

# MICROFLUIDIC SPERM SORTING CHIPS

# FERTILE<sup>®</sup>

# ULTIMATE

## Device Components:

- FERTILE ULTIMATE<sup>®</sup> Microfluidic Sperm Sorting Chips (10 pcs)
- Instructions for Use
- ID Card (10 pcs)

## Materials/Equipment Required, But Not Supplied:

- Sperm washing solutions: bicarbonate or HEPES-buffered
- 37°C incubator
- 5 mL Luer-tip syringes (3 pcs)
- Capped tubes

Learn more at [www.fertilechip.com](http://www.fertilechip.com)

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## Instruction for Use

Please read all instructions below prior to beginning use of this device.

1. Incubate semen sample to allow for liquefaction (15 minutes).
2. Carefully open the device package from corner.
3. Use a 5 mL syringe to draw an 3 mL aliquot of liquefied semen specimen. If there is insufficient volume, add sperm washing solution to give 3 mL.
4. Take approximately 3 mL of semen sample from the sample container with the help of an injector. Be careful not to get air bubbles into the syringe while taking samples due to its dense structure. These air bubbles will cause volume loss and affect the performance of the product (Figure 1).

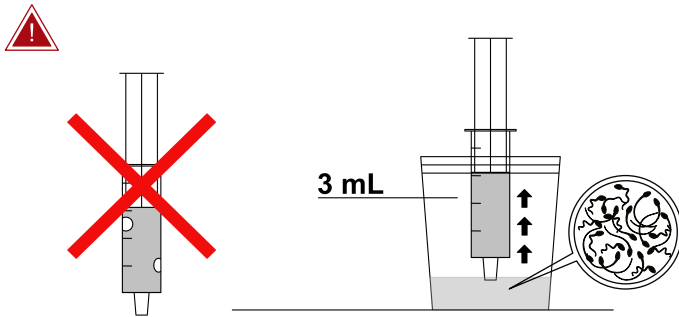


Figure 1. Draw 3 mL of the sample.

5. Hold the syringe in a vertical position, carefully insert the tip into the inlet and apply gentle pressure to achieve a seal. Be careful to avoid the formation of bubbles under the membrane (Figure 2).

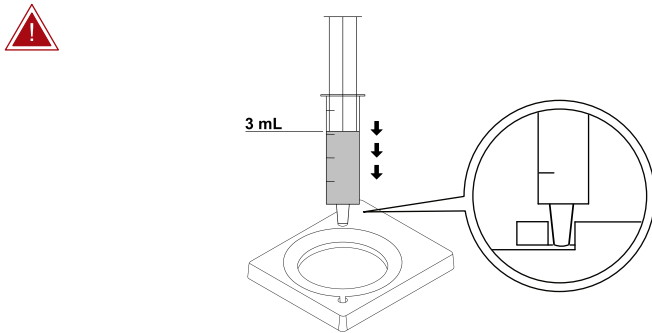


Figure 2. Fill the bottom chamber with 3 mL semen sample.

6. Prepare a fresh syringe with 2.5 mL of sperm wash solution. Cover the entire upper collection chamber. Ensure an uninterrupted flow of media over the membrane and the outlet port (Figure 3).

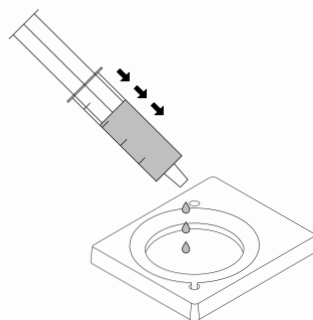


Figure 3. Cover the membrane surface with 2.5 mL sperm wash solution.

7. Incubate the prepared device at 37°C for 30 minutes. If you are using HEPES buffered media you don't need CO<sub>2</sub> incubator. If you use bicarbonate buffered media, you have to use 5% CO<sub>2</sub> incubator. (Figure 4).

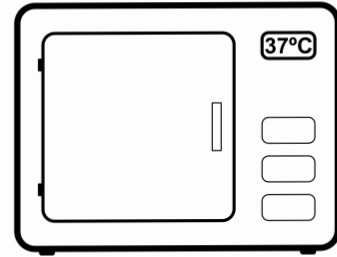


Figure 4. Incubate the prepared device at 37°C for 30 minutes.

8. After 30 minutes incubation, insert a fresh 5 mL syringe into the outlet port of device. Slowly aspirate a maximum of 1.5 mL of the sperm-containing fluid (Figure 5).

