

# FERTILE<sup>®</sup>

## MICROFLUIDIC SPERM SORTING CHIPS

### Device Components:

- FERTILE<sup>®</sup> Microfluidic Sperm Sorting Chips
- Instructions for Use

### Materials/Equipment Required, But Not Supplied:

- Sperm washing solutions: bicarbonate or HEPES-buffered
- 37°C incubator
- 2µL-20µL capacity adjustable micropipette
- 1µL-10µL capacity adjustable micropipette
- Recommended pipette tips:
  - 20µL: Rainin 30389189 / RT-UNV-A-20µL
  - 0-10µL: Rainin 30389163 / RT-UNV-A-10µL
- Capped tubes

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

CE  
1984

## Instruction for Use

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

1. Incubate semen sample to allow for liquefaction.
2. Carefully open the device package.
3. Use the 2-20µL micropipette fitted with the recommended tip to draw 15µL of sperm wash solution.
4. Carefully insert the tip into the inlet port (the inlet port is the smaller of the ports). Hold the micropipette in a vertical position and apply gentle pressure to achieve a seal. Do not allow the micropipette to "bottom out," which can hinder free flow of solution. Inject the sperm wash solution into the inlet port to fill the channel and outlet port (Figure 1). Do not trap air bubbles in the device.

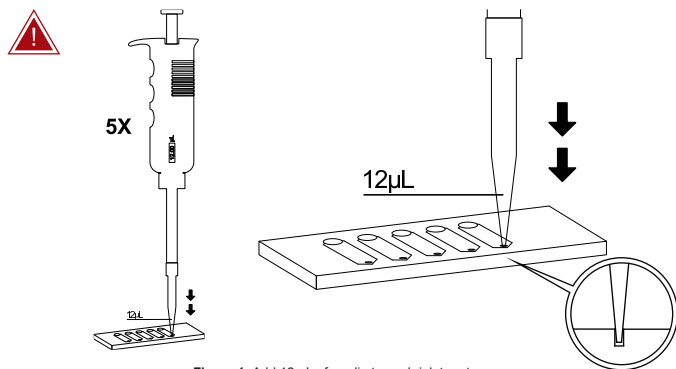


Figure 1. Add 12 µL of media to each inlet port.

5. Use the 1-10µL micropipette fitted with the recommended tip to slowly add 2µL of liquefied semen sample to the inlet port (Figure 2). As in the previous step, do not allow the micropipette to "bottom out". Ensure free flow of the semen sample. Ignore any excess solution buildup at the inlet port.

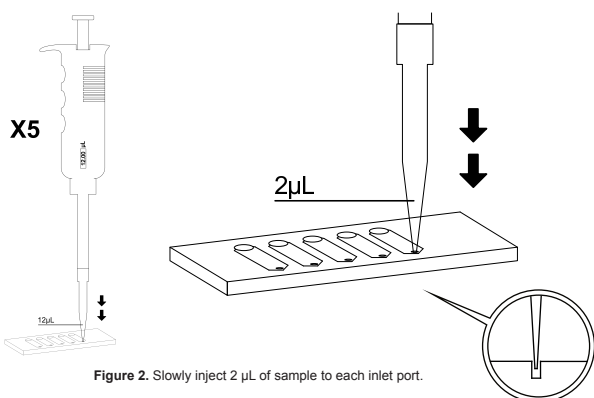


Figure 2. Slowly inject 2 µL of sample to each inlet port.

6. Use a 1-10µL micropipette fitted with the recommended tip to add a 2 µL oil overlay to the inlet and outlet ports (Figure 3).

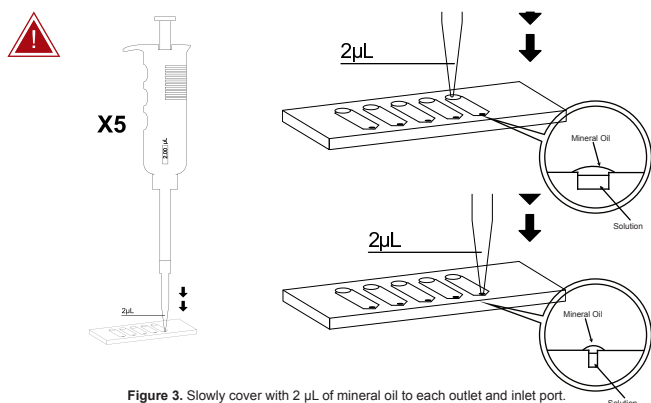


Figure 3. Slowly cover with 2 µL of mineral oil to each outlet and inlet port.

