

SpermGrad™

产品有效期及储存条件

生产有效期: 生产之日起12个月

储存条件: 避光, +2℃~+8℃

运输条件: 在运输过程中温度不得超过18℃, 但不得超过12℃, 最长运输时间不得超过7天。

SpermGrad™在包装标签上和生产批号旁的质量分析报告上, 显示有有效期和稳定的质量。

本产品为一次使用型。培养液瓶打开后不应再继续使用。使用后丢弃并彻底消毒。

生产日期: 见标签

使用期限: 见标签

en: Indication for use

Medium for gradient sperm separation.

Contraindications

Not known.

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 G-IVF PLUS or SpermRinse™.

–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 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 G-IVF PLUS or SpermRinse, contain gentamicin as an antibacterial agent.

The summary of safety and clinical performance can be found at www.vitrolife.com

SpermGrad is stable until the expiry date shown on the container labels and the LOT-specific Certificate of Analysis provided with each delivery.

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 provided with each delivery.

Media bottles should not be stored after opening.

Discard excess media after completion of the procedure.

Directions for use

The product should be used by an IVF professional.

The patient target group is an adult or reproductive-age population that undergoes fertility treatment. Media for dilution into desired concentrations. For use after dilution with G-IVF PLUS or SpermRinse™.

Dilution: SpermGrad REF 10099 and 10102: Mix SpermGrad with 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 G-IVF PLUS or SpermRinse. For 45% stock solution mix 4.5 mL SpermGrad with 5.5 mL 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.

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 and then slowly 1.5 mL of 45 % solution (SpermGrad Upper Layer) on the top of it. Finally, the semen is gently layered on the top. Centrifuge the tube for 20 minutes at 300–600 g to remove the two top layers. Transfer the sperm pellet into a tube as little of the 90 % solution (SpermGrad Lower Layer) as possible to a sterile conical tube with 5 mL of equilibrated G-IVF PLUS or SpermRinse. Centrifuge for 10 minutes at 300–600 g. Discard the supernatant and repeat the wash. Re-suspend the pellet in 1 mL of equilibrated G-IVF PLUS or SpermRinse. Assess the sample for motility and concentration. Inseminate according to normal laboratory procedures.

Specifications

Asepticly filtered

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

Human sperm recovery assay (recovery rate after gradient separation) [%] ≥25

Mouse Embryo Assay not performed

OT-smolified tested

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.

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.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Not for injection

Discard the product according to standard clinical practice for medical hazardous waste when the procedure is finished.

Symbols glossary

* Medical devices – Symbols to be used with information to be supplied by the manufacturer (ISO 15223-1:2021).

Symbol	Title	Reference and symbol ID
	Consult instructions for use	*Ref no. 5.4.3
	Caution	*Ref no. 5.4.4
	Manufacturer	*Ref no. 5.1.1
	Date of manufacture	*Ref no. 5.1.3
	Use-by date	*Ref no. 5.1.4
	Batch code	*Ref no. 5.1.5
	Catalogue number	*Ref no. 5.1.6
	Sterilized using aseptic processing techniques	*Ref no. 5.2.2
	Single sterile barrier system	*Ref no. 5.2.11
	Do not re-use	*Ref no. 5.4.2
	Temperature limit	*Ref no. 5.3.7
	Keep away from sunlight (light source)	*Ref no. 5.3.2
	Medical Device	*Ref no. 5.7.7
	CE Mark (Conformite Europeenne)	European conformity (CE) mark with Notified Body identification number as defined in Regulation (EU) 2017/745 Annex V

Caution: Federal (US) law restricts this device to sale by or on the order of a physician or practitioner trained in its use (Rx only).

CHINA

zh: 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

本产品适用于体外受精过程, 作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

产品型号	型号	规格
精子梯度分离液 SpermGrad™	10102	1x30mL
	10099	1x125mL
精子梯度分离液 (即用型) SpermGrad™-RTU	10138	2x30mL
	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20163180172

产品技术要求编号: 国械注进20163180172

禁忌证

未知

产品描述

所有的精子梯度分离液SpermGrad™都是含有硅烷包裹的胶体二氧化硅颗粒的碳酸盐和HEPES缓冲的分离液。

精子梯度分离液有以下可选:

–SpermGrad REF 10102 (30mL) and 10099 (125mL). 培养液可以稀释成所需浓度, 用G-IVF™ PLUS或SpermRinse™稀释后使用。

–SpermGrad REF 10138 (2x30mL), 10238 (30mL), 10338 (30 mL), 10139 (2x125 mL), 10239 (125mL) and 10339 (125mL) 含有: 梯度液SpermGrad Upper Layer and SpermGrad Lower Layer, 用于精子梯度分离的即用型溶液。

SpermGrad不含抗生素, 但用于稀释和精子清洗的培养液, 如G-IVF™ PLUS或SpermRinse™, 含有氨基糖苷类大药膏。

2024.13 SpermGrad™ © Vitrolife

выпущит мутной.

