

Device Components:

- ZyMöt™ Multi (850µL) Sperm Separation Device
- Instructions for Use

Materials/Equipment Required, But Not Supplied:

- Sperm washing solution: bicarbonate or HEPES-buffered
- 37°C incubator
- 1mL Luer-tip syringes (3)
- Recommended: Norm-Ject #4010-200V0, Henke Sass Wolf
- Capped tubes

Learn more at zymotfertility.com

Instructions for Use

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

1. Incubate semen sample to allow for liquefaction.
2. Carefully open the device package.
3. Use a 1mL syringe to slowly draw an 850µL aliquot of the liquefied semen specimen. If there is insufficient volume, add sperm washing solution to give 850µL (Figure 1).

If using a frozen sample:

Dilute the frozen sample 1:1 with sperm washing solution. Inject 850µL of the diluted sample into the device.

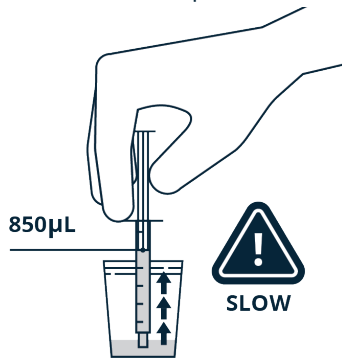


Figure 1. Draw 850µL of the sample.

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

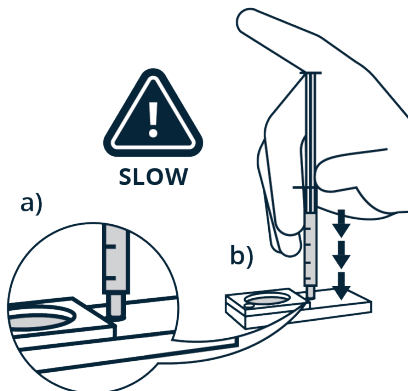


Figure 2. a) Achieve seal. b) Slowly inject sample.

5. Prepare a fresh syringe with 750µL of sperm wash solution (Figure 3a). Cover the entire upper collection chamber by first injecting about 50µL of solution in the outlet port – enough to fill the port and channel (Figure 3b). Remove syringe from port and apply remaining solution, 700µL, to the upper collection chamber until the entire surface area is covered (Figure 3c). Ensure an uninterrupted flow of media over the membrane and the outlet port.

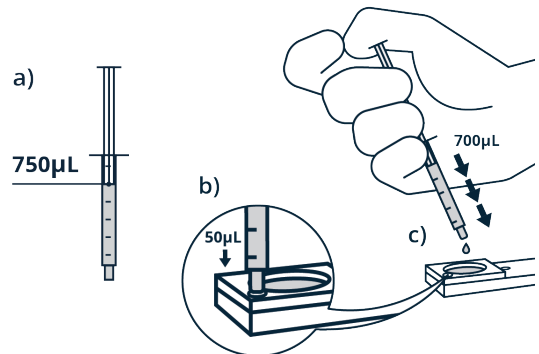


Figure 3. a) Draw 750µL of media. b) Prime outlet channel. c) Cover membrane surface.

6. Incubate the device at 37°C for 30 minutes.
7. Insert a fresh 1mL syringe into the outlet port of the device. Slowly aspirate a maximum of 500µL of the sperm-containing fluid (Figure 4).

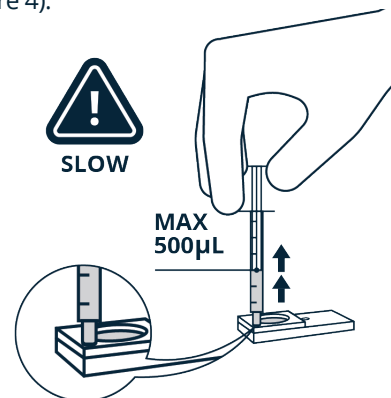


Figure 4. Slowly aspirate a maximum of 500µL.

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

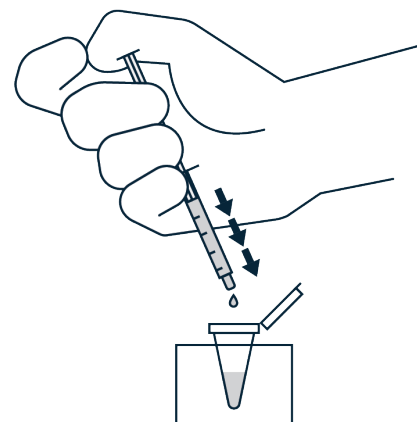


Figure 5. Transfer the collected material for later use.

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 Multi (850µL) Sperm Separation Device is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) and intrauterine insemination (IUI) 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.

