

FreezeKit™

Cleave



US

EN: Indication for use

Solutions for freezing of pronucleated oocytes and spermatozoa.

Product Description

FreezeKit™ Cleave contains two solutions for freezing of pronucleated oocytes and cleavage embryos. The solutions consist of MOPS buffered solution containing glycerol as an antifreeze agent and human serum albumin.

Equilibration solution, ES, contains no cryoprotectants. Freezing solution, FS, contains 1,2-propanediol and 2,3-bis(2-methylbutyl)crotonaldehyde in a solution.

Storage instructions and stability

FreezeKit™ Cleave is stable until the expiry date shown on the bottle labels and the LOT-specific Certificate of Analysis.

Media bottles can be used for up to two weeks after first opening, use aseptic technique and minimize the time outside the refrigerator. Record opening date on the bottle. Discard excess media no later than two weeks after first opening.

Directions for use

Cryopreservation may only be performed by staff trained in cryopreservation protocols. Adhering to recommended temperatures and time frames are important.

Check patient's identity and prepare all paperwork before you start the procedure. Label bottles and straps, pipette appropriate volumes of media and transfer the embryos into the storage vials. Equilibrate to room temperature. To avoid dilution, carefully transfer the embryos to the storage vials.

Place the embryos selected for freezing in ES or rinse medium. The embryos can stay in ES for 10 minutes. Transfer the embryos into the FS and expose for 10 minutes. Labeling of the prepared straps can start immediately after the embryos have been transferred to FS. The total exposure time for the embryos to the FS should not exceed 15 minutes. The straps are transferred to the storage vials in accordance with manufacturer's recommendation.

Place the straps in the freezing machine at room temperature and initiate the freezing program. Use the following freezing program:

- Cool the straw at a rate of -2.0°C/min to -6.0°C
- Hold -6.0°C and manually seed after 2 minutes.
- Cool the straw at a rate of -0.3°C/min to -30°C
- Cool the straw at a rate of -0.3°C/min to -150°C

Change the medium to fresh liquid nitrogen and arrange for storage at -196°C.

Specifications

Asepticly filtered SAL 10%

Media Embryo Assay (1-cell) [% expanded blastocyst within 96 hours] ≥ 80

Bacterial endotoxins (LAL assay) [EU/ml] < 0.5

pH tested

Osmolality tested

LOT-specific test results are available on the Certificate of Analysis provided with each delivery.

Precautions

FreezeKit™ Cleave iftote integrity is compromised. Do not use.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HBV, HCV, and HTLV III and HTLV I/II RNA and syphilis. No known test methods can offer assurance that infectious agents derived from human blood will not transmit infectious agents.

To avoid contamination VitroLife strongly recommends that product be opened and used only with aseptic technique.

The risk of reproductive toxicity and developmental toxicity of IVF media, including VitroLife IVF media, has not been determined and are uncertain. Not for injection.

Description of ISO Symbols

STERILE A Sterilized using aseptic processing techniques

TEMPERATURE Sensitive to temperature changes

CAUTION Consult accompanying documents.

CATALOG Number

BATCH Code

CE Mark (Conformité Européen)

CHINA

中文說明書

適應症

用于高轉錄率卵母細胞和精液凍存。

適應症及禁忌症

適應症：卵母細胞、精液凍存。

禁忌症：凍存液、凍存管、凍存盒、凍存架、凍存袋。

產品技術支持及技術要求書

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The risk of reproductive toxicity and developmental toxicity of IVF media, including VitroLife IVF media, has not been determined and are uncertain. Not for injection.

BG: Показания за употреба

Разрешено за замразяване на нуклеарни ооцити и сперматозоици в студио.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HBV, HCV, and HTLV III and HTLV I/II RNA and syphilis. No known test methods can offer assurance that infectious agents derived from human blood will not transmit infectious agents.

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CE Mark (Conformité Européen)

Opbevaringsinstruktion og stabilitet

Opbevaringsinstruktion og stabilitet

FreezeKit™ Cleave kan holde sig indtil udløbsdatoen der fremgår af flaskeetiketter og det iLOT-specifikke certifikat til analyse.

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