Повторное использование может привести к микробиологическому загрязнению и (или) изменению состава продукта.

Во избежание контаминации компания Vitrolife настоятельно рекомендует вскрывать и использовать средство только в соответствии асептической методики.

Риски репродуктивной токсичности и эмбриотоксичности сред для ЭКО, включая среды для ЭКО компании Vitrolife, не определены и остаются неснякими.

Обо всех серьезных несчастных случаях в связи с использованием устройств следует сообщать производителю и в компетентный орган государственной, в котором зарегистрировано пользоваться и/или пациент.

Не использовать для инъекций.

По завершении процедуры продукт подлежит утилизации в соответствии со стандартной клинической практикой в отношении опасных отходов.

Предупреждение: Федеральным агентством (США) разрешено продажу данного продукта только врачам или по распоряжению врача (Rx only).

Описание СИМВОЛОВ

Символ	Название
	Обратитесь к инструкции по применению.
	Осторожно!
	Изготовитель
	Дата изготовления
	Использовать до
	Код партии
	Номер по каталогу
	Стерилизация с применением методов асептической обработки
	Система с однократным стерильным барьером
	Не использовать повторно, утилизируйте после использования.
	Температурное ограничение
	Не допускать воздействия солнечного света
	Медицинское изделие
	Медицинское изделие (Европейское Соответствие)

EUROPE

en: Indication for use

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Dilution: SpermGrad REF 10099 and 10102: Mix SpermGrad with 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 G-IVF PLUS or SpermRinse. For 45% stock solution mix 4.5 mL SpermGrad with 5.5 mL 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.

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Remove the two top layers. Transfer the sperm pellet into a tube as little of the 90 % solution (SpermGrad Lower Layer) as possible to a sterile conical tube with 5 mL of equilibrated G-IVF PLUS or SpermRinse. Centrifuge for 10 minutes at 300–600 g. Discard the supernatant and repeat the wash. Re-suspend the pellet in 1 mL of equilibrated G-IVF PLUS or SpermRinse. Assess the sample for motility and concentration. Inseminate according to normal laboratory protocols.

Specifications

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Not for injection.

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bg: Показания за употреба

Сред за градиентно разделяне на сперма.

Противопоказания

Не са известни.

Описание на продукта

Всички среди тип SpermGrad™ са бифурбирани с биомаранит и с HEPES среда, която съдържа силизанирани колоници силициени частици.

SpermGrad се предлага под следната форма:

–SpermGrad REF 10102 (30 mL) и 10099 (125 mL). Сред за разреждане до желани концентрации.

За употреба след разреждане с G-IVF™ PLUS или SpermRinse™.

– SpermGrad REF 10138 (2 x 30 mL), 10238 (30 mL), 10338 (30 mL), 10139 (2 x 125 mL), 10239 (125 mL) и 10339 (125 mL) съдържат: Градиентни разтвори SpermGrad Upper Layer (горен слой) и SpermGrad Lower Layer (долен слой). Готови за употреба разтвори за градиентно разделяне на сперма.

SpermGrad не съдържа антибиотик, а средите за разреждане и промиване на сперма, като G-IVF PLUS или SpermRinse, съдържаат гентамицин като антибактериално средство.

Обобщение на информацията за безопасността и клиничните показатели може да бъде намерено на www.vitrolife.com.

Инструкции за съхранение и стабилност

Да се съхранява на тъмно при температура от +2° C до +8° C.

SpermGrad е стабилен до изтичане на срока на годност, обозначен върху етикета на опаковката и на спецификации за партидата Сертификат за анализ.

Бутилите със среда не трябва да се съхраняват след отваряне.

Изхвърлете остатъчното количество среда след приключване на процедурата.

Указания за употреба

Продуктът трябва да се използва от специалист по

Mediet til fortynding til ønskede koncentrationer. Til brug efter fortynding med G-IVF™ PLUS eller SpermRinse™.

–SpermGrad REF 10102 (30 x 30 mL), 10238 (30 mL), 10338 (30 mL), 10139 (2 x 125 mL), 10239 (125 mL) og 10339 (125 mL) indeholdende: Gradientløsningerne SpermGrad Upper Layer og SpermGrad Lower Layer.

Bugskiklare opløsninger til gradientseparation af sæd.

