

## EN: Indication for use

Media for warming of vitrified cleavage stage embryos (US: day 3 only).

## Product Description

SUPPLEMENTED WITH HSA

RapidWarm™ Cleave contains four solutions for the warming of vitrified day 3 cleavage stage embryos. The solutions consist of a MOPS buffered medium containing gentamicin as an antibacterial agent and human serum albumin.

Warm 1™ Cleave contains sucrose as a cryoprotectant.

Warm 2™ Cleave contains sucrose as a cryoprotectant.

Warm 3™ Cleave contains sucrose as a cryoprotectant.

Warm 4™ Cleave contains no cryoprotectants.

For use after warming to +37 °C in ambient atmosphere.

## Storage instructions and stability

Store dark at +2 to +8 °C.

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

Media bottles should not be stored after opening. Discard excess media after completion of procedure.

## Directions for use

The following is the general procedure for using RapidWarm™ Cleave.

Warning should only be performed by staff trained in warming procedures.

Note: Timing with warming is critical, ensure you follow the protocol precisely.

## Warnings:

Place 0.5-1 ml of each of the following media into separate wells of a 4-well plate and warm to 37 °C:

- Warm 1™ Cleave

- Warm 2™ Cleave

- Warm 3™ Cleave

- Warm 4™ Cleave

All manipulations of the embryos are carried out at 37 °C (on a heated stage).

In a cryodewar, bring the cryodewe containing the vitrified embryos close to the prepared wells.

Place the vitrified embryos quickly into Warm 1™ Cleave.

Allow the embryos to fall from the device and sink to the bottom. Leave for 10–30 sec.

Transfer the embryos into Warm 2™ Cleave and let the embryos remain in the solution for 1 min.

Transfer the embryos into Warm 3™ Cleave and let the embryos remain in the solution for 2 minutes.

Transfer the embryos into Warm 4™ Cleave and let the embryos remain in the solution for 5 min.

Rinse the embryos in culture media several times and continue culture according to laboratory practice.

## Specifications

Sterile filtered SAL 10³

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

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

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

## Precautions

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

RapidWarm™ 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 III 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.

Re-use may result in microbiological contamination and/or property changes in the product.

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.

The long-term safety of vitrification on children born following this method of embryo cryopreservation is unknown.

The safety and effectiveness of vitrification has not been fully evaluated in human embryos that have not yet reached the blastocyst stage of development.

Not for injection.

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

## Description of ISO Symbols

Sterile using aseptic processing techniques

Temperature limit

Do not reuse, discard after procedure.

Use by - see label.

Caution: Consult accompanying documents.

Catalog number

Batch code

CE Mark (Conformity Européen)

CE: Indication for use

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Vitrofife, non sono stati determinati e sono incerti.

La sicurezza a lungo termine della vitrificazione sui bambini nati secondo questo metodo di criopreservazione embrionale è sconosciuta.

La sicurezza e l'efficacia della vitrificazione non sono state completamente valutate negli embrioni umani che non hanno ancora raggiunto la fase di sviluppo blastocisti.

Non per iniezione.

Attenzione: la legge federale (dei Stati Uniti) limita la vendita del presente dispositivo dietro prescrizione medica.

#### LT: Naudojimo indikacija

Vitrificuoti skiliūs stadijos embrionų (JAV: tik 3 dienų) atidėjimo procedūra.

#### Produktu aprašas

PAPIRDYTAS HSA

RapidW™ Cleave® substancija reakčinė litigijos vitrifikacijai 3 dienų skiliūs stadijos embrionų atidėjimui. Tripus sudanu MOPS buferinė terpe, kurios sudėtyje yra gentamicinė, veikiančio kąpi antikörperių ir žmogaus serumo albuminu.

„Warm 1™ Cleave“ sudėtyje yra sacharozės, veikiančios kąpi krioprotektoriu.

„Warm 2™ Cleave“ sudėtyje yra sacharozės, veikiančios kąpi krioprotektoriu.

„Warm 3™ Cleave“ sudėtyje yra sacharozės, veikiančios kąpi krioprotektoriu.

„Warm 4™ Oocyte“ sudėtyje nėra krioprotektoriu.

Naudotu po atidėjimo iki +37 °C aplinkos atmosferoje.

#### Laikeymo nuorodų ir stabiliumas

Laikejti tamsoje nuo +2 iki +8 °C.

„RapidW™ Cleave“ yra stabili iki galajimo dienos, nėra standžiai atbulėtina etiketės ir partijos analizės siififikacijai.

Terpi buteliukui regalima laikyti po atidarymo. Baigtis procedūra, pasalintekite perteklinės terpes.

#### Naudojimo nuorodmai

Toliau pateikiama bendroios „RapidW™ Cleave“ naudojimo procedūros.

Atidėjimą gali atlikti tik atidėjimo procedūras atlikti išmokytį darbuotojai.

Pastaba: Atliekant atidėjimą labai svarbus veiksys yra laikas – patikrinkite, ar tiksliai laikotiks protokolo.

