



CRYOTEC Pro Instructions for Use

Main material: Body (Content: Polyethylene terephthalate 98%), film sheet (Content: Polyethylene terephthalate $\geq 99\%$)

Form: Tissue Storage

Model: PTEC010PB, PTEC010PG, PTEC010PP, PTEC010PY, PTEC010W

Packaging: Inside package: Gamma-resistant PP (Polypropylene) / Outside packaging: OPP (Oriented Polypropylene) bag

Sterilization: Gamma Sterilized

Temperature: Operating Temperature: Room Temperature, Storage Temperature: 10 °C~25 °C

Shelf-life: 2 years after the Gamma sterilized date.

Intended use: This product is used for preparation, vitrification, storage, and thawing of oocytes, pronuclear (PN) zygotes through cleavage stage embryos, and blastocyst stage embryos.

Indications for use: This product is a cryopreservation storage device that is intended for vitrification procedures to contain and preserve human oocytes and embryos.

Disposal process: Since the post-used product would be contaminated, please dispose properly according to the laws and regulations of the country.



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<https://reprolife.jp/ifu/other/>

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WARNINGS:

1. DO NOT HOLD the center of the cap with tweezers. Be careful not to push the cap too tightly at the bottom when closing it, as this may cause damage. Also, do not use broken or damaged caps or CRYOTEC Pro.
2. DO NOT USE if package is damaged/unsealed, product is damaged/dirty, or expiration date has passed. Discard properly according to local laws and regulations.
3. QUALIFIED USE ONLY ; This product must only be used by physicians or embryologists who have acquired proper knowledge and skills through training.
4. SINGLE USE ONLY ; NOT intended for re-use.
5. SAFETY PROTECTION ; Wear protective gloves and glasses when handling liquid nitrogen.

PRECAUTIONS:

1. Follow Instructions - Check instructions and protocol before use. Adhere to intended use/indications.
2. Clean Environment - Perform all procedures under clean and appropriate conditions.
3. Product Integrity - Use original packaging with corresponding cap. Check device under microscope before loading specimens (oocytes, zygotes, embryos).
4. Proper Handling - Do NOT clean device tip with alcohol or organic solvents. Do NOT apply unnecessary force. Handle carefully to avoid drops and accidents.
5. Authorized Materials - Use only proper solutions and plates according to their instructions.

Attention:

Serious incidents related to the device should be reported to the competent authorities in the Member State where the user is located.

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INSTRUCTIONS:

Vitrification

1. Prepare the cooling rack with fresh liquid nitrogen.
2. Open the sterile CRYOTEC Pro. To avoid contamination, handle the CRYOTEC Pro using aseptic techniques.
3. Prepare specimens for vitrification according to the protocol of the cryopreservation solution instructions for use.
4. Following vitrification procedures, place specimens just behind the black mark area on the tip of the CRYOTEC Pro.
5. Keep the sheet tip immersed in liquid nitrogen throughout the capping process.
6. Immerse the cap in liquid nitrogen. After bubbles disappear, while keeping the sheet tip in liquid nitrogen, grasp the upper part of the cap (near the black marker area) with forceps and cap the device.
7. After attaching the cap with forceps, place the CRYOTEC Pro vertically on the bottom of the cooling rack to prevent the cap from detaching. Gently press the CRYOTEC Pro against the bottom of the cooling rack until you hear a click.
8. Ensure that the CRYOTEC Pro remains immersed in liquid nitrogen until ready for thawing.

Warming

1. Prepare thawing solution according to the protocol of the solution instructions for use.
2. Prepare liquid nitrogen in the cooling rack (fill completely with liquid nitrogen). Remove the cane containing the CRYOTEC Pro from the liquid nitrogen tank and place it in the liquid nitrogen in the cooling rack.
3. Quickly remove the CRYOTEC Pro from the cane and lean it against the cooling rack, ensuring that the sheet tip does not come out of the liquid nitrogen.
4. While keeping the sheet tip immersed in liquid nitrogen, hook the forceps onto the constricted part at the top of the CRYOTEC Pro cap's iron core and remove the cap by pulling it downward. Do not remove the cap from the liquid nitrogen until the TS step is completed and you confirm the presence of specimens.
5. Quickly immerse the sheet part of the CRYOTEC Pro holding the specimens into thawing solution (within 1 second).
6. The remainder of the thawing procedures should follow the protocol outlined in the Instructions for Use for the thawing solution.

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Symbols

No.	Symbol	Description	No.	Symbol	Description	No.	Symbol	Description
1		Manufacturer	2		Product code	3		Batch code
4		Manufacturer date	5		Expiration date	6		Temperature limitation
7		Keep away from sunlight	8		Keep dry	9		Do not reuse
10		Don't use if unit package is opened or damaged	11		Consult instructions for use	12		Medical Device
13		Unique Device Identifier	14		Do not resterilize	15		Sterilized using irradiation
16		Single sterile barrier system with protective packaging outside	17			18		

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