative straws, leaving approximated 1.5 cm of an attitle and of the waw. Seal the strage.
- Dry each straw with a line in free cloth and share moreone move the air a bble to the centre of the share.
- Freeze the strates ventually jt above the liquid nitrogen level for 15 minutes
- Store the straws in liquid name

Thawing

- Retrieve the required straws from the liquid nitrogen.
- · Place the straws in tap water for 5 minutes.
- Cut off the end of the straw, place open end inside a container (e.g. test tube) and tap straw against the side of the container in order to allow complete evacuation of the mixture into the container.
- Dilute the concentrated sperm in a suitable insemination medium, at least 3 ml per 0.5 ml semen, mix thoroughly.
- · Centrifuge at 300-350g for 15 minutes.

 Resuspend the pellet in a suitable insemination medium (e.g. SpermTec® Wash)

SYMBOL	MEANING
REF	Catalogue number
LOT	Batch code
$\overline{\Sigma}$	Use by (expiry date)
1 to \$ 1 to 1	Temperature limitations
	Sterile medical device processed using aseptic schnique (filtration)
C€ 0344	Sonsult instructions for use CE mark

ibliography

- mahadevan M, Traman AD. A feet of cryoprotective method and dilution methods before preservation of human sperious Na. Andrologia, 1936; 15: 355-66.
- 2 Maharus M, Trounso AD, Leeton JF. Successful use of human come cryobanking for in vitro fertilization, artil Steril. 1888, 2: 355-66.
- Protherton Cryopreservation of human semen. Applies of Andrology, 1990; 25: 181-95.
- 4 Chayashi T, Kaneko S, Hara I, Park YJ, et al. Concentrating human sperm before cryopreservation. Artiologia, 1991; 23: 25-8.
- raczykowski JW, Siegel MS. Influence of sperm processing on the fertilizing capacity and recovery of motile sperm from thawed human semen. Archives of Andrology, 1991; 26: 155-61.