

Device Components:

- ZyMot™ 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).

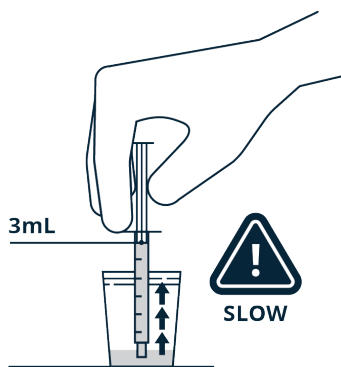


Figure 1. Draw 3mL of the sample.

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.

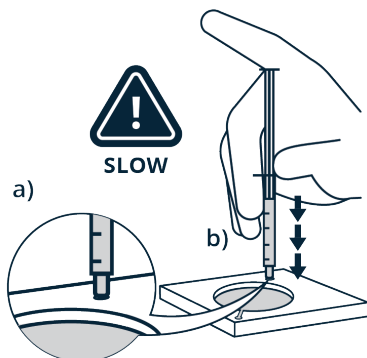


Figure 2. a) Achieve seal. b) Slowly inject sample.

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.

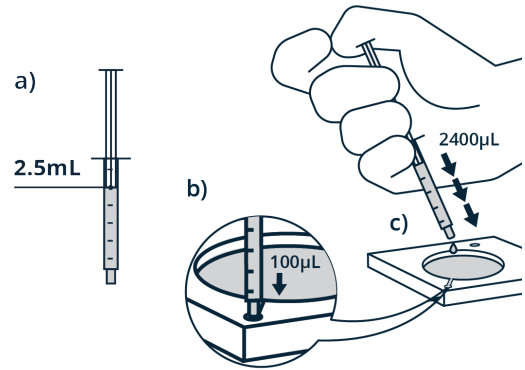


Figure 3. a) Draw 2.5mL of media. b) Prime outlet channel. c) Cover membrane surface.

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).

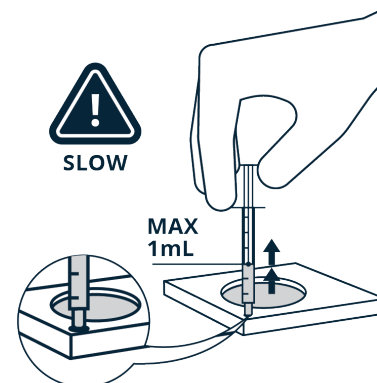


Figure 4. Slowly aspirate a maximum of 1mL.

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

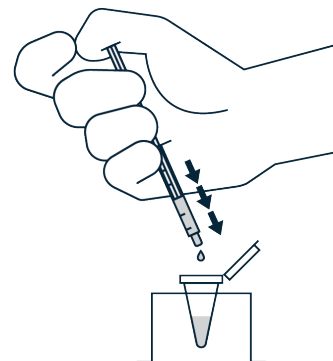


Figure 5. Transfer the collected material for later use.

Tips, Warnings and Precautions:

- 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:

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 (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.

Sterilization:

The sterilization method used for the ZyMöt devices is gamma radiation, at a dose level of 5kGy to 40kGy by the VD_{max}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.

Manufactured for:

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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.

USA Patent US10422737B2; EU Patent EP2710139B1; Japan Patent JP6524082B2; Australia Patent AU2014353050B2. Additional USA and other international patents pending.



Manufacturer



Date of Manufacture



Expiration Date



Lot Number



Catalog Number



Sterilized Using Irradiation



Do Not Resterilize



Do Not Use if Package is Damaged



Fragile Item, Handle Carefully



Keep Dry



Storage Temperature Limits



Do Not Reuse



Consult Instructions For Use



Caution



Conforms to Directive 93/42/EEC

