

# ThawKit™ Cleave



## Indication for use

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

## Product description

SUPPLEMENTED WITH HSA

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

Thawing solution 1 (TS1) and Thawing solution 2 (TS2) Buffered solutions containing decreasing concentrations of sucrose allowing removal of 1,2 -propanediol and gradual rehydration of the cells.

Equilibration solution (ES)

Buffered solution that does not contain any cryoprotectants used for final rehydration before culture.

## Storage instructions and stability

Store dark at +2 to +8 °C.

ThawKit™ 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 ThawKit™ Cleave. For more information on recommended use of ThawKit™ 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, pipette appropriate volumes (0.5-1.0 ml) of TS1, TS2 and ES into respective dishes. Equilibrate to room temperature. To avoid dilution, always transfer embryos in a minimum amount of solution.

Remove straw from liquid nitrogen and expose to air for 30 seconds.

Place the straw in a 30°C water bath for 45 seconds.

Remove the straw and wipe it carefully. Open the straw using aseptic technique and gently expel the embryos.

Expose the embryos to TS1 for 5 minutes.

Move the embryos into TS2 and expose for 5 minutes.

Move the embryos into ES and expose for 5 minutes.

Transfer the embryos to equilibrated culture medium, rinse embryos and culture according to standard laboratory procedure.

## Specifications

Aseptically filtered

Mouse 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.

## 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 ThawKit™ Cleave if it appears cloudy.

ThawKit™ 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.

---

**For technical support/Technischer  
Support/Asistencia técnica/Pour contacter  
l'assistance technique/Per l'assistenza  
tecnica:**

**Americas**

Tel: + 1-866-848-7687

support.us.fertility@vitrolife.com

**Europe, Middle East, Asia, Pacific, Africa**

Tel: +46-31-721 80 20

support.fertility@vitrolife.com

Vitrolife Sweden AB, Gustaf Werners gata 2, SE-421 32  
Västra Frölunda, Sweden (visiting address). Box 9080,  
SE-400 92 Göteborg, Sweden (postal address).

Vitrolife Inc., 3601 South Inca Street, Englewood CO  
80110, USA.

Vitrolife Pty. Ltd., Level 10, 68 Pitt Street, Sydney NSW  
2000, Australia.

[www.vitrolife.com](http://www.vitrolife.com)

 Manufactured by  
Vitrolife Sweden AB  
V.Frölunda, Sweden