7. Incubate the covered device at 37°C for 30 minutes (Figure 4).

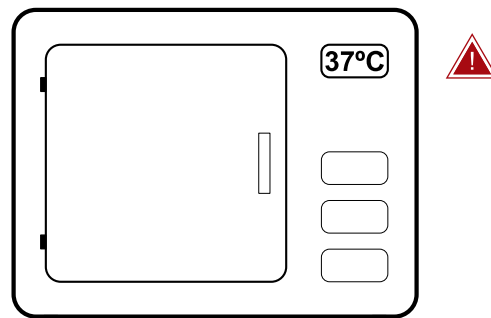


Figure 4. Incubate the covered device at 37°C for 30 minutes.

8. Use a micropipette to carefully remove 2µL of the sorted sperm-containing solution from each of the outlet ports (Figure 5).

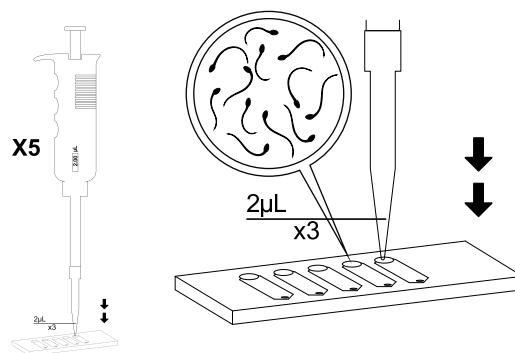


Figure 5. Slowly aspirate 2µL from each outlet port under the oil.

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

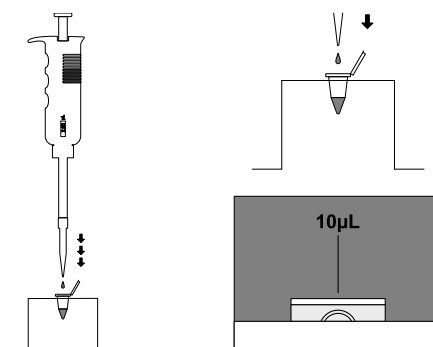


Figure 6. Transfer the collected material for later use.

## 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 2µL per micro channel. The FERTILE PLUS® has a processing volume of 850µL per device and FERTILE ULTIMATE® has 3mL.

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

**Kiwa Turkey** Istanbul Branch Office  
**Address:** ITOSB Tepeoren District 34957  
Tuzla / Istanbul TURKEY  
**Phone:** +90 216 593 25 75  
**Fax:** +90 216 593 25 74  
**E-Mail:** [info@kiwa.com.tr](mailto:info@kiwa.com.tr)



## 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.

## MANUFACTURER

**Manufacturer Name:** KOEK Biotechnology Bioengineering and Medical Services Industry and Trade Inc. Aegean Freezone Branch Office  
**Manufacturing Address:** Zafer Sb. District Nilufer Str. Aegean Freezone ESBAS B Block Apt. No:29/4 Gaziemir / IZMIR - TURKEY  
**Phone:** +90 232 503 37 08  
**E-Mail:** [info@koekbiotech.com](mailto:info@koekbiotech.com)

**R&D:** KOEK Biotechnology Bioengineering and Medical Services Industry and Trade Inc.  
**Address:** Inciraltı District. Mithatpasa Str. Dokuz Eylul Hospital Building. Morfoloji Apt. No:56-20/Z Balcova / IZMIR - TURKEY  
**Phone:** +90 232 236 78 14  
**E-Mail:** [info@koekbiotech.com](mailto:info@koekbiotech.com)

## Indications for Use:

The FERTILE® Microfluidic Sperm Sorting Chip is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI) 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® 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		

