ZyMōt™
MULTI (3mL)

Sperm Separation Device

ZMH3000

Device Components:
- ZyMōt™ Multi (3mL) Sperm Separation Device
- Instructions for Use

Materials/Equipment Required, But Not Supplied:
- Sperm washing solution: bicarbonate or HEPES-buffered
- 37°C incubator
- 5mL Luer-tip syringes (2)
  Recommended: Norm-Ject #4050-000VZ, Henke Sass Wolf
- 1mL Luer-tip syringe (1)
  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 5mL Luer-tip syringe to slowly draw a 3mL aliquot of the liquefied semen specimen. If there is insufficient volume, add sperm washing solution to give 3mL (Figure 1).

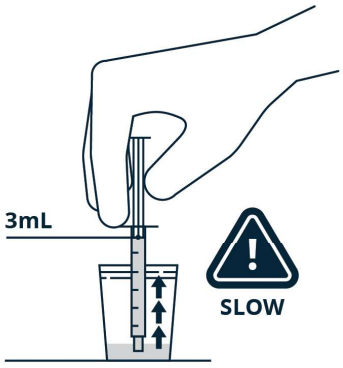

Figure 1. Draw 3mL of the sample.

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.

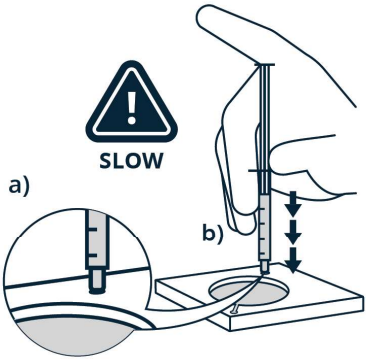

Figure 2. a) Achieve seal. b) Slowly inject sample.

5. Prepare a fresh syringe with 2.5mL of sperm wash solution (Figure 3a). Cover the entire upper collection chamber by first injecting about 100µL of solution in the outlet port – enough to fill the port and channel (Figure 3b). Remove syringe from port and apply remaining solution, 2400µL, 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.

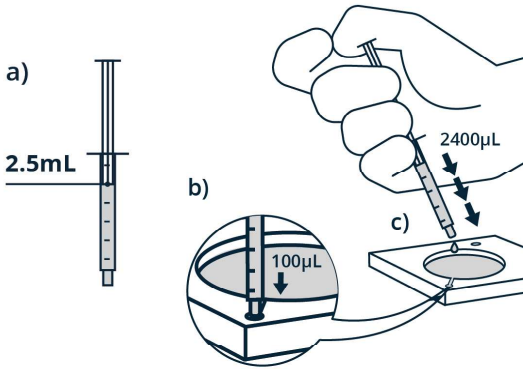

Figure 3. a) Draw 2.5mL of media. b) Prime outlet channel. c) Cover membrane surface.

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 1mL of the sperm-containing fluid (Figure 4).

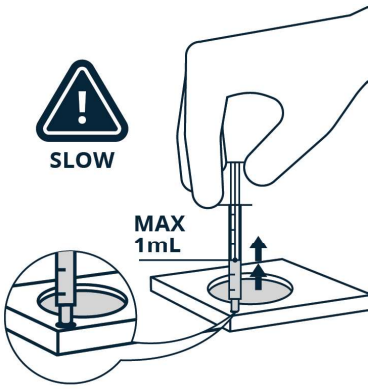

Figure 4. Slowly aspirate a maximum of 1mL.

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

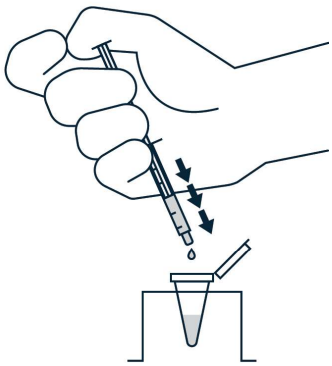

Figure 5. Transfer the collected material for later use.

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:
ZyMōt ICSI and ZyMōt Multi are sperm separation devices used to prepare motile sperm for assisted reproductive technology (ART) procedures. Both devices separate sperm based on motility. The ZyMōt ICSI and the ZyMōt Multi are sterile and single use only. The mechanism of action for both is separation of sperm based on motility within a micro-environment created by the micro channels of the ZyMōt ICSI or the micro-pores in the filter of the ZyMōt Multi. The primary difference between the devices is the processing volume. The ZyMōt ICSI has a processing volume of 2µL per micro channel. The ZyMōt Multi is manufactured in two (2) processing volumes, 850µL and 3mL.

The ZyMōt 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 micro-porous 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 ZyMōt Multi (3mL) Sperm Separation Device is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intrauterine insemination (IUI) and intracytoplasmic sperm injection (ICSI) procedures.

Note: To date, all studies and published clinical data regarding the use of ZyMōt Sperm Separation Devices have been focused on ICSI and IUI procedures. There have been no studies conducted, nor published data, on the use of ZyMōt devices for conventional insemination. ZyMōt Fertility is currently in the process of obtaining greater understanding and insight regarding the use of ZyMōt Multi devices for conventional insemination. Consequently, we are requesting that clinicians limit their use of ZyMōt Multi devices to ICSI and IUI cycles only.

Sterilization:
The sterilization method used for the ZyMōt devices is gamma radiation, at a dose level of 5kGy to 40kGy by the VDmax^{25} 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 ZyMōt ICSI and 97.7% for ZyMōt 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:
ZyMōt Fertility, a business unit of DxNow, Inc.
401 Professional Drive, Suite 130
Gaithersburg, MD 20879-3429 USA | www.zymotfertility.com
info@zymotfertility.com
+1.240.454.9893

Manufactured by:
KOEK Biotechnology Bioengineering and
Medical Services Industry and Trade Inc.
Zafer Sb. District Nilufer Str., Aegean Freezone
ESBAS B Block Apt. No: 29/4
Gaziemir / IZMIR – TURKEY | www.koekbiotech.com

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