ZyMōt™
MULTI (3ml)

Sperm Separation Device
ZMH3000

Instructions for Use

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
- Recommended 5ml Luer-tip syringes (3):
  Norm-Ject #4050-000VZ, Henke Sass Wolf
- Capped tubes

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 microenvironment created by the micro channels of the ZyMōt ICSI or the micropores 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 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 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 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 ZyMōt Multi (3ml) 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.

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 a 5ml Luer-tip syringe to draw an 3ml aliquot of the liquefied semen specimen. If there is insufficient volume, add sperm washing solution to give 3ml.
4. Hold the syringe in a vertical position, carefully insert the tip into the inlet and apply gentle pressure to achieve a seal. With gentle and steady pressure, inject the sample. Be careful to avoid the formation of bubbles under the membrane.
5. Prepare a fresh syringe with 2.5ml of sperm wash solution. Cover the entire upper collection chamber by inserting the syringe into the outlet port and injecting about 100µl – enough to fill the port and channel. Continue applying solution to the upper collection chamber until the entire surface area is covered. Ensure an uninterrupted flow of media over the membrane and the outlet port.
6. Incubate the device at 37°C for 30 minutes.
7. Insert a fresh 5ml Luer-tip syringe into the outlet port of the device. Slowly aspirate a maximum of 1ml of the sperm-containing fluid.
8. 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 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.

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 controlled room temperature.

Disposal:
Discard the used device and pipette tips as medical waste.

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