

# Follicle Aspiration Set

Vitrolife

US

## EN: Indication for use

The Follicle Aspiration Set is a sterile, single use device which is intended for flushing and/or aspiration of oocytes from ovarian follicles.

### Product Description

The Follicle Aspiration Set is comprised of one or more of the following components:

- 1. A stainless steel needle with a unique Medisteel™ PrecisionGrip™ design.
- 2. A silicone cork to be pushed into the opening of a sampling tube.
- 3. A length of Teflon low friction tubing for flushing and flushing.
- 4. A blunt stainless steel cannula for flushing.
- 5. A length of Teflon tubing with luer connection which is attached to the needle hub for flushing.
- Note: Tubing to be connected from the silicone cork to the vacuum pump is ordered and supplied separately.

• The Follicle Aspiration Set, Single Lumen is comprised of components 1-4.

• The Follicle Aspiration Set, Reduced Single Lumen is comprised of components 1-4.

• The Follicle Aspiration Set, Single Lumen, Luer is comprised of component 1.

• The Follicle Aspiration Set, Single Lumen, Luer with Tubing is comprised of components 1 and 3.

• The Follicle Aspiration Set, Reduced Single Lumen, Luer is comprised of component 1.

• The Follicle Aspiration Set, Double Lumen is comprised of components 1-3 and 5.

### Storage Instructions

Store at room temperature.

### Directions for use

1. Check that the Follicle Aspiration Set packaging is intact and that the "use by" date has not expired.

2. Prepare the patient for oocyte aspiration according to standard clinical practice.

3. Cover the ultrasound transducer with a sterile plastic cover which should contain a small amount of sterile contact gel at the tip of the transducer. Mount the sterile needle guide on the transducer. Scan the pelvis to locate the follicles.

4. Open the Follicle Aspiration Set packaging and check that the needle easily can be introduced through the needle guide.

5. Proceed with one of the following in preparation of the aspiration procedure:

a) Single Lumen and Reduced Single Lumen only: attach a sterile sampling tube to the silicone cork and connect a tubing to the Follicle Aspiration Set and to the vacuum pump.

b) Single Lumen, Luer, Single Lumen, Luer with Tubing, and Reduced Single Lumen, Luer only: attach a sterile syringe to the needle or tubing. Reconnect the vacuum pump and continue to aspirate the follicle until it is empty.

c) Double Lumen: attach a syringe with sterile media to the luer connection and flush. Continue to aspirate the follicle until it is empty.

6. Replace the sampling tube/syringe with a new one. When 2/3 of the sampling tube or syringe has been filled and if the follicle is not completely emptied:

7. Perform follicle aspiration according to established methods used at the clinic.

Needles of a gauge greater than 19G are thin and by nature more susceptible to certain abrupt movements through human tissue. The needle tip can slightly bend and thus come out of the ultrasound field of view. To eliminate this risk, withdraw the needle slightly from the ovary and re-puncture before aspirating the remaining follicles.

8. If flushing is necessary, proceed with one of the following:

a) Single Lumen and Reduced Single Lumen only: attach the sampling tube from the silicone cork and connect the aspiration tube to the aspiration tube. Attach a syringe to the aspiration tube. Reconnect the vacuum pump and continue to aspirate the follicle until it is empty.

b) Single Lumen, Luer, Single Lumen, Luer with Tubing, and Reduced Single Lumen, Luer only: detach the syringe, attach a new syringe with sterile media and flush. Reconnect the syringe and continue to aspirate the follicle until it is empty.

c) Double Lumen: attach a syringe with sterile media to the luer connection and flush. Continue to aspirate the follicle until it is empty.

9. Replace the sampling tube/syringe with a new one. When 2/3 of the sampling tube or syringe has been filled and if the follicle is not completely emptied:

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

### Precautions

The Follicle Aspiration Set may not be used for intrafoliopan procedures or in the presence of, or after, pelvic inflammatory disease.

Discard the product if the packaging or product is damaged.

The product may only be used by, or under the guidance of, a person qualified in gynaecological and follicle aspiration procedures.

