

G-GAMETE™

Vitrolife

US

EN: Indication for use

Medium for handling and manipulating oocytes and embryos in ambient atmosphere.

Product Description

SUPPLEMENTED WITH HSA

G-GAMETE™ is a MOPS and bicarbonate buffered medium containing human serum albumin and gentamicin as an antibacterial agent.

For use after equilibration at +37 °C and 6% CO₂ atmosphere.

Storage instructions and stability

Store dark at 2 to 8 °C.

G-GAMETE™ is stable until the expiry date shown on the bottle label and the specific Certificate of Analysis.

For non-EU: Media bottles should not be stored after opening. Discard excess media after completion of the procedure.

EU: Media bottles can be used up to two weeks after first opening, use aseptic technique and refrigerate after each use. Record the opening date on the bottle. Discard excess media no later than two weeks after first opening.

To maintain a suitable pH, G-GAMETE™ should not be used in ambient atmosphere for more than 7 minutes.

Directions for use

G-GAMETE™ for oocyte and embryo handling: Equilibrate medium in a sterile, non-embryotoxic dish at +37 °C and 6% CO₂. Equilibrate for 4–18 hours before use.

Oocyte identification:

Transfer the follicular aspirates to an empty dish. Identify the oocytes and remove them from follicular fluid and transfer them to a dish containing a sterile pipette. Rinse the oocytes in equilibrated G-GAMETE™, then in equilibrated G-IVF™ PLUS/ supplemented G-IVF™. Transfer the oocytes to dishes with equilibrated G-GAMETE™ plus/ supplemented G-IVF™ and return the dishes to the incubator immediately.

Fertilization assessment:

Place the denuded oocytes into G-GAMETE™ using a sterile pipette. Observe microscopically and record the number of polar bodies and the possible presence of a germinal vesicle. Nonfertilized or degenerated oocytes and oocytes with more than 2PN should be removed from culture. After assessment, the fertilized oocytes should be cultured in G-1™ PLUS/ supplemented G-1™ preferably under OVOIL™.

Denudation of oocytes prior to ICSI

Prepare multi well dishes with three wells of G-GAMETE™ for every well of HYASE™. Place 3 oocytes with a large bore pipette into the HYASE™ and gently pipette the HYASE™ and the oocytes to disperse the cumulus. Denude the oocytes to the HYASE™ solution for more than 30 s. Transfer oocytes from HYASE™ to the first G-GAMETE™ wash. With a fine bore denudation pipette, denude each oocyte singly up and down to remove the cumulus. Remove the last details of G-GAMETE™ to rinse the oocytes. Transfer the oocytes to G-GAMETE™ droplets for injection or, if needed, to G-1™ PLUS/ supplemented G-1™ for further incubation and maturation.

ICSI

Prepare dishes by placing a 1–10 µL droplet of ICSI™ in the centre of each dish and appropriate amount of 10 µL droplets of G-GAMETE™ in the periphery and cover with OVOIL™. Do not prepare more than one dish at a time, before covering with OVOIL™ to avoid evaporation of the droplets.

Equilibrate the dishes at +37 °C and 6% CO₂ for at least 4 hours.

Place a small volume (1–2 µL) of prepared sperm suspension into the centre of the ICSI™ drop. Place the denuded oocytes into the G-GAMETE™ droplets, one oocyte per droplet, maximum 4 oocytes at a time. Inject the oocytes.

After all oocytes are injected, rinse the oocytes in G-1™ PLUS/ supplemented G-1™ and then place them into prepared G-1™ PLUS/ supplemented G-1™ culture for further culture.

Specifications

Sterile filtered SAL 10³

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

Bacterial endotoxins (LAL assay) [EU/ml] < 0.25

LOI 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 G-GAMETE™ if it appears cloudy.

G-GAMETE™ contains gentamicin and human serum albumin. Do not use in patients known hypersensitivity/allergy to any of the components.

Culture media should be treated as potentially infected. Source material from which this product was derived was found negative when tested for antibodies to HIV, HBC, HCV and HTLV II and non-reactive for HsAg, 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.

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

Description of ISO Symbols

STERILE A 经无菌加工技术灭菌

REF 生产日期

REF 有效期

REF 警告:参考随附文件

LOT 产品编号

LOT 批次代码

CE 2460 CE Mark (Conformité Européenne)

EUROPE

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CE 2460 CE Mark (Conformité Européenne)

CHINA

CN: 配子处理液G-GAMETE™产品说明书

产品名称:配子处理液

适用范围:本产品适用于在大气环境中卵子、胚胎的处理和操作。

产品型号及规格

型号、规格: G-Gamete 1x30ml

产品注册证号:略

产品注册证编号:国械注进20153183138

产品技术要求编号:国械准字20153183138

产品性能及主要结构组成

组成成分:含人血清白蛋白

配子处理液(G-Gamete™)是MOPS(4-吗啉丙磺酸)和碳酸氢钠盐缓冲的培养液,其中包含人血清白蛋白以及作为抗凝剂的大剂量维生素E。

在+37 °C和二氯化碳浓度为6%的大气环境下孵育后使用。

产品有效期及储存条件

产品有效期:自生产之日起21周。

储存条件:避光,+2°C~+8°C。

运输条件:在运输过程中贮存温度可以超过8°C,但不超过25°C,且最长不能超过48小时。

G-Gamete™在包装标签上和该批产品的质量报告书上显示的有效期内是稳定的。

产品包装打开后不得再继续使用。使用后丢弃剩余产品。

为保持适当的pH值,G-GAMETE™不应在大气环境下使用超过分钟。

生产日期:见标签

使用期限:见标签

使用方法

用于处理和操作卵母细胞和胚胎的G-Gamete™

操作方法:

在+37 °C和二氯化碳浓度为6%的大气环境下孵育,使用前需平衡4~18小时。

卵母细胞的识别:

转移卵母细胞到一个空的培养皿中。

To avoid contamination Vitrolife strongly recommends that media should be opened and used only with aseptic technique from the pipette with centrifuge liquid.

使用前:

使用前:

使用方法:

