

Instructions for Use Sperm Purification Device

Device Components:

- VetCount™ Harvester Sperm Purification Device
- Instructions for Use
- 3 x 1 mL Syringes

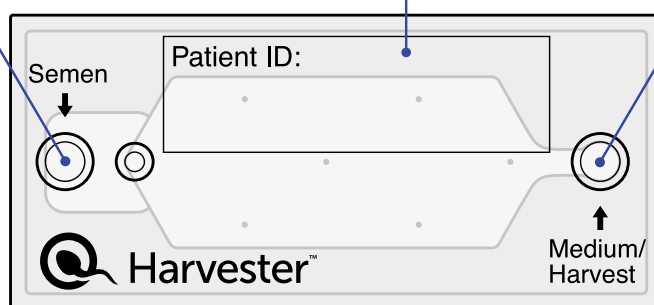
Equipment required, but not supplied:

- Sperm Preparation Medium (Sperm Extender)
- 37°C or 98.6°F incubator

Semen Inlet Port for:

1. Adding semen sample

Patient ID Label Space



Medium/Harvest Inlet Port for:

1. Loading Sperm Preparation Medium
2. Harvesting purified spermatozoa



Important Information

Please read detailed Instructions before use:

- Carefully adhere to the recommended volumes for each step
- Avoid both over- and/or underfilling of the device
- Always load and aspirate the VetCount™ Harvester device placed on a horizontal surface
- When moving the device to/from the incubator then keep the device on a horizontal surface
- The device is for single-use, only

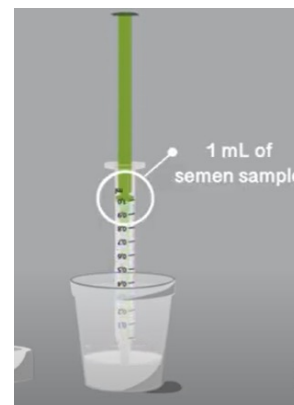
2. Aspirating sample

Before aspirating the semen sample, it must be homogeneous.

Aspirate 1 mL of sample using one of the included syringes. Avoid any airbubbles.

If there is insufficient sample volume then add Sperm Preparation Medium to bring the volume to 1 mL.

NOTE: If using a frozen sample then follow the instructions from the Sperm Bank for thawing.



1. Preparing the semen sample

Make sure that the semen sample is liquefied.

Gather all the equipment needed and work on a clean surface.



3. Inject the sample into the device

Place the 1 mL syringe filled with the semen sample into the Semen Inlet port.

Press the plunger of the syringe slowly and release the semen sample into the device.

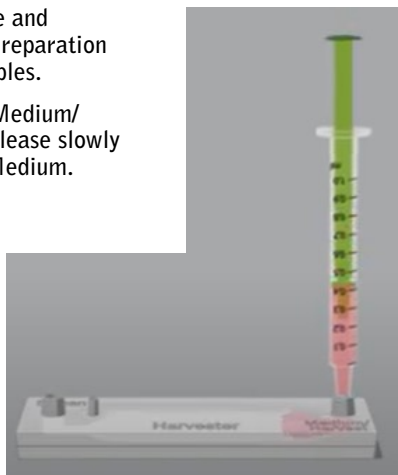
NOTE: Always handle the device on a flat horizontal surface (table).



4. Add the Sperm Preparation Medium

Use another 1 mL syringe and aspirate 0.8 mL Sperm Preparation Medium. Avoid any airbubbles.

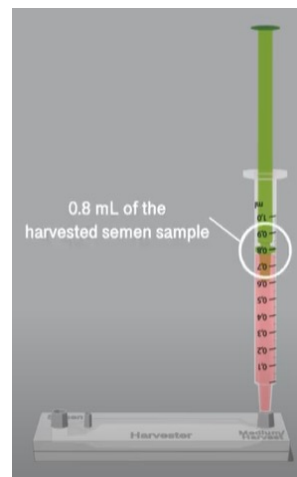
Place the syringe in the Medium/Harvest Inlet Port and release slowly the Sperm Preparation Medium.



6. Harvest

Remove the device from the Incubator.

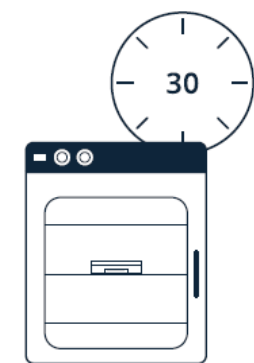
Use another 1 mL syringe and place it in the Medium/Harvest Inlet port and aspirate 0.8 mL of the purified semen sample.



5. Incubation

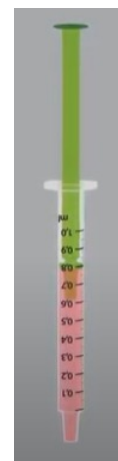
Incubate the device for 30 Min at 37°C or 98.6°F.

Keep the device horizontally at all times.



7. Sample is ready to be used

The harvested Progressive Motile Sperm Cells (PMSCs) are ready to be used.



Device Description:

The VetCount™ Harvester is a Sperm Purification Device. The device purifies the sperm sample by allowing only PMSCs to pass the Harvester's membrane system. The device is a semi-automatic system, in the sense that the design/technology utilizes the progressive motility of the sperm cells to separate the PMSCs from the rest of the sperm population.

The device consists of 3 components:

- Sample chamber 1 mL
- Medium/Harvest compartment
- Micropore filter

The device is used for Assisted Reproductive Technology (ART).

Indications for Use:

The device is a Sperm Purification Device that separates the PMSCs from the rest of the semen sample. The purified sample is used and can be used in ART in animal reproduction such as In-Vitro Fertilisation (IVF), Intra Cytoplasmic Sperm Injection (ICSI) or Insemination (IUI).

Sterilization:

The sterilization method used for the device is gamma radiation, at a dose level of 20kGy to 30kGy.

The device is radiation-sterilized with a sterility assurance level (SAL) of 10⁻⁶. It is individually packaged and for single-use only.

Storage:

Store at 2°C - 30°C (36°F - 86°F).

Disposal:

Discard the used device and materials as medical waste.

Manufactured by:

MotilityCount ApS

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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 Instruction For Use



Caution

Patents and Trademarks:

VetCount™ and the Sperm Cell symbol are trademarks of MotilityCount ApS.

Patent: PCT W02014/177157