

Instructions for Use



Sperm Separation Device | ZMH0850

Important Information:

- Carefully adhere to recommended volumes for each step. Avoid over- or under-filling the device.
- Do not exceed 30 minute incubation time.
- Keep the device level during use – do not tip or rock.
- Device is single-use only and should be restricted to a single individual per device. It may not be reused.

Note on Incubation:

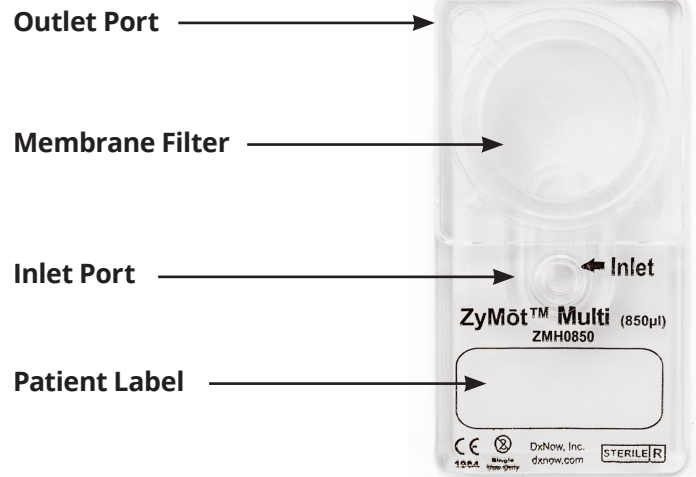
Good tissue practices necessitate matching media to incubation conditions. If using a bicarbonate-buffered media, incubate in a humidified, 37°C, gassed incubator. If using a HEPES-buffered media, incubate in a humidified, non-gassed incubator. If no incubator with humidity is available, add a 25mm dish of water, uncovered, to the Petri dish containing the device before placing the covered dish with the device and the 25mm water into the 37°C incubator.

Device Components:

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

Materials/Equipment Required, But Not Supplied:

- Sperm washing solution (media): bicarbonate- or HEPES-buffered media supplemented with 2-10% protein
- 37°C incubator
- 90mm Petri dish
- 1mL Luer-tip syringes (3) - Recommended: Norm-Ject #4010-200V0, Henke Sass Wolf
- Sperm-safe culture tube



PREPARATION

1. Gather your supplies and work on a clean surface.
2. Incubate semen sample at 37°C for 20-30 minutes to allow for liquefaction.
3. Carefully open the device package without touching the device membrane.

DRAW SAMPLE

4. Use a 1mL syringe to slowly draw an 850µL aliquot of the liquefied semen specimen (sample). If there is insufficient sample volume, add media to bring volume to 850µL (Figure 1).

Note if using a frozen sample: Follow cryobank instructions when thawing. Dilute thawed sample 1:1 with media. Gently mix. Inject 850µL of the diluted sample into the device.

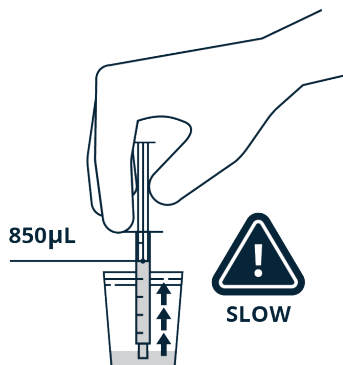


Figure 1. Slowly draw 850µL of the sample.

INJECT SAMPLE

5. Holding the device securely, carefully insert syringe into the device Inlet Port, applying gentle pressure to achieve a firm connection between syringe and device (Figure 2a).
6. Apply slow and steady pressure to inject the sample (Figure 2b).

Note: Be careful to avoid the formation of bubbles under the membrane.

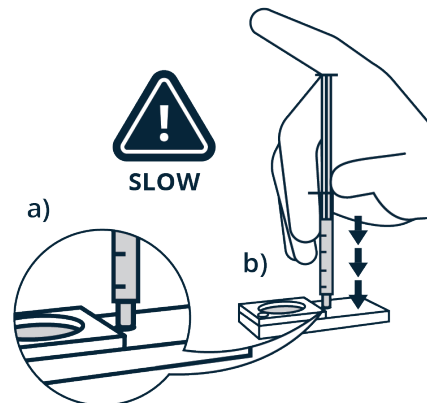


Figure 2. a) Firmly insert syringe into Inlet Port. b) Slowly inject sample.

CONTINUED ON REVERSE SIDE →

ADD MEDIA

- a) Prepare a syringe with 750µL of media (Figure 3a).
- b) Prime the Outlet Port by injecting a small volume of media (approximately 50µL – Figure 3b), until the media travels through the channel to the membrane.
- c) Disconnect the syringe from the Outlet Port and apply the remaining media in the syringe to the surface of the upper membrane by dropping from approximately 2cm above the membrane (Figure 3c).

Completely cover the upper membrane with media, making sure media touches all the edges of the upper chamber and connects with the droplet of media that was used to prime the Outlet Port.

Note: Do not tilt the device to spread the media.

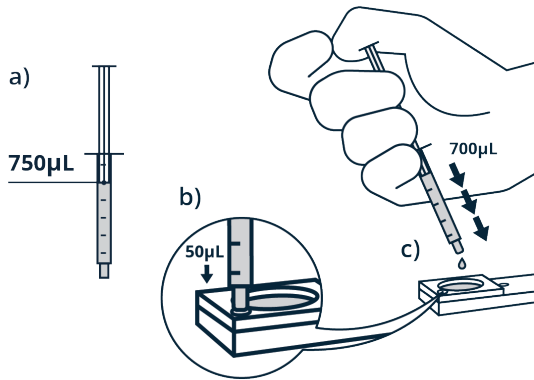


Figure 3. Prepare syringe, prime Outlet Port and cover membrane surface.

INCUBATE SAMPLE

- Place device into a Petri dish and cover. Keep the ZyMöt device horizontal and covered at all times during the incubation. Incubate at 37°C for 30 minutes.

COLLECT SEPARATED SPERM

- Insert a fresh 1mL syringe into the Outlet Port, achieving a firm connection. Slowly aspirate a maximum of 500µL of the sperm-containing fluid (Figure 4).

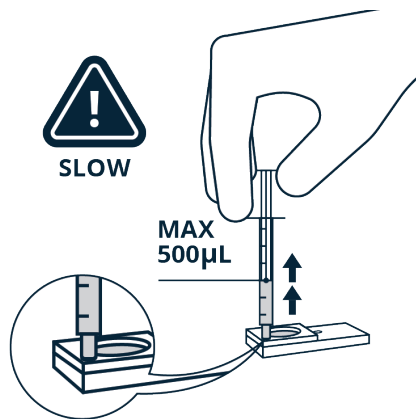


Figure 4. Slowly aspirate a maximum of 500µL.

- Transfer the collected sample to an appropriate culture tube: a 4mL round bottom culture tube with a snap top or into the bottom of a 15mL conical tube. Tubes using HEPES-buffered media may be held on the benchtop or tightly capped in an incubator. Tubes using bicarbonate-buffered media should be stored in a CO₂ incubator with the lid loosely closed.

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.
- Practice universal precautions when handling human body fluids.
- Do not use if the packaging is damaged.

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) and intrauterine insemination (IUI) procedures.

Sterilization:

The sterilization method used for ZyMöt devices is gamma radiation, at a dose level of 25kGy to 45kGy by the VD_{max}²⁵ method to meet a Sterility Assurance Level of 10⁻⁶.

Storage:

Store at 60°F - 77°F (15°C - 25°C).

Disposal:

Discard the used device and materials as medical waste.

Manufactured for:

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