SpermGrad er antibiotikafri, mens mediet til fortynding af SpermGrad med G-IVF PLUS eller SpermRinse indeholder gentamicin som antibakterielt middel.

Et resumé af den sikkerhedsoplysning og kliniske ydeevne kan findes på www.vitrolife.com.

Obervationsinstruktion og stabilitet

Opbevares mørkt ved +2 til +8 °C.

SpermGrad kan holde sig indtil udløbsdatoen, der fremgår af etiketterne på beholderne og det LOT-specifikke analysecertifikat.

Medeflasker må ikke opbevares efter åbning.

Procedur overvåges mediet efter færdiggørelse af proceduren.

Produktsikning

Produktet skal anvendes af en uddannet IVF-medicinlæge.

Patientmiljøet er voksne eller personer i den forplantningsdygtige alder, som modtager fertilitetsbehandling.

Forynding: SpermGrad REF 10099 and 10102: Bland SpermGrad med G-IVF PLUS eller SpermRinse™ i separate rør for at opnå 90% og 45% opløsningsblandinger på 90 % og 45%. Til 90 % opløsningsblandingen 9.0 mL SpermGrad med 1.0 mL G-IVF PLUS eller SpermRinse. Til 45 % opløsningsblandingen blandes 4.5 mL SpermGrad med 5.5 mL G-IVF PLUS eller SpermRinse. Bland opløsningerne grundigt. Opbevar dem i sterile, lukkede reagensglas eller sterile vævskulturfasker. Mark dem med dato, og opbevar dem på køl, indtil de skal bruges til fortynding.

SpermGrad REF 10138, 10238, 10338, 10139, 10239 og 10339: Klar til brug.

Preparation af prøven: Lad opløsningerne opnå stuetemperatur før brug.

Pipetter gradienten lagvis ned i et steril, konisk centrifugeringsglas mærket med patientens ID. Pipetter først 1.5 mL af 90 %-opløsningen (SpermGrad Lower Layer) i glasset, og pipetter derefter lagvis 1.5 mL af 45% opløsningen (SpermGrad Upper Layer) ovenpå. Til sidst anbringes sæden forsigtigt ovenpå.

Kentriuger glasset i 20 minutter ved 300-600 g. Fjern de to øverste lag. Overfør sædcellerne med mindst muligt af 90 %-opløsningen (SpermGrad Lower Layer) til et steril, konisk glas med 5 mL ækvilibreret G-IVF PLUS eller SpermRinse. Centrifuger i 10 minutter ved 300-600 g. Kasser supernatanten, og gentag skyllingen. Resuspendér pæletten i 1 mL ækvilibreret G-IVF PLUS eller SpermRinse. Vurder prøven for bevægelse og koncentration. Inseminer i overensstemmelse med almindelige laboratorieretorier.

Specifikationer

Asepticly filtreret

Bakterielle endotoxiner (LAL-analyse) [EU/ml] < 0.5

Analys af human sperm recovery (recovery rate efter gradientseparation) [%] ≥25

Museembryoassay er ikke udført

OT-smolified tested

LOT-specifikke testresultater fremgår af analysecertifikatet, der medfølger ved hver levering.

Foldsregler

Kasser produktet, hvis flaskens integritet er kompromitteret. Anvend ikke SpermGrad, hvis det er uklart.

Genbrug kan forårsage mikrobiologisk kontaminering og/eller andre potentielle genskabelser.

For at undgå kontaminering anbefaler Vitrolife på det kraftigste at mediet kun åbnes og anvendes ved hjælp af aseptisk teknik.

Risikoen for reproduktionstoksicitet og udviklings toksicitet er lavt.

Hvis der sker en alvorlig hændelse i forbindelse med brug af medicinsk udstyr til et indgreb, skal produktet og den og den kompetente myndighed i det medlemsland, hvor brugen aflegget patienten er etableret.

Vigtigt! I følge amerikansk lov må dette udstyr kun sælges af eller af ordination fra en læge eller en behandler, der er uddannet i brugen af det (Rx only).

De: Anwendungshinweise

Zur Dichtegradientenseparation von Spermien.

Gegenanzeigen

Keine Gegenanzeigen bekannt.

Produktbeschreibung

Sämtliche SpermGrad™-Medien sind Bikarbonat- und HEPES-gepufferte Medien, die Silan-beschichtete Kolloidsilica-Partikel enthalten.

SpermGrad ist erhältlich als:

–SpermGrad REF 10102 (30 ml) und 10099 (125 ml). Medien zur Verdünnung in gewünschten Konzentrationen. Zur Verwendung nach der Verdünnung mit G-IVF™ PLUS oder SpermRinse™.

–SpermGrad REF 10138

