

## EN: Indication for use

Medium for gradient sperm separation.

## Product Description

All SpermGrad™ media are bicarbonate and HEPES buffered media containing silane-coated, colloid silica particles.

SpermGrad is available as:

-SpermGrad™ REF 10102 (30 mL) and 10099 (125 mL). Media for dilution into desired concentrations.

For use after dilution with either supplemented G-IVF™, G-IVF™ PLUS or with SpermRinse™.

For details on how to perform the protein supplementation see Package Inserts for G-MM™ or HSA-Solution™.

-SpermGrad™ REF 10138 (2x30 mL), 10238 (30 mL), 10338 (30 mL), 10139 (2x125 mL), 10239 (125 mL) and 10339 (125 mL) containing: Gradient solutions SpermGrad™ Upper Layer and/or SpermGrad™ Lower Layer. Ready to use solutions for gradient sperm separation.

SpermGrad™ is antibiotic-free while the media for dilution and sperm wash, such as supplemented G-IVF™, G-IVF™ PLUS or SpermRinse™, contain gentamicin as an antibacterial agent.

## Storage instructions and stability

Store dark at +2 to +8°C. SpermGrad™ is stable until the expiry date shown on the container labels and the LOT-specific Certificate of Analysis.

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

## Directions for use

Dilution: SpermGrad™ REF 10099 and 10102: Mix SpermGrad™ with supplemented G-IVF™, G-IVF™ PLUS or SpermRinse™ in separate tubes to obtain 90% and 45% stock solutions. For 90% stock solution, mix 9.0 mL SpermGrad™ with 1.0 mL supplemental G-IVF™, G-IVF™ PLUS or SpermRinse™.

SpermGrad™ REF 10138 (4.5 mL) with 5.5 mL SpermGrad™ Upper Layer and/or SpermGrad™ Lower Layer. Mix the solutions thoroughly. Store in sterile non-toxic tubes or sterile tissue culture flasks. Label with date and refrigerate until use.

SpermGrad™ REF 10138, 10238, 10338, 10139, 10239 and 10339: Ready to use.

Preparation of sample: Allow the solutions to reach ambient temperature before use.

Layer the gradient in a sterile, conical centrifuge tube marked with patient ID. Pipette 1.5 mL of 90 % solution (SpermGrad™ Lower Layer) into the tube first. Then add the slowest 1.5 mL of 45 % solution (SpermGrad™ Upper Layer) on top. Finally, the semen is gently layered on top of the gradient. Centrifuge the tube for 20 minutes at 300–600 g. Remove the two top layers. Transfer the sperm pellet with as little of the 90 % solution (SpermGrad™ Lower Layer) as possible to a sterile conical tube with 5 mL of equilibrated supplemented G-IVF™, G-IVF™ PLUS or SpermRinse™. Mix the solutions thoroughly. Store in sterile non-toxic tubes or sterile tissue culture flasks. Label with date and refrigerate until use.

SpermGrad™ REF 10138, 10238, 10338, 10139, 10239 and 10339: Ready to use.

Preparation of sample: Allow the solutions to reach ambient temperature before use.

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SpermGrad™ REF 10138 (2x30 mL) and 10099 (125 mL). Media for dilution into desired concentrations.

For details on how to perform the protein supplementation see Package Inserts for G-MM™ or HSA-Solution™.

-SpermGrad™ REF 10102 (30 mL) and 10099 (125 mL). Human sperm recovery assay (recovery rate after gradient separation [%]) ≥ 25

Mouse Embryo Assay not performed

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 SpermGrad™ if it appears cloudy.

SpermGrad™ does not contain antibiotics.

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 risks 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] Sterilized using aseptic processing techniques

...K<sup>ac</sup> Temperature limit

(⊗) Do not re-use, discard after procedure.

...M<sup>W</sup> Date of manufacture

...U Use-by date

...A Caution: Consult accompanying documents.

...REF Catalog number

...LOT Batch code

CE 2460 CE Mark (Conformité Européenne)

## CHINA

## CN: 精子梯度分离液SpermGrad™产品说明书

## 产品名称: 精子梯度分离液

## 适用范围

本产品适用于体外生殖过程, 为密度梯度分离介质用于精子的收集和准备。

## 产品型号及规格

型号 规格

精子梯度分离液 10102 1x30mL

SpermGrad™ 10099 1x125mL

精子梯度分离液(即用型) 10138 2x30mL

SpermGrad™-RTU 10139 2x125mL

产品注册证及技术要求编号

产品注册证编号: 国械注进20161810172

技术参数要求书: 国械注进20161810172

## 产品性能及主要结构组成

所有的精子密度培养液都是含硅胶颗粒的碳酸氢钠和HSA-溶液的混合液。

-SpermGrad™ 型号10102和10099, 培养液可以稀释成所需浓度, 用添加过蛋白G-IVF™, G-IVF™ PLUS或SpermRinse™稀释后使用, 如何添加蛋白详见G-MM™或HSA-Solution™产品说明。

-SpermGrad™ 型号10138和10139含有所: SpermGrad™上层密度液体和下层密度液体。用以梯度分离精子的即用型培养液。

精子梯度分离液(SpermGrad™)本身不含抗生素, 但当与稀释和洗液的培养液, 比如添加蛋白的G-IVF™, G-IVF™ PLUS或SpermRinse™是含有抗菌剂大鼠瘤素的。

## 产品有效期及储存条件

储存条件: 避光, -2°C +8°C。

运输条件: 在运输过程中储存温度可以超过8°C, 但不超过12°C, 最长时间不能超过7天。

精子梯度分离液在包装瓶标签上和该生产批号的质检报告分析报告上显示的有效期内是稳定的。

产品包装封口后不得继续储藏。使用后丢弃剩余产品。

生产日期: 见标签

使用期限: 见标签

## 使用方法

稀释: SpermGrad™ 型号10102和10099: 将SpermGrad™和添加蛋白的G-IVF™, G-IVF™ PLUS或SpermRinse™在单独的试管中混合以得到90%和45%的储存液体。制备90%的储存溶液, 需要混合9.0 mL SpermGrad™与1.0 mL添加蛋白的G-IVF™

G-IVF™ PLUS或SpermRinse™。制备45%的储存液体, 需要混合5.5 mL SpermGrad™与5.5 mL添加蛋白的G-IVF™, G-IVF™ PLUS或SpermRinse™, 充分摇匀。在无菌无毒的试管和组织培养瓶中贮存。贴上标签, 标记日期, 高温保存直至使用。

SpermGrad™型号10138和10139: 直接使用。

标准操作: 使用平衡盐溶液室温。

将密度梯度分离层置于标记患者编号的无菌推注器中心管。吸取1.5 mL 90%梯度液(SpermGrad™上层液体)至中心管, 90%然后在上层慢慢加1.5 mL 45%梯度液(SpermGrad™下层液体)。最后, 在上层轻轻注入稀释液, 300–600 g离心20分钟, 并在两层液体间将精子沉淀转移至另一个含有5 mL 平衡好的添加蛋白的G-IVF™, G-IVF™ PLUS或SpermRinse™的无菌试管中。评估精子活力和浓度。根据实验室的标准操作规程进行人工授精。

SpermGrad™是唯一含有蛋白酶抑制剂, 而不是胰凝乳蛋白酶抑制剂的。

SpermGrad™是稳定性好于SpermRinse™的。

SpermGrad™是梯度液, 与移液管易于操作。

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