The Follicle Aspiration Set is intended for single use only and MAY NOT BE REUSED. Reuse may cause contamination, patient infection, and failed procedure.

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

### Specifications

Mouse Embryo Assay (1-cell)

[% expanded blastocyst within 96 hours] ≥ 80

Bacterial Endotoxins (LAL assay)

s 1.2 EU/device

### Description of ISO Symbols

	Sterilized using steam
	Do not re-use, discard after procedure
	Use by - see label.
	Caution: Consult accompanying documents
	Catalog number
	Batch code
	CE Mark (Conformité Européenne)

# CHINA

## CN: 一次性取卵针产品说明书

### 适应证

用于冲洗和/或从卵泡中采集卵母细胞

产品型号及型号

规格：见产品标签

产品注册证及技术要求编号

产品注册证编号：见标签

产品技术要求：见标签

### 产品描述

一次取卵针产品包含以下一种或两种组件：

1. 独特的Medisteel™ PrecisionGrip™设计的不锈钢针头。

2. 可以插入吸盘管的胶塞。

3. 一段带有冲刷和冲刷低摩擦Teflon软管。

4. 一段带有冲刷的带环塑料管。

5. 一段带环在针杆上，用于冲洗的带环Teflon软管。

注意：在硅胶套直置空腔的情况下冲洗管需要单独订购使用。

6. 按照操作指南进行冲洗或冲洗操作。

7. 根据目前的医疗实践进行的操作。

如果一次取卵针不能使用于输卵管内操作，存在盆腔炎或盆腔感染时不可以使用一次取卵针。

如果产品包装破损或产品使用后损坏，丢弃产品，使用前应仔细阅读产品说明。

一次取卵针为一次使用产品，切勿重复使用。重复使用可能会导致污染、患者感染以及操作失败。

### 规格

鼠胚胚胎活力（1细胞胎）

[%6小时内为96%以上]

细菌内毒素(LAL检测)

s 1.2 EU/device

### ISO符号描述

	蒸汽灭菌
	Do not re-use, discard after procedure
	Use by - see label.
	Caution: Consult accompanying documents
	Catalog number
	Batch code
	CE Mark (Conformité Européenne)



CE 2460 (Conformité Européenne)

## EUROPE

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- 4. A blunt stainless steel cannula for flushing.
- 5. A length of Teflon low friction tubing with luer connection which is attached to the needle hub for flushing.

Note: Tubing to be connected from the silicone cork to the vacuum pump is ordered and supplied separately.

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• The Follicle Aspiration Set, Double Lumen is comprised of components 1-3 and 5.

### Storage Instructions

Store at room temperature.

### Directions for use

1. Check that the Follicle Aspiration Set packaging is intact and that the "use by" date has not expired.

2. Prepare the patient for oocyte aspiration according to standard clinical practice.

3. Cover the ultrasound transducer with a sterile plastic cover which should contain a small amount of sterile contact gel at the tip of the transducer. Mount the sterile needle guide on the transducer. Scan the pelvis to locate the follicles.

4. Open the Follicle Aspiration Set packaging and check that the needle easily can be introduced through the needle guide.

5. Proceed with one of the following in preparation of the aspiration procedure:

a) Single Lumen and Reduced Single Lumen only: attach a sterile sampling tube to the silicone cork and connect a tubing to the Follicle Aspiration Set and to the vacuum pump.

b) Single Lumen, Luer, Single Lumen, Luer with Tubing, and Reduced Single Lumen, Luer only: attach a sterile syringe to the needle or tubing. Reconnect the vacuum pump and continue to aspirate the follicle until it is empty.

c) Double Lumen: attach a syringe with sterile media to the luer connection and flush. Continue to aspirate the follicle until it is empty.

9. Replace the sampling tube/syringe with a new one. When 2/3 of the sampling tube or syringe has been filled and if the follicle is not completely emptied:

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

### Precautions

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### Specifications

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### CG: 指示

#### 适应症

仅限于冲洗和/或从卵泡中采集卵母细胞

产品型号及型号

规格：见产品标签

产品注册证及技术要求编号

产品注册证编号：见标签

产品技术要求：见标签

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