

Device Components:

- ZyMot™ ICSI Sperm Separation Device
- Instructions for Use

Materials/Equipment Required, But Not Supplied:

- Sperm washing solution: bicarbonate or HEPES-buffered
- 37°C incubator
- 1µL-10µL and 2µL-20µL capacity adjustable micropipettes
- Water
- Recommended pipette tips:
 - 20µL: Rainin 30389189 | RT-UNV-A-20µL
 - 0-10µL: Rainin 30389163 | RT-UNV-A-10µL
- 35mm diameter and 100mm diameter Petri dish with lid
- Capped tubes

Learn more at zymotfertility.com

Instructions 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.

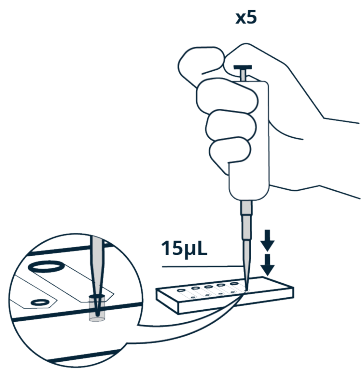


Figure 1. Add 15µL of media to each inlet port.

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.

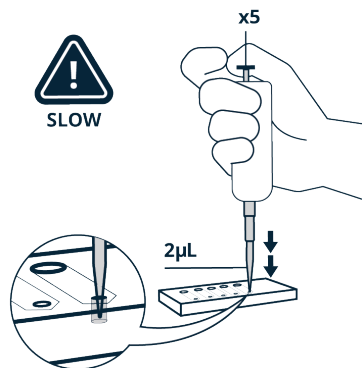


Figure 2. Slowly inject 2µL of sample to each inlet port.

6. Invert a 100mm Petri dish such that the lid becomes the base. Fill a 35mm Petri dish half-full with water. Place both the uncovered 35mm Petri dish and the device in the inverted Petri dish lid. Cover with the former 100mm Petri dish base (Figure 3).

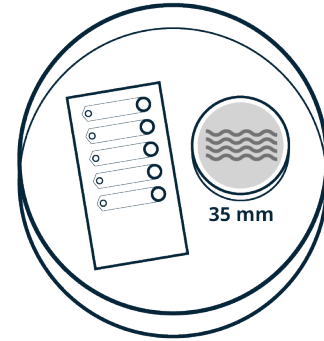


Figure 3. Prepare water. Place device in covered container.

7. 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 4).

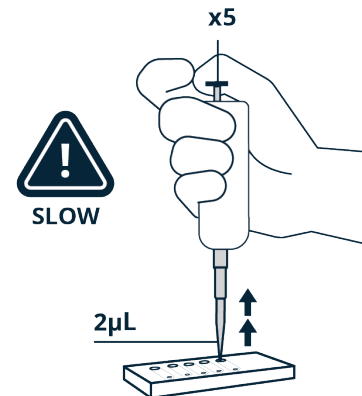


Figure 4. Slowly aspirate 2µL from each outlet port.

9. Transfer the collected material to a capped tube. Store for later use according to lab practice (Figure 5).

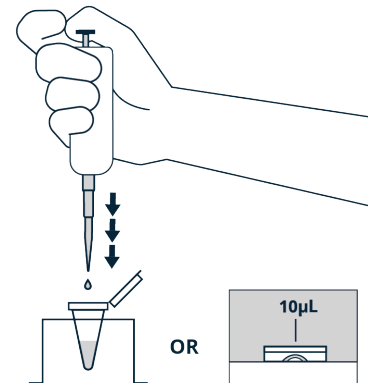


Figure 5. Transfer the collected material for later use.

Tips, Warnings and Precautions:

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

- Device should be used only by properly trained operators.
- 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:

ZyMöt ICSI and ZyMöt Multi are sperm separation devices used to prepare motile sperm for assisted reproductive technology (ART) procedures. Both devices separate sperm based on motility. The ZyMöt ICSI and the ZyMöt Multi 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 ZyMöt ICSI or the micropores in the filter of the ZyMöt Multi. The primary difference between the devices is the processing volume. The ZyMöt ICSI has a processing volume of 2µL per micro channel. The ZyMöt Multi is manufactured in two (2) processing volumes, 850µL and 3mL.

The ZyMöt Multi (provided with 850µL and 3mL collection chambers) has 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.

Indications for Use:

The ZyMöt ICSI Sperm Separation Device is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI) procedures.

Sterilization:

The sterilization method used for the ZyMöt devices is gamma radiation, at a dose level of 5kGy to 40kGy by the VDmax²⁵ method to meet a Sterility Assurance Level of 10⁻⁶.

Storage:

Store at 15°C - 25°C.

Disposal:

Discard the used device and pipette tips as medical waste.

Testing Performed for Devices Used in Assisted Reproduction:

Specific testing was performed for toxicity and functional screening appropriate for products used in assisted reproduction. As required by 21 CFR 884.6160, the following Special Controls were conducted (all tests were passed): human sperm survival assay (replacing the mouse embryo assay) and endotoxin testing.

Endotoxin Testing Results:

Using the Limulus Amebocyte Lysate (LAL) Analysis by the Gel-Clot Method, results were <0.0729 EU per device, which meets the acceptance level of ≤2.15 EU per device.

Human Sperm Survival Assay Results:

Using the Human Sperm Survival Assay, results were 96.2% for ZyMöt ICSI and 97.7% for ZyMöt Multi; both results meet the acceptance level of motility ≥80% of control at 24h after exposure for 30min.

Note: The above results are from testing required prior to USFDA 510(k) clearance. These tests are conducted on each manufacturing lot of devices as part of the lot release program. Individual lot results can be made available upon request.

Manufactured for:

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EU Patent EP2710139B1. Additional USA and international patents pending. ZyMöt, ZyMöt ICSI and ZyMöt Multi are trademarks of DxNow, Inc.