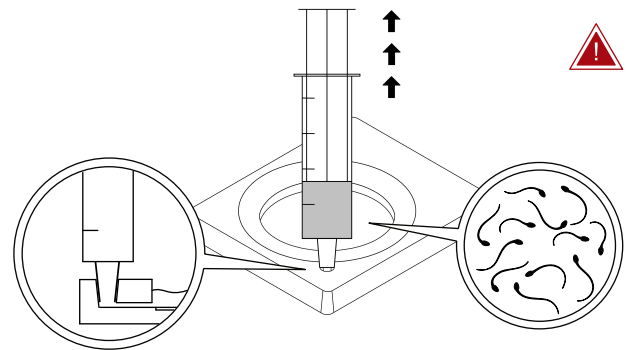


Figure 5. Slowly aspirate a maximum of 1.5 mL.

9. Transfer the collected material to a capped tube. Store for later use according to lab practice (Figure 6).

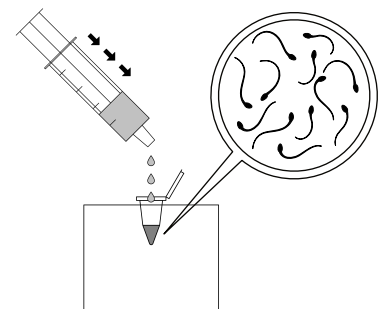


Figure 6. Transfer the collected material for later use.

## Tips, Warnings and Precautions:

- Device should be used only by properly trained operators; by or on the order of a physician.
- Avoid over- or under-filling the device.
- Keep the device level during use – do not tip or rock.
- Do not use if the packaging is damaged.
- Device is single-use only and should be restricted to a single individual per device. It may not be reused.
- Practice universal precautions when handling human body fluids.

## Device Description:

FERTILE®, FERTILE PLUS® and FERTILE ULTIMATE® are microfluidic sperm sorting chips used to prepare motile sperm for assisted reproductive technology (ART) procedures. Both devices separate sperm based on motility. The FERTILE®, the FERTILE PLUS® and the FERTILE ULTIMATE® are sterile and single use only. The mechanism of action for both is separation of sperm based on motility within a microenvironment created by the micro channels of the FERTILE® or the micropores in the filter of the FERTILE PLUS® and the FERTILE ULTIMATE®. The primary difference between the devices is the processing volume. The FERTILE® has a processing volume of 2 µL per micro channel. The FERTILE PLUS® has a processing volume of 850 µL per device and FERTILE ULTIMATE® has 3 mL.

The FERTILE PLUS® and FERTILE ULTIMATE® have an inlet port that communicates with the lower sample chamber. The sample chamber is separated from the upper collection chamber by a microporous filter. Untreated semen is added through the inlet port. After 30 minutes, the separated sperm are collected from the upper chamber through the outlet port.

## NOTIFIED BODY

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## Licenses, Patents and Trademarks:

KOEK Biotechnology is an exclusive sublicensee of DxNow, Inc., And a manufacturer of DxNow's sperm separation devices. These devices are manufactured and sold under the terms of DxNow Inc.'s exclusive worldwide patent license from The Brigham & Women's Hospital, Inc., Boston, Massachusetts, USA.

EU Patent EP2710139B1. Additional USA and international patents pending. FERTILE®, FERTILE PLUS® and FERTILE ULTIMATE® are trademarks of KOEK Biotechnology Inc.

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## Indications for Use:

The FERTILE ULTIMATE® Microfluidic Sperm Sorting Chip is intended for preparing motile sperm from semen for use in the treatment of infertile couples with low sperm count and high volume by ART procedures.

## Contraindication:

There is no known absolute and / or relative contraindication defined in the use of the device.

## Minimum Knowledge and Education Level:

The product is used in embryology and andrology laboratories for assisted reproductive treatments. For its use, it has to be someone who can use pipettes such as biology, biochemistry, medicine, laboratory technician and can perform routine procedures in embryology laboratories.

## Residual Risk:

Not available.

## Sterilization:

The sterilization method used for the FERTILE ULTIMATE® chip is gamma radiation, at a dose level of 5kGy to 40kGy by the VD<sub>max</sub><sup>25</sup> method to meet a Sterility Assurance Level of 10<sup>-6</sup>.

## Storage:

Store at 15°C - 25°C.

## Disposal:

Discard the used device and pipette tips as medical waste.

## WARNING DESCRIPTION

|  |  |  |  |
|--|--|--|--|
|  | Manufacturer Information                 |  | Breakable, Carefully Move                        |
|  | Manufacturing Date                       |  | Store in a Dry Place                             |
|  | Expiration Date                          |  | Storage Temperature                              |
|  | LOT Number                               |  | Do not re-use                                    |
|  | Catalogue Number                         |  | Please, read the Instruction for Use, before use |
|  | Sterilization Method                     |  | Observe Alerts                                   |
|  | Do not re-sterilize                      |  | Suitable for 93/42/EEC Standards.                |
|  | Do Not Use If The Packaging Is Corrupted |  |  |

