



Sperm Separation Device
ZIH0002

Instructions for Use

Device Components:

- ZyMöt™ ICSI Sperm Separation Device
- Instructions for Use

Materials/Equipment Required, But Not Supplied:

- Sperm washing solution: bicarbonate or HEPES-buffered
- 37°C incubator
- 2µl-20µl capacity adjustable micropipette
- 1µl-10µl capacity adjustable micropipette

- Recommended pipette tips:
 - 20µl Rainin 30389189
 - 0-10µl Rainin RT-10
- 35mm diameter Petri dish with lid
- 100mm diameter Petri dish with lid
- Capped tubes

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 ICSI has 5 micro channels; each accommodating 2µl of semen. More than one micro channel is available to accommodate multiple separations. Each channel has an inlet port for applying the semen sample and an outlet port for collecting the motile sperm. The ports are connected by a fluid-filled micro channel in which the separating occurs. Untreated semen is added through the inlet port. After a period of time, the separated sperm are collected from the outlet port.

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 a period of time, 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.

Instructions for Use:

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

1. Incubate semen sample at 37°C 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. Carefully insert the tip into the inlet port (the inlet port is the smaller of the ports).
4. Hold the micropipette in a vertical position and apply gentle pressure to achieve a seal. Do not allow the micropipette to “bottom out”. Once the tip is at the bottom, pull back and gently depress the plunger to allow free flow of the solution. Inject the sperm wash solution into the inlet port to fill the channel, then use the remaining solution to fill the outlet port. Do not trap air bubbles in the device.
5. Use the 1-10µl micropipette fitted with the recommended tip to add 2µl of liquefied semen sample to the inlet port. Add slowly. As in the previous step, do not allow the micropipette to “bottom out”. Once the tip is at the bottom, pull back to allow free flow of the semen sample. Ignore any excess solution buildup at the inlet port.
6. Invert a 100mm Petri dish such that the lid now 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.
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.
9. Transfer the collected material to a capped tube. Store for later use according to lab practice.

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.
- 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.

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 $\geq 80\%$ of control at 24h after exposure for 30min.

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 controlled room temperature.

Disposal:

Discard the used device and pipette tips as medical waste.

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USA and international patents pending.



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