

# FreezeKit™ Cleave



## Indication for use

Solutions for freezing of pronuclear (2PN) and cleavage-stage embryos.

## Product description

SUPPLEMENTED WITH HSA

FreezeKit™ Cleave contains two solutions for freezing of pronuclear (2PN) and cleavage-stage embryos. The solutions consist of MOPS buffered solution containing gentamicin as an antibacterial agent and human serum albumin.

Equilibration solution (ES) contains no cryoprotectants.

Freezing solution (FS) contains 1,2 - propanediol and sucrose as cryoprotectants for dehydration of cells.

## Storage instructions and stability

Store dark at +2 to +8 °C.

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

The following is the general procedure for using FreezeKit™ Cleave. For more information on recommended use of FreezeKit™ Cleave, please see the "G Series Manual". The Manual is available on

request from Vitrolife, and may be ordered through the company's internet website, [www.vitrolife.com](http://www.vitrolife.com). Directions for use in other languages can also be found at the website.

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

Check patient's identity and prepare all paperwork before you start the procedure.

Label dishes and straws, pipette appropriate volumes (0.5-1.0 ml) of ES and FS into respective dishes. Equilibrate to room temperature. To avoid dilution, always transfer the embryos in a minimum amount of solution.

Place the embryos selected for freezing in ES and rinse. The embryos can stay in ES for 10 minutes.

Transfer the embryos into the FS and expose for 10 minutes. Loading of the prepared straws can start immediately after the embryos have been transferred to FS. The total exposure time for the embryos to the FS should be 10 minutes. Load the straws in accordance with manufacturer's recommendation.

Place the straws in the freezing machine at room temperature and initiate the freezing program.

Use the following freezing program:

- Cool the straw at a rate of  $-2.0^{\circ}\text{C}/\text{min}$  to  $-6.0^{\circ}\text{C}$
- Hold at  $-6.0^{\circ}\text{C}$  and manually seed after 2 minutes. Keep the straw at  $-6.0^{\circ}\text{C}$  for a total time of 10 minutes. Do not seed close to the embryo
- Cool the straw at a rate of  $-0.3^{\circ}\text{C}/\text{min}$  to  $-30^{\circ}\text{C}$
- Cool the straw at a rate of  $-50^{\circ}\text{C}/\text{min}$  to  $-150^{\circ}\text{C}$
- Plunge the straw into liquid nitrogen and arrange for storage at  $-196^{\circ}\text{C}$

## Specifications

Aseptically filtered

Mouse Embryo Assay (1-cell)  
[% expanded blastocyst within 96 hours]  $\geq 80$

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.

## Description of ISO Symbols

	Sterilized using aseptic processing techniques
	Temperature limit
	Use by – see label
	Caution: Consult accompanying documents
	Catalog number
	Batch code
	CE Mark (Conformité Européenne)

## Precautions

**Caution: Federal (US) law restricts this device to sale by or on the order of a physician**

Discard product if bottle integrity is compromised. Do not use FreezeKit™ Cleave if it appears cloudy.

FreezeKit™ Cleave contains gentamicin and human serum albumin.

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, HbC, HCV, and HTLV I/II and non-reactive for HbsAg, HCV RNA and HIV-1 RNA and syphilis. No known test methods can offer assurance

that products derived from human blood will not transmit infectious agents.

To avoid contamination Vitrolife strongly recommends that media should be opened and used only with aseptic technique.

The risk of reproductive toxicity and developmental toxicity for IVF media, including Vitrolife's IVF media, have not been determined and are uncertain.

Not for injection.

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