#### Atidėjimas:

[ipiltik 0,5–1 ml iekiekviens iš šiuo terpi, į aštrukus ūžulinės 4 ūžulinės plökštėje ir pašildyti iki 37 °C temperatūros]:

• Warm 1™ Cleave

• Warm 2™ Cleave

• Warm 3™ Cleave

• Warm 4™ Cleave

Visos procedūros su očiaitakomais esanai 37 °C (ant išlydkes).

Ji kriolašintuvu iedėkite kriojingrinį su vitrifikuotais embrionais Šalia paruošti ūžulinę.

Gretaiti išmokytus embrionus į „Warm 1™ Cleave“.

Leiskeite embrionams kristi iš ūžinguinio ir ruginių iš apčiuj. Palikite 10–30 dienų.

Priekintekite išmokytus į „Warm 2™ Cleave“ ir palikite trupę 1 minučių.

Perkelkite embrionus į „Warm 3™ Cleave“ ir palikite trupę 5 minučių.

Kelis kartus nuplauskite embrionus auginiui skirtieje terpeje ir toliau išmokytite laikydami laboratoriškes praktikos metodą.

#### Specifikacijos

Šterliū filtruotas SAL 10<sup>3</sup>

Pelės embrionų tyrimas (1 lastėje) [% išplėstas blastočystose per 96 valandas] ≥ 80

Bakterių endotoksinas (LAL tyrimas) [EU/ml] < 0,5

Partijai būdingi bandymų rezultatai yra prienamai analizės sertifikate, kuris pateikiamas su iekievienu pristatymu.

#### Atsargumo priemonės

Jei buteliukas pažeista, produktą išmokytė. Nendruokite „RapidW™ Cleave“, jei jis drusmas.

„RapidW™ Cleave“ sudėtyje yra stabili genetinė žmogaus serumo albumino.

Atsargių priemonės turėtų būti laikomi polieskintiūs uždėjimais. Pradėti medžiagą, iš kurios bus gautas šis produktas, buvo išsiesta iekant antikūnus prieš HIV, HCV ir HTLV III ir rezultatu iš neigiamas, ji taja pat nereaguavo tyrimais HbsAg, HCV, RNR bei ŽIV-I NR ir sifilio. Nėra žinoma jokių bandymų metodų, viestiškai užtinkančių, kad produkcija, pagamintinė iš žmogaus kraujų, nebūtų infekcijos sukėlė.

Pakartotinai naudojant produktą gali būti mikrobiologiski užterštasis (arba) galį pakisti.

Perkelkite embrionus į „Warm 1™ Cleave“ ir palikite trupę 1 minučių.

Perkelkite embrionus į „Warm 2™ Cleave“ ir palikite trupę 5 minučių.

Kelis kartus nuplauskite embrionus auginiui skirtieje terpeje ir toliau išmokytite laikydami laboratoriškes praktikos metodą.

#### Atidėjimas

[ipiltik 0,5–1 ml iekiekviens iš šiuo terpi, į aštrukus ūžulinės 4 ūžulinės plökštėje ir pašildyti iki 37 °C temperatūros]:

• Warm 1™ Cleave

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• Warm 3™ Cleave

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Visos procedūros su očiaitakomais esanai 37 °C (ant išlydkes).

Perkelkite embrionus į „Warm 1™ Cleave“ ir palikite trupę 1 minučių.

Perkelkite embrionus į „Warm 2™ Cleave“ ir palikite trupę 5 minučių.

Siekiant išvengti „Užterštasis“ (praktiniuose rekomenduojantemis) terpės atidaryti ir naudoti tik ašpėninius salyminius.

IVF terpi, iškaitant Vitrifile (IVF terpe), reprodukcinio tokismuko ir toksinio poveikio vystymosi rizika nebuvo nustatyta ir yra neaiški.

Ilgalaikio vitrifikavimo saugumas – veiksmus, gumeisius tokinių iš embrionų kriokonservavimo procedūros metodą, nėra nustatytas.

Vitrifikavimo saugumas ir veikluminges žmogaus embrionams, dar nepasiūlytiems blastočystų vystymosi stadijos, nėra pakankamai įvertintas.

Neskirti injekcijoms.

Atsargių ferdinacių (JAV) įstatymai nustato, kad iš jėnginių galima parduoti tik gydytojui arba pagal gydytojo išlydką.

#### LV: Lietošanės instrukcija

Širdžiūs vitrifikacijai dėlaišanės stadijos embrionų sildžiūnai (USA: kiti 3, dienų).

#### Izstrādājuma apraksts

PAPIRDINTAS AR HSA

RapidW™ Cleave® Sildžiūs sūtis tris ūžulinės vitrifikacijai 3 dienų dėlaišanės stadijos embrionų sildžiūnai. Šildžiūs sastavas norūdėti MOPS buferinės sūtis, kuriai yra antikūnai ir ūžulinės.

Šildžiūs yra veiksmus, kurie nėra išmokytės.

Šildžiūs yra stabili išmokytė.

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